



ASLM

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2ND INTERNATIONAL CONFERENCE
abstracts

**INNOVATION AND INTEGRATION OF
LABORATORY AND CLINICAL SYSTEMS**

Reshaping the Future of HIV, TB, Malaria,
Flu, Neglected Tropical Diseases and
Emerging Pathogens in Africa

CAPE TOWN
INTERNATIONAL
CONVENTION CENTRE
Cape Town, South Africa

ORAL SESSIONS AT A GLANCE

ORAL SESSION 1.1: HIV DIAGNOSIS AND VIRAL LOAD TESTING		Monday, 1 December
CO-CHAIRS: Sergio Carmona and Laurent Bélec		Room 1.4
11:00	Continued Virological Failure and Unnecessary Switching of Antiretroviral Treatment for HIV-1 may Occur Despite Access to Viral Load Monitoring <i>Tamara Sonia Boender, Kim CE Sigaloff, Raph L. Hamers, Maureen Wellington, Margaret Siwale, Mariettes Botes, Cissy Kityo, Sulaimon Akanmu, Kishor Mandaliya, Tobias F. Rinke de Wit, Pascale Ondo</i>	
11:10	Breaking the Barriers to Antiretroviral Therapy Monitoring: Uganda's Strategy for Public Sector Viral Load Monitoring Implementation <i>Victor Bigira, Charles Kiyaga, Meghan Wareham, Isaac Sewanyana, Brian Ngwatu, Judi Lusike, Wilson Nyegenye, Steven Aisu</i>	
11:20	Performance of the Amplix® Real-Time PCR Assay for Plasma HIV-1 (non-B subtypes) RNA Quantification Using LRT and Gag Targets to Assess Virological Failure in HIV-infected Treated Children Living in Central Africa <i>Laurent Bélec, Christian Diamant Mossoro-Kpinde, Jean-Christostome Gody, Olivia Mbitikon, Jean De Dieu Longo, Gérard Grésenguet</i>	
11:30	Evaluation of Multispot HIV1/2 Rapid Test to Confirm and Type HIV Infection in Plasma and DBS Specimens CANCELLED <i>Hetal Patel</i>	
11:40	Time for Change? An Evaluation of the Tie-Breaker Algorithm and the Role of Weakly Reactive Test Lines in Contributing to a High Rate of False Positive HIV Results <i>Leslie Shanks, Ruby Siddiqui, Jarmila Kliescikova, Neil Pearce, Cono Arti, Libsework Muluneh, Erwan Pirou, Koert Ritmeijer, Johnson Masiga, Almaz Abebe</i>	
11:50	Monitoring the Quality of Rapid HIV Testing Using a National Register: Results from the Initial Implementation Phase in Kenya <i>Muthoni Jungphae, Franklin Kithaka, Samuel Mwalili, Mamo Umuro, Jane W. Mwangi</i>	
12:00	Q&A and Discussion	
ORAL SESSION 1.2: STRENGTHENING LABORATORY MANAGEMENT SYSTEMS		Monday, 1 December
CO-CHAIRS: Katy Yao and Giselle Guevara		Room 1.6
11:00	Evidence from 501 Laboratories in 39 Countries for SLMTA-Driven Improvement in Quality Management Systems <i>Katy Yao, Elizabeth Luman, The SLMTA Implementation Teams</i>	
11:10	Strengthening Laboratory Management Toward Accreditation (SLMTA) – A Systematic Review of Research Issues, Results, and Remaining Gaps <i>Elizabeth Luman, Katy Yao, John Nkengasong</i>	
11:20	Challenges Facing Implementation of Strengthening Laboratory Management Toward Accreditation (SLMTA) Program in Blood Transfusion Service in Kenya <i>Eric Wakaria, Charles Rombo, Margaret Oduor, Peter Mwamba, Kimberly Tilock</i>	
11:30	The Road to Laboratory Accreditation Through SLMTA: Key Success Factors <i>Thomas Gachuki, Jane Mwangi, Risper Sewe, David Turgeon, Mary Garcia, Elizabeth T. Luman, Mamo Umuro</i>	
11:40	The Impact of the Strengthening Laboratory Management Toward Accreditation (SLMTA) Training Program in Improving Laboratory Quality Systems in the Caribbean Region <i>Gisele Guevara, Floris Gordon, Yvette Irving, Ismae Whyns, Keith Parris, Songee Beckles, Talkmore Maruta, Nqobile Ndlovu, Rachel Albalak, George Alemnji</i>	
11:50	Perceptions and Attitudes Towards SLMTA among Laboratory Professionals and Hospital Chief Executive Officers in Ethiopia <i>Adino Desale, Tilahun Muchie Hiwotu, Achamyelch Mulugeta, Adisu Kebede, Habtamu Asrat, Abnet Abebe, Dereje Yenealem, Ebise Abose, Amha Kebede, Mary Kathryn Linde, Gonfa Ayana</i>	
12:00	Q&A and Discussion	
ORAL SESSION 1.3: TB DRUG RESISTANCE		Monday, 1 December
CO-CHAIRS: Phillip Onyebujoh and Hortense Faye-Kette		Room 2.4
11:00	Prevalence of TB Infection Among HIV Patients in Association to Drug Resistance at Kenyatta National Hospital Comprehensive Care Clinic <i>Anne Mutsami, Godfrey Jumbe</i>	
11:10	Mycobacterium tuberculosis and Anti-Tuberculosis Drug Resistance in HIV Negative and HIV Positive Cases in Jos, Nigeria <i>Chisom Ukaegbu, Agatha Ani, Yetunde Isah, Rosemary Pwol, Chindak Lekuk, Godwin Imade, Oche Agbaji</i>	
11:20	Evaluation of the FAST Plaque-Response in the Detection of Rifampicin Resistance among Mycobacterium tuberculosis Isolates from Egypt <i>Basant Motawi, Zeinab Mostafa, Youssef Soliman</i>	
11:30	Added Value of Performing a Second Xpert MTB/RIF Test on a Second Sputum Sample to Confirm Rifampicin Resistance: Analysis of Routinely Collected Data in MSF-Supported Sites in Mozambique, Zimbabwe and Kenya <i>Emmanuel Fajardo, Maryam Rumaney, Carol Metcalf, Peter Saranchuk, Marcela de Felo Freitas, Asma Ali, Sandra Simons, Helga Ritter, Helen Bygrave, Tom Ellman</i>	
11:40	Laboratory Based Second-line Anti-TB Drug Resistance Surveillance in Ethiopia <i>Abebaw Kebede, Zekarias Dagne, Muluwork Getahun, Zelalem Yaregal, Yetnebersh Fisiha, Abyot Meaza, Shewki Moga, Almaz Abebe, Eshetu Lemma</i>	
11:50	Illumina Technology for Multiplex-Amplicon Sequencing can be Used for Identification of Drug Resistant Tuberculosis <i>Daniela Maria Cirillo, Andrea Cabibbe, Ilaria Valente, Paolo Miotto</i>	
12:00	Q&A and Discussion	

ORAL SESSION 1.4: MALARIA AND OTHER PARASITIC DISEASES		Monday, 1 December
CO-CHAIRS: Adrian Puren and Lesley Scott		Auditorium 1
11:00	Evaluation de l'Efficacité Thérapeutique des Antipaludiques Usuels dans le Traitement du Paludisme Simple à Plasmodium falciparum Chez les Enfants de Moins de 5 ans à Bangui, République Centrafricaine <i>Ernest Lango-Yaya, Simon Pounquinza, Jean Pierre Bangamingo, Louis Namboua</i>	
11:10	Sero-Prevalence of Plasmodium Parasites Amongst Pregnant Women Attending Antenatal Clinic In Sokoto, Nigeria <i>Hussaini Alhassan Mohammed, Abdullahi Saidu Yaro, Mohammed Danfulani, Egua Maxwell, Nuradeen Mohammed Bello</i>	
11:20	A Study on Malaria Parasitaemia Carried Out in Kibera Community Health Centre Laboratory Nairobi, Kenya <i>Carolyne Mumo, Gertrude Kitetu</i>	
11:30	CXCL10 Gene Promoter Polymorphism -1447A>G is Associated with Severe Malaria in Ghanaian Children <i>Felix Botchway, Nana Wilson, Adel Driss, Carmen Dickinson_Copeland, Hassana Salifu, Jonathan Stiles</i>	
11:40	Translating Results of Diagnostic Tests into Practice: The Case of Shistosomiasis <i>Eleanor Ochodo, Gowri Gopalakrishna, Mariska Leeflang</i>	
11:50	Is Malaria an Opportunistic Infection Among HIV/AIDS Patients in Nigeria? <i>Joseph Enuma, Bernard Matur</i>	
12:00	Q&A and Discussion	
ORAL SESSION 1.5: EXTERNAL QUALITY ASSURANCE PROGRAMMES		Monday, 1 December
CO-CHAIRS: Michael Aidoo and Paula Fernandes		Roof Terrace Room
11:00	Field Evaluation of Dried Plasmodium falciparum Samples for Malaria RDT Quality Control and Proficiency Testing in Liberia and Ethiopia <i>Michael Aidoo, Afework Tamiru, T. Henry Kohar, Chritie M. Reed, Joseph L. Malone</i>	
11:10	Malaria Rapid Diagnostic Tests (RDTs) Field-Level External Quality Assurance (EQA) System: Which Way Forward? <i>Alex Ojaku, Elizabeth Streat, Anthony Nuwa, John Baptist Bwanika, Bosco Agaba, Joseph Nkodyo</i>	
11:20	Microscopist Proficiency Testing as Part of a Comprehensive Program to Assure the Quality of a Multi-Continental Harmonized Malaria Drug Efficacy Trial <i>Paula Fernandes, Ekaterina Milgotina, Mark Fukuda, Jeffrey McCollum, Karen Menge, Peter Obare, Alaina Thomas, James Cummings</i>	
11:30	Piloting External Quality Assurance for TB Line Probe Assay and GeneXpert in Nigeria <i>Susana Oguntoye, Abiola Tubi, Jelpe Tapdiyel, Thor Elliott, Shirematee Baboolal</i>	
11:40	Comparison of Stained versus Unstained Simulated <i>Mycobacterium tuberculosis</i> Microscopy Smears for Proficiency Testing <i>Crystal Viljoen, Marshagne Smith, Olga Perovic</i>	
11:50	Strengthening National Laboratory Proficiency Testing (PT) in Tanzania <i>Nzovu Ullenga, Aisa Muya, Guerino Chalamilla, Fausta Mosh</i>	
12:00	Q&A and Discussion	
ORAL SESSION 1.6: PARTNERSHIP AND LABORATORY NETWORKS		Monday, 1 December
CO-CHAIRS: Patrick Mateta and Jean Sakandé		Auditorium 2
11:00	The Role of Associations in Laboratory System Strengthening in Africa: Where Are We? Where Are We Going? <i>Talkmore Maruta, Nqobile Ndlovu, Teferi Mekonen, Corey White, Tsehaynesh Messele, Madeline DiLorenzo, Trevor Peter</i>	
11:10	Improving Blood Supply Safety & Adequacy in Developing Countries: Pan-African Blood Safety Perspectives <i>Assah Nkohkwo and Nigel Talboys</i>	
11:20	Regional Capacity Enhancement in Medical Laboratory Science: The West African Initiative <i>Godswill Okara</i>	
11:30	EID Lab Consolidation Supported by the Sample Transport Network has Improved Access and Program Monitoring in Uganda <i>Isaac Ssewanyana, Meghan Wareham, Victor Bigira, Grace Kushemererwa, Christine Namulindwa, Iga Tadeo, Steven Aisu, Charles Kiyaga</i>	
11:40	Improving Patient Referral Linkages Through Implementation of a National Sample Transportation Program in 7 Districts in Malawi <i>Carol Porter, Kundai Moyo, Wainings Manda, Mphatso Kachule, Kameko Nichols, Abdoulaye Sarr, James Kandulu, Reuben Mwenda, Lutho Zungu, Agnes Thawani</i>	
11:50	Building a Sustainable Team for Tanzania's Hospital Laboratories <i>Patrick Mateta and Charles Massambu</i>	
12:00	Q&A and Discussion	

ORAL SESSION 2.1: POINT-OF-CARE DIAGNOSTICS Tuesday, 2 December
CO-CHAIRS: Francois-Xavier Mbopi-Keou and Clement Zeh Room 1.4

11:00	Evaluation of a Novel Point-of-Care Test for CD4, %CD4, and Total Hemoglobin (Hb): The BD FACSPresto™ <i>Frank Angira, Clement Zeh, Paul Omolo, Benta Akoth, Valarie Opollo, Beverly Lu, Scott Bornheimer, Henok Tilahun, Laurie Byrne, Imelda Omana-Zapata</i>
11:10	Assessment of a Revised Protocol for Selection of HIV Rapid Tests for the National HCT Programme in South Africa <i>Beverley Anne Singh and Adrian Puren</i>
11:20	Dried Blood Spot Samples for Viral Load Testing Vary Significantly in Performance with Each of the Currently Available Viral Load Technologies <i>Lara Vojnov</i>
11:30	Connectivity: Instrument and Information Management at Point-of-Care – Experience vs. Expectation <i>Bradford Cunningham, Charlotte Jansen van Rensburg, Edwin Motsoloane, Lesley Scott, Wendy Stevens</i>
11:40	Positive Control Wells (PCW) for Malaria Rapid Diagnostic Tests (RDT): Training Effectiveness, Impact on RDT Use and Health Worker Perceptions in Lao PDR and Uganda <i>Daniel Kyabayinze, Jane Cunningham, Heidi Hopkins, Mayfong Mayxay, Koukeo Phommason, Elizabeth Streat, Iveth J. Gonzalez, David Bell</i>
11:50	Q&A and Discussion

ORAL SESSION 2.2: HIV CO-INFECTION (HEPATITIS B, STIs, AND CRYPTOCOCCUS) Tuesday, 2 December
CO-CHAIRS: Souleymane Sawadogo and Rosemary Adu Auditorium 1

11:00	Detection of Hepatitis B Virus DNA by Polymerase Chain Reaction (PCR) in Plasma of Blood Donors Negative for HBsAg in Abakaliki, Ebonyi State, Nigeria CANCELLED <i>Chinenye Mbamalu, Ifeoma Ekejindu, Emmanuel Nna</i>
11:10	Antibody Response to Hepatitis B Vaccine in Pediatric Patients Attending Rwanda Military Hospital in October-December 2013 <i>Judy Orikiiriza, Louis Mujuwisha, Elizabeth Karlsson, Johan Normark</i>
11:20	Séroprévalence des Marqueurs Spécifiques de l'Hépatite B Chez les Donneurs de Sang Vénévoles à Kinshasa, R.D. Congo <i>Eric Mukenge, Sylvain Yuma Ramazani, Guy-Olivier Mbensa Kuediasala, Blanchard Malenga Nkanga, Aimé Mbaya Tshiyamu, Franck Nzengu Lukusa, Jérémie Muwonga Masidi, Donatien Kayembe Nzongola, Ferdinand Mbayo Kalumbu, Steve Ahuka-Mundeke</i>
11:30	Prevalence of Cryptococcus Antigenemia (CrAg) among a Sample of HIV-infected Individuals in Namibia <i>Souleymane Sawadogo, Boniface Makumbi, Anne Purfield, Christophine Ndjavera, Gram Mutandi, Andrew Maher, Francina Kainjee Tjituka, Jon Kaplan, Benjamin J. Park, David W. Lowrance</i>
11:40	Molecular Typing of <i>Cryptococcus neoformans</i> and <i>Cryptococcus gattii</i> from Clinical and Environmental Sources in Nairobi, Kenya <i>Mourine Kangogo, Christine Bii, Olivier Bader, Hamadi Boga, Wanjiru Wayoike, Michael Weig, Uwe Groß</i>
11:50	Contribution à l'Amélioration de la Sécurité Transfusionnelle : Diagnostic Moléculaire des Virus d'Epstein Barr (EBV) et de l'Hépatite G (VHG) par PCR et RT-PCR Chez les Donneurs de Sang au Burkina Faso. <i>Issoufou Tao, Cyrille Bisseye, Alice Kiba, Mahmoudou Sanou, Tegwindé Rebeca Compaoré, Lassina Traoré, Jean Baptiste Nikiema, Jean Didier Zongo, Jacques Simpore</i>
12:00	The Burden Of Bacterial Vaginosis in Lagos, Nigeria CANCELLED <i>Chinedum Oparaugo, Rosemary Okoye, Adesegun Adesesan, Mariam Adetunji, Samuel Nduaga, Ini-obong Essien</i>
12:10	Q&A and Discussion

ORAL SESSION 2.3: IMPROVING TB DIAGNOSIS Tuesday, 2 December
CO-CHAIRS: Jean de Dieu Iragena and Tom Shinnick Room 1.6

11:00	Improving Access to MDR-TB Diagnosis in Africa: EXPAND-TB's Experience of Establishing Laboratories in 12 African Countries <i>Jesse Wambung and Kekeletso Kao</i>
11:10	Improved Laboratory Diagnosis of MDR-TB Cases is Revealing Care and Treatment Scale-Up Needs in Côte d'Ivoire <i>Raymond N'Guessan, Mah-Sévé Keita Sow, André Téhé, Alem Sinishaw, Adje-Toure Christiane, Jacquemin Kouakou</i>
11:20	Comparison of Tuberculosis Skin Test and QuantiFERON-TB Gold in Tube Assay for Diagnostic Workup of Childhood Tuberculosis. A Cross-Sectional Study Conducted at Tikur Anbesa Specialized Hospital, Ethiopia <i>Ibrahim Ali, Yimtubeznash Woldeamnuel, Amha Mekasha, Markos Abebe, Liya Wassie, Abraham Aseffa</i>
11:30	GeneXpert MTB/RIF: Observed Error Rates and Invalid Results After Twelve Months of Regular Use <i>Yetunde Isa, Agatha Ani, Rosemary Pwol, Chindak Lekuk, Tolupte Ashi-Sulaiman</i>
11:40	Comparison of SpeedOligo Test to Xpert MTB/Rif Test for Detection of Tuberculosis in Smear-Negative HIV-Infected Patients <i>Simon Walusimbi, Alfred Okeng, Edgar Kigozi, Samuel Kyobe</i>
11:50	Q&A and Discussion

ORAL SESSION 2.4: MONITORING ROTAVIRUS AND ENTERIC DISEASES		Tuesday, 2 December
CO-CHAIRS: Diane Waku and Elisabeth Pukuta		Room 2.4
11:00	Diversity of Group A Rotavirus Strains Circulating in RDC, January-December 2012 <i>Elisabeth Pukuta, V. Tubijinga, M. Landu, G. Kitambala, D. Monga, M. Essona, S. Mapaseka, A. Nkongolo, D. Waku, V. Ngum, M. Bowen, V. Mondonge, J.J. Muyembe</i>	
11:10	Estimated Rotavirus Gastroenteritis Prevalence in Children Below the Age of 5 Years in Swaziland During Period Jan-Dec 2013 <i>Nomcebo Phungwayo and Gugu Maphalala</i>	
11:20	The Necessity of Full Sepsis Work-Up in Neonatal Sepsis: Experience in a Resource-Limited Setting <i>Kenneth Onyedibe, Bose Toma, Udochukwu Diala, Omini Uket, Ubong Udoh, Okokon Ita, Mark Okolo, Tolulope Afolaranmi, Victor Nwadike</i>	
11:30	Epidemiology and Genotyping Characterization of Rotavirus Strains Detected in Under 5 with Acute Gastroenteritis at 2 Children's Hospitals in Zambia <i>Julia Simwaka, Evans Mpabalwani, Mwaka Monze, Jason Mwenda, Olusegun Babaniyi, Cynthia Phiri Mubanga, Idah Ndumba, Mazyanga Liwewe, Hellen Mutambo</i>	
11:40	Identifying Etiologic Agents of Diarrhoea Through Active Laboratory-Based Surveillance in Dadaab, Kenya, 2011-2013 <i>Fredrick Oyler, Shafe Ali Mowlid, Steve Biko Ochieng, Ahmed Unshur, Charles Okello, Barry Fields, Joel M. Montgomery, Maurice Ope, Nina Marano</i>	
11:50	Strengthening Laboratory Capacity Through the Surveillance of Rotavirus Gastroenteritis in Central Africa: The Surveillance Épidémiologique en Afrique Centrale (SURVAC) Project <i>Diane Waku-Kouomou, Mathew D. Esona, Elisabeth Pukuta, Ionela Gouandjika-Vasilache, Angelina Boula, Kathleen F. Cavallaro, Michael D. Bowen</i>	
12:00	A Comparison of Anatomically Designed Flocked Rectal Swab to Traditional Fibre Swab Samples for the Molecular Detection of Bacterial Enteric Pathogens <i>Margaret Mokomane, Andrew P. Steenhoff, B.A. Gashe, Jeffrey M. Pernica, Loeto Mazhani, Isaac Quaye, Kwana Lechiile, James Mahony, Marek Smieja, David M. Goldfarb</i>	
12:10	Q&A and Discussion	
ORAL SESSION 2.5: IMPROVEMENT TOWARD LABORATORY ACCREDITATION		Tuesday, 2 December
CO-CHAIRS: Eduardo Samo Gudo and Ernest Makokha		Roof Terrace Room
11:00	The Tipping Point in SLMTA Implementation: Kenya's Experience <i>Ernest Makokha, Daniel Kimani, Mercy Njeru, Jane Mwangi, Omu Anzala</i>	
11:10	Strengthening Laboratory Management Towards Accreditation (SLMTA) as a Practical Tool for Laboratory Quality Improvement: Ownership and Sustainability in Ethiopia <i>Achamyeleh Mulugeta, Habtamu Asrat, Adisu Kebede, Dereje Yenealem, Adino Desale, Abinet Abebe, Ebise Abose, Wondwosson Kassa, Amha Kebede, Gonfa Ayana</i>	
11:20	Keeping Pace Towards Accreditation in the Post-SLMTA Phase: Mozambique Experience <i>Eduardo Samo Gudo, Isabel Pinto, Patrino Chongo, Paula Mandlaze, Beth Skaggs, Jessina Massamha</i>	
11:30	Multi-Stakeholder Engagement for Sustainable SLIPTA Initiatives <i>Jane Mwangi, Ernest Makokha, Frank Basiye, Muthoni Junghae,</i>	
11:40	Assessment of Patient Customer Satisfaction at Kitale District Hospital Laboratory 2013 <i>Rosebella Rotich, Ogaro H, Wekesa D, Kutolo E</i>	
11:50	Taking a Laboratory from Zero to Five Stars – The ASM Approach to Mentoring Labs towards Accreditation <i>Susana Oguntoye, Sofia Viegas, Nureisha Kadir, Carla Madeira, Khalid Azam, Daisy Nakamura Sato</i>	
12:00	Q&A and Discussion	
ORAL SESSION 2.6: HUMAN RESOURCE DEVELOPMENT FOR LABORATORY		Tuesday, 2 December
CO-CHAIRS: Isatta Wurie and Rubina Imtiaz		Auditorium 2
11:00	Laboratory Workforce Mapping in 10 PEPFAR-Supported Countries: Major Gaps and Role for a Harmonized Intervention <i>Rubina Imtiaz, Ernest Makokha, Jane Mwangi, Abdulattif Ali, Bernard Nkrumah, Sunita Upadhyaya, Filomena Gomez da Silva, Margarida Rodrigues, Anthony O. Emeribe, Kenneth Iregbuo, Elizabeth Skaggs, Jessima Masamha, Anita Beukes, Bui T.T. Hien, Kyle Bond, Michael Mwasekaga</i>	
11:10	Laboratory Workforce Regulation in Africa's Top Five HIV Burden Countries <i>Andre R. Verani, Rubina Imtiaz, Anthony Emeribe, Fausta Moshia, Sagie Pillay, Abdulatif Ali, Jane Mwangi, Jean-Bosco Ndhokubwayo, Daniel Garcia, Tsehaynesh Messele</i>	
11:20	Building Capacity in Laboratory Medicine in Africa by Increasing Physician Involvement: A Laboratory Medicine Course for Clinicians <i>Jeannette Guarner, Timothy Amukele, Meheretu Mehari, Tufa Gemechu, Yimtubezinash Woldeamanuel, Annie Winkler, Daniel Asrat, Michael Wilson, Carlos del Rio</i>	
11:30	Strengthening Health Laboratory Human Resource Through a Structured Pre-Service Training Program: Sierra Leone Strategic Plan Direction <i>Sahr Gevao, Wendy Arneson, Ralph Timperi, Aji Sanneh, Isatta Wurie</i>	
11:40	Improving Service Quality Through Local Capacity Building: Looking Beyond PEPFAR <i>Bernard Nkrumah, Beatrice van der Puije, Veronica Bekoe, Samuel Duh, Nii Akwei Addo, Celia Woodfill</i>	
11:50	Barriers to Uptake of Laboratory Services for Antenatal Care. Findings from a Multilevel Qualitative Study in Senegal <i>Winny Koster, Aicha Sarr, Iyane Sow, Robert Pool, Constance Schultsz, Pascale Ondo</i>	
12:00	Implementing a Laboratory Quality Management System: One Country's Journey <i>Ernest Ruttoh, Joan Wasike, Tobias Nyanjong, Frederick Kobia, Patrick Kamau, Humphrey Aremo</i>	
12:10	Q&A and Discussion	

ORAL SESSION 3.1: ANTIMICROBIAL RESISTANCE **Wednesday, 3 December**
Room 1.4
CO-CHAIRS: William Ampofo and Coumba Touré Kane

11:00	Prevalence, Antimicrobial Susceptibility Pattern and Clinical Predictors of Group A Streptococci among Children with Pharyngitis <i>Getnet Tesfaw Tadege, Alemseged Abdissa Lencho, Gebre Kibru Tiga, Demeke Mekonnen Mengistie</i>
11:10	Molecular Characterisation of Methicillin-Resistant <i>Staphylococcus aureus</i> Isolated at the University Teaching Hospital, Lusaka, Zambia <i>Mulemba Samutela, James C.L. Mwansa, Chileshe Lukwesa-Musyani</i>
11:20	Risk Factors Associated with Antiretroviral Therapy Failure and Acquiring Drug Resistance Mutations among HIV-1 Adult Patients on ART – Results from a Nationwide Cross-Sectional HIV Drug Resistance Survey in Kenya <i>Guoqing Zhang, Lucy Nganga, Joshua DeVos, Evelyn Ngugi, Francesca Odhiambo, Irene Mukui, Abraham Katana, Lucy Kanyara, Elliot Raizes</i>
11:30	Dried Blood Spot Specimens are a Vital Alternative Specimen Type for HIV Drug Resistance Surveillance and Monitoring in HIV-1-infected Patients Initiating Antiretroviral Therapy in Nigeria <i>Rachel Suzanne Beard</i>
11:40	Evaluation of Antibiogram Techniques in some Laboratories in Cameroon <i>Tchoula Mamiako Corinne</i>
11:50	The Need for Genotypic Antiretroviral Resistance Testing for Children in Developing Countries <i>Annette Donnelly and Ellen HopeKearns</i>
12:00	Q&A and Discussion

ORAL SESSION 3.2: ADVANCES IN CD4 TESTING **Wednesday, 3 December**
Room 1.6
CO-CHAIRS: Larry Westerman and Matilu Mwau

11:00	Can CD4 Monitoring be Stopped Among Virologically Suppressed Patients: a Systematic Review and Meta-analysis <i>Nathan Ford and Andrew Hill</i>
11:10	Predictors of CD4 Count Changes after Initiation of Antiretroviral Treatment in Gondar University Hospital, Gondar, Ethiopia CANCELLED <i>Mihiretu Molla</i>
11:20	Validation of Muse[®] Auto CD4/CD4% Assay to Determine the Absolute Number and Percentages of CD4 T Cells Using Cameroonian Children and Adult Patients' Samples <i>Francois-Xavier Mbopi-Keou, Florence Tanghu Mimo, Hortense Gonsu Kamga, Pierrette Omgba Bassega, Martin Samuel Sosso, Joseph Mindimi Nkodo, Alexis Ndjolo, Côme Ebana Mvogo, Maurice Aurelien Sosso, Laurent Bélec</i>
11:30	Technical Performance Evaluation of the Zyomyx MyT4 Point of Care Technology for CD4+ T Cell Enumeration <i>Matilu Mwau, Silvia Kadima, Joy Mwendu, Maureen Adhiambo, Catherine Akinyi, Marta Prescott, Judi Lusike, Jackson Hungu, Lara Vojnov</i>
11:40	Geospatial Analysis: A CD4 Referral Network Optimization and Strategic POC Integration Model <i>Jason Williams</i>
11:50	Using Open Source Spatial Software to Analyze and Optimize Inter-laboratory CD4 Referral Patterns in South Africa CANCELLED <i>Oriel Mahlatsi, Naseem Cassim, Lindi Marie Coetzee, Deborah K. Glencross</i>
12:00	Q&A and Discussion

ORAL SESSION 3.3: ADVANCES IN EARLY INFANT DIAGNOSIS **Wednesday, 3 December**
Auditorium 1
CO-CHAIRS: Wendy Stevens and Charles Kasipo

11:00	Adherence to Early Infant HIV Diagnosis (EID) Testing Algorithm—Uganda's Experience <i>Charles Kiyaga and Helen Lee</i>
11:10	Selection and Evaluation of a Third Rapid HIV Assay as a Tie Breaker to Enhance Early HIV Diagnosis and Linkage to Care in the Kingdom of Swaziland <i>Rogers Kisame and Sindisiwe Susan Dlamini</i>
11:20	Task Shifting Training for Point-of-Care Technologies: The SAMBA Experience in Zimbabwe <i>Sekesai Mtapuri-Zinyowera, Douglas Mangwanya, Raiva Simbi, Neha Goel, Jose Paolo Magbanua, Peter Gumbo, Ellen Munemo, Lourdes M. Nadala, Angella Mushavi, Vasco Chikwasha, Helen Lee</i>
11:30	Evaluation of the Simple Amplification-Based Assay (SAMBA) Qualitative Point-of-Care HIV-1 Viral Detection Assay on Whole Blood Among HIV-exposed Infants in Western Kenya <i>Collins Odhiambo, Clement Zeh, Kenneth Ouma,</i>
11:40	Improved Sensitivity of a Dual-Probe HIV-1 Qualitative Test for Plasma and Dried Blood Spots <i>Robert Luo, Sergio Carmona, Stefanie Templer, Britta Seiverth, Paul Baum, Carole Devaux, Wendy Stevens</i>
11:50	Evaluation of the Alere q Point-of-Care system for Early Infant HIV Diagnosis <i>Nei-yuan Hsiao, Lorna Dunning, Catherine Clary, Max Kroon, Landon Myer</i>
12:00	Q&A and Discussion

ORAL SESSION 3.4: DIAGNOSTIC INNOVATIONS		Wednesday, 3 December
CO-CHAIRS: Emmanuel Fajardo and Daniela Maria Cirillo		Room 2.4
11:00	Improved Performance of the New Prototype Automated Abbott RealTime HIV-1 DBS Viral Load Assay*: Potential Use in Expanded Viral Load Testing in Resource Limited Setting (*For Research Use Only) <i>Shihai Huang, Sergio Carmona, Brian Erickson, John Salituro, Chadwick Dunn, Livhuwani Nxumalo, Jeffrey Wuitschick, Jens Dhein</i>	
11:20	Demonstration of the Idylla™ System for Rapid, Multiplexed Molecular Diagnosis of Infectious Diseases <i>Kathleen Tietje, Carmen Forsman, Heather White, Mitra Singhal, David Fredricks, Daisy Ko, Tina Fiedler, Katrien Vermeiren, Erwin Sablon, Rudi Rossau</i>	
11:30	Performance of Xpert® HIV-1 Quant Compared to Roche CAP/CTM v2 and Abbott RealTime HIV-1 on a Prequalification Plasma Validation Panel <i>Lesley Scott, Natasha Gous, Sergio Carmona, Wendy Stevens</i>	
11:40	Rapid Plasma Separation Device for Point-of-Care Viral Load Testing: A Proof-of-Concept <i>Emmanuel Fajardo, Racheal Shamiso Mandishora, Oscar Tapera, Elton Mbofana, Sekesai Mtapuri-Zinyowera</i>	
11:50	Validation and Comparison of Cyscope Microscope, Quantitative Buffy Coat, and Rapid Diagnostic Kit for Malaria Diagnosis among Clinic Attendees in Southwest Nigeria <i>Abiodun Ogunniyi, David Dairo, Femi Ajumobi, Patience Ogunjobi, Busola Ojo, Oyetunde Oyeami, Olufunmi Fawole, Hanna Dada-Adegbola, Oyibo Wellington</i>	
12:00	Q&A and Discussion	
ORAL SESSION 3.5: THE JOURNEY TO LABORATORY ACCREDITATION		Wednesday, 3 December
CO-CHAIRS: Talkmore Maruta and Thomas Gachuki		Roof Terrace Room
11:00	Progress Made in the Implementation of the Stepwise Laboratory Improvement Process <i>Jean-Bosco Ndiokubwayo, Talkmore Maruta, Nqobile Ndlovu, Sikhulile Moyo, Teferi Mekonen, Ali Ahmed Yahaya, Sheick Oumar Coulibaly</i>	
11:10	Using Scores in Checklist Sections to Identify Gaps in SLIPTA Implementation <i>Lawrena Okoro and Anthony Emeribe</i>	
11:20	High-level Advocacy to Build Support for Laboratory Accreditation <i>Nqobile Ndlovu</i>	
11:30	ISO Accreditation of First Public Laboratory in Kenya: Benefits and Experiences <i>Thomas Gachuki and Mamo Umuro</i>	
11:40	Customer Service and Corrective Action Top List of Sustained Laboratory Improvements in Resource-Limited Countries Striving to Earn International Accreditation <i>Cathy Robinson and Wendy Arneson</i>	
11:50	Rapid Ascent from Zero Quality to ISO Accreditation in 18 Months: A Case Study from Vietnam <i>Kyle Bond, Cuong Duong, Hien Bui, Nhan Dang, Nhanh Bui</i>	
12:00	Q&A and Discussion	
ORAL SESSION 3.6: THE ROLE OF THE LABORATORY IN OUTBREAK RESPONSE		Wednesday, 3 December
CO-CHAIRS: Amadou Sall and Peter Nsubaga		Auditorium 2
11:00	Genetic Diversity of Sporothrix Species Isolated From Clinical and Environmental Sources from an Outbreak among Gold Miners in Barberton, Mpumalanga <i>Tsidiso Gugu Maphanga, Thokozile G. Zulu, Nelesh P. Govender</i>	
11:10	Cholera Outbreak in Plateau State, Nigeria, 2011 <i>Samuel Badung, Gbenga Ajani, Okeke A. Lilian, Elmina A. Abiayi, Ndadihnasiya E. Waziri, Elisha Pede, Peterside Kumbish, Tony M. Joannis, Adebola T. Olayinka, Philip A. Okewole, Patrick Nguku</i>	
11:20	Re-emergence of Yellow Fever in Kedougou, Southeastern Senegal in 2010 – 2011 <i>Abdourahmane Sow, Yamar Ba, Diawo Diallo, Oumar Faye, Rubin Chen, Kathryn A Hanley, Scott C Weaver, Mawlouth Diallo, Amadou A Sall</i>	
11:30	An Outbreak of Measles in Techiman Municipality, Brong-Ahafo Region – Ghana, 2014 <i>Joseph Asamoah Frimpong, Gershon Kobla Anthony, Abdulai Marijanatu, Culbert Nuolabong, Iddrisah Florence, Kofi Mensah Nyarko</i>	
11:40	Mozambique Field Epidemiology and Laboratory Training Program (FELTP) – Strengthening Disease Detection through Laboratory Confirmation <i>Cynthia Semá Baltazar, Cátia Taibo, Jahid Sacarlat, Lorna Gujral, Eduardo Samo Gudo</i>	
11:50	Ebola Epidemic: Laboratory Lessons Learned in Uganda – Are You Ready? <i>Ali Elbireer</i>	
12:00	Q&A and Discussion	

ORAL SESSION 4.1: IMPACT OF SURVEILLANCE		Thursday, 4 December
CO-CHAIRS: Fausta Moshia and Alash'le Abimiku		Room 1.4
11:00	Surveillance of Seasonal Influenza in Tanzania: Five years of Sentinel Surveillance 2009-2013 <i>Miriam Matonya and Vida Mmbaga</i>	
11:10	Second Round National Anti-Tuberculosis Drug Resistance Surveillance – Ethiopia <i>Eshetu Lemma, Beniam Feleke, Abebaw Kebede, Muluwork Getahun, Zelalem Yaregal, Ribka Fantu, Yetnebersh Fiseha, Abyot Meaza, Zekarias Dagne</i>	
11:20	Drug Resistance Testing in HIV Infected on Treatment and Naïve: Implications on Treatment Outcome <i>Winfrida Cheriro, James Brooks, Ben Liang, Ji Hezhao, Raphael Lihana, Michael Kiptoo, Simeon Mining, Wilfred Emonyi, Elijah M. Songok</i>	
11:30	Supervision of Sexually Transmitted Infections in Senegal: a National Survey Conducted in 2006 and 2010 Respectively on 596 and 570 Female Sex Workers in Different STI Centres of Senegal <i>Awa Ba Diallo, Pape A. Niang Diallo, Maimouna Diakhaté-Touré, Aissatou Gaye-Diallo, Ndeye Coumba Touré-Kane, Halimatou Diop-Ndiaye, Astou Guèye-Gaye, Souleymane Mboup</i>	
11:40	Use of Clinical Laboratory Data to Determine Disease Prevalence and Diagnostics Services Provided in Kenya <i>Angela Amayo, John Mwihia, Benard Muture, Jedida Wachira, Matilu Mwau, Judy Mwangi</i>	
11:50	Uganda Viral Hemorrhagic Fever Surveillance, Laboratory and Outbreak Response Program, 2010-2014: A Model for Early Detection and Effective Outbreak Control <i>Trevor Shoemaker, Stephen Balinandi, Alex Tumusiime, Joseph F. Wamala, Luke Nayakarahuka, Barbara Knust, Ilana Schafer, Julius Lutwama, Ute Ströher, Pierre Rollin, Stuart Nichol</i>	
12:00	Q&A and Discussion	
ORAL SESSION 4.2: INFLUENZA AND RESPIRATORY INFECTIONS		Thursday, 4 December
CO-CHAIRS: Michael Owusu and Mpho Seleka		Room 1.6
11:00	A Fully Integrated Paper-based Assay for the Extraction, Isothermal Amplification, and Detection of Pandemic (H1N1) Influenza A RNA <i>Catherine Kapperich, Natalia Rodriguez, Andy Fan, Jacqueline Linnes, Christopher Chen</i>	
11:10	Molecular Epidemiology of Influenza B Viruses and Antigenic Profiles in South Africa: 2005-2013 <i>Mpho Seleka, Marietjie Venter, Florette K Treurnicht, Amelia Buys, Johanna McAnerney, Terry Besselaar, Orienka Hellferscee, Cheryl Cohen, Shabir A Madhi</i>	
11:20	Human Coronaviruses Associated with Upper Respiratory Tract Infections in Rural Areas of Ghana <i>Michael Owusu, Augustina Annan, Yaw Adu-Sarkodie</i>	
11:30	Co-colonization of Group B Streptococci and Other Respiratory Pathogens during Early Infancy in West Africa <i>Ebenezer Foster-Nyarko, Brenda Anna Kwambana, Jessica Mclellan, Ifedayo Adetifa, Odutola Aderonke, Fatima Ceesay, Abdoulie Bojang, James Jafali, Olatunde Ogundare, Martin M. O. Ota, Martin Antonio</i>	
11:40	Role of the Laboratory in a Cluster-randomized Trial: Effectiveness of Seasonal Influenza Vaccination of Children in Africa (Senegal) <i>Mbayame-Ndiaye Niang, Chris Victor, Aldiouma Diallo</i>	
11:50	Q&A and Discussion	
ORAL SESSION 4.3: HIV PROFICIENCY TESTING		Thursday, 4 December
CO-CHAIRS: Mamo Umuro and Nadia Siteo		Room 2.4
11:00	Monitoring the Quality of HIV-1 Viral Load Testing through Proficiency Testing Program using Dried Tube Specimens in Resource-limited Settings <i>Shon Nguyen, Artur Ramos, Joy Chang, Bin Li, Vedapuri Shanmugam, Debrah Boeras, John Nkengasong, Chunfu Yang, Dennis Ellenberger</i>	
11:10	Inter-operator Comparison of the Elispot Assay Proficiency Testing in HIV-1 Clinical Trials in Kenya <i>Bashir Farah, Robert Langat, Jackton Indangasi, Simon Ogola, Omu Anzala</i>	
11:20	Rapid HIV Testing, Going Beyond Numbers in the Era of Task Shifting to Non-laboratory Personnel while Maintaining Quality through Individual-based Proficiency Test Monitoring – The Kenyan Successful Experience <i>Muchiri Njogu, Frankline Kitheka, Sophie Mwanyumba, Kipkerich Bera, Umuro Mamo</i>	
11:30	The Performance of POC CD4 Technologies in Quality Assurance Systems is Comparable to the Performance of Conventional Technologies in Mozambique <i>Nadia Siteo</i>	
11:40	Quality Assurance Monitoring of Pima CD4 Testing: Operator Errors Attributing to Higher Invalid Test Rates <i>Larry Westerman, Nichole Arnett, Sehin Birhanu, Karen Chang, Mary Schmitz, Katie Tucker, Omotayo Bolu, John Nkengasong, Luciana Kohatsu, and Fausta Moshia</i>	
11:50	Does Laboratory Participation in EQA Programs have an Impact on Laboratory Performance? Results of Two Years Evaluation of Laboratories Performances in the National Proficiency Testing Scheme, Nigeria <i>Oluwaseun Aladesanmi, Eric Lugada, Olusegun Busari, Olumide Okunoye, Okechukwu C. Nwanyanwu, Ali Onoja, Jelpe Tapdiyel</i>	
12:00	Q&A and Discussion	

ORAL SESSION 4.4: SUSTAINABLE LABORATORY INFORMATION SYSTEMS		THURSDAY, 4 December
CO-CHAIRS: Ralph Timperi and Amitabh Adhikari		Roof Terrace Room
11:00	Review of Laboratory Information Management Systems in Mozambique: Quality Indicators <i>Beth Skaggs, Janise Richards, Mark DeZalia</i>	
11:10	Successful Utilization of Laboratory Information Systems in Establishing Quality Management Systems Leading to ISO Accreditation <i>Thomas Gachuki and Mamo Umuro</i>	
11:20	Rapid Scale up of the Basic Laboratory Information System (BLIS) in Ghana <i>Philip Boakye, Bernard Nkrumah, Anthony Ofose, Beatrice van der Puije, Samuel Duh, Ava Onalaja, Amitabh Adhikari, Reshma Kakkar, Celia Woodfill</i>	
11:30	Rift Valley Provincial General Hospital in Kenya Goes Paperless: Achieving 100% Automation of Laboratory Data in Developing Countries <i>Edwin Ochieng, Rufus Nyaga, Michael Mwangi, Winnie Migwi, Osborn Otieno</i>	
11:40	Towards Providing an Affordable and Sustainable Laboratory Information System for Developing Countries: Successful Implementation of BLIS-Kenya Open Source Laboratory Information System In Public Health Hospital Laboratories In Kenya <i>Emmanuel Kweyu, Roy Rutto, Emmanuel Kitsao, Brian Kiprop, Edwin Ochieng, Osborn Otieno, Amitabh Adhikari, Ralph Timperi</i>	
11:50	Q&A and Discussion	
ORAL SESSION 4.5: IMPROVING BIOSAFETY AND LABORATORY EQUIPMENT		Thursday, 4 December
CO-CHAIRS: Albert Bunyasi and James Olweny		Auditorium 2
11:00	The Maputo Declaration on Strengthening of Laboratory Systems: Where is Uganda on Equipment Harmonization and Standardization Six Years Down the Road? <i>James Olweny, Eric Nabuguzi, Henry Oundo, Paul Lotay, Sheba Nakimera, Wilson Nyegenye, Rashid Settaala, Soweddi Muyingo</i>	
11:10	Development of a New Laboratory Safety Evaluation Tool to Build Robust Safety Programs and Achieve QMS Accreditation <i>Thomas Stevens, David Bressler, Shanna Nesby, John Nkengasong</i>	
11:20	Laboratory Equipment Maintenance using Reagent Markup and Reagent Rental Strategy in Uganda <i>Wilson Nyegenye, Christina Mwangi, Ida Namakula, Eileen Burke, Steven Aisu, Sunday Izidoro, Victor Bigira, Sam Wasike, Sitra Mulepo, Philip Kasibante</i>	
11:30	Suivi des Stocks de Réactifs et Consommables de Laboratoire de Biologie Médicale : Développement d'un Outil de Calcul de la Couverture en Guinée <i>Mouslihou Mohamed, Howoro Loua, Sophie Ouvrard, Etienne Guillard</i>	
11:40	Biological Safety Cabinet Training for African Countries at Eagleson Institute USA <i>Mary Ann Sondrini</i>	
11:50	Partnering with Biosafety Associations in Africa to Strengthen Laboratory Biosafety <i>Maureen Ellis and Tubi Abiola</i>	
12:00	Q&A and Discussion	
ORAL SESSION 4.6: RETURN ON INVESTMENT IN LABORATORY		THURSDAY, 4 December
CO-CHAIRS: Edwin Shumba and Elaine Umubyeyi Nyaruhirira		Auditorium 1
11:00	Laboratory Tests Use and Laboratory Test Costs in Sub-Saharan Africa: A Comprehensive Survey of Clinical Laboratory Test Menus, Test Volumes, and Test Complexities in Kampala, Uganda <i>Lee F. Schroeder, Ali Elbireer, Timothy K. Amukele</i>	
11:10	Cost Effective Mix of Point-of-Care (POC) and Conventional Instrument Deployment in Zambia <i>Farouk Umaru and Fales Mwamba</i>	
11:20	Weighing the Costs: Implementing the SLMTA Program in Zimbabwe <i>Edwin Shumba, Phoebe Nzombe, Absolom Mbinda, Raiva Simbi, Douglas Mangwanya, Peter H. Kilmax, Elizabeth T. Luman, Sibongile N. Zimuto</i>	
11:30	SLMTA Return on Investment for Finance Managers <i>Kilian Songwe and Maryanne Otieno</i>	
11:40	Financing the Introduction of New TB Diagnostics and Treatment: Reflections from Rwanda and Uganda <i>Elaine Umubyeyi Nyaruhirira, S Chutima, F Matovu, M Gasana, C Mundy</i>	
11:50	A Market Assessment of HIV Immunological and Virological Testing Across Low- and Middle-Income Countries <i>Teri Roberts and Jennifer Cohn</i>	
12:00	Q&A and Discussion	

ORAL POSTERS AT A GLANCE

ORAL POSTERS 1.1: EVALUATING NOVEL TESTS		Monday, 1 December
CO-CHAIRS: Moses Joloba and George Alemnji		Ballroom East/West
13:00	1.11 Using Laboratory Data to Predict which Districts to Prioritize the Implementation of Cryptococcal Antigenaemia Detection Using a Combination of Automated EIA and a Manual Lateral Flow Assay South Africa <i>Nassim Cassim, Lindi Marie Coetzee, Deborah K. Glencross</i>	
13:10	1.12 Serum Hyaluronic Acid as a Non-Invasive Tool to Diagnose Schistosomal Periportal Fibrosis in <i>Schistosoma mansoni</i> Endemic Areas of Ethiopia <i>Filimon Mitiku Haile, Elsa Hagos, Nega Berhe, Bjørn Myrvang, Svein G. Gundersen</i>	
13:20	1.13 Laboratory Validation of SD BIOLINE HIV/Syphilis Duo Rapid Test <i>Natasha Gous, Lesley Scott, Tintswalo Mavutani, Norma Bosman, Wendy Stevens</i>	
13:30	1.14 Malaria Test Performance During an Outbreak in Kenya, 2012 <i>Emmanuel Okunga, Waqo Boru, Gura Zeinab, Galgalo Tura, Amwayi Samuel, Wences Arvelo</i>	
13:40	1.15 Validation of Multiplex PCR for Detection and Differentiation of Salmonellas <i>Iryna Gerilovych, Borys Stegnyy, Andrii Zavgorodnii, Anton Gerilovych, Vasyl Arefiev</i>	
13:50	1.16 Implementation and Evaluation of the Presto Combined Qualitative Real Time CT/NG Assay in Rwanda <i>Irith De Baetselier, Lambert Mwambarangwe, Vicky Cuylaerts, Viateur Musengamana, John Rusine, Claude Mambo Muvunyi, Agrippine Mukarurangwa, Janneke van de Wijgert, Evelyne Kestelyn, Tania Crucitti</i>	
ORAL POSTERS 1.2: HIV AND CO-INFECTIONS		Monday, 1 December
CO-CHAIRS: Charles Kiyaga and Teri Roberts		Ballroom East/West
13:00	1.21 CD4 Point of Care Testing (POCT) at Household-level in Kenya: Added Novelty from a Nationally-Representative Based Cross-Sectional Survey <i>Kepher Otieno, Ernest Makokha, Caleb Ogada, Grace Bartonjo, Mamo Umuro, Jane Mwangi</i>	
13:10	1.22 Dried Blood Spot (DBS) Validation in Viral Load Measurement using Abbott System m2000 in HIV Positive Patients Under Antiretroviral Treatment in DREAM Malawian and Mozambican Cohorts <i>Davide Brambilla, Richard Luhanga, Haswel Jere, Susanna Ceffa, Zita Sidumo, Tatiana Aidé, Erasmo Fernando, Remigio José Mugunhe, Fulvio Erba, Leonardo Palombi</i>	
13:20	1.23 Evaluation of CD4 Enumeration by Non-Laboratory Personnel Using PIMA Point of Care (POC) Instruments in Rural Clinics in Tutume Sub-District in Northern Botswana <i>Lucy Mupfumi, Madisa Mine, Mulamuli Moyo, Timothy Matsuokwane, Tuelo Mogashoa, Kenneth Mugisha, Lesedi Tsalaiile, Lesego Busang, Frank Mwangemi, Tendani Gaolathe</i>	
13:30	1.24 Taux de Séroconversion au VIH, VHB, VHC et Syphilis Chez les Donneurs Bénévoles Fidélisés de Sang de 2012 à 2013 au Centre National de Transfusion Sanguine, à Kinshasa/ République Démocratique du Congo <i>Cleophas Kalala, Eddy Sokolua, Viviane Munyemba Kasende, Huguette Kabulo Nday, Lilas Kongolo Mwamba, Pacifique Misingi Aye, Jean Baptiste Shuli Tchomba, Sylvain Yuma Ramazani</i>	
13:40	1.25 Can Dried Blood Spots or Whole Blood Liquid Transport Media Extend Access to HIV Viral Load Testing? <i>Natasha Gous, Lesley Scott, Wendy Stevens</i>	
13:50	1.26 HIV Passivity Rate Among Vertically Exposed Infants in Uganda is Steadily Declining and is Associated with the Increased Percentage of Mothers on ART During Antenatal <i>Isaac Ssewanyana, Proscovia Nambuya, Meghan Wareham, Victor Bigira, Grace Kushemererwa, Christine Namulindwa, Iga Tadeo, Steven Aisu, Charles Kiyaga</i>	
14:00	1.27 Determination of the Magnitude of Hepatitis B Viral Infection in Healthcare Workers, Addis Ababa, Ethiopia <i>Gizachew Taddesse Akalu, Kassu Desta Tulu, Addis Tamire Woldemariam, Abate Bane Shewaye</i>	
ORAL POSTERS 1.3: LABORATORY QUALITY IMPROVEMENT		Monday, 1 December
CO-CHAIRS: Lynee Galley and Varough Deyde		Ballroom East/West
13:00	1.31 Remarkable Reduction in Downtime Following Implementation of Laboratory Equipment Maintenance Strategy in FHI-360-Supported Hospitals in Nigeria <i>Humphrey Musuluma, Ndubueze Eigbe</i>	
13:10	1.32 Building Effective Onsite Laboratories in Developing Countries: A Case Study of Rinda Ubuzima <i>Lambert Mwambarangwe, Vicky Cuylaerts, Viateur Musengamana, Stephen Agaba, Evelyne Kestelyn, Tania Crucitti, Irith De Baetselier, Jennifer Van Nuij, Janneke van de Wijgert, Ndagijimana J. Claude</i>	
13:20	1.33 Quantification of Microbiology Laboratory Mentoring Progress in Tanzania <i>Lynee Galley, Douglas Abbott, John Aldom, Janet Maleski, Lilian Shija</i>	
13:30	1.34 Improvement of the Quality Management System at Mafikeng Laboratory: Benefits of SLMTA Improvement Projects <i>Stephina Nyoka, Nodathini Nazo, Tebogo Tjale, Richard Mareletse, Mankwana Titus, Frederick Lwanga</i>	
13:40	1.35 Innovative Improvements in Biosafety Practices Following Biosafety Skill-Based Trainings in Kenya <i>Angela Amayo, Doris Bota, Albert Bunyasi, Mamo Umuro, Jedida Wachira, Jacob Okello</i>	
13:50	1.36 Training-of-Trainers: A Strategy to Build Country Capacity for Effective SLMTA Expansion and Sustainability <i>Talkmore Maruta, Katy Yao, Sikhulile Moyo, Nqobile Ndlovu</i>	

ORAL POSTERS 2.1: LABORATORY INFORMATION MANAGEMENT SYSTEMS **Tuesday, 2 December**
CO-CHAIRS: Amitabh Adhikari and Matilu Mwau **Ballroom East/West**

13:00	2.11 Strengthening Laboratory Supply Chain Management Systems for Improved Uptake of Prevention of Mother-to-Child Transmission Services in Six States in Nigeria <i>Chioma Nwuba, Ogubuike Inmpey, Vincent Ihaza, Okechukwu Agbo, Sunday Aguora, Innocent Ibegbunam, Elvis Okafor, Theophilus Faruna</i>
13:10	2.12 Tracking ART Initiation with Laboratory Information Systems: The Implementation of HIV-Positive Infant Follow-Up Forms for Improved Retention in Care at Health Facilities in Uganda <i>Meghan Wareham, Victor Bigira, Brian Ngwatu, Betty Mirembe, Charles Kiyaga, Isaac Sewanyana, Peter Elyanu, Eleanor Magongo, Jeff Grosz</i>
13:20	2.13 Review of Laboratory Information Management Systems in Mozambique: Implementation Successes and Challenges CANCELLED <i>Mark DeZalia, Janise Richards, Beth Skaggs</i>
13:30	2.14 Scale-up of Laboratory Network in Support of HIV/AIDS Prevention Care and Treatment: Rwanda Experience <i>Claude Muvunyi, Wangeci Gatei, Edouard Ntagwabira, John Rusine, Eugene Habiyambere, Janvier Seromundo, Laetitia Gahimbare, Baptiste Mazarati</i>
13:40	2.15 Burden of Febrile Illness in Côte d'Ivoire: When Clinical Diagnosis Mismatched with Laboratory-Confirmed Cases in Malaria Control <i>Abdoulaye Ouattara, E.V. Adjogoua, A V Akran, M Kamagaté, G Ella, G T Gueu, M. Dosso</i>
13:50	2.16 Modernization of Laboratory Information Management System at the University Teaching Hospital, Zambia <i>Clement Ndongmo, Esther de Gourville, Victor Mudenda, Hamakwa Mantina, Edward Mwabuka, Charles Nyambe, Clement Phiri, Kenneth Langraaf</i>

ORAL POSTERS 2.2: ROLE OF LABORATORY IN EPIDEMIOLOGY **Tuesday, 2 December**
CO-CHAIRS: Namita Singh and Tura Galgalo **Ballroom East/West**

13:00	2.21 Non-Tuberculous Mycobacteria (NTM) in The Gambia – A Pilot Study <i>Catherine Okoi, Martin Antonio</i>
13:10	2.22 Prevalence and Risk Factors Associated with Intestinal Helminthic Infections with Special Emphasis to <i>Schistosoma mansoni</i> among Fishermen at Lake Hawassa, Southern Ethiopia <i>Tadesse Menjetta, Serkadis Debalke, Daniel Dana</i>
13:20	2.23 TEM, CTX-M and SHV Beta-Lactamases in Clinical Samples of <i>Klebsiella pneumoniae</i> Isolated in OAUTHC, Ile-Ife, Nigeria <i>Adegboyega Oladipo, Adekunle Olowe, Saturday Udoh</i>
13:30	2.24 Microbiological Investigation of the Risk of Nosocomial Infections in Four Services of Aristide Le Dantec Hospital, Dakar, Senegal <i>Seynabou Lo, Papa Amadou Niang Diallo, Awa Ba Diallo, Ndèye Amy Diagne, Aicha Marceline Sarr, Rokhaya Diagne, Mamadou Lamine Dia, Aissatou Gaye Diallo</i>
13:40	2.25 Facteurs de Pronostic de l'Accès Pernicieux Palustre de l'Enfant à Kinshasa <i>Patrick Malumba Kabitantshi</i>
13:50	2.26 Sero-Prevalence and Risk Factors of HBV Infection in Pediatric Patients Attending Rwanda Military Hospital (October-December 2013) CANCELLED <i>Louis Mujuwisha, Elizabeth Karlsson, Judy Orikiiriza, Johan Normark</i>
14:00	2.27 Newborn Screening Initiatives for Sickle Cell Disease in Africa <i>Jellili Ojodu and Lucy Maryogo-Robinson</i>

ORAL POSTERS 2.3: HIV-RELATED DIAGNOSTICS **Tuesday, 2 December**
CO-CHAIRS: Jackson Hungu and Madisa Mine **Ballroom East/West**

13:00	2.31 Laboratory Evaluation of the Frequency of CCR2-V64I Polymorphism in an HIV-infected South African Population <i>Nyasha Chin'ombe</i>
13:10	2.32 Effects of Antiretroviral Therapy on Lipid Profile Levels of HIV Positive Patients at the Nylon District Hospital, Douala, Cameroon <i>Ebot Walter Ojong, Eric Akum Achidi, Anna Longdoh Njunda, Henri Lucien F Kamga</i>
13:20	2.33 Serum Levels of Bone Minerals and Alkaline Phosphate Activities in HIV-Seropositive Subjects in Nnewi, Nigeria <i>Chukwuemeka Kennedy Ikechukwu, Adeola Olubayo, Charles Onyenekwe, Ejeatuluchukwu Obi</i>
13:30	2.34 Intestinal Parasitosis in Relation to CD4+T Cells Levels and Anemia among HAART Initiated and Non-HAART Initiated Pediatric HIV Patients in Zewditu Memorial Hospital, Addis Ababa, Ethiopia <i>Hylemariam Mihiretie, Asaye Birhanu, Bineyam Taye, Aster Tsegaye</i>
13:40	2.35 Life Threatening Elevated Serum Alanine Amino Transferase and Creatinine Levels among HIV-Infected Patients on HAART in Jos, North-Central Nigeria <i>Ekeh Evelyn, Mark Akindigh</i>
13:50	2.36 Assessment of the "Biocentric" and "Nuclisens" Assays Using DBS for HIV-1 Early Diagnosis and Viral Load Quantitation <i>Kwimatou Lekpa</i>

ORAL POSTERS 3.1: TESTING AND HEALTH SYSTEM STRENGTHENING		Wednesday, 3 December
CO-CHAIRS: Christina Mwangi and Emmanuel Idigbe		Ballroom East/West
13:00	3.11 Assessing Current Preanalytical Practices vs. Best Practices: A Benchmark for Improving Specimen Quality and Patient and Healthcare Worker Safety <i>Samuel Kwame Opoku and Aparna Jha Ahuja</i>	
13:10	3.12 Applying the Integrated Tiered Service Delivery Model (ITSDM) in KwaZulu-Natal (KZN) Province to Identify Optimal Placement of CD4 Testing Facilities <i>Lindi Marie Coetzee, Naseem Cassim, Deborah K. Glencross</i>	
13:20	3.13 Assessing the Impact of Implementing a Community CD4 Laboratory in a Rural Health District in South Africa <i>Nassim Cassim, Lindi Marie Coetzee, Deborah K. Glencross</i>	
13:30	3.14 Modular Containment Laboratory-Hybrid (MCL-H): A Novel Design Combining BSL3 Infectious Disease and BSL2 Molecular Laboratories in a Single, Transportable Unit <i>Barry Kosloff, Ingrid Terlouw, Gregers Chalker</i>	
13:40	3.15 Country-Based Testing Algorithms and Outcomes in a Blood Donation Setting: Implications on Cost and Future Testing <i>Joseph Mwangi, Joyceline Kinyua, Nancy Lagat</i>	
13:50	3.16 Quantitative Reference Ranges for Fasting Profiles and Oral Glucose Tolerance Test for Healthy Adults from Metropolitan Region (Nairobi) of Kenya <i>Stanley Kinge Waithaka, Eliud N. Njagi, Joseph N. Ngeranwa, Daniel M. Muturi, Wilfred K. Gatua, Bernard M. Chiuri, Leonard J. Njagi</i>	
14:00	3.17 Stability of Complete Blood Count and 3-part White Cell Differential Parameters with Storage Time and Temperature Variation Using Cell Dyn 1800 Automated Hematology Analyzer <i>Desalegn Tesema, Aster Tsegaye, Gonfa Ayana, Achamyeleh Mulugeta, Habtamu Asrat, Abnet Abebe</i>	
ORAL POSTERS 3.2: DRUG RESISTANCE		Wednesday, 3 December
CO-CHAIRS: Chunfu Yang and William Ampofo		Ballroom East/West
13:00	3.21 Bacteriological Profile and Antimicrobial Susceptibility Pattern of Blood Culture Isolates among Septicemia Suspected Children at Tikur Anbessa Specialized Hospital and Yekatit 12 Hospital Addis Ababa, Ethiopia <i>Adugna Negussie, Gebru Mulugeta, Ahmed Bedru, Ibrahim Ali, Damte Shimeles, Tsehaynesh Lema, Abraham Aseffa</i>	
13:10	3.22 Drug Resistance Profile and Molecular Characterization of Extended Spectrum Beta-lactamase (ESBL) Producing Escherichia coli Isolated in Lomé <i>Kodjovi Dodji Mlaga, Kodjovi D. Mlaga, Eugenie A. Anago, Ségla Togossou, Anoumou Y. Dagnra, Ambaliou Sanni</i>	
13:20	3.23 Optimization and Validation of an In-house HIV-1 Genotyping Protocol for Use on Dried Blood Spots in a South African Setting <i>Michelle Bronze, Kim Steegen, Azwidowi Lukhwareni, Maria A Papathanasopoulos, Wendy Stevens, Sergio C Carmona</i>	
13:30	3.24 Genetic Context for the Transmissible Quinolone-resistance Gene qnrS1 in Nigeria <i>Aaron Aboderin, Iruka Okeke, Eric Sumrall, Elizabeth Gallo, Adebayo Lamikanra</i>	
13:40	3.25 Resistance Pattern of Enterobacteriaceae Isolate from Urinary Tract Infections to Selected Quinolones in Yaoundé, Cameroon <i>Emilia Enjema Lyonga, Michel Toukam, Celine Nkenfou, Marie-Claire Okomo-Assoumou, Martha Mesembe, Agnes Eyoh, Georges Ikomey, Valentine Ngum Ndze, Sinata Koulla-Shiro</i>	
13:50	3.26 Detection of Extended Spectrum β-Lactamases in Invasive Klebsiella Pneumoniae Isolates from the University Teaching Hospital, Lusaka, Zambia <i>Enock Mulowa Mumbula, James C. L. Mwansa, Geoffrey Kwenda, Chileshe Lukwesa-Musyani</i>	
14:00	3.27 Persistence of Chloroquine-resistant Plasmodium Falciparum Mutant Haplotypes in Children with Uncomplicated Malaria in Lagos, Nigeria Four Years After Change of Chloroquine as First-line Antimalarial Drug <i>Oladipo Oladosu, Oyibo Wellington, Colin Sutherland</i>	
ORAL POSTERS 3.3: LABORATORY-BASED SURVEILLANCE AND EPIDEMIOLOGY		Wednesday, 3 December
CO-CHAIRS: Omu Anzala and Richard Njuom		Ballroom East/West
13:00	3.31 Plasmodium Ovale Curtisi and Plasmodium Ovale Wallikeri in North-West Ethiopia <i>Abebe Alemu, Hans-Peter Fuehrer, Gebeyaw Getnet, Belay Tessema, Harald Noedl</i>	
13:10	3.32 Improving Blood Supply Safety & Adequacy in Developing Countries: Pan-African Blood Safety Perspectives <i>Asa'ah Nkohkwo and Nigel Talboys</i>	
13:20	3.33 Evaluation of Laboratory-based Multi Drug Resistant Tuberculosis (MDR-TB) Surveillance System in Muhimbili (NIMR-CTRL) Tanzania, 2012 <i>Mura Ngoi, Fausta Moshia, Ahmed Abade, Mecky Matee</i>	
13:30	3.34 Emerging Zoonotic Diseases in the Coastal and Nairobi Regions of Kenya <i>Julius Oyugi, Antar Munira, Mike Drebot, Omu Anzala</i>	
13:40	3.35 Rift Valley Fever Sero-surveillance Using Recombinant Virus Nucleoprotein and Vesicular Stomatitis Virus Pseudotype-based Assays among Humans in Borno State, Nigeria <i>David Bukbuk, Shuetsu Fukushi, Hideki Tani, Tomoki Yoshikawa, Satoshi Taniguchi, Koichiro Iha, Shigeru Morikawa, Masayuki Saijo, Francis Kasolo, Saka Saheed Baba</i>	
13:50	3.36 Caractérisation Génétique des Rhinovirus et Entérovirus Associés au Syndrome Grippal au Sénégal <i>Mbayame Niang, David Kiori, Ousmane Kébé, Déborah Goudiaby, Ndongo Dia</i>	
14:00	3.37 The in vitro Susceptibility Pattern of Candida Blood Stream Isolates to 3 Antifungal Agents at Abuth Shika, Zaria, Nigeria <i>Joan Ejembi, Ronke Suleiman, Adebola Olayinka</i>	

ORAL POSTERS 4.1: DIAGNOSTIC INNOVATIONS		Thursday, 4 December
CO-CHAIRS: Mark Ware and Teferi Mekonen		Ballroom East/West
13:00	4.11 Comparison of SpeedOligo Test to Xpert MTB/Rif Test for Detection of Tuberculosis in Smear-Negative HIV-Infected Patients <i>Simon Walusimbi, Alfred Okeng, Edgar Kigozi, Samuel Kyobe</i>	
13:10	4.12 Development of an Enzyme-linked Immunosorbent Assay to Measure VWF Propeptide Levels in Plasma <i>Muriel Meiring and Precious Setlai</i>	
13:20	4.13 Quantitative Detection of <i>Plasmodium falciparum</i> Histidine Rich Protein 2 in Saliva <i>Felix Botchway, Cecilia Lekpor, David Dosoo</i>	
13:30	4.14 Evaluation of Mycobacteria Growth Indicator Tube (MGIT) for Drug Susceptibility Testing of Mycobacterium Tuberculosis Isolates from Egypt <i>Basan Motawi, Dalia Salem, Zeinab Mostafa, Yasser Mostafa, Randa El-Harizy</i>	
13:40	4.15 Preliminary Data on a New Flow Cytometry Assay for the Early Detection of Cryptococcal Antigenaemia <i>Keshendree Moodley, Lindi-Marie Coetzee, E. Shimp, B. Neary, B. Crider, D.K. Glencross</i>	
13:50	4.16 Concentration of Lymph Node Aspirate Improves the Sensitivity of Acid Fast Smear Microscopy for the Diagnosis of Tuberculous Lymphadenitis in Jimma, Southwest Ethiopia CANCELLED <i>Mulualem Tadesse Jano</i>	
14:00	4.17 Modalities of Prostate Specific Antigen Testing in Gauteng Clinics and Hospitals, South Africa <i>Mpho Maphayi, Jaya George, Braimoh Bello</i>	
ORAL POSTERS 4.2: POLICY AND NETWORKING		Thursday, 4 December
CO-CHAIRS: Charles Massambu and Jackson Amone		Ballroom East/West
13:00	4.21 An Essay on the Critical Role of Public-Private Partnerships in Strengthening Laboratory Medicine in Developing Countries <i>Ritu Shrivastava, Andy C Wilson, Christina Mwangi, Renuka Gadde, John N. Nkengasong</i>	
13:10	4.22 One Health: An Approach to Strengthen the Future of Laboratory and Clinical Health Systems to Solve Health Challenges in Africa <i>Faith Nawagi, Samuel George Okech, Cheryl Robertson, Samuel Majalija</i>	
13:20	4.23 Probable Human Rabies Death in an Urban Hospital in Kenya, August 2013 <i>Emmanuel Okunga, Oluoch David, Wako Boru, Gura Zeinab, Galgoro Tura, Amwayi Samuel, Wences Arvelo</i>	
13:30	4.24 Partenariat Publique/Privé en RDC Pour l'Implémentation de l'Option B Plus chez les Femmes Enceintes HIV Positives: le Cas du Programme DREAM <i>Julien Nzeze, Giovanni Guidotti, Stefano Capparucci, Anna Maria Doro Altan, Ceffa Susanna, Dirk Shaka, Leonardo Palomb, Essenge Freddy, Jacques-Devos Kabemba</i>	
13:40	4.25 Improving Surveillance of Neisseria gonorrhoea Antimicrobial Drug Resistance Based on Efficient Laboratory Network: Case of Cameroon-GASP <i>Ariane Nzouankeu, Marie-Christine Fonkoua, Gaëlle Tchouwa, Genevieve Tsobnang, Marcelle Abanda, Esther Sokeng, Antoinette Ngandjio</i>	
13:50	4.26 On-site Sensitization Meeting to Hospital Management Teams Enhance Implementation Laboratory Quality Systems through SLMTA Program to 5 Laboratories Funded Under East Africa Public Health Laboratories Network Project (EAPHLNP) in Tanzania <i>Abdul Mwanja, Fausta Moshia, Charles Masambu, Dickson Majige, Angelika Luguru, Jacqueline Mumba, Lawrence Lekashingo, Lugano Kyando</i>	
ORAL POSTERS 4.3: EXTERNAL QUALITY ASSURANCE PROGRAMMES		Thursday, 4 December
CO-CHAIRS: Henry Mbah and Lawrena Okoro		Ballroom East/West
13:00	4.31 Initiating an Innovative External Quality Assurance Programme for Xpert MTB/RIF Instrument in Ghana (Pilot Phase) <i>Alaine Umubyeyi Nyaruhirira, Catherine Mundy, Rhehab Chimzizi, Bismarck Adusei, Francesca Dzata, Sebaka Molabo, Lesly Scott, Pedro Suarez, Frank Bonsu</i>	
13:10	4.32 Improving Quality of Rapid HIV Testing Services in HIV Testing and Counseling Settings: Impact of Hands-On Refresher Training <i>Franklin Kithaka, Sophie Mwanyumba, Mamo Umuro</i>	
13:20	4.33 Use of Dried Tube Specimen Technology for Quality Assurance in Remote HIV Testing Sites Supported by FHI360 in Nigeria <i>Emmanuel Ojo, Henry Mbah, Humphrey Musuluma, Olufunmilayo Ojo, Sunday Ashaolu, Michael Dada, Uche Okudo, Olunmi Negedu-Momoh, Kwasi Torpey</i>	
13:30	4.34 Causes of Proficiency Testing Failures in CD4 Immune Monitoring in Nigerian Laboratories: Outcomes of Investigation and Corrective Action Onsite Visits to Unsatisfactory CD4 Proficiency Testing Laboratories in Nigeria <i>Oluwaseun Aladesanmi, Eric Lugada, Olusegun Busari, Olumide Okunoye, Sulieman Aminu, Okechuku Ogueri, Gregory Uchuno, Tosan Erhabor, Eruona Etubi, Jelpe Tapdiyel, Okechukwu C. Nwanyanwu</i>	
13:40	4.35 Coagulation Factors Level in Fresh Frozen Plasma in Rwanda <i>Schifra Uwamungu, Anthony Kebira Nyamache, Florance Masaisa, Serah Njoki Kaggia, Swaibu Katara</i>	
13:50	4.36 Are We Delivering the Wrong Results? Examining Misclassification of HIV Status and False Positive Test Results <i>Cheryl Johnson</i>	
14:00	4.37 Implementation of a National EQA Program for the Rwanda Hospital Laboratory Network <i>Esther Gathinji, Jennifer Anderson, Janvier Serumondo, Emmy Rusanganwa, Claude Muvunyi, Anicet G. Dahourou, Sally Liska</i>	

POSTERS AT A GLANCE

Prefunction of Ballroom East/West and Auditorium 1

- 1 Molecular Comparison and Diversity of Human Enteroviruses Circulating Between North and South Regions of Madagascar**
Richter Razafindratsimandresy
- 2 Investigation of Dengue in Nampula City, Nampula Province, Mozambique, 2014**
Inocencio Mate
- 3 Role of Selected Hematopoietic Micronutrient Status in Anemia Among Pregnant Teenagers Attending Antenatal Clinic at Two Healthcare Facilities in Bungoma County in Western Kenya**
George Sowayi, Evelyn Khabukwi Mulunji, Gabriel Wanyama Mukoya
- 4 Progress Toward Development of a Low-density Infection-detection Test to Support Active Detect-and-Treat Interventions Aimed at Regional Malaria Elimination**
Paul LaBarre, Kathy Tietje, Kenneth Hawkins, Christine Clerk, Kelly Ebels, Chris Crudder, Robert Burton
- 5 Factors Affecting Survival of HIV Positive Children Taking Antiretroviral Therapy at Adam Referral Hospital and Medical College, Ethiopia**
Adem Aman Kedir, Alem Desta, Girmatsion Fesseha
- 6 Distribution of Plasma C-Reactive Protein Measured by High-Sensitivity Assay in Apparently Healthy Adult Nigerians**
Isah Adagiri Yahaya
- 7 The Role of Pathologists' Assistants: Young Profession with Great Potential to Improve Anatomic Pathology in a Pathologist-Limited Continent – Africa**
Alejandra Meza and Stephanie Skinner
- 8 Implementing Laboratory Equipment Back-up Program: A Strategy to Minimize Service Interruption in APIN Laboratory Program**
Eke Ofuche, Jay Osi Samuels, Olatunde Kehinde, Prosper Okonkwo, Jean-Louis Sankale, Chukwuma Omoruyi
- 9 HBV Co-infection and Its Predisposing Factors among HIV Positives at Karamara Hospital: A Comparative Cross Sectional Study between Pre-ART and ART Initiated**
Fentabil Getnet, Henok Asresahegn, Beyene Meressa
- 10 Asymptomatic Oral Yeast Carriage among HIV and Non-HIV Individuals in Benin City, Nigeria**
Newton Esebelahie, Ifeoma Bessie Enweani, Richard Omoregie, Faithful O. Newton-Esebelahie
- 11 Impact of Management Commitment towards Implementation of Quality Management System: Our Experience from Federal Capital Territory Administration (FCTA) Hospitals' Laboratories**
Bolarinde Joseph Lawal, Ameh James, Maduka Maduabuchi Kenneth, Queen Nkeiruka Bola-Lawal
- 12 Research Methodology and Scientific Writing Course: Transforming Laboratory Personnel to Research Scientists**
Michael Kiptoo, Willie Githui, Willy Sang, Peter Wanzala, James Kariuki, Moses Mwangi
- 13 Survey, Isolation, and Characterization of Pathogenic Micro-organisms in the Outdoor Hospital Environment of Thika District Hospital in Kenya**
Gladys Esendi Chungu
- 14 Setting up a Quality Management System in a Community-based Clinical and Research Facility: Experiences and Challenges in a Rural Nigerian Setting**
John-Moses Uwanduoma Maduabuchi, Eusebius Sunday Ugwu, Ivy Ifeoma Ogbo
- 15 Comparative Study of Haematological Parameters in HIV Positive Individuals on Different HAART Regimen**
Ayodeji Olayanji and Richard Akele
- 16 Assessment of the Temperature Monitoring Systems in Public Health Laboratories in Kenya**
Bashir Farah, Pole Lewa, Benard Omondi, Omu Anzala
- 17 Smear Conversion Rates on New Smear Positive Pulmonary Tuberculosis Patients in Adama District, Ethiopia**
Tesfay Abreha Nigusse and Negussie Deyessa
- 18 Comparative Analysis of Putative Genes Mediating Invasion of Vertebrate Hosts by Plasmodium falciparum Parasite of Malaria**
Peter Waiganjo and Ann W. Muigai
- 19 Utilisation des Tests de Diagnostic Rapide du VIH dans le Cadre de la Délégation des Tâches: Quel Contenu pour la Formation des Agents de Dépistage?**
Mouslihou Diallo, Abdoulaye Toure, Aboubacar Savane, Penda Diallo, Kansiré Condé, Charlotte Deze, Etienne Guillard
- 20 Piloting Ogawa Kudoh for Solid TB Culture at District-level Laboratories in Mozambique**
Sofia Viegas, Susana Oguntoye, Nureisha Kadir, Carla Madeira, Khalid Azam, Daisy Nakamura Sato
- 21 Country Ownership Approach to Scaling-up Biosafety Practices in Kenya**
Mercy Njeru, Jane Mwangi, Daniel Kimani, Albert Bunyasi
- 22 Seroprevalence of HIV and Syphilis among Pregnant Women in Gondar, Northwest Ethiopia: Awaking Message**
Mulugeta Melku, Zelalem Addis, Bamlaku Enawgaw, Asemarie Kebede
- 23 Challenging Experience of Blood Units Supply in a Remote Area: Case of Mogadishu, Somalia**
Gapelba Aime and Errol Visser

24 Evolution du Réseau de Contrôle de Qualité des Laboratoires VIH en RDC

Jeanine Nkakulu Luzolo, Mah-Séré Keita Sow, Jean Willy Tshimpaka Tshiamala, Daniel Yavo, Jérémie Muwonga Masidi, Samuel Edidi Bazepeyo, Berthe Vantoto Mpova, Thérèse Mujanyi Kasonga, Antoinette Mayamba Tshindibu, Nadine Damaris Abiola

25 Antituberculosis Activities of Crude Extract and Fractions of the Bulb of Crinum Jagus against Mycobacterium tuberculosis Isolates

Adebola Akintola, A.O. Kehinde, O.E. Adebiji, O.G. Ademowo

26 Utilisation de l'Application Microsoft Excel® Comme Outil de Gestion des Données Qualité dans un Laboratoire de Biologie Clinique

Eric F. Nzeko, Jaures A.K. Noumedem, Clémence Olemba, Juliana Ndasi

27 Hematological Abnormality and Associated Factors among Children in Anti-retroviral Therapy Naïve and on Highly Active Anti-retroviral Therapy at Felege Hiwot Referral Hospital, Bahir Dar, Northwest, Ethiopia

Yakob Gebregziabher, Mulugeta, Zelalem, Agerie

28 Preliminary Investigation of Antimicrobial Potential of Giant African Land Snail (Archachatina marginata) Epiphram and Egg against Selected Pathogenic Isolates

John Abiona, Paul Akinduti, Ayodeji Osinowo, Mohammed, Onagbesan

29 Uptake of Free Viral Load Services in Kenya CANCELLED

Charity Hungu, Stella Vihenda, Samuel Ochieng, Steven Muriithi, Amina Abdullahi, Matilu Mwau

30 Quality Improvement Initiatives towards Provision of Safe and Sufficient Blood in Kenya

Eric Wakaria, Charles Rombo, Margaret Oduor, Peter Mwamba, Kimberly Tilock

31 Designing a Curriculum to Promote Publication of Laboratory Quality Improvement Work in Vietnam

Barbara McKinney

32 Viral and Bacterial Etiology of Severe Acute Respiratory Illness in Children <5 years of age in Niger, 2009-2012

Amadou Lagare, Halima Mainassara, Bassira Issaka, Ali Sidiki

33 Characterisation of Non-polio Enteroviruses Circulating in the South African Population

Wayne Howard, Adrian Puren, Leigh Berrie

34 Performance of an Early Infant Diagnostic (EID) Test, AmpliSens DNA-HIV-FRT (AmpliSens), in Comparison with Abbott Real Time HIV-1 Qualitative (Abbott Qualitative) and Roche COBAS® Ampliprep/COBAS® Taqman HIV-1 Qual Test (Roche CAP/CTM Qual) using Dried Blood Spots (DBS) Collected from Children Born to HIV-infected Mothers in Ukraine

Joy Chang, Tetyana Tarasova, Vedapuri Shanmugam, Marianna Azarskova, Shon Nguyen, Jennifer Sabatier, Dennis Ellenberger, Chunfu Yang, Charles Vitek, Nataliya Nizova

35 Surveillance des Méningites Bactériennes Pédiatriques à Streptococcus pneumoniae et à Haemophilus influenzae de 2011 à 2013 au Malipermettre d'Évaluer l'Impact du Vaccin Conjugué anti pneumocoque sur les Sérotypes Inclus dans le Vaccin

Mahamadou Abdou, Seydou Diarra, Souleymane Coulibay, Flabou Bougoudogo, I. Guindo

36 Sensitivity and Specificity of Diagnostic Assay Loop-mediated Isothermal Amplification for Identification of Influenza A Virus

Volodymyr Postoienko, Karpulenko Maksym, Sapacheva Maria

37 Etude Prospective et Descriptive de la Prévalence de la Dengue dans des Episodes Fébriles à Abidjan, Côte d'Ivoire

Veronique Akran Agbaya, E.V. Adjougou, A. Ouattara, M. Kamagaté

38 Comparison of Two Communities Affected by Cholera in Kasese District in Uganda

Scholastica Okui, George Pariyo, David Ndungutse

39 Adopting Traffic Light System to Monitor SLMTA Progress (Sierra Leone Experience)

Isatta Wurie, Eric Sefoi, Doris Harding, Ralph Timperi

40 CD4 Count and some Trace Elements in Seropositive HIV Undergoing Highly Active Antiretroviral Therapy in Osun State

Akintunde Akintayo Akinjinmi, Samson Olaitan Omole, Adeyemi Anthony Olanrewaju

41 Comparison of Malaria Rapid Diagnostic Tests with Microscopy for the Diagnosis of Malaria at Lubwe Mission Hospital, Samfya, Zambia

Aaron K. Tembo, R. Mushibwe, G. Kahenya, H. Lumano

42 Creating a Sustainable Culture of Quality through the SLMTA Program in a District Hospital Laboratory in Kenya

Phidelis Maruti, Ekesa A. Mulianga, Lorna N. Wambani, Melda N. Wafula, Fidelis A. Mambo, Shadrack M. Mutisya, Erick N. Wakaria, Erick M. Mbat, Angela A. Amayo, Jonathan M. Majani, Bryan Nyary, Kilian A. Songwe

43 Prevalence of Bacterial Vaginosis among Women of Reproductive Age Attending Thika District Hospital, Kenya

Joseph Nzomo, L. Muchiri, P. Okemwa

44 Epidemiology of Laboratory Confirmed Rubella Cases in Ethiopia, 2008-2012 from Measles/Rubella Case-Based Surveillance Data

Mekonen Getahun Baynesagn, Berhane Beyene, Tassew Kassa, Mesfin Tefera, Birke Teshome, Almaz Abebe

45 Isolation and Antibiotic Susceptibility Patterns of Shigella and Salmonella among under 5 years Children with Acute Diarrhea, in Selected Health Facilities Addis Ababa, Ethiopia

Yeshwondm Mamuye, Asaye Birhanu, Kassu Desta, Surafel Fantaw, Gesit Metaferia

46 Access to CD4 Testing Improves Provision of HIV Quality Services (A Case Study of Two AHF-Kenya Supported Clinics)

Geoffrey Maitha, Lydia Buzaalirwa, Paul Nganga

47 Diagnostic Outcome of GeneXpertMTB-RIF versus Ziehl Neelsen Smear Microscopy*Agatha Ani, Yetunde Fadairo, Rosemary Pwol, Chindak Lekuk, Toluope Ashi-Sulaiman, Patrick Akande, Godwin Imade, Maxwell Akambi, Oche Agbaji***48 Assessment of Feto-maternal Hemorrhage among Rhesus D Negative Pregnant Mothers using the Kleihauer-Betke Test (KBT) and Flowcytometry (FCM) in Addis Ababa, Ethiopia CANCELLED***Fekadu Urgessa, Aster Tsegaye, Yirgu Gebrehiwot, Asaye Birhanu***49 Evaluation of a Malaria Rapid Diagnostic Test among Febrile Children in Nasarawa, North Central, Nigeria***Akyala Ishaku, Olufemi Ajumobi, Adebola Olayinka***50 Isolation, Antibiotic Susceptibility Profile of Escherichia coli Pathotypes and Factors Associated with Well and Boreholes Water Contamination in Mombasa County***Thani Suleiman, Samuel Lifumo, Hamadi Iddi Boga, Joseph Oundo***51 Aflatoxins and Fumonisin Contamination of Home-made Food (Weanimix) from Cereal-Legume Blends for Children CANCELLED***Justice Kumi, Nicole J. Mitchell, Asare George, Timothy D. Phillips***52 Malaria Parasitaemia and CD4+ T Cell Count in HIV Patients Attending Tertiary Medical Center, Nigeria***Olaniran Olarinde and Saturday Jack Udoh***53 Hematological Manifestation in HIV-Infected Children***Felix Botchway, William Ababio, Patience Bannerman Williams, Cecilia Lekpor***54 Diagnostic Predictive Value of Platelet indices for Discriminating Hypo-productive versus Hyper-destructive Thrombocytopenia in Patients Attending Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia***Mikias Negash, Aster Tsegaye, Amha G/Medhin***55 Drug Resistant Pattern of M. tuberculosis among TB Suspected Children at Tikur Anbessa Specialized Hospital, Ethiopia***Ibrahim Ali, Yimtubeznash Woldeamnuel, Amha Mekasha, Markos Abebe, Demissew Beyene, Shiferaw Bekele, Abraham Aseffa***56 Laboratory Systems and Quality Improvement. Accreditation: The Nyumbani Diagnostic Laboratory Experience***Mungai Ndlung'u, Janet Robinson, David Onyango, Joseph Ochieng***57 Development and Validation of PCR-based Tools for Laboratory Diagnostics of Animal Brucellosis***Borys Stegnyy, Anton Gerilovych, Andrii Zavgorodnii, Olga Obukhovska, Oleksii Solodiankin***58 Prevalence of Vancomycin Resistant Enterococci and Associated Risk Factors among Clients with and without HIV in Northwest Ethiopia: A Cross-sectional Study***Mengistu Seid, Wondwosson Abebe, Moges Tiruneh, Feleke Moges***59 Barriers, Facilitators, and Outcomes Related to the Introduction of a Point-of-Care (POC) CD4 Testing Program in Rural Tanzania: Perceptions of Health Service Providers and Recipients***Maggie Wilson, Madeleine Buck, Bathseba Liduke, Sonia Semenic***60 Mise en Place d'une PCR Quantitative Temps Réel pour l'Evaluation de la Charge Virale à Kinshasa***Erick Kamangu***61 Worm Infestation and Tuberculosis Diagnosis: a Case Study***Chisenga Kalunga, Sinkamba. E., Chomba Obbie, Zulu Kachaka, S.Phiri, Mbulo***62 Evaluating a STAT Laboratory Performance with Quality Indicators***Horace Gumba, Brett Lowe, Moses Mosobo, Tuda Otieno***63 Reliable and Accurate CD4 T Cell Count and Percent of the New Portable Flow Cytometer CyFlow MiniPOC***Andrea Cossarizza, Milena Nasi, Sara De Biasi, Elena Bianchini, Lara Gibellini, Marcello Pinti, Alda Tiziana Scacchetti, Vanni Borghi, Tommaso Trenti, Cristina Mussini***64 Etude Microbiologique de l'Environnement du Service de Chirurgie de l'Hôpital de la Mère et de l'Enfant et de l'Hôpital de l'Amitié Tchad-Chine de N'Djamena***Michel Kengne***65 Overcoming the Challenges of Implementing Quality Control in a Manual African Laboratory***Ifeyinwa Osegbe, Martin Ugonabo, Ijeoma Meka***66 Strengthening Mozambican Clinical Laboratory Technologists' Knowledge and Skills through an Intensive Technical In-service Training Program in Brazil***Sergio Ramagem, Orlando Ferreira, Antonio A. Assane***67 Effects of Co-administration of Red Palm Oil and Rooibos on Glycaemic and Liver Function Parameters in Streptozotocin-induced Diabetic Rats***Ademola Ayeleso, Oluwafemi Oguntibeju, Nicole Brooks***68 Cost-effectiveness of PimaTM Point-of-Care CD4+ Lymphocyte Cell Count Testing in Antenatal Centers, Tanzania 2013***Marissa Courey***69 Improving Laboratory and Staff Testing Proficiency through Inter-laboratory Comparison in the Absence of Proficiency Testing Scheme: a Pilot Study of Inter-lab Comparison in Kuje Area Council, Abuja, Nigeria***Dorathy Ugwuodo, Ameh James, Itohan A-Ameh, Saleem*

70 Implementing Laboratory Quality Systems in Preparations for Accreditation, Experience of the National External Quality Assessment Centre, Zaria, Nigeria*Oluwaseun Aladesanmi, Eric Lugada, Olusegun Busari, Olumide Okunoye, Okechukwu C. Nwanyanwu, Ali Onoja, Jelpe Tapdiyel, Oke Odafen, Vanessa Hechter***71 Breaking Down Barriers to Quality Improvement***Patrick Mateta, Sheila Woodcok, Charles Massambu***72 Application of Quality Management System Principles Results in Laboratory Accreditation: A Tanzanian Success Story***Patrick Mateta, Sheila Woodcok, Charles Massambu***73 The Prevalence, Distribution of Diarrheagenic E.coli Categories, and their Antimicrobial Susceptibility Patterns in Kenya***Willie Sang and Rael Too***74 Determination and Comparison of Tuberculosis Drug Activity and Minimum Inhibitory Concentration of Second Line Anti-Tuberculosis Drugs among Multi-Drug Resistant Tuberculosis (MDR-TB) Patients Admitted at Kibong'oto Infectious Diseases Hospital***Richard Kinyaha***75 The Clinic-Laboratory-Interface (CLI) – Assessment of Facilities' Post-analytic Systems and Processes to Receive Pathology Test Results, Manage Abnormal Results and Review Laboratory Use, in Five Districts in Eastern Cape and KZN Provinces, SA***Irvin Mothibi, Leonie Coetzee, Peter Manyike, Selwyn Leonard, Kevin Kelly, Timothy Tucker, Sisanda Gaga, Dion Nortje***76 Prevalence of Intestinal Parasites and its Associated Risk Factors among Yadot Primary School Children of South-eastern Ethiopia: A Cross-sectional Study***Begna Eticha***77 Presumptive Treatment of Malaria During a Peak Transmission Season in a Malaria Endemic Setting: A Cross-sectional Study***Victoria Katawera, Charles O. Odongo, Peter Wambi, Jennifer Ajok, Ian Musinguzi, Samuel Oluka, Anita Wanyana, Denis Anywar, Alfred Andama***78 Performance of LED Microscopy in the Diagnosis of Pulmonary Tuberculosis in HIV Positive Individuals in Addis Ababa, Ethiopia***Konjit Getachew, Tamrat Abebe, Abebaw Kebede, Adane Mihret***79 Determination of Hematological and Immunological Parameters among HIV Positive Patients Taking Highly Active Antiretroviral Treatment and Treatment Naïve in the Antiretroviral Therapy Clinic of Gondar University Hospital, Gondar, Northwest Ethiopia: A Comparative Cross-sectional Study***Bamlaku Enawgaw***80 Implementing Quality Control Program at the HIV Counselling Testing Units at the Primary Health Centers (PHCs) in Lagos State, Nigeria***Anthony Ani, Eke Ofuche, Jay Samuels, Remi Olaitan***81 Molecular Detection of Clostridium difficile, Pathogenicity, Virulence and Moxifloxacin Resistance in Stool from Children with Diarrhea at Mulago Hospital***Josephine Tumuhanye, Rebecca Esther Khainza, Freddie Bwanga, Ezekiel Mupere, Grace Ndeezi, Jamir Mugalu***82 Five Years of Early Infant Diagnosis in Papua New Guinea, Making Early Initiation of ART Possible***Evelyn Lavu, Helen Keno, Sandra Ilaisa, Nella Renton, Jessica Markby, Caroline Chavellier, Mobumo Kiromat***83 Post Market Vigilance for Diagnostic Tests in Africa: A Pilot Study***Patience Dabula, Post Market Surveillance Working Group***84 Harmonizing Regulation of Medical Devices and In Vitro Diagnostics to Improve Quality and Access***Ruth McNerney and Chinyere Ilonze***85 Standardised Monitoring and Evaluating Framework for Xpert MTB/RIF Test Implementation***Andre Trollip, Victoria Harris, Mathabo Lebina, Saidi Mfaume, Basra Doulla, Mathabo Mareka, Heidi Albert***86 Controle de Qualité Externe du Dépistage Sérologique du VIH par le Drieb Tube Specimen dans les Regions de Segou, Sikasso et dans le District de Bamako (Mali)***Souleymane Ongoiba, Seydou Diarra, Albertine Niass, Sékou Traore, Ibrehima Guindo, Lobo Koita, Chiaka Fofana, Mamadou Souncale Traoré, Adama Sangare***87 Laboratory Information System Implementation in Ethiopia: Success and Challenge***Adino Desale, Gonfa Ayana, Tigist Habtamu, Kehulum Belayneh, Achamyelch Mulugeta, Feyissa Challa, Habtamu Asrat, Adisu Kebede, Ebise Abose, Dereje Yenealem***88 Antibiotic Susceptibility Profile of Enterococcus spp. Isolated from Patients with Urinary Tract Infection and Health Care Environment in Two Reference Hospitals in Cameroon***Hortense Gonsu Kamga, Myriam Sango, Michel Toukam, Michel Kengne, Didier Mbakop, Sinata Koulla Shiro***89 Implementation of CDC Global HIV/AIDS HIV-1 Viral Load Proficiency Testing in Ethiopia***Adisu Kebede, Ebise Abose, Achamyelch Mulugeta, Habtamu Asrat, Abnet Abebe, Deraje Yenealem, Feven Girmachew, Getnet Hailu, Adino Desale, Amha Kebede, Gonfa Ayana***90 The Second Cohort of SLMTA Implementation in Mozambique***Patrina Laurinda Chongo, Eduardo Gudo, Isabel Pinto, Ana Paula Mandlaze, Solon Kidane, SLMTA Mozambique technical group***91 Phenotypic Characterization of Klebsiella spp. Producing Beta Lactamase and Carbapenemase in Three Referral Hospitals of Cameroon***Hortense Gonsu Kamga, Anicette Betbeui Chafa, Michel Toukam, Didier Calixte Mbakop, Sinata Koulla Shiro*

92 Implementation of One World Accuracy Proficiency Testing Program: Ethiopian Experience*Ethiopian Public Health Institute, Addis Ababa, Ethiopia***93 Using Local Postal Courier to Facilitate External Quality Assessment Programs: Ethiopian Experience***Adisu Kebede, Wondwossen Kassa, Achamyeleh Mulugeta, Habtamu Asrat, Dereje Yenealem, Tesfaye Mekonnen, Adino Desale, Amha Kebede, Gonfa Ayana***94 Using Laboratory Information System Data to Assess Successes and Challenges of an HIV Early Infant Diagnosis (EID) Programme***Jean Maritz, Nei-yuan Hsiao, Wolfgang Preiser***95 Dosage des CD4 : Identification des Facteurs Associés à une Prise en Charge Tardive des Patients Infectés par le VIH en Guinée***Abdoulaye Toure, Penda Maladho Diallo, Aboubacar Savané, Falaye Traore, D'Ortenzio Eric, Mouslihou Diallo, Lamine Koivogui***96 A Snapshot of the State of Adult ART Programmes – an Analysis of Aggregated Laboratory HIV Viral Load Testing Data***Nei-yuan Hsiao, Jean Maritz, Landon Myer, Wolfgang Preiser***97 Strengthening Laboratory Management Toward Accreditation Significantly Improved the Quality of Laboratory Results in Uganda***William Lali, Richard Batwita, Kamaranzi Bakunda, Aloysius Bingi, Philip Kasibante, Benson Ouma, Richard Walwema, Steven Aisu, Gaspard Guma***98 Multidrug Resistant Salmonella enterica serovars typhi and paratyphi B Isolated at the University Teaching Hospital in Lusaka, Zambia, from 2010-2012***Annie Kalonda, Geoffrey Kwenda, Chileshe Lukwesa-Musyani, James C. L. Mwansa***99 Comparison of Manual and Automated Nucleic Acid Extraction for HIV-1 Drug Resistance Genotyping***Dorcas Maruapula***100 Automatic Quantification Malaria Test of Thick Smear***Pedro Catarino and Carmen Bernardes***101 Evaluation of a Chlamydia trachomatis Rapid Test in Rwanda: The BioChekSwab Rapid Test***Irith De Baetselier, Lambert Mwambarangwe, Vicky Cuylaerts, Viateur Musengamana, Stephen Agaba, Evelyne Kestelyn, Janneke van de Wijgert, Claude Mambo Muvunyi, Tania Crucitti***102 Prevalence of HIV Transmission among Transfused Children with Sickled Cell Anaemia in Bungoma***Vincent Aliong'o***103 Influenza Surveillance in Zambia in the Last 5 Years: Successes, Challenges & Limitations***Andros Theo, C. Malama, K. Muzala, E. Chizema, M. Monze***104 Evaluation of Morphology Flags on the Advia 2120 Haematology Analyser at a Large Academic Hospital***Mariam David and Elise Schapkaiz***105 Performance Analysis of Data Management and Quality Improvement at Arthur Davidson Children's Hospital PCR Laboratory in Ndola, Zambia***Hilary Lumano, Mangani Zulu, Peter Mutale, Fales Zulu***106 Marqueurs Virologiques de l'Hépatite B chez les Patients Initiant la Thérapeutique Antirétrovirale au Sénégal***Gora Lo, I. Madiouba, H. Diop-Ndiaye, Dia A., M. Mané, A. Sow-Sall, F. Diop, K. Kébé-Fall, S.B. Gueye, S. Diallo, A. Gaye-Diallo, S. Mboup, C. Toure-Kane***107 Preparing for Seasonal Flu Vaccination in Uganda: Flu Seasonality and the Most Vulnerable Population***Barbara Namagambo, J. T. Kayiwa, T. Byaruhanga, R. Chiza, N. Owor, N. Babi, I. Nabukenya, B. Bakamutumaho, J. J. Lutwama***108 Implementation of POC CD4 Testing in Uganda: Lessons Learned***Wilson Nyegenye, Christina Mwangi, Victor Bigira, Bernard Bitwababo, Philip Kasibante, Tephy Mujurizi, Steven Aisu, Sunday Izidoros, Martin Howera, Sam Wasike***109 Organization and Practice of Rapid Albuminuria and Glycosuria Testing in Senegal: A Barrier to the Optimal Utilization of Laboratory Test in Antenatal Care?***Aicha Marceline Sarr, Winny Koster, Roughyatou Ka, Rokhaya Diagne, Oulimata Diémé, Adja Khady Datt-Fall, Constance Schultsz, Robert Pool, Ahmad Iyane Sow, Pascale Ondo***110 Outcome of Adequate Adherence to Antireviral Drug in the Prevention of Mother-to-Child Transmission of HIV. A Study Conducted at Federal Medical Center Abeokuta, Nigeria **CANCELLED*****Esther Obiakor***111 Expanding Access to HIV Viral Load Testing: A Systematic Review Re-examining RNA Stability in EDTA Whole Blood and Plasma beyond current Recommendations***Teri Roberts, Kimberly Bonner, Reed Siemieniuk, Andrew Boozary, Nathan Ford, Jennifer Cohn***112 Toxoplasma gondii IgG Antibody Avidity Testing at National Health Laboratory Services, Tygerberg Academic Hospital Cape Town. A Case of Value Added***Kenneth Hammond-Aryee, Andre Roux, Monika Esser, Paul Van Helden***113 Plasmids and Antibiotic Resistant Profile of Extended Spectrum Beta Lactamase (ESBL) Producing Escherichia coli in Jos, Nigeria***Kenneth Onyedibe, Francisca Nwaokorie, Samson Isa, Mark Okolo, Clement Da'am, Edmund Banwat, Daniel Egah***114 Implementation of the ISO15189 Quality Management System at Ndola Central Hospital Pathology Laboratory (NCH-PL) through Training and Mentorship***Fedius Ernest Lungu*

115 Mains Power Quality Monitoring and Analysis for Innovative Medical Equipment Power Management Development*Mark J. Fisher, Jeffrey D. Lackey, Abhishek K. Agarwa, Rob Dickinson, Kara M. Palamountain***116 Factors Affecting Implementation of Chemistry Tests in Rural Areas in Zambia***Charles Nyambe and Naofumi Hashimoto***117 Coagulation Factors Level in Fresh Frozen Plasma in Rwanda***Schifra Uwamungu, Anthony Kebira Nyamache, Florance Masaisa, Serah Njoki Kaggia, Swaibu Katara***118 Genotype Diversity of Mycobacterium Isolates from Children in Jimma, Ethiopia***Wondewosen Tsegaye Sim, Bereket Workalemahu, Abraham Aseffa***119 Drug Susceptibility Pattern and Genotypic Diversity of Mycobacterium tuberculosis isolates Collected from Community-based Survey in Ethiopia***Muluwork Worku, Gobena Ameni, Abebaw Kebede, Zelalem Yargal, Elena Hailu, Grimay Medihn, Daniel Demssie, Zeleke Alebachew, Almaz Abebe, Amha Kebede, Eshetu Lemma***120 Same-day Diagnosis ('SPOT- SPOT') versus the Conventional Strategy ('SPOT-MORNING-SPOT') with Three Specimens, Direct Ziehl-Neelsen and Flourescet Microscopy on both HIV+ and HIV- Patients***Araya Ferede, Daniel Mekonen, Yosef Gashaw, Feker Asera***121 The Impact of Laboratory Infrastructure on the WHO AFRO Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) in the Bamenda Regional Hospital Laboratory (BRHL), Cameroon***Victor Fondoh, Wansuh Stephany, Siyem Christa, Nakeli Noline, Charles Awasom, Kinge Thompson, Yoky Estel, Njukeng Patrick, Judith Shang***122 The Use of an Internal Quality Control Programme to Monitor Quality Assurance of HIV Rapid Testing in the Limpopo Province, South Africa***Dumisani Mhlongo, Adrian Puren, Beverley Singh, Amanda Mohlala, Robert Molale, Prudence Khumalo, Zodwa Dam, Joesph Honwani, Moloatelo Makwela, Thebe Tsheola, Zawadi Chipeta***123 Evaluation of the Performance of SD BIOLINE HIV/syphilis Duo Kit as a Point-of-Care Assay at a Rural Health Center in Southwestern Uganda***Daniel Omoging, Victoria Katawera, Mark Siedner, Yap Boum II***124 Prevalence of Some Intestinal Parasitic Infections and Malaria Parasitaemia in Relation to Body Mass Index of Children Resident in Orphanages in Anambra State, Nigeria***Bernard Oluboyo, Ifeoma Enweani, Ifeoma Ekejindu, Adeola Oluboyo***125 Assessing the Performance of CareStart™ Malaria Pf/Pv Combo Test against Thick Blood Film in the Diagnosis of Malaria in Northwest Ethiopia***Tadesse Hailu***126 Establishing an Occupational Safety and Health Program to Improve Laboratory Biosafety in Kenya***Daniel Kimani, Mercy Njeru, Ernest Makokha, Jane Mwangi, Shanna Nesby***127 Piloting SLMTA in South Africa: Overview of Deviations and Operational Challenges in the Implementation of the Program***Neliswa Chigudu, NHLS Trainers, Patience Dabula***128 From Zero to Five Star: The Improvement Process of 44 Nigerian Army Reference Hospital Laboratories***Olatilewa Amusu, Godwin I. Ayuba, Johnbull Mbibi***129 Performance of GeneXpert MTB/RIF in Diagnosis of Tuberculosis and Rifampicin Resistance in 68 Nigerian Army Reference Hospital, Yaba, Lagos, Nigeria***Olatilewa Amusu, Idemudia Otaigbe, Nkiru Nnadi, Augustine Akindoye, Yeibo Bibode, Jacinta Elemere, Barnabas Nzekwe***130 Diagnosis and Phylogenetic Analysis of Orf Virus from Goats in Tanzania: A Case Report***Julius Mwanandota, Chanasa. A.R. Mpelumbe-Ngeleja, Raphael Sallu, Mmeta Yongolo, Timothy Holton, Mercy Macharia***131 The Magnitude of Anemia among Geriatric Patients Attending at Gondar University Hospital, Gondar, Northwest Ethiopian: An Ignored Problem***Mulugeta Melku and Betelihem Terefe***132 Serological Evidence of Acute Dengue Virus Infection among Febrile Patients Attending Plateau State Specialist Hospital (PSSH) Jos, Nigeria***Joshua Dawurung, Marycelin Baba, David Bukbuk, Christiana Dawurung***133 Maximizing Mentorship: Variations in Laboratory Mentorship Models Implemented in Zimbabwe***Phoebe Nzombe, Elizabeth Luman, Sibongile Zimuto, Edwin Shumba, Douglas Mangwanya, Raiva Simbi, Peter Kilmarx***134 Rubella Outbreak – Southern Nations and Nationalities People's Region, Ethiopia, 2012***Lemma Bogale and Lucy Boulanger***135 Conversion of the WHO AFRO Stepwise Laboratory Improvement Process towards Accreditation (SLIPTA) Checklist to a Dynamic Digital Tool Capable of Supporting Multiple Checklists and Audit Tools***Lucy Maryogo-Robinson, Patina Zarcone, Jon Lipsky*

136 The Establishment of a Laboratory Information System Support Unit at Ministry of Health in Lesotho Assists in Assuring Quality Patient Results*Mokenyakenya Matoko, Kim Lewis, Malebanye Lerotholi, David Mothabeng, Tsietsi Mots'oane, Sherrie Staley, Yohannes Mengistu***137 The Use Telecommunication Networks to Remotely Monitor Data Quality of POC CD4 Testing Data Amongst HIV Infected Clients in Cameroon***Terence Asong and M.Rioja***138 Assessment of Anaemia and Iron Status in Pregnant Women with Co-infections of Malaria, Intestinal Helminthes, and HIV in Southwest Nigeria***George Ademowo, Olawunmi Rabi, Ayokulehin Kosoko, Hannah Dada-Adegbola, Ganiyu Arinola, Catherine Falade***139 Integration of HIV Point-of-Care Diagnostics into Existing Centralized Laboratory Networks: Uganda's Experience***Victor Bigira***140 African Center for Integrated Laboratory Training: Improving Patient Outcomes in Africa through Stronger Laboratories***Elsie van Schalkwyk, Ritu Shrivastava, Richard Poxon, Alison Coppin, Zawadi Chipeta, Varough M. Deyde***141 First Achievements of Strengthening Laboratory Management towards Accreditation (SLMTA) in Angola***Yolanda Cardoso, Cláudia Ramos, Cátia Marques, Ana Pinheiro, Jaqueline Tenente, Vasco Agostinho, Filomena Silva, Isilda Neves***142 Clinical Characteristics of Patients Tested for Pneumocystis jirovecii as Part of Severe Acute Respiratory Infection (SARI) Surveillance at Three Sites in South Africa***Desiree Du Plessis, John Frean, Bhavani Poonsamy***143 The Role of the Laboratory in Nutrition Surveillance in Zimbabwe***Arthur Pagiwa, Takudzwa Mtisi Chagumaira, Tasiana Krispin Nyadzayo, Bernard Samende, Patience Musasa***144 Working Towards International Certification/Accreditation: The NEQAL Experience***Tosan Erhabor, Onyekachukwu F. I. Okeke, Gregory Uchuno, Joshua Barde, Tyondo Henry, Vincent Obi, Lawrena Okoro, Anthony Emeribe***145 Tuberculosis Infection among Health Care Workers in Two District Hospitals – Kenya, August 2013***Evalyne Kanyina and Gerald Mucheru***146 Mentoring Laboratory Personnel in Viral Load and CD4 Testing in Botswana: Successes and Challenges***Mulamuli Moyo, Madisa Mine, Lucy Mupfumi, Timothy Matsuoqwane, Tuelo Mogashoa, Tendani Gaolathe***147 Phased Approach for Laboratory Information System Implementation and Expansion in Ethiopia***Adino Desale, Tigist Habtamu, Achameleh Mulugeta, Dereje Yenealem, Wondwassen Kassa, Getnet Hailu, Andargachew Gashu, Amha Kebede, Gonfa Ayana***148 Détermination du Taux Normal des Lymphocytes TCD4+ chez le Sujet Sain Séronégatif au VIH par une Méthode de Cytométrie en Flux à Cotonou, République du Bénin***Edgard Lafia, R. Moudachirou, A. D. Sayi, M. D. Zannou, B. Lafia, P. Sogbohossou, E. Lozes, L. Anani, S. Anagonou***149 The Prevalence of HIV-Associated Nephropathy in pre HAART patients at the University Teaching Hospital (UTH) Lusaka, Zambia***Levy C. Kanguya, Aggrey Mweemba, Clement B. Ndongmo, Timothy Kantenga***150 Rubella Disease Trends in Kenya, January-November, 2012***Caroline Ngunu-Gituathi, Raphael Mulli, Jane Githuku-Mungai, Samuel Amwayi***151 New Paradigms in Building Framework to Ensure Sustainable Implementation of Laboratory Technologies and Programs in Resource-limited Countries: The Mozambique Experience***Eduardo Samo Gudo, Patrícia Laurinda Chongo, Isabel Pinto, Nadia Siteo, Jessina Massamha, Beth Skaggs, Ilesh Jani***152 The WANETAM-TB Network Impact in the Surveillance of Tuberculosis Infection in Senegal***Awa Ba Diallo and Makhtar Camara***153 From Grass to Grace: How SLMTA Revolutionized the Bamenda Regional Hospital Laboratory in Cameroon***Siyem Christa Nkwawir, Awasom N. Charles, Talkmore Maruta***154 Laboratory Based Surveillance for Bacterial Meningitis in Selected Health Facilities of Nairobi County, Kenya, March 2014***Alfred Karagu, Nkatha Meme, Lilly Muthoni, Lilly Kirui, Waqo Boru, Ian Njeru***155 Improving the Quality of Laboratory Systems through Strengthening Laboratory Management towards Accreditation (SLMTA) in Rwanda***Innocent Nzabahimana, Sebasirimu Sabin, Gatabazi John Baptiste, Ruzindana Emmanuel, Kayobotsi Claver, Mary Kathryn Linde, Mazarati Jean Baptiste, Serumondo Janvier, Claude Mambo Muvunyi***156 Invalid Assessment Cases in the PCR Results Quality of the Virology – Bacteriology Laboratory of the National Institute of Public Health Research (INRSP) in Mali from 2009 to 2013: Challenges and Prospects***Alou Sanogo, Y. Cissé, S. Coulibaly, I. Guindo, D. Koita, G. Mamadou, T. Thiéro, F. Bougoudogo, F. Maïga, A. Sylla***157 Late Presentation of Pediatric Patients to Clinics: A Major Barrier to Uptake of Laboratory Services in Nigeria***Chinonyelum Okolo, Anselem Akabueze, Joy Nzei*

158 Performance of GeneXpert MTB/RIF Assay Over Smear Microscopy in the Diagnosis of Tuberculosis in both HIV-Positive and Negative Patients*NNkiru Nwokoye, Catherine Onubogu, Peter Nwadike, Abigail Abiodun, Toyosi Raheem, Uche Igbasi, Oni Idigbe***159 The HIV Rapid Test Proficiency Test Programme in Zambia: Successes, Limitations, and Challenges***Esther de Gourville, Fales Z. Mwamba, Kunda G. Musonda, Katoba K. Musukwa, Mutinta Shisholeka-Yumbe, Mwaka A. Monze, Clement B. Ndongmo***160 Development of the First Kenya Essential Medical Laboratory Commodities List (KEMLCL)***Rosalind Kirika, Ali Abdulatiff, Mamo Abudo, Samuel Mbugua, Andes Imbunga, J. Mukoko, Alice Micheni, Ndinda Kusu***161 EQA Programme for AFB Slides Improves Laboratory Presumptive Diagnosis of TB in Regions of Zambia***Esther de Gourville, Mathias Tembo, Denson Ng'ona, Ngula M. Kabelenga, Nathan Kapata, Maurice Mwanza, Namushi Mwananyambe, Edward W. Schroder***162 Infectious Disease Diagnostic***Zelalem Teklemariam Kidanemariam***163 Laboratory-Clinical Interface: Safe Phlebotomy Training Program Promotes a Shared Customer Service Culture in Public Hospitals in Kenya***Angela Amayo, John Mwhia, Benard Muture, Jedida Wachira, Matilu Mwau, Judy Mwangi***164 Identification of Candida spp, Cryptococcus spp, and Susceptibility Pattern of Candida spp. Isolates from Patients Admitted at the Central Hospital of Maputo, Mozambique***Rafael Joaquim, Rau Vaz, Dinis Jaintital, Oscar Fraile, Susana Oguntoye, Tomás Zimba***165 HIV Rapid Testing Policies and Practices in the Caribbean Region: Interventions, Outcomes, Challenges, and Recommendations***George Alemniji, Giselle Guevara, Keith Parris, Mireille Kalou, Stephanie Behel, Bharat Parekh, John Nkengasong, Rachel Albalak***166 Comparison of Four Commercial HIV-1 Viral Load Detection Technologies***Deidre Greyling, Adrian Puren, Ewalde Cutler, Marthi Pretorius***167 Ensuring Continuous Access to HIV Laboratory Services by Routine Monitoring of Stock Status to Attain National Commodity Security***Samuel Mbugua, Susan Gathua, Joseph Mukoko, Omar Abdi Mohamed, Alice Micheni***168 ASM's EQA Plan Improves AFB Microscopy Services in Namibia***Shirematee Baboolal, Maritza Urrego, Shireen Sissing, Gerhard van Rooyen***169 Association between Phenylthiocarbamide (PTC) Taste Perception and Malaria***Olusegun Ogundokun and Oluwayemisi Owwoeye***170 Protein Patterns in Serum and Urine of Prostate Cancer Subjects***Adeola Oluboyo, Samuel Meludu, Charles Onyenekwe, Bernard Oluboyo, Chidi Oranusi, Timothy Mbaeri***171 Evaluation of Laboratory Information Management Systems: Matching Issues and Methods***Janise Richards, Mark DeZalia, Beth Skaggs***172 Over-diagnosis of Malaria: The Role of Non-Adherence to Test Negative Results***Eleanor Ochodo, David Sinclair, Paul Garner*

MONDAY, 1 DECEMBER 2014

ORAL SESSION 1.1 HIV DIAGNOSIS AND VIRAL LOAD TESTING

DATE: **Monday, 1 December**

TIME: **11:00 – 12:45**

LOCATION: **Room 1.4**

CO-CHAIRS: **Sergio Carmona**, National Health Laboratory Service, South Africa
Laurent Bélec, Université Paris Descartes, France

11:00

Tamara Sonia Boender¹, Kim CE Sigaloff¹, Raph L. Hamers¹, Maureen Wellington², Margaret Siwale³, Mariettes Botes⁴, Cissy Kityo⁵, Sulaimon Akanmu⁶, Kishor Mandalija⁷, Tobias F. Rinke de Wit¹, Pascale Ondo¹

¹ Department of Global Health, Academic Medical Center of the University of Amsterdam, Amsterdam Institute for Global Health and Development, ² Newlands Clinic, Harare, Zimbabwe, ³ Lusaka Trust Hospital, Lusaka, Zambia, ⁴ Muelmed Hospital, Pretoria, South Africa, ⁵ Joint Clinical Research Centre, Kampala, Uganda, ⁶ Lagos University Teaching Hospital, Lagos, Nigeria, ⁷ Coast Province General Hospital, Mombasa, Kenya

Continued Virological Failure and Unnecessary Switching of Antiretroviral Treatment for HIV-1 May Occur Despite Access to Viral Load Monitoring

Background: The World Health Organization recommends switching antiretroviral therapy (ART) from first- to second-line after two consecutive plasma viral load (VL) tests of >1000 HIV-RNA copies/ml, despite good adherence. We evaluated the use of locally available VL test results in ART switch decisions in the Pan-African Studies to Evaluate Resistance (PASER-M) observational cohort.

Methods: HIV-1 infected people initiating ART were enrolled from 13 sites in Kenya, Nigeria, Uganda, Zimbabwe, Zambia and South Africa. Seven sites had access to local VL testing. Retrospective VL and drug resistance testing was done for all participants through PASER-M.

Results: 2,737 participants initiated first-line ART. After 12 months, 175 persons (6.4%) experienced viral failure (VF) as retrospectively determined. After 24 months, 34 of these 175 (19.4%) had re-suppressed VLs, 37 (21.1%) were switched to second-line ART, 3 (1.7%) had deceased, 30 (17.1%) were lost-to-follow-up and 8 (4.6%) missed VL results. Sixty-three of 175 persons (36.0%) were still experiencing VF at 24 months, despite access to local VL testing for 51.7% of them. Eighty-three percent of patients with continued VF harboured drug resistance mutations.

Ninety-four (3.4%) participants were switched to second-line ART within 24 months of ART. Nineteen (20.4%) had undetectable VL at the time of switch; unnecessary switching also occurred in sites where VL testing was available (12 of 55 cases, 21.8%). Four (4.3%) switchers harboured wild-type virus.

Conclusion: Availability of VL testing does not necessarily imply use of VL test results in clinical management of patients on ART. Significant numbers of patients with VF are not switched timely and accumulate drug resistance mutations. Patients are unnecessarily switched to second-line ART, even in the presence of VL testing. Implementing VL testing should be accompanied by clinical decision-making support. Enhanced adherence support is needed to increase patient retention in care, increase viral re-suppression, thus averting unnecessary switches.

11:10

Victor Bigira¹, Charles Kiyaga², Meghan Wareham¹, Isaac Sewanyana², Brian Ngwatu¹, Judi Lusike¹, Wilson Nyegenye², Steven Aisu²

¹ Clinton Health Access Initiative, Kampala, Uganda, ² Central Public Health Laboratories, Ministry of Health, Kampala, Uganda

Breaking the Barriers to Antiretroviral Therapy Monitoring: Uganda's Astrategy for Public Sector Viral Load Monitoring Implementation

Background: The June 2013 World Health Organization (WHO) consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection recommend viral load (VL) as the preferred monitoring approach to diagnose and confirm antiretroviral treatment (ART) failure. However, access to viral load testing in resource limited settings has been severely constricted by prohibitive costs and the complexity of specimen handling logistics needs, resulting in poor quality and/or unnecessary loss of life. Current access to VL testing in Uganda is below 10% and is confined to private, research-oriented institutions.

Methods: In an effort to adopt WHO guidance and improve the quality of ART monitoring, the Ministry of Health (MOH) with support from CHAI and other development partners created a concept for scaling up public sector VL testing in September 2013. Key to this concept was the negotiation of lowered VL test prices comparable to those of current CD4 testing needs, negotiation of free equipment placement, and the adoption of whole blood Dried Blood Spots (DBS) as the specimen of choice. The system leverages the existing National Specimen and Result Transport Network (NSRTN) to enable expedited access.

Results: Following review by a technical assistance team from PEPFAR, the concept has been adopted into the National Viral Load Monitoring Implementation Plan, providing for the establishment of a Ministry-owned molecular laboratory targeting to deliver a total of 700,000 VL tests at 10.5 US\$/test and an all-inclusive cost of 14M US\$ by the end of 2016 with funding support from PEPFAR, Global Fund and free equipment placement by Abbott Molecular. The lab is scheduled to start testing by June 2014.

Conclusion: Despite funding constraints, Uganda will be an early adopter of the 2013 WHO guidelines and will be a model for a number of other developing countries in the implementation of VL monitoring.

11:20

Laurent Bélec¹, Christian Diamant Mossoro-Kpinde², Jean-Christophe Gody³, Olivia Mbitikon³, Jean De Dieu Longo⁴, Gérard Grésenguet⁵

1 Hôpital Européen Georges Pompidou, Paris, France, 2 Laboratoire National de Biologie Clinique et de Santé Publique, Bangui, Central African Republic, 3 Complexe Pédiatrique, Bangui, Central African Republic, 4 Ministère de la Santé Publique, Bangui, Central African Republic, 5 Faculté des Sciences de la Santé, Bangui, Central African Republic

Performance of the Amplix[®] real-time PCR Assay for Plasma HIV-1 (non-B subtypes) RNA Quantification Using LRT and Gag Targets to Assess Virological Failure in HIV-infected Treated Children Living in Central Africa

Background: The capability of intermediate open platform to measure plasma HIV-1 RNA load is essential in sub-Saharan Africa to assess virological failure according to the 2013-revised WHO recommendations. The geopolitical context of the Central African Republic urges to evaluate carefully the escalating risk of antiretroviral drug resistance in vulnerable populations, especially HIV-treated children. In 2009, 34% of children receiving a first-line regimen were in therapeutic failure.

Methods: 242 HIV-infected treated children (median age, 11 years) followed in the pediatric complex in Bangui were consecutively included in 2012. Plasma HIV-1 RNA load ("VL") was assessed in parallel by the intermediate open platform Amplix[®] real-time PCR assay using LRT and gag targets (All Diag, Strasbourg) and by the reference method COBAS[®] AmpliPrep/COBAS[®] TaqMan ("CAP/CTM" SS) HIV-1 test v2.0 (Roche Molecular Systems, Inc., Branchburg, NJ). Direct sequencing of HIV protease and reverse transcriptase genes was performed using the Abbott Viroseq kit on plasma samples with HIV-1 RNA >1000 copies/ml.

Results: Detectable plasma HIV-1 RNA was observed in 68% of children under first-line treatment, and virological failure (i.e. VL >1,000 copies/ml) was diagnosed in 61%, which was associated in 85% of cases with viruses harboring at least one drug-resistance mutation to NRTI or NNRTI, and in 41% of cases with at least one major drug resistance mutation to NRTI or NNRTI when excluding the M184V mutation. Overall, the proportion of children receiving a first-line regimen for a median of 27 months with virological failure associated with drug-resistance mutations, and thus eligible for a second-line treatment, was estimated at 43% of the whole cohort. The incidence of therapeutic failure in first-line treated children was >3% per year. Unexpectedly, high proportion (71%) of children in therapeutic failure harbored normal CD4 T cell count levels (i.e. >500/mm³). By reference to the Roche platform, the Amplix[®] real-time PCR platform showed 100%-sensitivity and 98%-specificity to assess HIV virological failure, at cost 3-fold less elevated.

Conclusion: High rate and incidence of virological failure associated with major antiretroviral drug resistance mutations are frequently associated with frequent normal level of CD4 T cell count in the Bangui's cohort, thus with the selection of children harboring dissociated virological and immunological responses to treatment. The main hypothesis is that long-term survivor children have been selected in the cohort. The simple open Amplix[®] real-time platform is fully adapted to assess at lower cost virological failure in African context.

11:30 **CANCELLED**

Hetal Patel

International Laboratory Branch, Division of Global HIV/AIDS, Centers for Disease Control and Prevention, Georgia, USA

Evaluation of Multispot HIV1/2 Rapid Test to Confirm and Type HIV Infection in Plasma and DBS Specimens

Background: A standard HIV diagnostic algorithm uses an enzyme immunoassay (EIA) followed by confirmatory Western blot (WB) testing. Bio-Rad Multispot HIV-1/2 (MS) can distinguish between HIV-1 and 2 infections and reduce cost and complexity associated with WB testing. Expanding use of MS with dried blood spot (DBS) would increase its applicability for surveillance use. This study compared performance of 1) diagnostic algorithm using EIA/MS with EIA/WB on plasma and 2) EIA/MS/WB algorithm on DBS

Methods: Plasma specimens (N=795) from several countries were used to prepare DBS by mixing with HIV- O+ packed cells (1:1) and applying 100 µL/spot on Whatman 903 filter paper. Plasma and eluted antibodies from DBS were tested on Genetic Systems HIV 1/2 Plus O EIA, Cambridge Biotech HIV-1 WB and MS.

Results: The EIA/WB algorithm identified 576 specimens as HIV-1, 21 as indeterminate, and 198 as negatives. MS classified all WB indeterminate specimens as HIV-2. EIA/MS algorithm classified 561 as HIV-1, 30 as HIV-2, 7 as HIV-1/2 (dual) and 197 as negative. All MS HIV-2 specimens were reactive on HIV-2 peptide-EIA. One EIA/WB-negative specimen was positive by EIA/MS; one EIA/WB-positive specimen was negative by EIA/MS. Agreement was 97.1% between the two algorithms for HIV diagnosis with 91.3% of discrepant results contributed by WB indeterminate specimens. Agreement was 99.4% between plasma and DBS specimens with EIA/MS algorithm. Addition of WB confirmed the remaining 5 EIA+/MS- DBS as HIV-1, increasing concordance to 100%.

Conclusion: EIA/MS algorithm with plasma allowed confirmation and typing of HIV infection with better accuracy than EIA/WB algorithm. EIA/MS/WB algorithm can be successfully used for DBS specimens to confirm, type HIV infection, and eliminate indeterminate results for surveillance studies. Ease of use, reduced cost and decreased turn-around-time when using MS prior to WB are benefits of the proposed algorithm.

11:40

Leslie Shanks¹, Ruby Siddiqui², Jarmila Kliescikova¹, Neil Pearce³, Cono Arti³, Libsework Muluneh⁴, Erwan Pirou¹, Koert Ritmeijer¹, Johnson Masiga¹, Almaz Abebe⁴

1 Médecins Sans Frontières, Amsterdam, The Netherlands, 2 Médecins Sans Frontières, London, UK, 3 London School of Hygiene and Tropical Medicine, London, UK, 4 Ethiopian Health and Nutrition Research Institute, Addis Ababa, Ethiopia

Time for Change? An Evaluation of the Tie-breaker Algorithm and the Role of Weakly Reactive Test Lines in Contributing to a High Rate of False Positive HIV Results

Background: Many countries continue to use tiebreaker algorithms instead of WHO recommended serial or parallel algorithms to diagnose HIV. Further growing evidence suggests that weakly reactive test lines increase the risk of a false positive result. We undertook an evaluation of the positive predictive value (PPV) of the tiebreaker algorithm in Ethiopia. Secondary objectives were to assess the PPV of weakly reactive test lines, and assess the addition of a simple to use confirmation test to the algorithm.

Methods: The study was conducted in two sites in Ethiopia and recruited HIV testing clients until 200 positive samples were reached. Each sample was re-tested in the laboratory on the 3 RDTs and on the Origenics Immunocomb Confirmation (OIC). The gold standard test was the Western Blot, with indeterminate results resolved by PCR testing.

Results: 2620 subjects were included in the main study, with a HIV prevalence of 7.7%. The serial algorithm with 2 RDTs had a single false positive result (PPV 99.5%, 95%CI: 97.3%-100%). The tiebreaker algorithm resulted in 16 false positive results (PPV 92.7%, 95%CI: 88.4%-95.8%). Adding the OIC confirmation test to either algorithm eliminated the false positives. All the false positives had at least one weakly reactive test line in the algorithm. The PPV of weakly reacting RDTs was significantly less than those with strong positive test lines.

Conclusion: The risk of false positive HIV diagnosis in a tiebreaker algorithm is significant. We recommend abandoning the tie-breaker algorithm in favour of two test serial or parallel algorithms, and adding a confirmation test to the RDT algorithm. In addition, these data demonstrate an urgent need for more research on how to incorporate a change in interpretation at patient level of weakly reactive test lines to indeterminate (except for blood transfusion).

11:50

Muthoni Junghae¹, Franklin Kitheka², Samuel Mwalili¹, Mamo Umuro², Jane W. Mwangi¹

1 Centers for Disease Control and Prevention (CDC), Division of Global HIV/AIDS (DGHA), Nairobi, Kenya, 2 National HIV Reference Laboratory, Nairobi, Kenya

Monitoring the Quality of Rapid HIV Testing Using a National Register: Results from the Initial Implementation Phase in Kenya

Background: Efforts by the Kenyan HIV program towards universal access for HIV testing have resulted in expansive scale up of HIV testing services. Monitoring quality of testing is essential to ensure accuracy of results. In 2010, Kenya introduced a standardized logbook, the HIV Testing and Counseling (HTC) Laboratory Register, as part of the Multistep Approach for ensuring quality HIV testing. Full implementation of the register as a quality assurance (QA) tool requires routine data analysis.

Methods: In August 2012, the National HIV Reference Laboratory carried out an evaluation of HTC Registers in 385 facilities. Data on the registers' availability, and utilization between June and July 2012 was collected. For data analysis, adjustments were done to the attenuated proportions in regions with small sample sizes (n<30).

Results: HTC registers were available in 83.2% of facilities with Coast and Western regions having the highest proportion (99.6% and 97.0%, respectively) while North Eastern had the least (54.2%). Documentation inconsistency including lack of name, lot number and test kit expiry date, was observed in 32% (98) of facilities, with Eastern region and laboratories contributing disproportionately. The algorithm was not appropriately followed in a number of facilities. In 11.5% of cases, positive results obtained on initial screening, were not confirmed with a repeat test as required. Agreement between the first and second tests in the algorithm was 81%. The proportion of pages with supervisors' signatures was low at 35.8%. A third (31.6%) of HTC service providers were enrolled in the national HIV proficiency testing scheme.

Conclusion: Non-adherence to quality elements such as the national algorithm and regularity of supervision can be captured through HTC register data analysis. All HTC service providers, including laboratory personnel, should be trained on use of the register, to enable real time monitoring of HIV testing services.

ORAL SESSION 1.2 STRENGTHENING LABORATORY MANAGEMENT SYSTEMS

DATE: **Monday, 1 December**

TIME: **11:00 – 12:45**

LOCATION: **Room 1.6**

CO-CHAIRS: **Katy Yao**, Centers for Disease Control and Prevention, United States of America
Giselle Guevara, Centers for Disease Control and Prevention, Barbados

11:00

Katy Yao, Elizabeth Luman, The SLMTA Implementation Teams
Centers for Disease Control and Prevention, Atlanta, GA, USA

Evidence from 501 Laboratories in 39 Countries for SLMTA-Driven Improvement in Quality Management Systems

Background: Few management and leadership development programs have been implemented on a truly global scale or evaluated based on results-oriented outcome measures. The Strengthening Laboratory Management Toward Accreditation (SLMTA) program is a large-scale global effort to improve the quality of laboratories in resource-limited countries. This study sought to evaluate the first 5 years of SLMTA program implementation.

Methods: The SLMTA program consists of a series of short courses and work-related learning projects designed to improve laboratory management. Program results are measured before (baseline) and after (exit) implementation using a comprehensive standardized audit checklist which results in a percentage score and a rating of 0 to 5 stars. Country-level data were submitted by SLMTA program leads and compiled globally.

Results: From 2009-2013, SLMTA was implemented in 39 countries in Africa, the Caribbean, Latin America, and Southeast Asia. 1644 people were trained from 501 laboratories. At baseline audit, 82% of laboratories were below the 1-star level (median score 38%). At exit audit, 71% achieved at least 1 star (median score 67%). Performance was similar across laboratory types and sizes. Program sustainability and impact were also evaluated. Of 47 laboratories that conducted a post-SLMTA surveillance audit (median 9-months after exit audit), 74% further increased their scores, including 53% whose score increased by >10 percentage points. In total, the 501 SLMTA laboratories reported conducting approximately 96 million tests each year. Sixteen percent of these tests were conducted by laboratories with at least 1 star at baseline (3% with 3+ stars); this number increased to 67% after SLMTA training (31% with 3+ stars).

Conclusion: SLMTA has helped transform the laboratory landscape in resource-limited countries worldwide. These data suggest that the SLMTA program has the potential to make a substantial and sustainable impact on the quality of laboratory testing and patient care.

11:10

Elizabeth Luman, Katy Yao, John Nkengasong

International Laboratory Branch, Division of Global HIV/AIDS, Center for Global Health, US Centers for Disease Control and Prevention, Atlanta GA, USA

Strengthening Laboratory Management Toward Accreditation (SLMTA) – A Systematic Review of Research Issues, Results, and Remaining Gaps

Background: Since its introduction in 2009, the Strengthening Laboratory Management Toward Accreditation (SLMTA) training program has been implemented in 501 labs in 39 countries. We examined results from local, national, and global studies to determine the evidence of the program's impact and critical issues remaining unsolved.

Methods: A systematic literature search identified 33 manuscripts publishing results from SLMTA implementation. Results were reviewed and summarized.

Results: Global program data show improved quality in SLMTA laboratories in every country, with average improvements on audit scores of 26 percentage points (range 5-45). To build capacity for program scale-up, a rigorous training-of-trainers strategy using teach-back methodology has been implanted to produce 433 SLMTA trainers.

Conclusion: Local and national studies provide substantial information on the benefits and effective types of mentorship, the importance of management buy-in to ensure country ownership, the need to instill a culture of quality in the laboratory, the cost of implementation and projected cost of expansion, the importance of laboratory audits to measure improvement and identify areas of improvement, and the impact of quality improvement. Several studies documented 50%-95% reduction in turn-around times, 75%-93% reduction in specimen rejection rates, 81%-100% reduction of service interruptions, 30%-230% increase in patient satisfaction rates, 76% increase in clinician satisfaction rates, 83% improvement in external quality assurance results, and 67% increase in staff punctuality. Another study found that the increased cost of developing in-country facilitators is more expensive initially, but is cost-saving at the second SLMTA round. Local, national, and global results suggest that the SLMTA roll-out has been overwhelmingly successful in transforming laboratory quality management. Future areas of interest include impact on patient health, long-term sustainability of results, program cost-effectiveness, optimal strategies for expansion at national levels, and adaptation of the training methods for use in other areas of public health.

11:20

Eric Wakaria¹, Charles Rombo², Margaret Oduor², Peter Mwamba¹, Kimberly Tilock¹

¹CHF International-Kenya, Nairobi, Kenya, ²Kenya National Blood Transfusion Service, Nairobi, Kenya

Challenges Facing Implementation of Strengthening Laboratory Management Toward Accreditation (SLMTA) Program in Blood Transfusion Service in Kenya

Background: The Strengthening Laboratory Management Toward Accreditation (SLMTA) approach is accepted regionally to effectively implement the requirements for clinical laboratories international accreditation standards. Apart from quality laboratory testing, quality practices in collection, transporting, storing and issuing of blood are also essential. The Global Communities Blood Safety program funded by the U.S. Centers for Disease Control and Prevention (CDC) through U.S. President's Emergency Plan for AIDS Relief (PEPFAR) supports the Kenya National Blood Transfusion Service (KNBTS) to implement SLMTA in its national office and the regional centers.

Methods: In January 2013, a baseline audit was conducted at 6 regional blood transfusion centers and the national office using the SLIPTA checklist. SLMTA I and II workshops were held and intervening mentorship visits were conducted. Gaps identified in each phase of implementation of the program were noted and discussed with relevant stakeholders. Solutions were suggested to address the challenges and to improve the program.

Results: There was shortage of trained assessors with technical expert in blood transfusion medicine to conduct the baseline audit. The SLIPTA checklist did not cover some aspects of blood transfusion services including blood donor management, transportation and storage. Since workshop participants were drawn from various cadres, learning activities needed customization to suit the scope of services and relevance to blood transfusion. Successful implementation of improvement projects required involvement of various departments in blood transfusion hence more time was required to implement them. Experienced mentors and trainers in blood transfusion medicine were not easily available.

Conclusion: Challenges were encountered in all phases of the SLMTA implementation including: baseline audits, workshops and mentorships. Mentors with experience in blood transfusion have been identified for the next cycle of mentorship. An additional SLMTA trainer of trainer from KNBTS has been trained to aid in the implementation of SLMTA. Learning activities relevant to blood transfusion are used during the training. There is need for SLMTA toolkit to be more easily customizable to cover blood transfusion services

11:30

Thomas Gachuki¹, Jane Mwangi², Risper Sewe³, David Turgeon⁴, Mary Garcia⁵, Elizabeth T. Luman⁴, Mamo Umuro³

¹ National Public Health Laboratories, Kenya, ² Laboratory Branch, Division of Global HIV/AIDS, U.S. Centers for Disease Control and Prevention, Nairobi, Kenya, ³ Kenya Ministry of Health, National public Health laboratories (National HIV Reference laboratory), Kenya, ⁴ International Laboratory Branch, Center for Global Health, Division of Global HIV/AIDS, U.S. Centers for Disease Control and Prevention, Atlanta, GA, USA, ⁵ Clinical Pathology Laboratories, Texas, USA

The Road to Laboratory Accreditation Through SLMTA: Key Success Factors

Background: In 2010, immediately after the launch of the WHO/CDC Stepwise Laboratory Improvement Process towards Laboratory Accreditation (SLIPTA), the Kenya Ministry of Health set a goal of international accreditation for National HIV Reference Laboratory (NHRL).

Methods: NHRL participated in the Strengthening Laboratory Management towards Accreditation (SLMTA) program in 2010-2011. Improvement projects were undertaken to address gaps in the 12 quality system requirements. The laboratory organizational structure was redefined with formation of teams with specific objectives and work plans aimed at contributing to the vision for accreditation. Structural renovations were performed to enhance workflow and biosafety. Regular internal audits were conducted, and scores were used to determine progress along a 5-star grading scale. Standard quality indicators (turn-around time, specimen rejection rates, and service interruptions) were measured.

Results: The laboratory scored 45% at baseline in March 2010, corresponding to zero stars; in October 2011, it scored 95%, equivalent to 5 stars. By 2013, turn-around times for viral load, HIV ELISA, and CD4 testing had improved by 50% to 95%. Specimen rejections were reduced by 93%, and service interruptions decreased from 15% in 2010 to 0% in 2013. In 2013, NHRL became the first public health laboratory in Kenya to attain ISO 15189 accreditation. The total cost associated with achieving accreditation was approximately \$75,000 (USD).

Conclusion: International accreditation is an achievable goal through the SLMTA program, even for a laboratory with limited initial quality management systems. Substantial improvements to laboratory quality require focused mentorship and total commitment of government and laboratory staff. Countries wishing to achieve accreditation must ensure adequate funding and support.

11:40

Gisele Guevara¹, Floris Gordon², Yvette, Irving², Ismae Whyms³, Keith Parris¹, Songee Beckles⁴, Talkmore Maruta⁵, Nqobile Ndlovu⁵, Rachel Albalak¹, George Alemnji¹

¹ Centers for Disease Control and Prevention, Caribbean Regional Office, Barbados, ² African Field Epidemiology Network, Caribbean Office, Jamaica, ³ Princess Margaret Hospital, Bahamas, ⁴ Ladymeade Reference Unit, Barbados, ⁵ African Society for Laboratory Medicine, Addis Ababa, Ethiopia

The Impact of the Strengthening Laboratory Management Toward Accreditation (SLMTA) Training Program in Improving Laboratory Quality Systems in the Caribbean Region

Background: Clinical laboratories in the Caribbean region have been slow to implement quality management systems and achieve accreditation despite past efforts to train laboratory staff in quality systems improvement

Methods: Five national reference laboratories from 4 countries participated in the SLMTA program that incorporated classroom teaching and implementation of improvement projects. Mentors were assigned to the laboratories to guide trainees on their improvement projects and to assist in development of the Quality Management System (QMS). Audits were conducted at baseline, 6 months, exit (at 12 months) and post-SLMTA (at 18 months) using the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) checklist, to measure changes in implementation of the QMS during the period. At the end of each audit a comprehensive implementation plan was developed to address gaps, which the mentor assisted the laboratory to execute.

Results: Baseline audit scores across the five laboratories ranged from 19%-52%, corresponding to 0 stars. However, after 18 months, one laboratory attained four stars, two attained three stars, and two attained two stars on the SLIPTA 5-star scale. There was also a decrease in total nonconformities and the development of more than 100 management and technical standard operating procedures in each of the five laboratories. After 24 months, one laboratory attained accreditation, from the College of American Pathologists, while 3 others have applied for accreditation and are awaiting their final assessments by the respective Accreditation bodies.

Conclusion: The quality improvement seen in these 5 Caribbean national reference laboratories illustrates that SLMTA coupled with mentorship appears to be an effective, user-friendly, flexible, and customizable approach to implementation of laboratory QMS. Other laboratories in the Caribbean region may consider using the SLMTA training program as they engage in quality systems improvement and preparation for accreditation.

11:50

Adino Desale¹, Tilahun Muchie Hiwotu¹, Achamyelch Mulugeta¹, Adisu Kebede¹, Habtamu Asrat¹, Abnet Abebe¹, Dereje Yenealem¹, Ebise Abose¹, Amha Kebede¹, Mary Kathryn Linde², Gonfa Ayana¹

¹ Ethiopian Public Health Institute (EPHI), Addis Ababa, Ethiopia, ² Shawnee State University, Portsmouth, Ohio, USA American Society for Clinical Pathology (ASCP)

Perceptions and Attitudes towards SLMTA Among Laboratory Professionals and Hospital Chief Executive Officers in Ethiopia

Background: Strengthening Laboratory Management Toward Accreditation (SLMTA) is a competency-based management training programme designed to bring about immediate and measurable laboratory improvement. Assessment of health professionals' views of SLMTA is essential to planning, implementing and evaluating SLMTA's training, communication and mentorship components. The aim of this study is to assess laboratory professionals' and hospital chief executive officers' perceptions and attitudes towards the SLMTA programme in Ethiopia.

Methods: A cross-sectional descriptive survey was conducted in March 2013 using a structured questionnaire to collect qualitative data from 72 professionals in 17 facilities, representing all regions and two city administrations in Ethiopia. Focus groups were conducted with laboratory quality officers and managers to gain insight into the strengths and challenges of the SLMTA programme to guide future planning and implementation.

Results: Laboratory professionals at all levels had a supportive attitude towards the SLMTA programme in Ethiopia. They believed the SLMTA programme substantially improved laboratory services and served as a catalyst for total health care reform and improvement. They also noted that the SLMTA programme achieved marked progress in laboratory supply chain systems, sample referral systems, instrument maintenance and data management systems. In contrast, the participating chief executive officers were sceptical about the SLMTA programme, believing the benefits of SLMTA were outweighed by the level of human resources and time commitment required. They also voiced concerns about the cost of SLMTA and the lack of regular mentorship visits.

Conclusion: This study highlights the need for stronger engagement and advocacy with hospital administration, and to address concerns about the cost and sustainability of the SLMTA program.

ORAL SESSION 1.3 TB DRUG RESISTANCE

DATE: **Monday, 1 December**

TIME: **11:00 – 12:45**

LOCATION: **Room 2.4**

CO-CHAIRS: **Philip Onyebujoh**, World Health Organization Regional Office for Africa, Zimbabwe
Hortense Faye-Kette, Institut Pasteur, Côte d'Ivoire

11:00

Anne Mutsami^{1,2,3}, Godfrey Jumbe^{4,5}

1 Jomo Kenyatta University of Agriculture and Technology- Institute of Tropical Medicine and Infectious Diseases, Nairobi, Kenya, 2 Department of Medical Laboratory Sciences, Mount Kenya University, Thika, Kenya, 3 Kenya Medical Research Institute (KEMRI), Centre for Infectious and Parasitic Diseases Control Research (CIPDCR), Busia, Kenya, 4 University of Nairobi, Institute of Tropical and Infectious Diseases (UNITID), Nairobi, Kenya, 5 Kenyatta National Hospital, Comprehensive care clinic, Nairobi, Kenya

Prevalence of TB Infection Among HIV Patients in Association to Drug Resistance at Kenyatta National Hospital Comprehensive Care Clinic

Background: The epidemics of HIV-1 and tuberculosis in Kenya are closely related. High mortality rates in co-infected patients have improved with antiretroviral therapy, but drug-resistant tuberculosis has emerged as a major cause of death. We assessed the prevalence and consequences of multidrug-resistant (MDR) and extensively drug-resistant (XDR) tuberculosis in a rural and urban areas in Kenyatta National Hospital Comprehensive Care clinic.

Objective: to determine the prevalence of MDR among HIV positive patients attending CCC, Kenyatta National Hospital.

Design: A retrospective descriptive study involving archived strains from previous studies carried out at the Kenya Medical Research Institute (KEMRI) between January, 2013 to March 2014. Setting: CMR, KEMRI.

Methods: Sputum was obtained from a total of 1143 patients were used. Surveillance for drug-resistant tuberculosis with sputum culture and drug susceptibility testing in HIV patients with known or suspected tuberculosis was done. Genotyping was done for isolates resistant to first-line and second-line drugs.

Results: From 1143 patients, tuberculosis was detected in 222 patients, of whom 52 had extensively drug resistant tuberculosis. Prevalence among 470 patients with culture-confirmed tuberculosis was 39% (190 patients) for MDR and 6% (30) for XDR tuberculosis. Only 55% (26 of 47) of patients with XDR

tuberculosis had never been treated for tuberculosis; 67% (28 of 42) had a recent hospital admission. All 44 patients with TB who tested for HIV were co-infected. 51 patients with XDR tuberculosis succumbed, with median survival of 16 days from time of diagnosis among the 42 patients with confirmed dates of death. Genotypes of isolates indicated 46 patients with TB had resembling strains.

Conclusion: MDR tuberculosis is more prevalent than previously realized in the medical set up. Tuberculosis has been a co-infection to HIV patients associated with high mortality. The observations suggest urgent medical intervention and threaten the break through of treatment programmes for TB and HIV infections in the country.

11:10

Chisom Ukaegbu¹, Agatha Ani², Yetunde Isah², Rosemary Pwof², Chindak Lekuk², Godwin Imade², Oche Agbaji²

1 Department of Medical Microbiology, Faculty of Medical Sciences, University of Jos, Jos, Plateau State, Nigeria, 2 APIN/JUTH, HIV Centre, Jos, Plateau State, Nigeria.

Mycobacterium Tuberculosis and Anti Tuberculosis Drug Resistance in HIV Negative and HIV Positive Cases in Jos, Nigeria

Background: Tuberculosis (TB) continues to pose health challenges globally with 95% of estimated incident cases found in developing countries. Nigeria has an incident rate of 108 per 100,000 population ranking among the top TB burdened countries in Africa. The challenges of drug resistance in Mycobacterium tuberculosis (MTB) and its co infection with HIV/AIDS favour the rising trend and complications of TB in most resource limited countries. A rapid molecular method was used to study the prevalence of MTB and its susceptibility/resistance to isoniazid (INH) and rifampicin (RIF) in Jos, Nigeria.

Methods: A total of 90 AFB positive sputum specimens from 42/90 TB+HIV- and 27/90 TB+HIV+ patients received at three different DOT centres in Jos, Nigeria were tested by Genotype MTBDRplus for MTB and its susceptibility to INH and RIF. Tests were performed according to specified standard methods.

Results: Eighty three of the 90 (92%) total number of the specimens were positive while 7/90 (8%) were negative by MTBDRplus. Thirty seven of 83 (45%) MTB positive cases were pan susceptible to INH and RIF, single-resistance was observed in a total of 34/83 (41%); RIF 20/83(24%), INH 14/83 (17%) and multi-resistance to RIF plus INH (MDR) in 12/83 (14%) cases.

Conclusion: Resistance to anti-TB drugs occurred in both TB/HIV negative and TB/HIV co-infected patients. The high rate MDR cases (14%) and single resistance to RIF (24%) in this study underscores the need for improved strategies of TB management in the country in order to reduce the rate and spread of the disease.

11:20

Basant Motawi¹, Zeinab Mostafa², Youssef Soliman³

¹ Department of Medical Microbiology & Immunology, Faculty of Medicine, Aien Shams University, Cairo, Egypt, ² Tuberculosis research Unit, Faculty of Medicine, Cairo University, ³ Department of Chest Diseases, Faculty of Medicine, Cairo University

Evaluation of the FASTPlaque-Response in the Detection of Rifampicin Resistance among Mycobacterium Tuberculosis Isolates from Egypt

Background: With almost 9 million new cases annually, Tuberculosis (TB) remains one of the most fearful diseases on earth. Moreover, the emergence of Multi-drug resistant TB (MDR-TB) and Extended-drug resistant TB (XDR-TB) represents a major threat for TB control programs. Thus, there is an urgent need for rapid, reliable, and economic methods for drug susceptibility testing of Mycobacterium tuberculosis (*M. tuberculosis*).

Methods: Aim of the Work: To evaluate a mycobacteriophage-based test (FASTPlaque-Response) as a rapid phenotypic method for detecting rifampicin (RIF) resistance among *M. tuberculosis* isolates.

The present study was conducted during the period from June 2012, till July 2013, 110 TB patients -admitted to the chest Hospitals, Cairo, Egypt- were included. Susceptibility patterns of *M. tuberculosis* isolates to RIF were evaluated – in comparison to indirect proportion method- using FASTPlaque-Response test.

Results: The FASTPlaque-Response showed an agreement of 84.8% with the indirect proportion method.

Conclusion: The FASTPlaque-Response appears to be a reliable, rapid, and convenient method for performing indirect drug susceptibility testing of *M. tuberculosis* in low-resource settings.

11:30

Emmanuel Fajardo¹, Maryam Rumaney¹, Carol Metcalf¹, Peter Saranchuk¹, Marcela de Felo Freitas², Asma Ali², Sandra Simons³, Helga Ritter⁴, Helen Bygrave¹, Tom Ellman¹

¹ Médecins Sans Frontières, Southern Africa Medical Unit, Cape Town, South Africa, ² Médecins Sans Frontières, Maputo, Mozambique, ³ Médecins Sans Frontières, Harare, Zimbabwe, ⁴ Médecins Sans Frontières, Nairobi, Kenya

Added Value of Performing a Second Xpert MTB/RIF Test on a Second Sputum Sample to Confirm Rifampicin Resistance: Analysis of Routinely Collected Data in MSF-Supported Sites in Mozambique, Zimbabwe and Kenya

Background: In settings or patient groups with a low prevalence of MDR-TB, the WHO recommends that Xpert MTB/RIF (Xpert) rifampicin-resistant (RIF) results be confirmed with the Line Probe Assay (LPA) or phenotypic drug susceptibility testing (DST). However, LPA is not available in many African countries and DST is generally available only at central laboratories with long turn-around times (TAT) for results. We investigated the added value of performing a second Xpert test on a second sputum sample to confirm rifampicin resistance.

Methods: We analysed the confirmatory test results and TAT among 164 patients from TB programmes in Mozambique, Zimbabwe and Kenya, who tested RIF-positive on Xpert between June 2011 and April 2013. Sputum samples were collected for confirmatory testing using a second Xpert test and/or DST.

Results: Of 112 patients with a second Xpert test, the second test result was RIF-positive in 98 (87.5%; 95% CI: 79.9 – 93.0%), indeterminate in 4 (3.6%), and sensitive in 10 (8.9%). Of 30 patients with two RIF-positive tests and DST, 27 (90%; 95% CI: 73.5 – 97.9%) had rifampicin resistance confirmed by DST. Of 26 patients with only one Xpert test and DST, 23 (88.4%; 95% CI: 69.8 – 97.6%) had rifampicin resistance confirmed by DST. None of those with a drug-sensitive second Xpert result had DST results. The proportion with rifampicin resistance confirmed by DST did not differ significantly according to the number of RIF-positive tests ($p = 0.8527$). The median TAT for reporting DST results was 82 days (IQR: 57.3 – 98 days).

Conclusion: These preliminary results do not provide evidence that a second Xpert test has value in confirming rifampicin resistance. Assessing the DST results of patients with discordant RIF results is necessary in order to draw conclusions about the added value of a second Xpert test among patients who test RIF-positive on Xpert

11:40

Abebaw Kebede, Zekarias Dagne, Muluwork Getahun, Zelalem Yaregal, Yetnebersh Fisiha, Abyot Meaza, Zelalem Yaregal, Shewki Moga, Almaz Abebe, Eshetu Lemma
Ethiopian Public Health Institute (EPHI), Addis Ababa, Ethiopia

Laboratory Based Second-line Anti-TB Drug Resistance Surveillance in Ethiopia

Background: Extensively drug-resistant tuberculosis (XDR-TB) is defined as a form of multidrug-resistant tuberculosis (MDR-TB) with additional resistance to fluoroquinolones (FQ) and at least one of the injectable drugs used in tuberculosis treatment: amikacin, kanamycin and capreomycin. It was classified by WHO as a serious threat to tuberculosis (TB) control. In Ethiopia, only two cases reported in previously conducted studies. The aim of the study is to determine the second-line anti-TB drug resistance pattern of MDR-TB isolates from MDR suspects referred to eight TB culture laboratories in Ethiopia.

Methods: Laboratory confirmed MDR clinical isolates were collected and tested for second-line drugs; AK (1.0µg/ml), KM (2.5µg/ml), CM (2.5µg/ml), OFX (2.0µg/ml), and ETH (5.0µg/ml), using MGIT supported with TBeXIST Software and GenoType MTBDRsl Assay.

Results: Seventy five MDR-TB cases collected thus far and among these 16 and 37 were tested with MGIT second-line DST and MTBDRsl assay, respectively. In both methods, there was no a single XDR case detected; however, any resistance was observed. Any resistance was 25% (N=16) and 29.7 (N=37) using MGIT and MTBDRsl assay, respectively. High rate (67.6%) of Ethambutol resistance was detected using MTBDRsl assay. C1402T was the predominant type of mutant gene that indicates the presence of resistance to Amikacin, Kanamycin and Capreomycin. M3061 was the common mutant for Ethambutol resistance.

Conclusion: There was no a single XDR and FQ resistance case detected in both methods. High prevalence of Ethambutol resistance has observed in MDR strains. Since the finding is preliminary, it does not indicate the absence of XDR in Ethiopia. More and more laboratory confirmed MDR isolates required to be collected and analyzed. It is at early stage to judge the diagnostic accuracy of MTBDRsl assay.

11:50

Daniela Maria Cirillo, Andrea Cabibbe, Ilaria Valente, Paolo Miotto

San Raffaele Scientific Institute TB Supranational Reference Laboratory and WHOCC, Milan Italy

Illumina Technology for Multiplex-Amplicon Sequencing Can Be Used for Identification of Drug Resistant Tuberculosis

The rapid identification of drug-resistant (DR) phenotype in *M. tuberculosis* (MTB) is essential for an appropriate management of tuberculosis (TB) patients. Whole gene sequencing by Sanger method does not allow a large-scale analysis of genes due to limitations in terms of throughput, speed and readout, and it has been overcome by Next Generation Sequencing approaches (NGS).

In our study we developed a multiplex-amplicon sequencing approach using Illumina technology and we compared the results to those obtained by Sanger method.

An overall of 1024 MTB isolates were included in the study. Whole gene sequencing was carried out for *pncA* (n=901) and for *gyrA* (n=123) genes, involved respectively in pyrazinamide and fluoroquinolone resistances. The two genes were amplified by standard PCR. After purification, *pncA* and *gyrA* amplicons were then mixed at equimolar concentrations, fragmented and tagged with unique adapter sequences, and finally index sequences were added on both ends of the DNA, thus enabling sequencing of pooled libraries on Illumina MiSeq System. Out of these strains, 139 MTB isolates were considered for comparing this approach with the standard Sanger single-amplicon technique.

Illumina sequencing allowed obtaining complete results for 1008/1024 (98.4%) samples. The use of a multiplex-amplicon approach enabled to analyze different genomic regions in only one reaction, requiring an easy DNA preparation and 6 days for obtaining sequencing results for two genomic regions from 96 different samples.

High concordance (95.8%) was observed between Illumina - Sanger results. Discordant cases occurred for the presence of double pattern sequences: Illumina showed higher sensitivity in detecting mixed populations being able to identify less than 10% of each single variant, whereas the limit for the Sanger method was about 30%.

Our data proved that the Illumina approach reduces cost and time for analysis of MTB DR-related genes, with high throughput and accuracy. The multiplex-amplicon approach can be easily improved and suited for the simultaneous analysis of more genes leading to resistance to the main anti-TB drugs, representing a crucial advantage compared to Sanger method. This technology has the potential to be easily introduced a low cost in algorithms for retesting results obtained by Xpert MTB/rif or other close-to patients technology for DR detection

Moreover, our data suggest that Illumina sequencing allows discriminating hetero-resistance at much lower frequencies than Sanger, giving precious information on this preliminary stage of the full resistance

ORAL SESSION 1.4 MALARIA AND OTHER PARASITIC DISEASES

DATE: **Monday, 1 December**

TIME: **11:00 – 12:45**

LOCATION: **Auditorium 1**

CO-CHAIRS: **Adrian Puren**, National Institute for Communicable Diseases, South Africa
Lesley Scott, National Health Laboratory Service, South Africa

11:00

Ernest Lango-Yaya¹, Simon Pounguinza¹, Jean Pierre Bangamingo², Louis Namboua²

¹ Laboratoire National de Biologie Clinique et de Santé Publique, Bangui, République Centrafricaine, ² Ministère de la Santé Publique, République Centrafricaine

Evaluation de l'Efficacité Thérapeutique des Antipaludiques Usuels dans le Traitement du Paludisme Simple à Plasmodium Falciparum Chez les Enfants de Moins de 5 ans à Bangui, République Centrafricaine

Background: La situation du paludisme s'est aggravée par le phénomène de la résistance du parasite aux antipaludiques usuels et du vecteur aux insecticides utilisés. Pour palier à cette situation, la Centrafrique a souscrit à l'initiative préconisée par l'OMS de faire Reculer le Paludisme par l'introduction du traitement à base des dérivés de l'artémisinine. L'objectif de cette étude est d'évaluer l'efficacité thérapeutique de l'association artemether-luméfantine (A-L), artesunate -amodiaquine(AS-AQ) et amodiaquine-sulfadoxine-pyriméthamine (AQ-SP) dans le traitement du paludisme simple à Plasmodium falciparum chez les enfants de 6 à 59 mois à Bangui (RCA)

Methods: Il s'agit d'une étude descriptive, comparative et randomisée qui a été effectuée du 1er juillet au 30 octobre 2013. Les enfants qui présentent une infection monospécifique à Plasmodium falciparum avec : une parasitémie comprise entre 1000 et 200 000 parasites/ μ l de sang ; une température axillaire supérieure ou égale à 37,5°C étaient inclus dans l'étude. Les médicaments utilisés étaient : l'association sulfadoxine-pyriméthamine (25 mg/kg de poids corporel pour la sulfadoxine et 1,25 mg/kg de poids corporel pour pyriméthamine) plus amodiaquine (30 mg/kg de poids corporel) ; artémether (2mg/kg de poids corporel) plus luméfantine (12 mg/kg de poids corporel) ; artesunate (4 mg/kg de poids corporel) plus amodiaquine (pour la même dose). Nous avons étudiés les réponses aux traitements jusqu'à 28 jours conformément aux protocoles de l'OMS de 2003

Results: Sur 2272 patients reçus pendant cette étude, 186 sujets sont inclus et 166 ont été suivis et évalués pendant 28 jours, soit 76,9%. Pour les enfants traités avec AQ-SP, nous avons une

réponse clinique parasitaire adéquate de 96,56%. Il existe aucune différence entre les 3 schémas thérapeutiques utilisés ($p = 0,36$). Les cas d'échecs observés sont dus globalement à des nouvelles infections.

Conclusion: Cette étude a permis de conclure que les combinaisons thérapeutiques surtout celles à base des dérivés de l'artémisinine apparaissent plus efficaces dans le traitement de l'accès palustre simple, depuis leur introduction sur le marché national Centrafricain. L'association AQ-SP devrait être recommandée en cas de rupture de médicaments à base d'artémisinine.

11:10

Hussaini Alhassan Mohammed¹, Abdullahi Saidu Yaro¹, Mohammed Danfulani², Egua Maxwell³, Nuradeen Mohammed Bello¹

¹ Department of Immunology, Faculty of Medical Laboratory Science, Usmanu Danfodiyo University, Sokoto, Nigeria, ² Department of Radiology, Usmanu Danfodiyo University, Sokoto, Nigeria, ³ Department of Pharmacology, College of Health Sciences Usmanu Danfodiyo University, Sokoto, Nigeria

Sero-Prevalence of Plasmodium Parasites Amongst Pregnant Women Attending Antenatal Clinic In Sokoto-Nigeria

Background: Malaria is dangerous to both the mother and fetus. Pregnant women are at greater risk of malaria infection and of symptomatic malaria disease than non-pregnant adults. Malaria in adolescent and young adult women are more commonly parasitemic than older adults. This study aimed to evaluate and determine the sero-prevalence of malaria parasite and plasmodium specie amongst pregnant women in Sokoto State, Nigeria

Methods: Blood was collected by vein puncture from 300 pregnant women and subjected to: Rapid diagnostic test: This was carried out, to detect the presence an antibody to P.parasites. and microscopic examination of thin and thick blood films for confirmation of the P.species. The results were analyzed using SPSS.

Results: Out of the 300 pregnant women examined, 115(38.33%) were infected with Plasmodium parasites. 98 (85.22%) were infected with P. falciparum, 2(1.74%) were infected with P.malariae, 14(12.17%) were infected with P. Vivax, and only 1(0.87%) were infected with P. ovale. The prevalence rates of 48(41.74%), 38(33.04%), 22(19.13%) 6 (5.23%), and 1(0.87%) were observed for the the ages of 15-20, 21-25, 26-30, 31-35 and 36-40 respectively. Pregnant women in their first, second and third trimesters had prevalence rates of 4.35%, 38.26% and 57.39% re. Prevalence rates for primigravidae, secundigravidae and multiparous women were 40.87%, 36.52% and 22.61% respectively.

Conclusion: Malaria is still a major threat to full realization of the goals of public health in Nigeria and needs to be given more priority due to its negative impact on pregnant women and their unborn children as indicated in this research.

11:20

Carolyne Mumo¹, Gertrude Kitetu²¹ Jomo Kenyatta University of Agriculture and Technology, Nairobi, Kenya, ² REF Kenya, Tawa, Kenya**A Study on Malaria Parasitaemia Carried Out in Kibera Community Health Center Laboratory Nairobi, Kenya**

Background: Kenya has made progress in malaria control. However, the country is still far from defeating the disease. The central highlands including Nairobi are categorized as a low risk malaria area while the western and coastal regions are endemic areas. Laboratory tests play an essential role in management of malaria and this involves either microscopic examination of blood smears and/or use of the malaria rapid diagnostic tests.

Methods: A cross-sectional study was carried out between September 2013 and March 2014.

Results: Out of the 1157 patients tested for malaria, 199 tested positive for Plasmodium falciparum with 20.6%, 7.03%, 10.05% and 7.53% cases in September, October, November and December respectively. This was followed by a sudden rise in January with 30.6% cases and declined with 14.57% and 9.54% cases in February and March respectively. 63.8% of the positive cases had <500 parasites/200WBCs, 14.6% with 500-1000 parasites/200WBCs, 2.5% with >1000 parasites/200wbc while 18.6% tested positive for P. Falciparum with rapid diagnostic kits.

Conclusion: The change in malaria cases is attributed to travelling in endemic areas in the Western and Nyanza provinces especially in the months of August and December leading to high malaria cases in September and January respectively since Nairobi province is a low risk malaria area. Microscopic quantification of malaria parasites aids in determining the severity of the cases unlike RDTs which only indicate presence of malaria. There is need for interventions to prevent transport cases and application of parallel RDT and Microscopy diagnosis of malaria to prevent missing out the parasites in light infections and to classify the severity.

11:30

Felix Botchway¹, Nana Wilson², Adel Driss², Carmen Dickinson_Copeland², Hassana Salifu², Jonathan Stiles²¹ Department of Chemical Pathology, University of Ghana Medical School, Accra, Ghana, ² Morehouse school of Medicine, Atlanta GA, USA**CXCL10 Gene Promoter Polymorphism -1447A>G is Associated With Severe Malaria in Ghanaian Children**

The influence of host genetics on susceptibility to Plasmodium falciparum malaria has been extensively studied over the past twenty years. Plasmodium falciparum malaria kills nearly a million people annually. Over 90% of these deaths occur in children under five years of age in sub-Saharan Africa. Malaria parasites

have imposed strong selective forces on the human genome in endemic regions. The risk factors for severity of malaria pathogenesis and the wide variation in clinical manifestations of malaria are poorly understood. Recent studies indicate that interferon gamma inducible chemokine, CXCL10, is a strong predictor of both human and experimental cerebral malaria. In the present study, we hypothesized that in a subset of malaria patients, susceptibility to severe malaria is associated with variation in CXCL10 expression. We determined whether polymorphisms in the CXCL10 gene promoter region played a role in the clinical status of malaria patients and addressed the genetic basis of CXCL10 expression during malaria infection. One reported single nucleotide polymorphisms in the CXCL10 promoter (-1447A>G [rs4508917]) were identified among 60 severe/complicated malaria and 120 uncomplicated malaria children using PCR-restriction fragment length polymorphism assay. Individuals with the -1447(A/G) genotype were susceptible to severe malaria (adjusted odds ratio [AOR]=2.60, 95% CI=1.13–5.74, p=0.024). Polymorphisms in the CXCL10 gene promoter sequence were associated with severe malaria in Ghanaian patients. These results suggest that the -1447A>G polymorphism in CXCL10 gene promoter could be partly responsible for the reported variation underlying severe malaria outcomes in malaria children.

11:40

Eleanor Ochodo¹, Gowri Gopalakrishna², Mariska Leeftang²¹ Centre for Evidence-based Health Care, Faculty of Medicine and Health Sciences, Stellenbosch University, Cape Town, South Africa, ² Department of Clinical Epidemiology, Biostatistics and Bioinformatics, Academic Medical Center, University of Amsterdam, The Netherlands**Translating Results of Diagnostic Tests into Practice: the Case of Shistosomiasis**

Background: Interpreting and reporting results of diagnostic test accuracy studies in a way that health care workers and policy makers can understand is a challenge for many authors. This makes it difficult for diagnostic tests to be implemented. We present a format for presenting results of diagnostic accuracy studies from a systematic review and meta-analysis we conducted, that estimated the diagnostic accuracy of urine reagent strips and circulating cathodic antigen point of care tests for human schistosomiasis.

Methods: We applied the summary results of sensitivity and specificity to a hypothetical cohort of 1000 people and estimated the number of infections the tests would miss (false negatives) and the number of non-cases the tests would falsely diagnose and expose people to unnecessary treatment (false positives). We considered the true prevalence of infection and also calculated the observed prevalence of infection the tests would present should they be applied.

Using an example of the CCA-POC test for S. mansoni, we translate its results of sensitivity (87%) and specificity (61%) into natural frequencies below. The results of the other tests can also be presented in this format.

Results: If the point estimates of CCA-POC test for *S. mansoni* are applied to a hypothetical cohort of 1000 individuals suspected of having active *S. mansoni* infection, where 440 persons actually are infected, then the CCA-POC test for *S. mansoni* would be expected to miss 57 and falsely diagnose 218 cases respectively. This would result in an observed prevalence of 60% which is far from the true prevalence of 44%.

Conclusion: We recommend that authors translate test accuracy results into natural frequencies and stress on the consequences of applying the results to a hypothetical cohort of people in the discussion section of a paper.

11:50

Joseph Enuma¹, Bernard Matur²

¹ National Agency For The Control Of AIDS (NACA), Abuja Nigeria, ² Department of Biological Sciences, University of Abuja, Abuja Nigeria

Is Malaria an Opportunistic Infection among HIV/AIDS Patients in Nigeria?

Background: Nigeria is endemic for Malaria with the second largest global HIV burden next to South Africa. Both infections and sequelae have become public health priorities with devastating socio economic implications for Nigeria. Most HIV patients frequently present with Malaria at treatment sites in Nigeria. We sought to investigate malaria fever as an opportunistic infection in HIV infection.

Methods: A total of 600 subjects were investigated in a cross sectional study from October 2013 to March, 2014. Three study groups were constituted, 200 HIV negative participants (control,), 200 HIV positive participants on ARV treatment, (ARV group) and 200 HIV positive participants not on ARV treatment (, NOARV group). Malaria parasites (mp), malaria density (md) and absolute CD4 count was carried out on all the 3 groups. Participants with CD4 count less than 350 were considered immunocompromised and likely to develop opportunistic infections. Data were captured on Epi info and analyzed on SPSS version 19 using cross tabulations for proportion and analysis of variance for means at $p=0.05$

Results: The mean absolute CD4 count was significantly different across groups ($p < 0.001$) from 834 cells in the control group, to 354 cells in the ARV group and 300 the NOARV group. There was no significant ($p=0.56$) difference in the prevalence of malaria in the ARV (40.5%) and NOARV (39.5%) groups relative to the control (44.5%). Though prevalence of malaria parasitaemia among immunocompromised participants was higher than non immunocompromised counterpart (42%, 40.8% respectively), this difference was not significant ($p=0.69$).

Conclusion: This study shows that though HIV positive patients may present with malaria and should be treated for same upon diagnosis, Malaria is not an opportunistic infection in HIV/AIDS.

ORAL SESSION 1.5 EXTERNAL QUALITY ASSURANCE PROGRAMMES

DATE: **Monday, 1 December**

TIME: **11:00 – 12:45**

LOCATION: **Terrace Meeting Room**

CO-CHAIRS: **Michael Aidoo**, Centers for Disease Control and Prevention, United States of America
Paula Fernandes, Global Scientific Solutions for Health, United States of America

11:00

Michael Aidoo¹, Afework Tamiru², T. Henry Kohar³, Chritie M. Reed⁴, Joseph L. Malone⁵

¹ Centers for Disease Control and Prevention, Atlanta, GA, USA, ² Ethiopia Health and Nutrition Research Institute, Oromia, Ethiopia, ³ Liberia National Malaria Control Program, Ministry of Health and Social Welfare, Monrovia, Liberia, ⁴ President's Malaria Initiative/Centers for Disease Control and Prevention, Monrovia, Liberia, ⁵ President's Malaria Initiative/Centers for Disease Control and Prevention, Addis Ababa, Ethiopia

Field Evaluation of Dried Plasmodium Falciparum Samples for Malaria RDT Quality Control and Proficiency Testing in Liberia and Ethiopia

Background: The use of malaria rapid diagnostic tests (RDTs) has contributed significantly to the increased access to malaria diagnostic testing as reported by the 2013 World Malaria Report. Despite the increased use of RDTs, the lack of a systematic method of quality control (QC) to assess RDT performance in the field and for proficiency testing of health workers remains a major obstacle to assuring quality testing under field conditions. We evaluated a novel dried tube specimen (DTS) method for preserving *Plasmodium falciparum* parasite samples at specific concentrations for use as QC samples for RDTs. In the laboratory, we showed DTS to be stable for > 12 weeks when stored at 4°C, 25°C or 35°C. When stored at 4°C, DTSs were stable for >18 months.

Methods: The feasibility of storing and using DTS as QC and proficiency testing (PT) samples at the point of care was tested by setting up two pilot studies in the Oromia Region of Ethiopia and in Monrovia, Liberia. In both countries, replicate DTS samples containing 0, 500 and 1000 parasites/μl were prepared and stored at 4°C at a reference laboratory (RL) and at ambient temperatures at two nearby health facilities (HF). At 0, 4, 8 and 12 weeks the DTS were tested on duplicate RDTs stored under manufacturer recommended temperatures at the RL and on RDTs stored under site-specific conditions at the outlying HFs. Reactivity of DTS stored at 4°C at the RL on RDTs stored at the RL was the gold standard for assessing DTS stability. A PT panel with one negative and three positive samples was administered at weeks 12 and 24.

Results: DTS assembled into a PT panel proved to be a good source of samples with known reactivity for assessing health worker performance and for training on RDT use. DTS stability was highly concordant with expected reactivity in Ethiopia but not in Liberia. The latter was due to incomplete sample rehydration resulting from age of sample and likely humidity.

Conclusion: Results from these two field assessments show that the DTS method has the potential to be used as QC and proficiency testing panels for malaria RDTs. However, sample preservation needs to be prioritized for optimal results.

11:10

Alex Ojaku¹, Elizabeth Streat¹, Anthony Nuwa¹, John Baptist Bwanika¹, Bosco Agaba², Joseph Nkodyo³

¹ Malaria Consortium, Kampala, Uganda, ² National Malaria Control Programme, Kampala, Uganda, ³ Central Public Health Laboratories, Kampala, Uganda

Malaria Rapid Diagnostic Tests (RDTs) Field Level External Quality Assurance (EQA) System; Which Way Forward?

Background: Malaria case management in Uganda is currently centered on microscopy and use of rapid RDTs. The introduction of RDTs makes it possible to implement the test and treat policy in Uganda. Although microscopy remains the 'reference standard', incompetence of malaria microscopists diminishes its potential as a valid and trusted diagnostic tool. Evidence exists that RDT test accuracy in the field is variable, due to exposure to high temperatures and humidity and that negative results are frequently ignored by end users.

Methods: We developed a comprehensive EQA program aimed at maintaining test quality and reducing the likelihood of misdiagnosis with RDTs. Six health facilities using RDTs from five districts of Uganda were selected and provided with temperature monitoring gadgets in their storage facilities. Fifteen laboratory staffs were trained on two EQA methodologies of field stability monitoring with control samples and comparative smear methods. EQA rounds were conducted every quarter for one year.

Results: With field stability monitoring the results showed that diagnostic accuracy of the RDTs was maintained at 100% overtime from the five EQA sites. With comparative smear method a total of 1,205 tests were done with both microscopy and RDTs. The microscopy results showed that 38.0% (n = 458) of those tested were positive for malaria. The overall sensitivity of the test compared to the gold standard (microscopy) was 94.5% (433/458) with positive predictive value of 0.79 and the specificity was at 84.3% (630/747) and negative predictive value of 0.96.

Conclusion: Field stability monitoring of RDTs is easy to implement at the health facility level and can provide immediate results on the quality of RDTs to clinicians in the health facility. The comparative smear method can help to track persistent antigenemia and increases health workers confidence and trust in RDT results.

11:20

Paula Fernandes¹, Ekaterina Milgotina¹, Mark Fukuda², Jeffrey McCollum³, Karen Menge¹, Peter Obare⁴, Alaina Thomas³, James Cummings³

¹ GSSHealth, Baltimore, MD, USA, ² USAID, Bangkok, Thailand, ³ AFHSC-GEIS, Silver Spring, MD, USA, ⁴ Malaria Diagnostics Center, Kisumu, Kenya

Microscopist Proficiency Testing as Part of a Comprehensive Program to Assure the Quality of a Multi-continental Harmonized Malaria Drug Efficacy Trial

Background: A robust network of quality-assured surveillance laboratories is critical to ensure accurate and timely identification of emerging antimicrobial resistance. Despite the obvious need, few research laboratories operate internal quality assurance (QA) programs and fewer still participate in proficiency testing (PT) and external quality assessment (EQA). We describe one component of a comprehensive QA program implemented to assure harmonization and quality in a multi-continental malaria drug efficacy trial.

Methods: Microscopy methods were harmonized across the network. PT sets were designed to assess microscopists' competency (using the harmonized procedures) in four categories: sensitivity, specificity, species identification, and parasite counting. Statistical considerations (error tolerance limits, lower bound of 95% CI, and proficiency benchmark) and malaria microscopy specifics (parasite density, distribution of parasites and WBCs, and morphological features) were taken into account upon design of the PT slide set. Four 82-slide PT sets were prepared by MDC USAMRU-K. The sets were comprised of well-characterized negative and positive slides with low, moderate, and high parasitemias. Aside from *P. falciparum*, the subset of positive slides included *P. vivax*, *P. malariae*, and *P. ovale*, as well as mixed infections.

Results: Data were analyzed across all microscopists and misread slides were summarized. The most problematic slides were in the parasite counting category. For the assessment of parasite counts, the median \pm 2MAD (median absolute deviations) inclusion interval was employed, as it provided robust statistics, "tolerance" to outliers, and stricter criteria for certification of microscopists.

Conclusion: To date, 72% of microscopists have passed the PT. Participants who failed to pass first time were allowed a single retake after feedback and corrective training. The effectiveness of PT prior to initiation should not be underestimated, especially where microscopy is key for the primary study objective.

11:30

Susana Oguntayo^{1,2}, Abiola Tubi², Jelpe Tapdiyel³, Thor Elliott¹, Shirematee Baboolal¹

¹ American Society for Microbiology, USA – soguntayo@asmusa.org; ² National TB and Leprosy Control Programme, Nigeria; ³ US Centers for Disease Control and Prevention, Nigeria

Piloting External Quality Assurance for TB Line Probe Assay and GeneXpert in Nigeria

Background: Regular external quality assessment (EQA) surveys for molecular methods have not been routinely implemented in TB laboratories. To develop a molecular EQA survey for Nigeria, the National TB and Leprosy Control Program (NTP) worked with ASM to pilot three novel panels for Line Probe Assay (LPA) and GeneXpert (Xpert). ASM provided onsite training to laboratory and NTP staff on panel preparation and validation for LPA and Xpert. A pilot EQA survey, comprised of three panels produced at the training, was sent to all laboratories performing LPA and Xpert in Nigeria. The results were used to determine the best panels for LPA and Xpert EQA.

Methods: The training, provided to 17 participants, comprised one week of theory related to panel preparation, validation, handling and testing, and practical sessions for proficiency panel preparation and validation.

Three types of panels (dried culture spots on filter paper (Whatman 903 filter cards), dried culture tubes (5ml snap cap falcon tubes) with loading dye (Sigma-Aldrich) and heat killed DNA (liquid) bacilli panels) were sent to all (five LPA and 34 Xpert) laboratories conducting molecular testing within a two-week period. Instructions on how to handle the panels prior to testing and a reporting template were sent with the panels.

Reports and feedback were sent back to each participating laboratory within four weeks of receiving results, so they could implement timely corrective action.

Results: 100% (5/5) of the LPA laboratories and 50% (17/34) of the Xpert laboratories responded with results within four weeks. Analysis of the results received from the survey showed that the heat killed DNA performed best of the three panels sent, with 96% of LPA and 97% of Xpert giving expected results.

Conclusions: Nigeria now plans to rollout this survey nationally. ASM will provide further support to the NTP toward this effort."

11:40

Crystal Viljoen¹, Marshagne Smith¹, Olga Perovic^{1, 2}

¹ Centre for Opportunistic, Tropical and Hospital Infections, National Institute for Communicable Diseases, a Division of the National Health Laboratory Service, South Africa, ² Faculty of Health Sciences, University of Witwatersrand, South Africa

Comparison of Stained versus Unstained Simulated Mycobacterium Tuberculosis Microscopy Smears for Proficiency Testing

Background: Mycobacterium tuberculosis (TB) smear microscopy is extensively used in most laboratories despite advances in molecular diagnosis. The TB Microscopy Proficiency Testing Scheme (PTS) is provided by the Microbiology External Quality Assessment Reference Laboratory (MEQARL) at the National Institute for Communicable Diseases. The PTS is conducted every four months and results are monitored continuously to indicate timely interventions when problems are identified. Each survey consisted of 10 simulated smears.

Methods: Simulated TB smears are produced by MEQARL. Five different quantifications are prepared (negative, scanty, 1+, 2+ and 3+). Five smears are stained with the Ziehl Neelson automated method and the other five are stained by the participant using routine staining method performed in their laboratory. A comparison of stained versus the unstained results was completed. Following analysis of results, which indicated discrepancies between stained and unstained smears, a decision was made by the Advisory Committees to send all 10 smears to participants unstained.

Results: Smears stained by participants showed better correlation with the expected results. The stained smears of 1+ or scanty were more challenging and a large number of participants reported negative for the scanty stained smears. While most of participants scored better for scanty unstained smears as very few reported negative results. There was excellent correlation among all quantifications with the expected results when participants stain all the smears.

Conclusion: Although these possible areas of measurement of uncertainty still exist, e.g. number of personnel that examine the smears, we are confident to report that the most likely cause of discrepant results has thus far been due to the automated staining technique and reagents. Results of one survey where all smears were sent unstained were analysed and there has been a remarkable improvement in the agreement of the smears with the same quantification.

11:50

Nzovu Ulenga^{1,2}, Aisa Muya¹, Guerino Chalamilla¹, Fausta Masha³

¹ Management and Development for Health (MDH), Dar-es-Salaam, Tanzania, ² Harvard School of Public Health, Boston MA, USA, ³ Tanzania Ministry of Health and Social Welfare, Dar-es-Salaam, Tanzania

Strengthening National Laboratory Proficiency Testing (PT) in Tanzania

Background: Laboratory External Quality Assessment (EQA) is a critical aspect of laboratory quality management. Tanzania has about 6000 rapid HIV testing facilities and prior to 2012 less than 15% of the facilities were involved in Proficiency Testing (PT) as part of EQA. The Management and Development of Health (MDH) in collaboration with the Ministry of Health and Social Welfare (MoHSW) implemented a plan to expand EQA activities to cover all testing facilities in the country.

Methods: MDH provided technical, logistical, and administrative support to the national EQA programs in all regions of Tanzania that included PT panel preparation, transportation, results collection, analysis, report generation and dissemination. All these activities combined with health care workers training contributed to improving HIV rapid testing PT program in Tanzania.

Results: Within a year and half of implementing the national EQA expansion program the number of testing facilities increased from 1057 sites in 2012 to 2000 sites in 2014. The number of participating testing facilities with above 90% PT performance increased from 46% to 87% of all sites that responded. The numbers of facilities that report their PT result in time increased from 719 to 925. A total of 1800 health care workers were trained in the country, and the number of districts covered increased from 130 to 141.

Conclusion: In one and half years the program expanded HIV rapid testing quality monitoring activities to all regions in Tanzania. The major challenge facing the program is to improve the number of facilities that submit results after testing PT panels. The outcome of this program underscores the importance of close partnership between the government and development partners in improving laboratory services in Tanzania.

ORAL SESSION 1.6 PARTNERSHIP AND LABORATORY NETWORKS

DATE: **Monday, 1 December**TIME: **11:00 – 12:45**LOCATION: **Auditorium 2**

CO-CHAIRS: **Patrick Mateta**, Clinical Laboratory Standards Institute, United States of America
Jean Sakandé, University of Ouagadougou, Burkina Faso

11:00

Talkmore Maruta¹, Nqobile Ndlovu¹, Teferi Mekonen¹, Corey White¹, Tsehaynesh Messele¹, Madeline DiLorenzo¹, Trevor Peter²

¹ African Society for Laboratory Medicine, Addis Ababa Ethiopia, ² Clinton Health Access Initiative, Boston USA

The Role of Associations in Laboratory System Strengthening in Africa: Where Are We? Where Are We Going?

Background: Laboratory associations are established, among other things, to develop, promote and advocate for laboratory professional practice. Associations have created unity and organized representation of laboratory professionals. As a pan-African professional body, the African Society for Laboratory Medicine (ASLM) advocates for the critical role and needs of laboratory medicine through advancement of professional laboratory medicine practice, science, systems, and networks in Africa. The paper outlines how the collaboration between ASLM and in-country associations is key to achieving their mutual goals.

Methods: Where are we? ASLM has implemented different strategies to actively partner with in-country associations. During the implementation of the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) program, joint debrief meetings were held with local Ministries of Health. Association members constituted the SLIPTA audit teams and in other cases observed SLIPTA audits on behalf of the Ministry. In others an association coordinated country logistics for the SLIPTA audit teams. Associations have also played a critical role in recruiting individual membership for ASLM. To formalize the relationship, a Memorandum of Understanding (MOU) is signed between ASLM and the association. Implementation of joint activities is also guided by the framework for collaborating with partners developed by ASLM.

Results: To date, associations have partnered with ASLM in various activities that included participation in centralized SLIPTA audits debriefs (9), coordinating in-country logistics for audits teams (1), observing SLIPTA audits (1) and constituted audit teams (3). Seven (7) MOUs have been drafted. 49% of the current ASLM membership was recruited in 2013, a period that overlaps with active engagements of associations.

Conclusion: Where are we going? More models to support the establishment and strengthening of local associations will need to be developed. These will include supporting associations in applying for partner funded projects (e.g. the PEPFAR funding for the Botswana Institute for Clinical Laboratory Professionals). To increase association visibility, ASLM will partner with associations in its in-country activities and expansion of ASLM membership recruitment. ASLM will engage associations more in SLIPTA implementation namely auditing, auditor training and mentoring as well as partner with them in the establishment of local chapters and appointment of ASLM ambassadors. The strength of ASLM is enhanced by collaborations and strengthening of in-country associations.

11:10

Assah Nkohkwo^{1,2,3}, Nigel Talboys⁴

¹ The Care Quality Commission, ² UK-National Health Service, ³ Terumo BCT Europe-Africa, ⁴ Terumo BCT, Belgium

Improving Blood Supply Safety & Adequacy in Developing Countries: Pan-African Blood Safety Perspectives

Background: Blood supply adequacy & safety in Africa present serious public health challenges. We examined whether these would be more effectively and responsively addressed through engagement of public health professionals, among other key stakeholders, into a pan-African Blood Safety Alliance.

Methods: Following a review of the literature, we engaged professional stakeholders and service user organisations across Africa during the years 2012-2014, through correspondences, direct discussions and seminars.

Results: Challenge (I): adequacy & safety of supply "Shortage of blood donations is a problem we faced constantly while working in Cameroon and we watched many children/adults die unnecessarily while at the CHU Yaoundé" (a Cameroonian Infectiologist based in the UK, June 2013). In sub-Saharan Africa: 3million whole blood (WB) collections are undertaken per year of which 2 million are still transfused as WB. Median overall risks of becoming infected with HIV, HBV, and HCV from a blood transfusion in sub-Saharan Africa were 1, 4.3, and 2.5 infections per 1000 units, respectively, projected by the WHO, to 28,595 HBV infections, 16,625 HCV infections, and 6,650 HIV infections every year. Public Health Challenge (II): There was an acute need for a robust and accessible African solution, a technology that exhibits: Effectiveness & Efficacy; Safety; Affordability Challenge (III): We identified a crying need for a meaningful user-focused professional alliance, including patients & professional associations and biotechnology companies.

Conclusion: A Pan-African Blood Safety Alliance (PABSA) will promote the availability of adequate and the safest possible supply of blood or its products across the continent. It not only instigate, but support the introduction through proper peer scrutiny of emerging potential robust solutions including Pathogen Reduction Technologies (PRT), such as Terumo BCT's Mirasol PRT system for whole blood

11:20

Godswill Okara^{1,2}

¹ Association of Medical Laboratory Scientists of Nigeria, Abuja, Nigeria, ² Steering Board, West African Postgraduate College of Medical Laboratory Science, Abuja, NIGERIA.

Regional Capacity Enhancement in Medical Laboratory Science, the West African Initiative

Background: The World Health Organization Afro Region in the Maputo Declaration 2008 "called on countries and all partners to urgently address the broader laboratory human resources agenda for laboratory strengthening including training, recruitment and retention of laboratory workers and their adequate financing". Objective The challenge of emerging diseases of epidemic and pandemic potentials are a constant reality, especially in the West African region with resource limitations. The need to strengthen medical diagnostic capacity and enhance the healthcare delivery system in the region prompted a meeting by the West African delegates at a conference in 2010 in Kenya. A resolution to establish a regional College to develop training curriculum and conduct examinations for the award of postgraduate professional Fellowship in the various specialties of medical laboratory science was made.

Methods: A follow up meeting of the Presidents of country Associations in September, 2010 led to the adoption of a Draft Constitution for the commencement of the West African Postgraduate College of Medical Laboratory Science. The College is to be ultimately integrated into the West African Health Organization.

Results: The Memorandum of Understanding for the Establishment of the College was signed by the Presidents of seven countries including Anglophone and Francophone countries. The governance structures for the College are being put in place. Contacts are ongoing to formally present the College to the ECOWAS Health Ministers Forum.

Conclusion: Human resource remains the most essential and critical factor in the fight against diseases and promotion of human and animal health. The College will foster regional integration, harmonize and upgrade knowledge and practice standards across the region.

11:30

Isaac Ssewanyana¹, Meghan Wareham², Victor Bigira², Grace Kushemererwa³, Christine Namulindwa³, Iga Tadeo³, Steven Aisu³, Charles Kiyaga¹

¹ Central Public Health Laboratories, Ministry of Health, Kampala, Uganda, ² Clinton Health Access Initiative, Kampala, Uganda, ³ Central Public Health Laboratories, Ministry of Health, Kampala, Uganda

EID Lab Consolidation Supported by the Sample Transport Network has Improved Access, and Program Monitoring in Uganda

Background: HIV remains a major challenge in Uganda, with an estimated 100,000 newborn babies exposed to vertical HIV transmission each year. Early Infant Diagnosis (EID) is a critical component of Elimination of Mother-to-Child Transmission (eMTCT) and early identification of infected children for treatment initiation. In 2007 Uganda rolled out EID services through 8 partner run laboratories. However, high cost, coordination challenges posed significant access and monitoring challenges. In 2011, Uganda adopted a centralized EID testing lab that is supported by a national sample transport network with the aim of alleviating the above challenges. This innovation led to the creation of a consolidated EID database in which all EID, eMTCT and health facility related data is entered. This has enabled the Ministry of Health to routinely and effectively monitor EID coverage across the country.

Methods: EID testing data from August 2011 to December 2013 was analyzed for changes in 1) volume of samples being submitted, 2), number of health facilities submitting DBS samples 3) program monitoring indicators.

Results: The number of EID tests has doubled from 3,560 per month in August 2011 to an average of 7,286 per month by December 2013. The number of testing facilities has more than doubled from 1,003 by close of 2011 to 2,213 by end of December 2013, fairly covering the country. The number of exposed children receiving first PCR test has increased by 37% from 2,000 infants per-month in August 2011 to 5,415 infants per-month by December 2013. The database posts several monitoring indicators including; volumes and their distribution, turnaround time, active and dormant health facilities, positivity rates by categories, etc.. This is posted on a dashboard accessible by all key stakeholders, which was not there before

Conclusion: The centralization of EID testing supported by the sample transport network has increased access to EID testing and improved EID program monitoring in Uganda.

11:40

Carol Porter¹, Kundai Moyo¹, Wainings Manda¹, Mphatso Kachule², Kameko Nichols², Abdoulaye Sarr³, James Kandulu⁴, Reuben Mwenda⁴, Lutho Zungu⁴, Agnes Thawani¹

¹ Howard University Technical Assistance Project, Lilongwe, Malawi, ² Riders for Health, Lilongwe, Malawi, ³Centers for Disease and Control, Lilongwe, Malawi, ⁴ Ministry of Health, Lilongwe, Malawi

Improving Patient Referral Linkages through Implementation of a National Sample Transportation Program in 7 Districts in Malawi

Background: In 2012 the Malawi Ministry of Health in collaboration with Riders for Health and Howard University Technical Assistance Project implemented a national sample transportation (ST) program in 7 districts in Malawi. Samples and tests results for Early Infant Diagnosis (EID), Tuberculosis (TB) diagnostics and CD4 were transported by motorcycles from 181 health facilities to referral laboratories from the 7 districts and back on a routine scheduled basis. The aim of the analysis was to assess the impact of sample transportation on access to laboratory services to improve patient referral linkages to care and treatment.

Methods: Data was collected from the specimen and patient tracker logbooks where the number of specimens and results transported were recorded. The number of specimens tested and turnaround times for test results were collected from the laboratory registers. The number of specimens tested before and during the sample transportation program was also compared.

Results: During the first 8 months of implementation, 14,316 specimens were transported. Out of the 14,316 specimens transported 5,799 (41%) were for EID, 3,572 (25%) for CD4 and 2,971 (21%) for TB. Analysis of laboratory testing data prior to and during the ST program, showed on average a 31% (1074 to 1409) increase in the number of CD4 counts performed, 18% (940 to 1113) increase in TB and 3% (767 to 788) increase in EID tests performed respectively due to more samples being transported. The average turnaround time for results improved from 42 to 28 days, which resulted in patients receiving their results earlier.

Conclusion: The findings suggest that a coordinated and efficient sample transportation mechanism can increase the number of samples tested and reduce the turnaround times for patients receiving their test results thereby improving referral linkages to care and treatment. Further evaluation of the impact of the program on improving referral linkages is needed to support wider implementation.

11:50**Patrick Mateta**¹, Charles Massambu²

¹ Clinical & Laboratory Standards Institute (CLSI), Wayne, PA, U.S.A, ² Ministry of Health and Social Welfare, Dar es Salaam, Tanzania

Building a Sustainable Team for Tanzania's Hospital Laboratories

Background: Funding was awarded by PEPFAR to improve laboratory quality, which required collaboration between the Ministry of Health and Social Welfare (MOHSW), CDC Tanzania, the Clinical & Laboratory Standards Institute (CLSI) and the organizations selected to work with hospital laboratories.

Methods: At the outset of the CLSI technical assistance to Tanzania in 2007, the CDC and MOHSW assumed an arms length position, providing direction and guidance to CLSI. As time progressed both organizations became much more directly involved. CDC and MOHSW became active participants in annual assessment visits to the Zonal hospital laboratories by reviewing the results of the assessments and planning for next steps.

Results: After the first four years of the project to improve laboratory quality, it became very apparent that the laboratories themselves could only make changes within the scope of their authority. The MOHSW had to support them by removing barriers that prevented progress. These included supply chain delays, and equipment maintenance problems, as well as lack of staffing. CDC served as the facilitator, contributing to problem solving discussions and providing support where necessary. With the partners working together the six laboratories involved in the technical assistance were able to implement all of the quality system requirements and ultimately achieve accreditation.

Conclusion: Strong leadership and senior management support are essential for the success of any large change project. In this case hospital laboratories needed guidance and support to improve quality and efficiency. A strong project management team, consisting of MOHSW, CDC and CLSI, working collaboratively, achieved accreditation of four of the six laboratories. These laboratories now provide mentorship for other laboratories in their regions. The team has established a framework that will support sustainability of the improvements made and extend them to other smaller hospitals operating under the MOHSW.

TUESDAY, 2 DECEMBER 2014

ORAL SESSION **2.1** POINT-OF-CARE DIAGNOSTICS

DATE: **Tuesday, 2 December**

TIME: **11:00– 12:45**

LOCATION: **Room 1.4**

CO-CHAIRS: **Francois-Xavier Mbopi-Keou**, University of Yaounde, Cameroon
Clement Zeh, Centers for Disease Control and Prevention, United States of America

11:00

Clement Zeh¹, Frank Angira¹, Paul Omolo¹, Benta Akoth¹, Valarie Opollo¹, Beverly Lu², Scott Bornheimer², Henok Tilahun², Laurie Byrne², Imelda Omana-Zapata²

¹ KEMRI/CDC Program HIV-Research Laboratory, Kisumu, Kenya, ² BD Biosciences, San Jose, California, USA

Evaluation of a Novel Point of Care Test for CD4, %CD4, and Total Hemoglobin (Hb): the BD FACSPresto™

Background: Point of care diagnostic systems for CD4 testing can improve HIV/AIDS management by increasing access to care and enabling test-and-treat on a single patient visit. The BD FACSPresto™ offers CD4, %CD4, and Hb results from a single drop of capillary or venous blood in less than 25 minutes, with throughput of 10 samples per hour. The performance characteristics of this unique system were evaluated.

Methods: Accuracy was conducted using capillary and venous samples from HIV-infected patients in KEMRI/CDC. For comparison, venous samples were tested using Sysmex® KX-21N for Hb and BD FACSCalibur™ with BD Tritest™ CD3/4/45 reagent, BD Trucount™ tubes, and BD Multiset™ software for CD4 and %CD4. Stability of results was compared from 18-120 minutes incubation and for venous samples <6-24h post-draw, and reference intervals for hematologically normal samples were established. In San Jose, USA, precision and linearity (CLSI EP-5 & EP-6A) were tested.

Results: Accuracy of the BD FACSPresto for CD4 and %CD4, for venous (N ~190) and capillary (N ~160) samples, analyzed independently, gave Deming regression slopes within 0.97–1.03 and R² ≥0.96. Results are stable around 500 and 350 CD4 cells/μL. For Hb venous Deming regression results (N ~190), R² = 0.96 and slope = 0.94. Hb capillary results (N ~160) were within 2% bias in the clinical range of 9.5–11.5 g/dL. Results showed stability within 10% across variation in stain time and age of venous blood. Precision was <3.5% coefficient of variation for CD4, %CD4, and Hb, except for low CD4 samples (<6.8%). Linearity was 50–4,000 CD4+ lymphocytes/μL, 200–10,000 total lymphocytes/μL, and 2–20 Hb g/dL. The BD FACSPresto system reliably produced results for >95% of cartridges.

Conclusion: The BD FACSPresto provides accurate, precise clinical results for capillary or venous samples and is suitable for point of care CD4 testing.

11:10

Beverley Anne Singh², Adrian Puren¹

¹ National Institute for Communicable Diseases, National Health Laboratory Service, South Africa, ² Division of Virology and Communicable Diseases, School of Pathology, University of the Witwatersrand, South Africa

Assessment of a Revised Protocol for Selection of HIV Rapid Tests for the National HCT Programme in South Africa

Background: South Africa has the largest number of patients on antiretroviral therapy. To achieve these numbers of patients on treatment requires large-scale facility-based HIV counseling and testing (HCT) using HIV rapid test devices (RTDs). The accuracy of HIV rapid testing is thus critical. In South Africa, selection of test devices is conducted through a biennial national tender. The withdrawal of the SD Bioline testing device from the WHO-approved list of RTDs led to a WHO review of the National Institute of Communicable Diseases (NICD) processes for RTD selection. In response, the NICD embarked on a revision of its processes to ensure a rigorous approach in RTD evaluations.

Methods: The NICD reviewed and changed its standard operating procedures that governed the laboratory-based RTD evaluation processes and included pre-selection and laboratory-based changes. The criteria for pre-selection included evidence of internationally recognized evaluations or certification of RTDs e.g. WHO pre-qualification, USAID/CDC evaluations and/or CE or FDA-approval. The laboratory-based evaluations included challenging panels e.g. seroconversion panels, specimens identified as recently infected and specimens with low OD or S/CO. The accuracy of the RTDs was performed on kits that achieved the required score (80% or above) on the challenging panels.

Results: The revised processes were applied to the National tender announced in 2013. The number of RTDs (n=19) submitted for evaluation using pre-screen selection criteria was reduced by threefold compared to the previous tender. The sequential laboratory-based screening using challenging panels eliminated additional kits and six RTDs met the criteria for selection for the national tender.

Conclusion: The pre-selection and laboratory process provided an opportunity to focus on fewer RTDs than previous evaluations and with improved likelihood of selecting kits meeting the requirements for accuracy. The process improvements require high levels of staffing and skills. Nevertheless, the refinements have led to an efficient and improved selection of RTDs.

11:20

Lara Vojnov

Clinton Health Access Initiative, Dar es Salaam, Tanzania

Dried Blood Spot Samples for Viral Load Testing Vary Significantly in Performance with Each of the Currently Available Viral Load Technologies

Background: Accurate routine HIV viral load testing is essential for assessing the efficacy of ART regimens and the emergence of drug resistance. The storage and transportation time of whole blood for viral load testing is limited and most health care facilities in resource-limited settings lack the necessary infrastructure and cold chain. Though the WHO strongly recommends viral load testing for monitoring, the performance of dried blood spots (DBS) samples remains unclear. Therefore, we conducted a meta-analysis of available data comparing results from DBS samples with those from plasma on the five currently available viral load platforms to inform the use of viral load testing within national scale-up programs.

Methods: Twenty-seven of 38 identified independently published and unpublished studies from different countries submitted primary data for inclusion in the meta-analysis. We used a bivariate random effects model to determine the bias, accuracy, precision and misclassification for each viral load technology to account for between-study variation.

Results: We received approximately 75% of the available primary data sets resulting in more than 6,500 paired DBS:plasma data points. Data collected compared the performance of DBS to plasma samples for viral load testing on one or more of the currently available viral load technologies: Abbott m2000, Biocentric, bioMerieux NucliSens, Siemens Versant, and Roche COBAS Ampliprep/TaqMan. Each technology varied significantly in its performance compared to plasma at several potential thresholds for ART failure.

Conclusion: We could not identify a consistent and optimal DBS threshold for identifying ART failure across the different viral load platforms that was comparable to the WHO-recommended thresholds of 1,000 or 5,000 copies/ml for plasma. This may be due to variations in the test chemistry of each technology when using DBS samples. The Abbott m2000 and bioMerieux NucliSens technologies, however, appear to hold promise for using DBS samples for viral load testing. While previous systematic reviews have been completed, this meta-analysis included almost all available primary data including recent studies allowing for clearer conclusive performance comparisons. This meta-analysis should provide critical insight to country programs looking to implement viral load testing using DBS samples.

11:30

Bradford Cunningham¹, Charlotte Jansen van Rensburg¹, Edwin Motsoloane¹, Lesley Scott¹, Wendy Stevens^{1, 2}

¹ Department of Molecular Medicine and Haematology, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa, ² National Health Laboratory Service and National Priority Program, Johannesburg, South Africa

Connectivity: Instrument and Information Management at Point of Care – Experience vs Expectation

Background: Connectivity and data management at Point of Care (POC) is a crucial requirement for quality POC device testing. A number of middleware solutions are available for use at POC but not all instruments provide an open interface for this support and compatibility, practicality and implementation in low resource settings has yet to be evaluated.

Methods: Two middleware solutions were evaluated at two POC testing sites: AegisPOC (Alere), a purely web-based system and POCcelerator (Conworx, Germany) which has limited functionality without being connected to the internet. At each site a Pima CD4 (Alere), Hemocue (Quest), Reflotron Plus (Roche) and GeneXpert (Cepheid) instruments were placed. AegisPOC supported interfaces of PIMA, GeneXpert and Hemocue with the Reflotron Plus requiring manual entry for test and quality control results. Conworx supported interfaces for the Reflotron Plus, GeneXpert and Hemocue but no interface to the PIMA was available at the commencement of the study. A user review based on the experience of these systems was conducted.

Results: Evaluation of the data manually entered through the middleware solutions was compared to that captured in the study CRF and highlighted a number of issues in terms of the data integrity: 1.5% (3/208) results had incorrect patient identifiers; 8% (17/208) results were captured with transcription errors; 19% (40/208) results were duplicated and 18% (39/208) results not captured. Additional problems encountered were web-access abuse resulting in high data usage and acquisition of viruses.

Conclusion: POC testing for ART initiation requires multidisciplinary platforms and therefore suitable middleware solutions. Currently there is not one middleware solution that eliminates manual data entry. As demonstrated in the real clinical scenario this remains fraught with errors and thus full connectivity requires open interface development, standardization and seamless integration into clinical demographics.

11:40

Daniel Kyabayinze¹, Jane Cunningham², Heidi Hopkins³, Mayfong Mayxay⁴, Koukeo Phommassone⁴, Elizabeth Streat⁵, Iveth J. Gonzalez³, David Bell⁶

¹ Foundation for Innovative New Diagnostics, Kampala, Uganda, ² World Health Organization, Geneva, Switzerland, ³ Foundation for Innovative New Diagnostics, Geneva, Switzerland, ⁴ Lao-Oxford-Mahosot Hospital-Wellcome Trust Research Unit, Vientiane, Lao People's Democratic Republic, ⁵ Malaria Consortium, Kampala, Uganda, ⁶ Intellectual Ventures Lab, Seattle, USA

Positive Control Wells (PCW) for Malaria Rapid Diagnostic Tests (RDT): Training Effectiveness, Impact on RDT Use and Health Worker Perceptions in Lao PDR and Uganda

Background: Malaria rapid diagnostic tests (RDT) are widely used in health facilities and in community-based care settings in endemic countries. To maintain health worker (HW) and patient confidence in RDT and to optimize their utility, RDT must have consistently reliable results; tools to assess the quality of malaria RDT at the point-of-care are unavailable. Prototype positive control wells (PCW), plastic tubes containing critical concentrations of lyophilized recombinant antigens (HRP2, pLDH, aldolase) that are reconstituted with water, have been developed for HWs to test RDT stocks at their health facilities, to ensure RDT validity and accuracy.

Methods: HWs routinely using RDTs in Lao PDR (n=269) and Uganda (n=289) underwent standardized half-day training on the use of PCWs; >70% were village health volunteers. After training, HWs were supplied with PCWs for 6 months, and recorded frequency and reason for PCW use and action taken. HW competence in PCW use was measured immediately after training and 3 and 6 months later. Data on RDT use during the study period were extracted from HW logbooks in control and intervention areas. Focus group discussions and interviews were conducted to capture HW preferences for PCW implementation as well as feasibility, acceptability and value of use.

Results: Initial analysis shows that on strict observation immediately following training, 241 (90%) participants in Lao and 244 (84%) in Uganda performed all critical PCW steps correctly; performance was generally maintained after 6 months. Most common errors were failing to fill the water dropper provided exactly to the measured mark, and failing to transfer exactly one drop of PCW solution to the RDT well. Overall, $\geq 91\%$ of participants could correctly identify 'good' and 'bad' RDT and $\geq 89\%$ could report appropriate action. 784 PCW were reportedly used during the study period in Lao PDR and 1679 in Uganda. The most common reasons cited for performing PCW during routine work were receiving a new stock of RDT, and wanting to check on RDT stock quality. Initial field reports of negative RDT with PCW were not confirmed upon repeat testing. Data on RDT usage and adherence to RDT results will be available in May 2014.

Conclusion: PCW training was effective and in general, PCW appear to improve HW confidence in RDT results.

ORAL SESSION 2.2

ORAL SESSION: HIV COINFECTION (HEPATITIS B, STIs, AND CRYPTOCOCCUS)

DATE: **Tuesday, 2 December**

TIME: **11:00 – 12:45**

LOCATION: **Auditorium 1**

CO-CHAIRS: **Souleymane Sawadogo**, Centers for Disease Control and Prevention, Namibia
Rosemary Audu, Nigerian Institute of Medical Research, Nigeria

11:00 **CANCELLED**

Chinenye Mbamalu¹, Ifeoma Ekejindu², Emmanuel Nna³

¹ Federal Teaching Hospital, Medical Laboratory Services Department, Abakaliki, Ebonyi State, Nigeria, ² Nnamdi Azikiwe University, Nnewi Campus, Department of Medical Laboratory Science, Anambra State, Nigeria, ³ University of Nigeria, Enugu Campus, Safety Molecular Pathology Laboratory, Faculty of Health Sciences and Technology, Enugu State, Nigeria

Detection of Hepatitis B Virus DNA by Polymerase Chain Reaction (PCR) in Plasma of Blood Donors Negative for HBsAg in Abakaliki, Ebonyi State, Nigeria

Background: Hepatitis B virus infection is endemic in many parts of sub-Saharan Africa including Nigeria. The infection is usually defined by the presence of Hepatitis B surface Antigen (HBsAg) in the blood. However, a challenging clinical entity characterized by the absence of Hepatitis B surface Antigen (HBsAg) and low viral Hepatitis B virus (HBV) DNA replication known as occult hepatitis B virus infection (OBI) exists. This study aimed at detecting the presence of Hepatitis B virus (HBV) DNA in the plasma of blood donors negative for Hepatitis B surface antigen (HBsAg) in Abakaliki, Ebonyi State, Nigeria.

Methods: A total of 113 informed consented blood donors enrolled in the study were serologically screened for HBsAg using a rapid test kit. Subsequently, all samples that were negative to HBsAg were subjected to Hepatitis B virus DNA detection using nested Polymerase Chain Reaction (PCR). HBV viral load was then determined by real time PCR-Taqman chemistry.

Results: 13 donors (11.5%) tested positive to Hepatitis B surface Antigen (HBsAg) out of 113 donors screened. Nested Polymerase Chain Reaction (PCR) detected occult Hepatitis B Virus infection as 8.0% (8 donors). The HBV viral load results of each of the 8 donors were ≥ 200 IU/ml. 12 out of the 13 sero positive (HBsAg +) cases were confirmed positive by nested PCR but one sample was negative (had only S region positivity).

Conclusion: This data suggests that the risk of HBV transmission by blood transfusion in Nigeria is relatively high. Therefore, the detection of HBV DNA by sensitive amplification technique serves as an essential supplementary tool besides serology in a number of clinical settings, especially in determining occult Hepatitis B Virus infection among blood donors.

11:10

Judy Orikiiriza^{1,2}, Louis Mujuwisha¹, Elizabeth Karlsson³, Johan Normark³

1 Department of Pediatrics and Child Health, School of Medicine, College of Medicine and Health Sciences, University of Rwanda, Rwanda, 2 Rwanda Military Hospital, Kigali, Rwanda, 3 Department of Molecular biology, Umea University Institute, Sweden

Antibody Response to Hepatitis B Vaccine in Pediatric Patients Attending Rwanda Military Hospital in October-December 2013

Background: Hepatitis B vaccine offers protection in over 85% and thus governments have endeavored to provide free vaccination under the routine immunization programs in most low resource countries (LRCs). Since 2002, Rwanda introduced the HBV vaccine however there is paucity of information in LRSs in the pediatric population concerning HBV infection and the impact of HBV vaccination since introduction. Our general objective was to assess the humoral response to Hepatitis B vaccine in Pediatric patients attending Rwanda Military Hospital after widespread hepatitis B vaccination. The study hypothesis was: HBV vaccination weans significantly with time.

Methods: This was a prospective cross sectional study design carried out at Rwanda Military Hospital from October 2013 – December 2013. Children aged 3.5 months -18 years were recruited in the study after fulfilling the study criteria. A standardized questionnaire was used to capture the demographic parameters of participants. Blood samples were removed to carry out HBsAg, antibodies to the HBsAg, and HIV. Data was entered and analyzed using STATA version 10. Ethical and Scientific approval was sought from the Institutional Review Board (IRB) at RMH, College of Medicine and Health Sciences School of Medicine University of Rwanda IRB and Umea Molecular Biology University IRB.

Results: Three hundred and four children were analysed, with a male: female ratio of 1.4:1. They were aged 3.5 months to 18 years with a mean age of 7.88 years (SD= $\bar{A}\pm 5.5$ years).

The overall reported vaccination rate by the primary care taker was found to be 214/304(70.4%) however 108/247(35.5%) were found to have anti-HBs titer >10IU that conferred protection and HBV infection was 12/248(4.8%). It was noted that the protective vaccination titers were found to be 61.9% and 10.3% for ages between 3.5 months-11 year, >11year-18 years respectively in the vaccinated children. Of those reported to be vaccinated 59.9% had adequate Abs HBsAg titers the proportion of anti- HBs levels decreased with increasing age with a p value= ≤ 0.001 . “Abs to HB wean with age amongst the vaccinated group and the commonest age group with high HB infection was in the older age thus there is need for providing HB vaccination boosters for the older age group to maximise HB prevention strategies.

Conclusion: A larger study is recommended to determine the predictors of possible low HB antibody titers in our children and to come up with the appropriate timing for booster doses so that more relevant vaccine programs can be rolled out.

11:20

Eric Mukenge¹, Sylvain Yuma Ramazani², Guy-Olivier Mbensa Kuediasala^{3,5}, Blanchard Malenga Nkanga^{1,3}, Aimé Mbaya Tshiyamu¹, Franck Nzengu Lukusa¹, Jérémie Muwonga Masidi^{1,5}, Donatien Kayembe Nzongola¹, Ferdinand Mbayo Kalumbu¹, Steve Ahuka-Mundeke^{1,4}

1 Departement de Biologie Médicale, Cliniques Universitaires de Kinshasa, RDC, 2 Centre National de Transfusion Sanguine, Kinshasa, RDC, 3 Hôpital de l'Amitié Sino-Congolaise de N'Djili (HASC), RDC, 4 Institut National de Recherche Biomédicale, Kinshasa, RDC, 5 Ministère de la Santé Publique, Kinshasa, RDC

Séroprévalence des Marqueurs Spécifiques de l'Hépatite B Chez les Donneurs de Sang Vénévoles à Kinshasa, R.D. Congo

Background: La RDC est considérée comme faisant partie des régions de forte endémicité de l'hépatite B. Cependant, nous n'avons pas trouvé des publications en relation avec la présence réelle du Virus de l'Hépatite B(VHB) en RDC. Sa pré valence réelle n'a pas encore été estimée. Seules quelques études portant sur de populations sélectionnées (donneurs de sang, femmes enceintes,...) ont rapporté des prévalences établies sur la présence de l'AgHBs. L'objectif de cette étude était de déterminer la prévalence de l'hépatite chez les donneurs de sang bénévoles en utilisant d'autres marqueurs de l'infection de l'hépatite B.

Methods: Du 1er au 30 Juin 2013, nous avons prélevé 10 ml de sang auprès de donneurs de sang bénévoles, consentant et recrutés au CNTS et aux CUK sur base des critères préétablis. Nous avons recherché l'AgHBs, Ac anti-HBs et l'Ac anti-HBc en utilisant la technique ELISA. L'infection a été définie suivant l'algorithme établi dans le diagnostic de l'infection par le VHB.

Results: 180 donneurs de sang ont été prélevés parmi lesquels 9/180 (5%) possédaient l'AgHBs et 40/180 (22,2%) avaient les Ac anti-HBs et 82/180 (45,6%) possédaient les Ac anti-HBc. Aucun Ac anti-HBs n'a été retrouvé chez les 9 donneurs AgHBs positifs qui pourtant possédaient les Ac anti-HBc. 15% (27/180) possédaient à la fois les Ac anti-HBs et Ac anti-HBc. Enfin respectivement 7% (13/180) et 25,5% (46/180) avaient l'Ac anti-HBs et Ac anti-HBc de manière isolée.

Conclusion: Au cours de cette étude, nous avons montré que la prévalence réelle de l'infection par le VHB peut varier de 5% à 46% selon le type de marqueur utilisé, suggérant une sous estimation de la pré valence de l'hépatite B en n'utilisant que l'AgHBs. D'autres études incluant un large panel des marqueurs de l'infection par le VHB et un échantillon considérable sont recommandées.”

11:30

Souleymane Sawadogo¹, Boniface Makumbi², Anne Purfield³,
Christophine Ndjavera², Gram Mutandi¹, Andrew Maher⁴, Francina Kainjee Tjituka⁵,
Jon Kaplan⁶, Benjamin J. Park³, David W. Lowrance¹

¹ Division of Global HIV/AIDS (DGHA), Centers for Disease Control and Prevention (CDC), Windhoek, Namibia, ² Namibia Institute of Pathology (NIP), Windhoek, Namibia, ³ Mycotic Disease Branch, CDC Atlanta, GA, US, ⁴ Global Health Sciences, University of California San Francisco, CA, US, ⁵ Directorate of Special Programs, Ministry of Health and Social Services, Windhoek, Namibia, ⁶ Division of Global HIV/AIDS (DGHA), Centers for Disease Control and Prevention (CDC), Atlanta, GA

Prevalence of *Cryptococcus Antigenemia (CrAg)* Among a Sample of HIV-infected Individuals in Namibia

Background: Cryptococcal disease (CD) is common among severely immunosuppressed individuals and is associated with high mortality. Despite scale-up of antiretroviral treatment (ART) services, many HIV-infected patients still present with advanced immunodeficiency and are therefore at risk for CD-related morbidity and mortality. WHO recommends consideration of routine cryptococcal antigen (CrAg) screening in ART-naïve adults with a CD4+ count <100 cells/mm³ where CrAg antigenemia (CA) prevalence is above 3%, followed by pre-emptive antifungal therapy for CrAg-positive patients. Most studies in sub-Saharan Africa have reported CA prevalence rates of 2-15% among persons with CD4+ <100; no CA data exist regarding prevalence of CrAg antigenemia (CA) among HIV-infected persons in Namibia.

Methods: Using a cross-sectional design, CrAg testing was performed on de-identified remnant plasma specimens collected during the period of November 2013 to January 2014 for routine CD4+ testing from HIV-infected patients at all public facilities in Namibia. Specimens were tested for CrAg using the IMMY[®] Lateral Flow Assay (LFA). Data were analyzed using Stata/SE 12.1.

Results: A total of 833 specimens from patients with CD4+ count <200 cells/mm³ were collected with median CD4+ count of 85 (range 51-114). Overall, 317 (38.1%) CD4+ cell count samples were 100-200 cells/mm³ and 516 (61.9%) were <100 cells/mm³. The overall prevalence of CA among the 833 samples was 3.4% (95% CI: 2.1-4.6). CrAg positivity rate was 4.1% (2.4-5.8) and 2.2% (0.5-3.8), respectively, amongst samples in the CD4+<100 cells/mm³ and 100≤CD4+<200 cells/mm³ strata.

Conclusion: CA prevalence rates among patients with CD4+<200 and <100 cells/mm³ were somewhat lower than those reported from other countries in the region. However CA was >3.0% in persons with CD4+<100 cells/mm³; thus, according to WHO guidelines CrAg screening and treatment of positive individuals should be considered in HIV care and treatment services in Namibia.

11:40

Mourine Kangogo¹, Christine Bii², Olivier Bader³, Hamadi Boga⁴,
Wanjiru Wayoike⁴, Michael Weig³, Uwe Groß³

¹ Department of Medical Microbiology, Jomo Kenyatta University of Agriculture and Technology, Nairobi, Kenya, ² Medical Mycology Unit, Center for Microbiology Research, Kenya Medical Research Institute, Nairobi, Kenya, ³ Institute for Medical Microbiology, University Medical Center Göttingen, Göttingen, Germany, ⁴ Botany Department, Jomo Kenyatta University of Agriculture and Technology, Nairobi, Kenya

Molecular Typing of *Cryptococcus Neoformans* and *Cryptococcus Gattii* from Clinical and Environmental Sources in Nairobi, Kenya

Background: Cryptococcal meningitis caused by *Cryptococcus neoformans* is a leading cause of death among persons living with HIV/AIDS in sub-Saharan Africa. *C. neoformans* has historically been divided into three varieties of five serotypes based on antigenicity of the capsule: *C. neoformans* var. *grubii* (serotype A), *C. neoformans* var. *gattii* (serotypes B and C), *C. neoformans* var. *neoformans* (serotype D), and one hybrid (serotype AD). In 2002, *C. neoformans* var. *gattii* (serotypes B and C) was awarded species status and renamed *Cryptococcus gattii*. From environmental distribution point of view, the species is ubiquitous in nature, however, variety *grubii* found mainly in pigeon excreta and decaying wood, variety *neoformans* in pigeon excreta *C. gattii* mostly associates with decaying wood. Variety *grubii* and variety *neoformans* infect immunocompromised patients with particular predilection for central nervous system while *C. gattii* attacks immunocompetent individuals causing pulmonary cryptococcosis. This is the first report on the occurrence of *Cryptococcus* molecular types from environmental sources in Kenya. Restriction fragment length polymorphism (RFLP) which groups *Cryptococcus* into various molecular types is important in epidemiological studies.

Methods: The molecular types of 123 *Cryptococcus* isolates (70 clinical and 53 environmental). Typing was done using Orotidine monophosphate pyrophosphorylase (URA5) gene Restriction Fragment Length polymorphism (RFLP) with HhaI and Sau961 in a double digest. The environmental isolates were recovered from different environmental sources in Nairobi, Kenya. The clinical isolates were taken from culture collections at Medical Mycology Laboratory, Kenya Medical Research Institute. The isolates were identified as *Cryptococcus* species by morphology, biochemical and physiological tests.

Results: The majority of the isolates [104/123(84.6 %)] were *C. neoformans* variety *grubii* (VNI) while [16/123 (13%)] were *C. gattii* molecular type VGI, [2 /123(1.6%)] were *C. neoformans* variety *grubii* (VNII) while only [1/123 (0.8%)] was *C. neoformans* variety *neoformans* (VNIV).

Conclusion: The findings clearly show the presence of several molecular types of *C. neoformans* and *C. gattii* from clinical and environmental sources in Nairobi, Kenya. Further studies on other possible reservoirs are needed for understanding other molecular types, diagnostic, management and prevention of cryptococcosis in debilitating conditions.

11:50

Issoufou Tao^{1,2}, Cyrille Bisseye¹, Alice Kiba³, Mahmoudou Sanou³, Tegwindé Rebeca Compaoré¹, Lassina Traoré¹, Jean Baptiste Nikiema¹, Jean Didier Zongo², Jacques Simporé¹

¹ Centre de Recherche Biomoléculaire Pietro Annigoni (CERBA)/LABIOGENE, Université de Ouagadougou, Burkina Faso, ² Laboratoire de Génétique, Université de Ouagadougou, Burkina Faso, ³ Centre National de Transfusion Sanguine, Ouagadougou, Burkina Faso

Contribution à l'Amélioration de la Sécurité Transfusionnelle : Diagnostic Moléculaire des Virus d'Epstein Barr (EBV) et de l'Hépatite G (VHG) par PCR et RT-PCR Chez les Donneurs de Sang au Burkina Faso

Background: Dans beaucoup de pays au sud du Sahara, le dépistage des infections transmissibles par le sang concerne essentiellement le VIH, le VHB, le VHC et *Treponema Pallidum*. Plusieurs virus comme Epstein Barr Virus (EBV) et le VHG aussi transmissibles par la transfusion sanguine posent aujourd'hui la problématique de l'extension du dépistage prétransfusionnel à ces agents pathogènes. Cette étude a pour but d'évaluer la prévalence de EBV et VHG chez les donneurs de sang de premier don à Ouagadougou.

Methods: Cinq cent cinquante et un (551) donneurs de sang de premier don ont été inclus dans cette étude. 84,2% étaient des hommes et 15,8% des femmes. Une recherche des anticorps anti-HBsAg, HIV-1/2 et VHC a été effectuée en utilisant la technique ELISA (ARCHITECT-i1000SR ABBOTT Santa Clara, California, United States of America). Ceux anti *Treponema pallidum* ont été recherchés par un test RPR rapid plasma reagin (Cypress Diagnostics, Langdorp, Belgium).

Les infections par EBV et VHG ont été recherchées par PCR et par RT-PCR respectivement en employant un kit commercial (Sacace Biotechnologie, Italie).

Results: 99,5% des donneurs étaient effectivement des donneurs de premier don. L'ADN viral de EBV a été retrouvé chez 5,4% (30/551) des donneurs ; 7,4% (41/551) étaient porteurs du virus de l'hépatite G. La prévalence de EBV était similaire chez les VIH séropositifs (8.3%) comparé aux individus VIH séronégatifs (6.1%), mais elle était plus élevée chez les donneurs dont l'âge est <20 ans comparé à la tranche d'âge comprise entre 20-29 ans ($p < 0.001$). HGV était principalement associé au VHB (5.6%), HCV (1.0%) et la syphilis (0.4%).

Conclusion: Cette étude rapport pour la première fois les prévalences d'EBV et VHG chez les donneurs de sang au Burkina Faso. Des études plus poussées permettront de déterminer leurs impacts sur les sujets infectés.

12:00 **CANCELLED**

Chinedum Oparaugo¹, Rosemary Okoye¹, Adesegun Adesesan¹, Mariam Adetunji¹, Samuel Nduaga¹, Ini-obong Essien¹

¹ Nigerian Institute of Medical Research Yaba, Lagos, Nigeria

The Burden Of Bacterial Vaginosis In Lagos Nigeria

Background: Bacterial Vaginosis (BV) is an identified cause of reproductive ill health in women. However, little work has been done on the burden of illness among Nigerian women.

Methods: Objective: To determine the burden of BV among women with genital tract complaints.

HVS was collected from women presenting with genital tract complaints at Clinical Diagnostic Laboratory, Nigerian Institute of Medical Research Yaba, Lagos over a twenty four month period (September 2009 to September 2011). Samples were examined using Amstel Criteria and diagnosed as having BV if three out of the four criteria were present. Data management was with EPI INFO statistical software version 2002.

Results: During the period of study, HVS was collected from 283 women after informed consent. The age of the women ranged from 18 to 65 years with a mean 31.2 years. Two hundred and sixty six (93.9%) had abnormal discharge, 178 (62.9%) had moderate to profuse discharge, 242 (85.5%) had vaginal pH of ≥ 4.5 . Positive amine test was observed in 142 (50.2%) patients and 101 (35.7%) had clue cells in the discharge. Only 175 (61.8%) of the women had BV using Amstel Criteria.

Conclusion: The rate of BV (6.8%) among the women in this study is high and thus calls for public enlightenment / health education on the dangers of unhealthy vaginal practices and indiscriminate use of antibiotics among our women.

ORAL SESSION 2.3 IMPROVING TB DIAGNOSIS

DATE: **Tuesday, 2 December**

TIME: **11:00 – 12:45**

LOCATION: **Room 1.6**

CO-CHAIR: **Jean de Dieu Iragena**, World Health Organization, Switzerland
Tom Shinnick, Centers for Disease Control and Prevention, United States of America

11:00

Jesse Wambugu^{1,2}, Kekeletso Kao¹

¹ Foundation for Innovative New Diagnostics, Geneva, Switzerland, ² Global TB Programme, World Health Organization, Geneva, Switzerland

Improving Access to MDR-TB Diagnosis in Africa: EXPAND-TB's Experience of Establishing Laboratories in 12 African Countries

Background: MDR-TB diagnosis remains a challenge in many African countries and particularly in the context of HIV. In 2012, only 47% of the estimated 38,000 MDR cases in Africa received laboratory confirmed diagnosis. In 2009 UNITAID approved funding for the EXPAND-TB (EXPanding Access to New Diagnostics for Tuberculosis) project, a collaboration between World Health Organization (WHO), the Global Laboratory Initiative (GLI), the Stop TB Partnership Global Drug Facility (GDF) and the Foundation for Innovative New Diagnostics (FIND), with the aim of increasing access to MDR-TB diagnostics in 27 high TB/MDR-TB countries 12 of which were in Africa. A total of 13,027 MDR-TB cases were targeted for diagnosis over 6 years in 12 countries.

Methods: Agreements were signed with each country to delineate responsibilities between the partnership and National TB Programmes and 26 national TB reference and regional laboratories were targeted for liquid culture/DST and LPA and 16 laboratories for Xpert MTB/RIF support. Laboratory infrastructure was upgraded and biosafety standards improved to required levels. Commodities for liquid culture/DST, LPA and Xpert MTB/RIF were introduced into the laboratories and over 89 laboratory personnel trained on the various techniques. Diagnostic algorithms were revised to promote rational use of the new MDR-TB diagnostics. Collaboration with other partners was also sought to ensure efficient use of resources and avoid duplication.

Results: A number of challenges slowed the project's progress including delays in infrastructure upgrades, high staff turnover, poor referral systems, lack of equipment maintenance and delays in customs clearance for commodities. Despite these challenges, since 2009, 37/42-targeted laboratories are operational and 6,170 MDR-TB cases have been diagnosed in the 12 countries.

Conclusion: Political commitment, a strong network of technical personnel and collaborative efforts with partners are required to improve MDR-TB diagnosis in Africa and improve the quality management systems.

11:10

Raymond N'Guessan¹, Keita Sow², André Téhé³, Alem Sinishaw², Adje-Toure Christiane³, Jacquemin Kouakou⁴

¹Institut Pasteur de Côte d'Ivoire, Abijan, Côte d'Ivoire Mah-Séré, ²American Society for Microbiology, Washington DC, USA, ³Centers for Disease Control and Prevention, Côte d'Ivoire, ⁴Programme National de Lutte contre la Tuberculose

Improved Laboratory Diagnosis of MDR-TB Cases is Revealing Care and Treatment Scale-up Needs in Côte d'Ivoire

Background: In 2012, with the help of international and national partners, laboratories of culture for Tuberculosis in Côte d'Ivoire were renovated and equipped. The laboratory of Pasteur Institute Côte d'Ivoire serves as the national TB reference laboratory (NTRL). In addition, CeDReS, a central laboratory has developed the capacity to diagnose and identify Multi-Drug Resistant- TB.

Methods: The capacities of the NTRL and CeDReS laboratories were built in a phased process. Through funding from CDC/PEPFAR-Côte d'Ivoire and technical assistance from international partners such as the American Society for Microbiology (ASM) and the Foundation for Innovative New Diagnostics (FIND), the laboratories were renovated to establish a negative pressure gradient; they were equipped and the laboratory staff trained to perform new technologies for TB including Liquid TB culture and Molecular assays (LIPA).

Results: In accordance with the national algorithms, sputum samples of patients eligible for retreatment identified in TB centers were collected and transported to the NTRL and CeDReS laboratories. The sputum samples were decontaminated by The NALC method. Culture and MTBDRplus assay were performed with pellet. From 2012 to 2013, among patients eligible for retreatment 235/435 (54%) and 327/785 (41.6%) were MDR-TB cases respectively. For these 562 MDR-TB cases notified, only approximately one-third of these patients are under treatment.

Conclusion: As laboratory capacity is built to detect drug resistant TB, these efforts should be paralleled with the strengthening of care and treatment facilities to ensure that newly diagnosed patients receive adequate and prompt treatment.

11:20

Ibrahim Ali¹, Yimtubeznash Woldeamnuel¹, Amha Mekasha¹, Markos Abebe², Liya Wassie², Abraham Aseffa²

¹Addis Ababa University, Addis Ababa, Ethiopia, ²Armauer Hansen Research Institute, Addis Ababa, Ethiopia

Comparison of Tuberculosis Skin Test and QuantiFERON-TB Gold in Tube Assay for Diagnostic Workup of Childhood Tuberculosis. A Cross-sectional Study Conducted at Tikur Anbesa Specialized Hospital, Ethiopia

Background: The tuberculin skin test (TST) has been in use as a screening tool for TB for decades. However, there is increasing evidence of better sensitivity and specificity of the newer Interferon- γ release assays (IGRAs). Objective: To compare

performance of TST and QuantiFERON-TB gold in tube assay (QFT-GIT) for the diagnosis of active TB in children.

Methods: A cross-sectional study was conducted in 310 children who visited Tikur Anbesa Specialized Hospital for the diagnosis of tuberculosis. After clinical evaluation study participants were tested for TST and QFT-GIT.

Results: Three hundred and ten children were enrolled for the study. Out of these, 281 children had a full data set on clinical, chest X ray and laboratory investigations. The median age of the study participants was 73 months; 27.7% had low weight for age and 28.5 % had contact history with adult TB cases. TB was culture confirmed in 10.7% of cases and 27.8 % of cases were clinically diagnosed without microbiological conformation. HIV was detected in 19.6% of cases. The overall TST and QFT-GIT positivity was 28.1% and 24.6% respectively. TST was found positive in 70% of confirmed TB cases, 38.5 % clinically diagnosed and 16.8% none TB cases. QFT-GIT was positive in 60.3 % of confirmed TB cases, 47.4 % of clinically diagnosed and 13.9% of non TB cases. The sensitivity of TST and QFT-GIT was found 70 % and 60.3 % respectively. The specificity of TST and QFT-GIT was found 76.9% and 80% respectively. The concordance of the two tests was found 83.3%. Patient contact history with known TB cases, low weight for age, and culture or AFB positivity were found highly associated with both TST and QFT-GIT ($p < 0.01$).

Conclusion: TST was found comparable with QFT-GIT for the diagnostic work up of childhood tuberculosis.

11:30

Yetunde Isa¹, Agatha Ani¹, Rosemary Pwol¹, Chindak Lekuk¹, Tolulope Ashi-Sulaiman²

¹ AIDS Prevention Initiative Nigeria, Jos University Teaching Hospital, Jos, Plateau State Nigeria, ² AIDS Prevention Initiative Nigeria, Abuja, FCT, Nigeria

GeneXpert MTB/RIF: Observed Error Rates and Invalid Results after Twelve Months of Regular Use

Background: The XpertMTB/RIF is one of the two molecular methods approved by the World Health Organization for the rapid detection of TB and drug resistance. The test procedure is very simple to perform with no requirements for specific skills. Expected results could be one of five possibilities; 'MTB detected', 'MTB not detected', 'Error', 'Invalid' or 'No result'. We observed the pattern and frequency of inconclusive results obtained at our facility with a view to assess the possible implications of such results.

Methods: A total of 476 sputum specimens were tested from February 2013 to December 2013. Results obtained were classified in the respective formats according to the manufacturer's specified codes

Results: The total rate of inconclusive results was 51/476 (10.7%), Type 'E5011' (35%) occurred most frequently, followed by 'Invalid' (17.6%), 'E5007' (13.7%), and 'E2008' (9.8%). Repeated tests reproduced same results for 5/51 (9.8%) while 46/51(90.1%)

were corrected for errors. The total error rates reduced to E5011 (0.4%), E5007 (0.2%), E2008 (0.8%), following troubleshooting and implementation of corrective actions.

Conclusion: The total rate (10.7%) of inconclusive findings obtained at our facility was higher than the recommended standard of <3%. High error rates have obvious consequences in cost and turnaround time as extra cartridges are required to retest specimens while patients may also be required to produce fresh specimens. Strict compliance to procedural requirements is necessary for maximum attainment and sustainable system function.

11:40

Simon Walusimbi, Alfred Okeng, Edgar Kigozi, Samuel Kyobe

Makerere University, Department of Medical Microbiology, Kampala, Uganda

Comparison of SpeedOligo Test to Xpert MTB/Rif Test for Detection of Tuberculosis in Smear-Negative HIV-Infected Patients

Background: Laboratory diagnosis of Tuberculosis (TB) traditionally relies on smear microscopy and culture. However, recent advances in technology have seen the introduction of molecular tests for diagnosis of TB because they are more sensitive compared to microscopy and more rapid compared to culture. We compared a new molecular test called SpeedOligo[®] DIRECT Mycobacterium tuberculosis test (SpeedOligo) to Xpert MTB/Rif test (Xpert) for detection of TB in smear-negative HIV-infected patients. SpeedOligo is a PCR based test, attached to a dipstick used for the qualitative detection of Mycobacterium tuberculosis (MTB) and Non-Tuberculosis Mycobacteria (NTM). Xpert is an automated PCR test used for detection of TB and Rifampicin resistance in a one-off test giving results within three hours. Xpert was recommended by the World health Organization as the initial diagnostic for HIV-associated TB since 2010.

Methods: One hundred and nine (109) smear-negative sputum samples were tested with SpeedOligo. The SpeedOligo results were compared to the Xpert results which were not available until the final results of SpeedOligo were reported. The test results of both SpeedOligo and Xpert were then compared to a combination of liquid (MGIT) and solid (L-J) culture results.

Results: Of the 109 samples, 79% (86/109) had complete results including those of culture. The sensitivity and specificity of SpeedOligo compared to Xpert was 64% (95% CI: 35%-87%) and 83% (95% CI: 73%-91%) respectively. A substantial proportion of the tests 57% (12/21) which were positive on SpeedOligo were negative on Xpert and culture. We observed that when the SpeedOligo strips were incubated for longer than 3 minute background bands occurred which were misinterpreted as positive for MTB.

Conclusion: SpeedOligo has moderate sensitivity and high specificity for smear-negative TB when compared to Xpert. The visual interpretation of the test resulted into a substantial proportion of false positive results, which could limit its implementation in routine laboratory practice.

ORAL SESSION **2.4****MONITORING ROTAVIRUS ENTERIC DISEASES**DATE: **Tuesday, 2 December**TIME: **11:00 – 12:45**LOCATION: **Room 2.4**CO-CHAIRS: **Diane Waku**, Centers for Disease Control and Prevention, United States of America
Elisabeth Pukuta, Institut National de Recherche Biomedicale, Democratic Republic of the Congo**11:00****Elisabeth Pukuta**¹, V. Tubijinga², M. Landu², G. Kitambala³, D. Monga⁴, M. Essona⁵, S. Mapaseka⁶, A. Nkongolo⁷, D. Waku⁵, V. Ngum⁸, M. Bowen⁵, V. Mondonge⁷, J.J. Muyembe¹

1 Institut National de Recherche Biomedicale, Kinshasa, RDC, 2 Hôpital Pédiatrique de Kalembelembe, Kinshasa, RDC, 3 Centre Hospitalier de Kingasani, Kinshasa, RDC, 4 Hôpital Sendwe, Lubumbashi, Katanga, RDC, 5 Division of Viral Diseases, National Center for Immunization and Respiratory Diseases, United States Centers for Disease Control and Prevention, Atlanta, Georgia, US United States, 6 MRC/ Diarrheal Pathogens Research Unit (DPRU), University of Limpopo, Medunsa, South Africa, 7 Organisation Mondiale de la Santé, Kinshasa, RDC, 8 Centre Mère-Enfant, Yaoundé, Cameroun

Diversity of Group A Rotavirus Strains Circulating in RDC, January-December 2012

Background: Rotavirus is a leading cause of severe diarrhea among children under five in the world and that of child mortality in developing countries. Several usual (G1, G2, G3, G4 and G9) and unusual genotypes (G6, G8, G10 and G12) are circulating worldwide and vaccination prevents the disease. In the Democratic Republic of Congo (DRC), rotavirus vaccine is not yet introduced in the immunization schedule. Previous data from sentinel site surveillance shows that rotavirus is the principal cause of acute diarrhea. The aim of this study was to determine the diversity of rotavirus strains circulating in DRC.

Methods: Stool samples were collected between January and December 2012, from children under five years with acute diarrhea. The group A rotavirus were detected by Elisa, positive samples were genotyped using G and P nomenclature by One Step RT-PCR. Genotyping results were confirmed by sequencing.

Results: From 606 samples analyzed by ELISA, 323 were positive (64%). Genotyping results showed that the most prevalent G genotypes was G1, 145 (45%), followed by G2, 75 (23%) and G6, 43 (13%). For P genotype, the most common was P8, 138 (43%), followed by P6, 137 (42%) and P4, 6 (2%). The unusual G genotypes were G6 with 13%, G8 and G12 with 2%. The predominant combination strains were G1P8 (38%), G2P6 (20%); G6P6 (13%) and G1P6 (7%). Some unusual combinations strains were detected, G6P6, (13%), G6P8, G8P4, G8P6, G8P8, G12P6 and G12P8 with less than 1%. The genotype could not be determined for 37 samples (11%),

Conclusion: This study shows a high diversity of strains circulating in DRC and an emergence of unusual genotypes (G6P6, G6P8). It is very important to continue the molecular surveillance of rotavirus strains as these data will help monitor the impact of the rotavirus vaccine, plan to be introducing in DRC in 2017.

11:10**Nomcebo Phungwayo**¹, Gugu Maphalala²

1 National Reference Laboratory, Mbabane, Swaziland, 2 Swaziland Health laboratory Services, Mbabane, Swaziland

Estimated Rotavirus Gastroenteritis Prevalence in Children Below the Age of 5 Years in Swaziland During Period Jan- Dec 2013

Background: Rotavirus is the leading cause of severe diarrhea in infants and young children worldwide. Globally, it causes more than half a million deaths each year in children younger than 5 years of age. In Swaziland approximately 10% of Swazi children hospitalised die due to diarrhoea. The Rotavirus surveillance in Swaziland was launched in April-2013 and the objectives were 1. To estimate the burden of rotavirus disease among children 0-59 months diagnosed with acute gastroenteritis (AGE) and admitted to the Pediatric wards in the two sentinel site hospitals; Mbabane Government hospital and Raleigh Fitkin Memorial hospital 2. To determine the seasonal distribution of RV 3. To determine the most affected age group. Period of Data set: January-December 2013 Design Hospital-based surveillance.

Methods: A total of 121 samples were collected from all patients who came with diarrhoea and were admitted in paediatric wards from both sites, were tested in the National Reference Laboratory using the Prospect Enzyme immunoassay kit.

Results: Prevalence of rotavirus was determined to be (54/121) 44.6%. The Seasonal distribution indicated that the Rotavirus was most Prevalent in the months June and July. The rotavirus infection was determined in children of age groups followed by > 6months = 27.8%, 6-12 months = 51.9%, 13-24 months = 16.7% and >24months = 3.6%.

Conclusion: The prevalence of 44.6% indicated that the rotavirus infection was very high in the two referral hospitals. The children aged 6-12 months were found to be the mostly affected by rotavirus disease compared to the other age groups. Continuous rotavirus surveillance is required to monitor the disease trends and further testing to determine the circulating strains is required. There is high burden of rotavirus in Swaziland thus there is need for the introduction of rotavirus vaccine that will protect the Swazi children from the rotavirus infections.

11:20

Kenneth Onyedibe¹, Bose Toma², Udochukwu Diala², Omini Uket³, Ubong Udoh³, Okokon Ita³, Mark Okolo¹, Tolulope Afolaranmi⁴, Victor Nwadike⁵

¹ Department of Medical Microbiology, Jos University Teaching Hospital, Jos, Nigeria, ² Department of Paediatrics, Jos University Teaching Hospital, Jos, Nigeria, ³ Department of Medical Microbiology, University of Calabar Teaching Hospital, Calabar, Nigeria, ⁴ Department of Epidemiology and Community Health, University of Jos, Jos, Nigeria, ⁵ Department of Medical Microbiology, Federal Medical Center, Abeokuta, Nigeria

The Necessity of Full Sepsis Work-up in Neonatal Sepsis; Experience in a Resource Limited Setting

Background: Diagnostic tests that differentiate infected from non-infected neonates have the potential to make significant impact on neonatal care. This study aimed at ascertaining the necessity of a full sepsis work up and its effectiveness in making the diagnosis of neonatal sepsis in a resource limited environment.

Methods: This was a cross sectional study conducted in Jos University Teaching Hospital (JUTH), Jos, Nigeria. The Integrated Management of Childhood Illnesses (IMCI) criteria for diagnosis of neonatal sepsis were used to select subjects for the study. Blood samples, Cerebrospinal fluid (CSF) and urine samples were collected from 165 neonates through aseptic procedures. Samples were processed and analyzed by standard methods in the microbiology laboratory of JUTH.

Results: A total of 68 isolates were recovered from 165 sets of blood culture samples representing 41.2% positive blood culture results. Only three (1.8%) organisms were isolated from 165 CSF samples. Five isolates were recovered from 165 urine samples representing 3.0% of the total urine sampled. Three neonates had both CSF and blood isolates of the same organism. Similarly, four of the five neonates with urine isolates also had blood isolates of the same organism.

Conclusion: The study found that blood culture is the most effective sample for laboratory diagnosis of neonatal sepsis. We recommend that urine and CSF samples be collected only when specifically indicated and may not be considered a necessity in all cases so as not to put the already sick neonate through unnecessary procedures.

11:30

Julia Simwaka¹, Evans Mpabalwani¹, Mwaka Monze², Jason Mwenda³, Olusegun Babaniyi⁴, Cynthia Phiri Mubanga¹, Idah Ndumba¹, Mazyanga Liwewe¹, Hellen Mutambo⁴

¹ Ministry of health, University Teaching Hospital, Department of Pathology and Microbiology, Virology Laboratory, Lusaka, Zambia, ² Ministry of health, University Teaching Hospital, Department of Pediatrics, Lusaka, Zambia, ³ WHO Afro, Congo Brazzaville, ⁴ WHO Country Office, Zambia

Epidemiology and Genotyping Characterization of Rotavirus Strains Detected in Under 5 with Acute Gastroenteritis at 2 Children's Hospitals in Zambia

Background: In anticipation of rotavirus vaccine introduction, the Zambian Ministry of Health initiated rotavirus surveillance in 2006 to determine the disease burden and characterize the genotypic

strains including the rotavirus epidemiological trends among the under five children who present to the hospital with acute gastroenteritis.

Methods: Stool samples were collected from under 5 years children from August 2006 to December 2013. The samples were screened for group A rotaviruses by antigen detection ELISA (ProSpecT™ Rotavirus Microplate Assay) and selected rotavirus positive samples were characterized by polyacrylamide gel electrophoresis (PAGE) VP7 and VP4 RT-PCR to determine the genotypes.

Results: About 6948 under five children were recruited and 6786 stool samples were collected from between August 2006 to December 2013 from the two hospitals. Of the 6786 stool samples collected, 2574(37.9%) were positive for rotavirus. The average positivity rate for the analysis period was 36.1%. Most of the PAGE results exhibited long electrophoretotypes and a few short patterns. The predominant circulating genotypes included G1[P6] 44%, G8[P6] 22% G1[P8] 34%, G9[P8] 37%, G12[P6] 21% and G2P[4] 34%.

Conclusion: The continuation of rotavirus surveillance is crucial for the detection of different circulating genotypes in order to detect the varying genotypes that may come on board after the rotavirus vaccine which has already been introduced in the national immunization schedule and assess for adverse events that may be as a result of the vaccine.

11:40

Fredrick Oyier¹, Shafe Ali Mowlid¹, Steve Biko Ochieng¹, Ahmed Unshur¹, Charles Okello², Barry Fields², Joel M. Montgomery², Maurice Ope², Nina Marano²

¹ Kenya Medical Research Institute/Centers for Disease Control and Prevention, Nairobi, Kenya, ² US Centers for Disease Control and Prevention, Nairobi, Kenya

Identifying Etiologic Agents of Diarrhoea through Active Laboratory-based Surveillance in Dadaab, Kenya, 2011-2013

Background: Diarrhoeal diseases cause substantial morbidity and mortality in refugee camps; however, etiological data of diarrhoea in African refugee camps are scarce. We sought to determine the relative contribution of selected bacterial and viral pathogens and the antibiogram patterns of bacterial isolates obtained from persons with diarrhoea in Dadaab refugee camps.

Methods: From January 1, 2011, to December 31, 2013, we collected stools from consenting patients with diarrhoea (≥ 3 loose stools in 24 hours). Stools were tested for bacterial pathogens using standard microbiologic techniques. Kirby-Bauer disk diffusion antimicrobial susceptibility testing was done, with *Escherichia coli* ATCC 25922 as control. Stools from children aged <5 years were tested for rotavirus using Premier™ Rotaclone ELISA.

Results: Of 2,883 patients with diarrhoea, 2,738 (95.0%) stools were cultured. Median age of patients was 24 months (range=1 month – 95 years). Seven hundred thirty-one (26.7%) grew bacterial pathogens, including *Shigella* (n=431; 59.0%), *Vibrio cholerae* O1 (n=154; 21.0%), *Aeromonas hydrophila* (n=92; 12.6%), *Salmonella* (n=56; 7.7%), and *Campylobacter jejuni* (n=30; 4.1%). Most *Shigella* isolates were resistant to tetracycline

(n=395; 91.4%), cotrimoxazole (n=379; 87.7%), and ampicillin (n=354; 82.1%), and susceptible to ciprofloxacin (n=425; 98.6%), ceftriaxone (n=410; 95.1), and nalidixic acid (n=367; 85.0%). *V. cholerae* O1 isolates were resistant to cotrimoxazole (n=151; 98.1%), streptomycin (n=153; 99.4%), furazolidone (n=104; 67.5%), and ampicillin (n=79; 51.3%), and susceptible to ciprofloxacin (n=154, 100%), ceftriaxone (n=118; 76.6%), and erythromycin (n=106; 68.8%). Rotavirus was detected in 355/1641 (21.6%) stools from children. Most rotavirus cases (n=334; 94.1%) were in children aged <3 years.

Conclusion: Rotavirus disproportionately affected children aged <3 years. *Shigella* and *Vibrio cholerae* were the most common bacterial causes of diarrhoea. Both were resistant to commonly used antibiotics but were mostly susceptible to ciprofloxacin and ceftriaxone. Surveillance to establish diarrhoeal etiology and pathogens antibiogram is critically important to control diarrhoeal diseases in Dadaab refugee camps.

11:50

Diane Waku-Koumou¹, Mathew D. Esona¹, Elisabeth Pukuta², Ionela Gouandjika-Vasilache³, Angelina Boula⁴, Kathleen F. Cavallaro¹, Michael D. Bowen¹

¹ Centers for Disease Control and Prevention (CDC), Atlanta, Georgia, USA, ² Institut National de Recherche Biomedicale, Kinshasa, Democratic Republic of the Congo, ³ Pasteur Institute, Bangui, Central African Republic, ⁴ Centre Mère et Enfant, Yaoundé, Cameroon

Strengthening Laboratory Capacity through the Surveillance of Rotavirus Gastroenteritis in Central Africa: the Surveillance Épidémiologique en Afrique Centrale (SURVAC) Project

Background: The goal of the SURVAC project was to strengthen disease surveillance and response in selected countries in Central Africa: Central African Republic (CAR), Democratic Republic of the Congo (DRC) and Cameroon (CAE). This includes strengthening laboratory capacity and networks, and data management systems.

Methods: Laboratories designated by the Ministry of Health of CAR, DRC and CAE, to conduct rotavirus surveillance were provided with equipment, reagents, and supplies. CDC staff provided on-site classroom and bench training in biosafety, quality control (QC), specimen handling and transport, rotavirus diagnosis using Enzyme Immunoassay (EIA), and G and P genotyping of rotavirus strains using Reverse-Transcription PCR (RT-PCR). QC of genotyping data was performed at the CDC. Laboratories participated in the proficiency test program for rotavirus genotyping. Laboratory data were reported through WHO /AFRO.

Results: RT-PCR for rotavirus genotyping capacity was introduced with the training of seventeen staff members. Genotyping results from 2890 samples collected from 5 sentinel surveillance sites, from January 2011 to December 2012, showed that of 83 (CAR), 800 (DRC), and 588 (CAE) ELISA positive samples, the genotype could be identified for 83 (CAR), 272 (DRC) and 476 (CAE) strains. Genotype G2P[6] was most common in CAR (49%) and DRC (10%) while in CAE, G1P[8] (30%) was most common. Proficiency test scores in 2012 ranged from 56 to 100%.

Conclusion: Laboratory capacity was strengthened through equipping and training of laboratory staff, and establishing a sub-regional laboratory workforce for rotavirus gastroenteritis surveillance. Proficiency test scores were very good for the first year. Each of the countries generated timely rotavirus disease burden and genotyping data, enabling the mapping of circulating genotypes. These results will help monitor the impact of imminent rotavirus vaccination in the three countries. Acquired skills and equipment are available for the surveillance of other priority diseases.

12:00

Margaret Mokomane¹, Andrew P. Steenhoff², B.A. Gashe³, Jeffrey M. Pernica⁴, Loeto Mazhani³, Isaac Quaye⁵, Kwana Lechiile¹, James Mahony⁴, Marek Smieja⁴, David M. Goldfarb⁴

¹ Botswana National Health Laboratory, Botswana, ² Botswana UPenn Partnership, Botswana, ³ University of Botswana, Botswana, ⁴ McMaster University, Canada, ⁵ University of Namibia, Namibia

A Comparison of Anatomically Designed Flocked Rectal Swab oo Traditional Fibre Swab Samples for the Molecular Detection of Bacterial Enteric Pathogens

Background: Diarrheal disease is a leading cause of global child morbidity and mortality. Collecting bulk stool samples can be a challenge, particularly in resource-limited settings. We evaluated the performance of anatomically-designed pediatric flocked rectal swab samples compared to matched traditional fibre wound rectal swab samples for the molecular detection of bacterial enteric pathogens in children hospitalized with acute gastroenteritis in Gaborone, Botswana.

Methods: All samples underwent identical specimen collection and then testing with previously validated multiplex polymerase chain reaction (PCR) assays that detected the following bacterial pathogen targets: *Salmonella* spp., *E. coli* ST/LT toxins, *Shigella* spp., *Campylobacter jejuni/coli*. McNemar's test for paired samples was used to assess flocked swab (FS) vs. traditional swab (TS) detection of identified target pathogens. Matched t-test was used to compare mean cycle threshold (Ct) values for matched positive samples.

Results: A total of 69 matched swab pairs were tested for *Shigella* spp., *Campylobacter jejuni/coli*, and *Salmonella* spp. and 40 matched swab pairs were tested for ETEC ST/LT toxin. For *Campylobacter jejuni/coli*, 40 samples were concordant, 8 were FS only, and 5 were TS only. For *Shigella* spp: 2 were concordant and no discordants. For ETEC ST/LT 2 pairs were concordant and 2 were only detected in the FS. For *Salmonella* spp. 3 pairs were concordant and 2 were only detected with the FS. Overall there were 12 targets only detected with FS and 5 targets only detected with TS (p = 0.14). For matched positive samples (n= 47) the FS samples had a lower Ct value with a mean difference of 1.04 (95% confidence interval 0.42 to 1.85; p = 0.0015).

Conclusion: Flocked rectal swabs resulted in improved yield of bacterial enteric pathogen nucleic acid when compared with traditional fibre rectal swab samples.

ORAL SESSION 2.5 IMPROVEMENT TOWARD LABORATORY ACCREDITATION

DATE: **Tuesday, 2 December**

TIME: **11:00 – 12:45**

LOCATION: **Terrace Meeting Room**

CO-CHAIRS: **Eduardo Samo Gudo**, Ministry of Health,
Mozambique
Ernest Makokha, Centers for Disease Control
and Prevention, Kenya

11:00

Ernest Makokha¹, Daniel Kimani¹, Mercy Njeru¹, Jane Mwangi¹, Omu Anzala²

¹ US Centers for Disease Control and Prevention, Division of Global HIV/AIDS – Kenya, Nairobi, Kenya, ² Kenya AIDS Vaccine Initiative Laboratory, University of Nairobi, Kenya

The Tipping Point in SLMTA Implementation: Kenya's Experience

Background: Kenya enrolled the 1st cohort of laboratories into the Strengthening Laboratory Management Toward Accreditation (SLMTA) program in 2010. To date, 6 cohorts of laboratories supported by 7 partners are implementing laboratory quality improvement through SLMTA. During implementation, many laboratories across all cohorts progressed rapidly, reaching 3-star rating within 9 months and stagnating at this level. Factors for this stagnation in cohorts I-IV are described.

Methods: We reviewed our SLMTA-implementing partners' progress reports as well as baseline, mid-term (after SLMTA workshop #2) and exit audit data for each laboratory. Progress was rated according to the World Health Organization Regional Office for Africa's (WHO-AFRO) Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) 5-star scale. Non-conformances were recorded and reported to the upper management as opportunities for improvement.

Results: A total of 37 laboratories implementing SLMTA were enrolled at different times: cohort I (12 labs), cohort II(8), cohort III (7) and Cohort IV (10). At baseline, all laboratories across different cohorts were rated at Star 0. After 9 months of SLMTA implementation, all laboratories recorded significant improvement in areas of facility and safety; quality management systems documents, customer service and client management and, information management. On average and irrespective of the implementing partner, 17(45%) of laboratories had progressed to 3 stars mid-term. However, on exit audit only 3 (18%) of these had progressed beyond star 3 with 2 of these progressing to achieve ISO 15189 accreditation. Non-conformances associated with stagnation at 3 stars were: lack of equipment maintenance, service interruption, lack of task-based competency assessments, inconsistent process management and, weak management support for momentum towards accreditation.

Conclusion: SLMTA enabled many laboratories attain 3 stars within 9 months with a majority stagnating at this level. We identified several resource management-dependent quality systems essentials (QSE) as major challenges hindering progress of laboratories beyond 3 stars.

11:10

Achamyelch Mulugeta, Habtamu Asrat, Adisu Kebede, Dereje Yenealem, Adino Desale, Abinet Abebe, Ebise Abose, Wondwosson Kassa, Amha Kebede, Gonfa Ayana

Ethiopian Public Health Institute (EPHI), Addis Ababa, Ethiopia

Strengthening Laboratory Management Towards Accreditation (SLMTA) as a Practical Tool for Laboratory Quality Improvement: Ownership and Sustainability in Ethiopia

Background: Strengthening Laboratory Management Towards Accreditation (SLMTA) has been adopted to expedite laboratory quality improvement and 45 laboratories were enrolled. This paper evaluated the sustainability of SLMTA program implementation after exit assessment. Major implementation challenges were also identified in relation to ownership and sustainability. The impact of turnover of SLMTA trained staff on laboratory quality implementation was assessed.

Methods: The 45 laboratories were divided into 2 cohorts, consisting of 24 and 21 laboratories which were enrolled in the first and second phase of SLMTA program, respectively. Exit audits were conducted on 44 of the 45 SLMTA-enrolled laboratories in 2010 and 2011. After Exit assessment, another assessment was conducted involving 37 laboratories in May 2013 and availability of SLMTA trained personnel was assessed. Major challenges associated with SLMTA implementation, sustainability and facility ownership were identified by focused group discussions.

Results: The May 2013 assessment showed that 46% (17/37) of laboratories have improvement from the exit assessment by an average score of 9.7% (1-27%) while decrements were recorded in 51% (19/37) of laboratories by an average score of 12.3% (1-26%) and one laboratory maintained the same status. Thirty five percent of laboratories had no SLMTA trained personnel, 49% had only one out of the two trained and 16% of laboratories had two. There was association between SLMTA trained staff turnover and decrement of laboratory quality improvement ($P < 0.05$). Staff turnover, poor harmonization of SLMTA with other facility activities and lack of efficient mechanism for independent external audit and recognition were found to be the main reasons for stagnancy and deceleration of progresses.

Conclusion: SLMTA has proved to be a dynamic tool for improvements. But maintaining trained staff and integrating the program into facility main plan are critical to ensure continuity of successes. Continuous gap filling SLMTA trainings to counteract staff turnover, establishment of national mechanism for external audits and recognitions, and engaging facility for ownership are crucial to keep the momentum of efforts towards international accreditation.

11:20

Eduardo Samo Gudo¹, Isabel Pinto², Patrino Chongo¹, Paula Mandlaze¹, Beth Skaggs³, Jessina Massamha⁴

1 National Institute of Health, Ministry of Health, Maputo Mozambique, **2** Central Laboratory Department, Ministry of Health, Maputo Mozambique, **3** Division of Global HIV and AIDS, International Laboratory Branch, Centers for Disease Control and Prevention, Atlanta, GA, USA, **4** Division of Global HIV and AIDS, Centers for Disease Control and Prevention, Maputo Mozambique

Keeping Pace Towards Accreditation in the Post-SLMTA Phase: Mozambique Experience

Background: In 2011, Mozambique enrolled 8 laboratories in the Strengthening Laboratory Management Toward Accreditation (SLMTA) program as its first cohort. In 2012, upon graduation of the first cohort, the second cohort was initiated with additional 11 laboratories. Sustaining the hard-earned gains while ensuring continuous improvement towards accreditation has been a challenge for those laboratories that have completed the SLMTA process. MoH-Mozambique developed and implemented a framework to ensure those laboratories keep their pace towards accreditation after SLMTA.

Methods: The post-SLMTA improvement framework engages the laboratories in cycles of continuous improvement and performance evaluation, and includes five elements. They are: i) embedded mentorship: quality officers trained in the previous round become the mentor for their own labs, ii) surveillance audits: each lab is audited once a year using the World Health Organization Regional Office for Africa Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) checklist, iii) workshops: each laboratory is allowed to send 3 additional lab technicians to the next round of SLMTA training, iv) Improvement projects (IP): each laboratory implements a comprehensive IP to address all the nonconformities identified in the exit audit, v) enrollment into SLIPTA process: laboratories must compete for official SLIPTA audits based on set criteria.

Results: We assessed the effectiveness of this framework using SLIPTA audit results held one year after exit audit was performed for our first cohort laboratories. Four laboratories were subsequently selected for official ASLM SLIPTA audits with three laboratories achieving similar score of the exist audit (one with 3 stars and two with 2 stars) and one laboratory dropping from two stars to one stars.

Conclusion: Our results demonstrated that our framework based on cycles of continuous improvement, positive competition, and continuous monitoring may be an effective framework in sustaining the progress in quality improvement towards accreditation.

11:30

Jane Mwangi, Ernest Makokha, Frank Basiye, Muthoni Junghae

Centers for Disease Control and Prevention, Kenya

Multi-stakeholder Engagement for Sustainable SLIPTA Initiatives

Background: Optimal laboratory quality practice is essential for sustained response to disease diagnosis, management and control. Continuous quality improvement using the Stepwise Laboratory quality Improvement Process Towards Accreditation (SLIPTA) framework and the Stepwise Laboratory Management Towards Accreditation (SLMTA) tool to achieve it was launched by Centers for Disease Control and Prevention and WHO in 2010 to strengthen laboratories in cost effective and sustainable ways.

Methods: Kenya embraced a multi-stakeholder SLIPTA approach to promote integration into national systems, country ownership and sustainability. The concept was disseminated to: the Ministry of Health (MOH), the national laboratory regulatory body – Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB), the national accreditation body – Kenya Accreditation Services (KENAS), laboratory professional associations and PEPFAR implementing partners. Consensus was obtained on objectives, roles were defined for each stakeholder and a roll-out strategy was developed. Two years later liaisons were expanded to include World Bank, private public partnerships (PPP) and research laboratories.

Results: The MOH has included accreditation as an annual performance measure for laboratory personnel, developed a pool of SLMTA mentors and established a SLIPTA support office. KENAS trained a team of SLIPTA auditors. KMLTTB has incorporated a minimum set of quality requirements for annual registration of laboratories. Professional bodies have established continuing education sessions in laboratory quality. World Bank - East Africa Public Health Laboratory Network and Becton Dickinson PPP support five laboratories each in SLIPTA implementation. Four research laboratories support 10 laboratories in SLIPTA implementation.

Conclusion: Through a multi- stakeholder approach built on existing national structures, SLIPTA has been successfully woven into the fabric of Kenyan health systems. Expectation of laboratory quality is now established as a standard by professionals, regulators and service delivery organizations. Organizations beyond PEPFAR are investing in laboratory quality systems.

11:40

Rosebella Rotich^{1,2}, Ogaro H², Wekesa D², Kutolo E²¹ Field Epidemiology and Laboratory Training Program-Kenya, ² Ministry of Health, Kenya**Assessment of Patient Customer Satisfaction at Kitale District Hospital Laboratory 2013**

Background: The concept of customer service has often been overlooked in laboratory practice. However, it is important to note that laboratory is a service organization and its clients should receive quality health care. For a laboratory to achieve accreditation, the implementation of quality standards such as ISO 15189 and ISO 17025 emphasize on customer satisfaction in the improvement of laboratory service. The objective of this study was to assess patient customer satisfaction at Kitale Hospital Laboratory, Kenya, with a view of knowing the weakness and getting solutions to improving laboratory services.

Methods: We conducted a survey using a standardized questionnaire in June 2013. Systematic random sampling was used to select the study participants from the laboratory register. Frequencies and factors associated with dissatisfaction were determined.

Results: Of 260 participants enrolled, 207 (79%) had passed through outpatient department while 53 (20.4%) went directly to the laboratory for testing. The laboratory results are released from a minimum of 0-30 minutes to a maximum of 2 hours, 1-2hrs 96 (38.6%), >2hrs+ 53 (21.3%), 30mins-1 hr 58 (23.3), 0-30mins 42 (16.9%). From the study 234 (90.0%) participants were satisfied with the laboratory services while 26 (10%) were dissatisfied. Factors that were associated with dissatisfaction included Turn around Time, courtesy of the staff when handling the patient and whether the laboratory staff made appropriate replies to the queries and doubts made by the patients. The paying for toilet services was significantly associated with dissatisfaction. [Odds ratio (OR)=2.2, 95% confidence interval (CI)=0.9-5.1].

Conclusion: From the study the Health Management Team made efforts to improve Turn Around Time and toilet services made free of charge.

11:50

Susana Oguntoye¹, Sofia Viegas², Nureisha Kadir², Carla Madeira², Khalid Azam², Daisy Nakamura Sato¹¹ American Society for Microbiology, USA, ² National Institute of Health, National TB Reference Laboratory, Maputo**Taking a Laboratory from Zero to Five Stars – The ASM Approach to Mentoring Labs towards Accreditation**

Background: The Nigerian Institute for Medical Research (NIMR) in Lagos, Nigeria, provides clinical TB services as a national reference laboratory. To help the NIMR TB Laboratory provide quality diagnostics, the American Society for Microbiology (ASM), with the National TB and Leprosy Control Program (NTBLCP) and US-Centers for Disease Control and Prevention (CDC), applied a structured mentoring approach to implement lasting behavior change that would enable quality diagnostics in line with international quality laboratory management standards (ISO 15189 for Medical laboratories) while providing technical capacity building. ASM mentored the laboratory over a period of three years (2009-2012), taking them from zero to five stars using the WHO-AFRO Strengthening Laboratory Improvement Process Towards Accreditation (SLIPTA).

Methods: An ASM mentor was engaged to visit the laboratory at least three times a year and spend four to six weeks after a SLIPTA assessment correcting non-conformities, and supporting the implementation of quality management systems (QMS). The mentor introduced new technical methods (Nitrate Reductase Assay methods for solid culture; Liquid Culture using the MGIT 960 machine; Line Probe Assay for drug susceptibility testing) and implemented test menus, standard operating procedures (SOPs) and algorithms in line with international standards.

Results: After mentoring ceased in 2012, external auditors confirmed the self-assessed FIVE-star status of the laboratory using the 2012 WHO-AFRO SLIPTA checklist. This rating was again confirmed one year later (in 2013).

Conclusion: The NIMR TB reference laboratory, one of only a handful in Africa to attain FIVE-star status, was mentored entirely by ASM for almost three years. The ability for the lab to maintain the FIVE-star rating after mentorship ceased in 2012 demonstrates the sustainability and efficacy of the mentoring approach implemented by ASM.

NIMR now serves as a model for laboratories in Nigeria and across Africa.

ORAL SESSION 2.6 HUMAN RESOURCE DEVELOPMENT FOR LABORATORY

DATE: **Tuesday, 2 December**

TIME: **11:00 – 12:45**

LOCATION: **Auditorium 2**

CO-CHAIRS: **Isatta Wurie**, Ministry of Health and Sanitation,
Sierra Leone
Rubina Imtiaz, Centers for Disease Control and
Prevention, United States of America

11:00

Rubina Imtiaz¹, Ernest Makokha², Jane Mwangi², Abdulatif Ali³, Bernard Nkrumah⁴, Sunita Upadhyaya⁵, Filomena Gomez da Silva⁶, Margarida Rodrigues⁷, Anthony O. Emeribe^{8, 9}, Kenneth Iregbu¹⁰, Elizabeth Skaggs, Jessima Masamha, Anita Beukes, Bui T.T. Hien, Kyle Bond, Michael Mwasekaga

1 Division of Global HIV/AIDS, CGH, US Centers for Disease Control & Prevention (CDC), Atlanta, GA, USA, **2** CDC Kenya, Nairobi, Kenya, **3** Division of Laboratory Services, MOH, Nairobi, Kenya, **4** CDC Ghana, Accra, Ghana, **5** CDC India, N. Delhi, India, **6** Anglan National Public Health Institute, Angola, **7** Independent Consultant, **8** MLSCN, Nigeria, **9** African Society for Laboratory Medicine, **10** National Hospital, Abuja, Nigeria, **11** Centers for Disease Control and Prevention-Mozambique, Maputo, Mozambique

Laboratory Workforce Mapping in 10 PEPFAR-Supported Countries: Major Gaps and Role for a Harmonized Intervention

Background: Africa bears 24% of the global disease burden, has only 3% of the world's health workforce and less than 1 lab professional per 10,000 population. To generate data on the laboratory workforce (LWF), which was otherwise unavailable, we conducted a rapid survey of CDC staff based in countries.

Methods: A short, self-response questionnaire was e-mailed to the CDC's country-based "Field Offices" in March 2013, focusing on 5 key areas: key lab cadres (nomenclature and qualifications), training resources, laboratory professional and regulatory bodies, career paths and percentage of indigenous LWF (versus "imported").

Results: 10/26 countries responded within 3 weeks of sending the questionnaire (Angola, Ghana, India, Kenya, Mozambique, Namibia, Nigeria, South Sudan, Tanzania and Vietnam). 80% CDC respondents were nationals and 80% consulted their respective MOH partners in the response. At least 95% of lab professionals across 10 responding countries are indigenous. Stated challenges for the LWF included non-standardized professional cadres (range: 1 – 6; 50% reported 4 key cadres), only 2/10 countries reported having clearly defined career paths with promotional policies, tier level of placement for each cadre not defined in 9/10 countries. Training resources: 9/10 reported dissatisfaction with the quality and adequacy, citing lack of bench training, mentorship etc. Training is not standard for similar cadres across countries and lacked regulatory review in 8/10. The number of professional lab bodies and their membership reach appeared to correlate

with better defined national lab policies, regulations, and cadres (range: 0-10). Only 3/10 countries had published lab regulations addressing the LWF.

Conclusion: This survey confirms gaps in harmonization of lab cadres, curriculum and quality regulation. Few countries have strong professional lab bodies which are successfully engaged in policy and regulation and these countries also have strong LWF structure. Countries should map and strengthen key LWF areas to help achieve major health goals.

11:10

Andre R. Verani¹, Rubina Imtiaz¹, Anthony Emeribe², Fausta Mosh³, Sagie Pillay⁴, Abdulatif Ali⁵, Jane Mwangi⁶, Jean-Bosco Ndhokubwayo⁷, Daniel Garcia⁸, Tsehaynesh Messele⁹

1 Division of Global HIV/AIDS, Center for Global Health, U.S. Centers for Disease Control and Prevention, Atlanta, GA, USA, **2** Medical Laboratory Science Council of Nigeria, Abuja, FCT, Nigeria, **3** National Health Laboratory Quality Assurance and Training Center, Ministry of Health and Social Welfare, Dar es Salaam, Tanzania, **4** National Health Laboratory Service, South Africa, **5** Diagnostic Laboratory services, Ministry of Health, Nairobi, Kenya, **6** U.S. Centers for Disease Control and Prevention-Kenya, Nairobi, Kenya, **7** World Health Organization, Regional Office for Africa, Brazzaville, Republic of Congo, **8** U.S. Centers for Disease Control and Prevention-Mozambique, Maputo, Mozambique, **9** African Society for Laboratory Medicine, Addis Ababa, Ethiopia

Laboratory Workforce Regulation in Africa's Top Five HIV Burden Countries

Background: The International Health Regulations require all World Health Organization (WHO) Member States to achieve minimum capacities for public health surveillance and response, including for laboratories. Similarly, global HIV/AIDS commitments necessitate functional laboratory networks at all levels. Laboratory professionals are essential to meeting these goals, as are domestic laws establishing and delineating the functions of National Laboratory Professional Regulatory Councils. In 2012, the African Society for Laboratory Medicine (ASLM) joined with several Ministers of Health from Africa to issue the Ministerial Call for Action, resolving "to establish or strengthen National Laboratory Professional Regulatory Councils in every country to ensure the quality of the laboratory workforce..." Also in 2012, a global laboratory workforce meeting comprised of ASLM, WHO, and global partners recommended that such Councils perform six key functions: 1) define code of conduct, 2) set minimum training standards, 3) approve curriculum, 4) accredit training institutes, 5) license lab professionals, and 6) standardize lab cadre nomenclature and minimal qualifications.

Methods: An online desk review was conducted of the five highest HIV burden countries in Africa, to determine whether National Laboratory Professional Regulatory Councils were established by law, and if so, whether each Council was charged with performing the six key functions.

Results: Four of five countries (Kenya, Nigeria, South Africa, and Tanzania) have laws or regulations creating a National Laboratory Professional Regulatory Council and delineating its functions, including but not limited to the six aforementioned functions. Mozambique does not have such a Council. The extent to which the six functions are reflected in the national laws and regulations varies considerably.

Conclusion: Establishing or strengthening laws and regulations that govern the laboratory workforce may facilitate the desired improvement in quality of laboratory services and associated health outcomes. Future research should assess implementation of such laws and policies.

11:20

Jeannette Guarner¹, Timothy Amukele², Meheretu Mehari³, Tufa Gemechu⁴, Yimtubezinash Woldeamanuel⁴, Annie Winkler¹, Daniel Asrat⁴, Michael Wilson⁵, Carlos del Rio⁶

¹ Department of Pathology and Laboratory Medicine, Emory University, Atlanta, GA, USA, ² Department of Pathology and Laboratory Medicine, Johns Hopkins University, Baltimore, Maryland, US, ³ Black Lion Hospital, Addis Ababa, Ethiopia ⁴ College of Health Sciences, School of Medicine, Addis Ababa University, Addis Ababa, Ethiopia, ⁵ Department of Pathology and Laboratory Medicine, University of Colorado, Denver, Colorado, US, ⁶ Hubert Department of Global Health, Rollins School of Public Health, Emory University, Atlanta, GA

Building Capacity in Laboratory Medicine in Africa by Increasing Physician Involvement: A Laboratory Medicine Course for Clinicians

Background: In Africa, as in most resource constrained settings, syndromic diagnoses and treatment is commonly used; however, overlapping signs and symptoms that require different treatments can only be distinguished by using laboratory testing. In order to bring awareness of what clinical laboratories do, a short course on laboratory medicine for clinicians was implemented as part of the Medical Education Partnership Initiative between Emory and Addis Ababa University. Here we present the implementation and evaluation of the course.

Methods: Each day was dedicated to a specific topic: hematology, blood bank, microbiology, and chemistry and coagulation. The course included lectures, case-based learning, discussion of the cases, and laboratory tours. Interactive cases were also prepared to be done as homework. The same knowledge quiz regarding Laboratory Medicine was given to participants before and after the course.

Results: Twenty eight participants took the quiz before the course and 21 after completing the course. There were 21 residents, 3 faculty members, and 4 people that work in the laboratory. The clinical specialties represented included anatomic pathology, internal medicine, surgery, dermatology, obstetrics and anesthesia. The average for the initial quiz was 5.28 (range 2-10) with only 2 of 12 questions answered correctly by 60% or more of the trainees. The average on the second quiz was of 8.09 (range 4-11) with 8 questions answered correctly by 60% or more of students ($p=0.0001$). Of the teaching methods used, over 80% of participants rated as most valuable the case-based learning and case discussions.

Conclusion: Knowledge base on Laboratory Medicine increased after participation in the course as did attitudes towards the use of the laboratory. We believe that courses like this will improve clinician awareness of the value of the clinical laboratory and improve use of laboratory services in Africa.

11:30

Sahr Gevao¹, Wendy Arneson², Ralph Timperi³, Aji Sanneh², Isatta Wurie³

¹ College of Medicine and Allied Health Science (COMHAS), University of Sierra Leone, Sierra Leone, ² American Society for Clinical Pathology (ASCP), USA, ³ Association of Public Health Laboratory (APHL), USA

Strengthening Health Laboratory Human Resource through a Structured Pre-service Training Program: Sierra Leone Strategic Plan Direction

Background: There is severe shortage of laboratory personnel in Sierra Leone with less than 20 trained medical laboratory technicians for filling 150 positions within the public health laboratory system. At the moment, there is no training at degree level to provide senior technical middle level or leadership. This impedes reaching the U.N. Millennium Development Goals in Health Systems Strengthening. In order to address this challenge, the Ministry of Health and Sanitation (MOHS) and other stakeholders recommended starting a BSc biomedical laboratory science (BMLS) training program to help address quality and quantity of workforce and to support the country's strategic plan for improved laboratory services.

Methods: A structured preservice training program was developed through a series of workshops with mentorship from implementing partner laboratory educators. Key to the process of this new program was selection of knowledgeable faculty members through leveraging from the medical school and other college science departments. The process included the formulation of student-centered training curriculum, development of semester and course lessons; outcomes-oriented teaching content for knowledge, skills, and attitudes using a standardized template and clinical skill guidelines and checklist. Faculty underwent pedagogical training to assist in implementation.

Results: The new curriculum including clinical internship will be taught over 4 years and culminates in a BSc. degree. Approved course timetables, key lectures and laboratory lesson plans for each of the 67 courses and a comprehensive logbook incorporating quality indicator elements were developed. The newly developed curriculum received faculty senate and university court approval and matriculation of the first class of students is planned for 2014.

Conclusion: With country leadership and commitment, the formulation of a pre-service training program at degree level is critical for improving the middle level laboratory professionals in a resource limited country.

11:40

Bernard Nkrumah¹, Beatrice van der Puije², Veronica Bekoe³, Samuel Duh², Nii Akwei Addo³, Celia Woodfill¹

1 Centers for Disease Control and Prevention, Accra, Ghana, **2** Global Health Systems Solutions, Accra, Ghana, **3** Ghana Health Service, National AIDS/STI Control Program, Accra, Ghana

Improving Service Quality Through Local Capacity Building: Looking Beyond PEPFAR

Background: The recent drive towards strengthening laboratory systems in Africa by WHO-AFRO and PEPFAR is a historic step to support health systems. However, this effort is hampered by the lack of indigenous skilled and qualified laboratory personnel. The National Strategic Plan for Ghana prioritizes the development of local capacity to support the delivery of quality results for improved patient care and treatment. In 2009, Ghana adopted Strengthening Laboratory Management Toward Accreditation (SLMTA). With limited PEPFAR funding, we used only local human resources to drive the program forward.

Methods: Two local partners led the implementation of the SLMTA program. After qualifying as master trainers, two Ghana-based facilitators conducted an in-country Training-of-Trainers workshop to grow more local trainers. A mentorship training program was developed, placing trained fulltime mentors within SLMTA laboratories. The Ghana Standards Authority provided internal audit training. Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) auditors were trained by the African Society for Laboratory Medicine (ASLM) and CLSI with participants from both public and private sectors who had prior knowledge of SLMTA, SLIPTA, Quality Management Systems (QMS) and ISO 15189 standard.

Results: Presently, our local SLMTA team includes 18 trainers, 15 mentors, 11 auditors, and 2 master trainers. This team has single-handedly implemented 3 rounds of SLMTA for a total of 16 laboratories. In November 2013, 4 laboratories received official SLIPTA audits by ASLM. Three laboratories scored four stars and one scored one star from an average baseline score of 35% (no stars). Averagely, \$40,000 was spent per laboratory to cover mentors' salaries, SLMTA training and improvement project support.

Conclusion: Building local capacity through local partners is the most sustainable and rewarding way of improving service quality for resource constrained countries like Ghana. It promotes and ensures country ownership, capacity building and the use of local human resources to expand SLMTA.

11:50

Winnie Koster¹, Aicha Sarr², Iyane Sow², Robert Pool³, Constance Schultz¹, Pascale Ondo¹

1 Amsterdam Institute for Global Health and Development – Academic Medical Centre (AIGHD), Amsterdam, The Netherlands, **2** Direction des Laboratoires, Ministère de la Santé et de l'Action Sociale, Dakar, Senegal, **3** Centre for Social Science and Global Health, University of Amsterdam, Amsterdam, The Netherlands

Barriers to Uptake of Laboratory Services for Antenatal Care. Findings from a Multilevel Qualitative Study in Senegal

Background: Under-utilization of laboratory tests undermines the quality of health care delivery. We explored barriers to uptake of standard screening tests during antenatal care (ANC) delivery in Senegal.

Methods: Test uptake includes: test request and execution. Data collection over a period of 6 months was multi-level, using qualitative methods: ethnography in laboratories and ANC clinics in 2 hospitals and 2 health centers across 4 regions; interviews with 114 women visiting the laboratory for ANC tests; in-depth interviews with 80 pregnant women and family in the community.

Results: At ANC services-level, clear national and/or institution-level recommendations for minimal/desirable ANC test package were not systematically present. One ANC clinic used a standard test-request form. In the other clinics, test requests decisions were based on midwives' judgment, resulting in under-prescription. Midwives' reasons for under-prescription included: assuming women's financial problems; forgetting tests; relying on clinical symptoms. Barrier at the laboratory-level was the relatively high price of standard ANC tests (average 18€ = 4-5x the average daily income). Only one health center had reduced prices for a minimal ANC test package (9€) and a desirable package (12€) – with Hepatitis B-screening. Results were available only the next day in two laboratories, entailing extra client cost. All laboratories were otherwise adequately equipped and supplied for ANC testing – with few stock-outs. Although at the community-level, most considered ANC important, barriers to test uptake were found in 1/3 of women – either because they had received no ANC or no test request, or did not take the request to the laboratory for financial reasons.

Conclusion: High cost of ANC screening tests and midwives who, as gatekeepers, limit the access to testing were the main barriers to uptake. To increase ANC testing uptake, we recommend availability of clear national guidelines on ANC test package and reduction of ANC testing cost.

12:00

Ernest Ruttoh¹, Joan Wasike², Tobias Nyanjong³, Frederick Kobia⁴, Patrick Kamau⁵, Humphrey Aremo⁶

¹ Management Science for Health, ² Bungoma County Referral Hospital, Kenya, ³ Jaramogi Oginga Odinga Teaching and Referral Hospital, Kenya, ⁴ Meru County Referral Hospital, Kenya, ⁵ Karatina Hospital, Nyeri County, Kenya, ⁶ Kenya Medical Training Center, Kenya

Implementing a Laboratory Quality Management System: One Country's Journey

Background: Implementation of laboratory Quality Management Systems (QMS) in South Sudan is part of the Ministry of Health's commitment to improve healthcare. In July 2013, South Sudan entered the program of Strengthening Laboratory Management towards Accreditation (SLMTA) and embraced the Stepwise Laboratory Quality Improvement Process towards Accreditation (SLIPTA) to prepare laboratories for ISO 15189 accreditation. Two laboratories implemented different aspects of a comprehensive QMS to improve service delivery.

Methods: Juba Teaching Hospital Laboratory (JTHL) and Al Sabah Children's Hospital Laboratory (ASHL) began the quality improvement process through a cooperative agreement provided by Centers for Disease Control and Prevention (CDC) and implemented by Association of Public Health Laboratories (APHL). In February 2013, an action plan was developed for quality improvement based on 12 Quality System Essentials (QSE) of Clinical Laboratory and Standards Institute to address gaps in quality management identified during a baseline assessment of each laboratory. Selected laboratory personnel attended an ISO 15189:2012 Implementation and Quality Audit course, a biosafety and biosecurity course, and two SLMTA workshops. Subsequently, improvement projects were initiated for development of standardized operating procedures (SOP), laboratory safety, and competency of personnel. Progress in implementation was measured by quantification using the SLIPTA checklist.

Results: Job descriptions were written for all positions and key personnel were appointed as quality, safety, and store managers in line with the requirements of ISO 15189. The laboratories identified a need to produce 73 SOPs; 35 were written and 17 were approved for use. JTHL improved their score on a standardized safety assessment by 21% and ASHL improved by 39%. Competency assessments were partially done at both facilities due partly to the lack of some testing SOPs. Section heads were trained to conduct competency assessments which were completed for 24 of 59 laboratory staff.

Conclusion: Significant progress was made in the development of QMS for two laboratories and with continued improvement, ISO 15189 accreditation is achievable. South Sudan intends to enroll more laboratories in the SLMTA program despite numerous geopolitical challenges. With the effective implementation of QMS, South Sudan may realize its vision of a quality laboratory system that promotes the health of its population.

WEDNESDAY, 3 DECEMBER 2014

ORAL SESSION **3.1** ANTIMICROBIAL RESISTANCE

DATE: **Wednesday, 3 December**

TIME: **11:00 – 12:45**

LOCATION: **Room 1.4**

CO-CHAIRS: **William Ampofo**, University of Ghana, Ghana
N. Coumba Touré Kane, National Reference Center for HIV and STD Laboratory, Senegal

11:00

Getnet Tesfaw Tadege¹, Alemseged Abdissa Lencho¹, Gebre Kibru Tiga¹, Demeke Mekonnen Mengistie²

¹ Department of Medical Laboratory Science and Pathology, Jimma University, Jimma, Ethiopia, ² Department of Pediatrics, Jimma University, Jimma, Ethiopia

Prevalence, Antimicrobial Susceptibility Pattern and Clinical Predictors of Group A Streptococci among Children with Pharyngitis

Background: Group A streptococci (GAS) are important cause of morbidity and mortality with clinical presentation ranges from pharyngitis to life threatening immunological complications including acute rheumatic fever and glomerulonephritis.

Methods: A cross sectional study was conducted to determine prevalence, antimicrobial susceptibility pattern and clinical predictors of GAS on 355 children (5-15 years) presented with pharyngitis between May-December, 2013 in Jimma Town, Ethiopia. Demographic and clinical data were collected by using questionnaire. Throat swabs were inoculated on to 5% sheep's blood agar plates and incubated for 24-48 hrs at 35-37°C with 5% CO₂. Colonies that were susceptible for 0.04U bacitracin and pyrrolidonylarylamidase positive considered as GAS. Disc diffusion method was used for antimicrobial susceptibility testing. Descriptive statistics and multivariate logistic regression analysis was done by SPSS.

Results: The mean ± SD age of the study participants was 8.5 ± 2.7 years. The prevalence of GAS was 11.3%. All isolates of GAS were 100% susceptible to penicillin, erythromycin, clindamycin, chloramphenicol and ceftriaxone but 52.5% resistant to tetracycline. Absence of cough, tonsillar swelling and temperature >38°C (p<0.05) were independent predictors for GAS pharyngitis. The sensitivity and specificity of a total modified centor score ≥4 was 65% and 87.9%, respectively compared to culture result.

Conclusion: The prevalence of GAS was 11.3%. GAS isolates remains 100% susceptible to penicillins and macrolides. Absence of cough, presence of tonsillar swelling and temperature >38°C

are independent predictors for GAS pharyngitis. The use of modified centor score value ≥4 has a good diagnostic performance to identify GAS among children with pharyngitis. Thus, further study should be done among children with rheumatic heart disease to show proportion of GAS related complications. Furthermore, in resource-limited settings where culture facilities are not available, the modified centor score can be considered for the diagnosis of GAS.

11:10

Mulemba Samutela¹, James C.L. Mwansa², Chileshe Lukwesa-Musyani²

¹ University of Zambia, School of Medicine, Department of Biomedical Sciences, Lusaka, Zambia, ² University Teaching Hospital, Department of Pathology and Microbiology, Lusaka, Zambia

Molecular Characterisation of Methicillin-Resistant Staphylococcus aureus Isolated at the University Teaching Hospital, Lusaka, Zambia

Background: Methicillin-resistant Staphylococcus aureus is one of the major causes of nosocomial infections worldwide. It is endemic in hospitals and prevalent in the community and amongst livestock. Morbidity and mortality amongst MRSA patients is high due to resistance to many antibiotics. In Zambia, there has been an increase in the number of cases of Methicillin-resistant Staphylococcus aureus, from 23% in 2003 to 30.7% in 2010, but its molecular characteristics are unknown and its antibiotic resistance patterns are not clearly defined. Therefore, the objective of this study was to characterise Methicillin-resistant Staphylococcus aureus isolated from the University Teaching Hospital in Lusaka, Zambia using molecular tools.

Methods: This was a laboratory-based cross-sectional study. Ninety-five clinical isolates of Staphylococcus aureus collected between June 2009 and December 2012 at the University Teaching Hospital in Lusaka, Zambia, were analysed by SCCmec and spa typing. Antibiotic susceptibility testing was also performed on the isolates using the Kirby-Bauer Disk Diffusion method.

Results: The results demonstrated that, of the 95 S. aureus isolates, 41% were Methicillin-resistant Staphylococcus aureus strains. Antibiotic resistance to common anti-staphylococcal drugs ranged from 68% to 100%. Multi-drug resistance rates ranged from 17.5% to 35%. The most prevalent SCCmec types were SCCmec type IV (63%) and SCCmec type III (14.6%). Five spa types, which included a novel type, were detected and the most prevalent spa type was t064 (13%).

Conclusion: The prevalence of multidrug resistant Methicillin-resistant Staphylococcus aureus was found to be high and has continued to increase. The high prevalence of SCCmec type IV and spa type t064 suggests that the strains circulating are hospital-acquired and that there may be high genetic exchange amongst the bacterial strains. Regular surveillance and screening is recommended for infection control and treatment guidance.

11:20

Guoqing Zhang¹, Lucy Nganga², Joshua DeVos¹, Evelyn Ngugi², Francesca Odhiambo³, Irene Mukui⁴, Abraham Katana², Lucy Kanyara⁴, Elliot Raizes¹

1 Division of Global HIV/AIDS, Centers for Disease Control and Prevention, Atlanta GA, US, 2 Division of Global HIV/AIDS, Centers for Disease Control and Prevention, Nairobi, Kenya, 3 Institute of Human Virology, University of Maryland, Baltimore, MD, US, 4 Kenya Ministry of Health, Nairobi, Kenya,

Risk Factors Associated with Antiretroviral Therapy Failure and Acquiring Drug Resistance Mutations among HIV-1 Adult Patients on ART—Results from a Nationwide Cross-Sectional HIV Drug Resistance Survey in Kenya

Background: Identifying risk factors associated with virological failure (VF) and HIV drug resistance (HIVDR) development for patients on antiretroviral therapy (ART) is essential to achieve durable efficacy for national ART programs and minimize the need to switch to costly 2nd-line regimens. We performed analyses to investigate factors that may influence ART outcomes and acquiring HIVDR mutations (DRM) from a national cross-sectional survey of acquired HIVDR in Kenya.

Methods: Fifteen sentinel ART clinics in Kenya's national ART program were selected. After obtaining patient's consent, demographic, clinical and ART data were extracted, and whole blood was collected to prepare dried blood spots (DBS) for viral load (VL) testing; those with VF (defined as VL $\geq 1,000$ copies/ml) were genotyped. Complex samples logistic regression analyses were conducted.

Results: The survey consecutively enrolled 906 adult patients on ART for 12-15 and 24-36 months, of whom 101 (11.1%, 95% confidence interval: 8.0%-15.4%) experienced VF, and 83 of the 91 DBS successfully genotyped carried ≥ 1 DRMs. Univariate and multivariate analyses indicated that patients <35 years old and having CD4 count <200 cells/ μ l at ART initiation were more likely to fail ART [adjusted odds ratio (AOR)=1.66 and 1.71, $p=0.048$ and 0.008, respectively] or acquire DRMs (AOR=1.85 and 1.99, $p=0.012$ and 0.01, respectively). Patients on efavirenz-containing regimens ($n=429$) were less likely to fail ART (AOR=0.52, $p=0.065$) or acquire DRMs (AOR=0.47, $p=0.025$) than non efavirenz-containing regimens after adjusting for ART duration, use of tenofovir, clinic size, clinic type and gender.

Conclusion: Logistic regression analyses reveal that efavirenz-containing regimens are better at preventing VF and HIVDR acquisition than non efavirenz-containing regimens. Young adults on ART or ART initiation for patients in advanced stages of HIV-infection may increase the risk of VF and HIVDR acquisition. Thus, early ART initiation not only could increase treatment success but also minimize acquiring HIVDR.

11:30

Rachel Suzanne Beard

Division of Global HIV/AIDS, Center for Global Health, Centers for Disease Control and Prevention

Dried Blood Spot Specimens are a Vital Alternative Specimen Type for HIV Drug Resistance Surveillance and Monitoring in HIV-1-infected Patients Initiating Antiretroviral Therapy in Nigeria

Background: Because of limited or lack of cold chain systems for plasma specimen transport in resource-limited settings, alternative specimen collection types are needed. Dried blood spots (DBS) are a suitable alternative specimen type for HIV drug resistance (HIVDR) surveillance. However, few studies have shown the utility of DBS for HIVDR surveillance in prospective cohorts.

Methods: Between January and July 2008, 283 patients (≥ 18 years and eligible for ART) were enrolled into a prospective cohort in Nigeria. DBS and plasma were prepared from blood specimens collected from patients at baseline and 12-15 months after ART initiation. Genotyping was performed for baseline and follow-up specimens from patients with virological failure, (VF) (defined as VL ≥ 1000 copies/mL), and DR mutations (DRMs) were analyzed with Stanford HIVdb algorithm.

Results: At baseline, we analyzed 239 matched DBS and plasma specimens. Eighteen patients had 41 DRMs in plasma specimens while DBS detected 40 (97.6%, 95% CI: 0.874- 0.9957) DRM. An additional three minor DRMs were detected from DBS only. At follow-up, 11 of the 12 patients with VF harbored 36 DRMs in plasma, 35 of them (97.2%, 95% CI: 0.8583- 0.9951) were also detected by DBS. The major relevant DRMs at baseline were M41L (2), V75M against nucleoside reverse-transcriptase inhibitors (NRTIs), and G190A (2), K101E (2), V108I, and K103N against non-NRTIs (NNRTIs); and at follow-up were M184V (6), K70R (2), K65R (2), and K219E against NRTIs, and Y181C (4), K103N (3), A98G (3), V108I, Y188L, G190A, and L100I against NNRTIs. Of the two DRMs missed by DBS, A98G could lead to intermediate-level resistance to nevirapine.

Conclusion: This study confirms that DBS is a vital alternative specimen type for monitoring HIVDR in prospective cohorts. As expected, however, some minor differences in detecting DRMs by DBS could lead to different clinical decision-making in ART patient care.

11:40

Tchoula Mamiafo Corinne

Department of Microbiology, School of Health Sciences, Catholic University of Central Africa, Yaounde, Cameroon

Evaluation of Antibiogram Techniques in some Laboratories in Cameroon

Background: The increasing bacterial resistance to antimicrobial agents has rendered the antibiogram an indispensable tool for appropriate antibiotic selection. The information obtained should be correct, accurate and reproducible. This study aimed to evaluate the technical methods of antimicrobial susceptibility testing in some medical laboratories in Cameroon.

Methods: We conducted a descriptive, cross-sectional and prospective study. We collected in each laboratory, informations about all their steps of realization of antibiogram by the use of a questionnaire and an observation sheet. These collection tools were based on the standards currently found in various countries and those found in our laboratories.

Results: In total we enrolled 13 laboratories including 03 private and 10 public institutions. In 69.2% of cases the laboratories were headed by biologists. From a general point of view agars prepared were appropriate for non-fastidious bacteria, but that was not the case for those requiring special conditions. Quality control of media and antibiotic discs as well as their conservation did not comply with the standards. We found that 76.9% of laboratories did not have the standard range of Mac Farland. One hundred percent (100%) of the laboratories used dishes with diameters of 90mm in which they introduced between 05 to 14 discs per dish with a mean of 08 discs per Petri dish. The reading of inhibition zones was done by visual estimation in 56.8% of laboratories. More than ¾ of the laboratories lacked reference strains. The interpretation of crude antibiogram results were not made by the majority of the laboratories.

Conclusion: These results suggest that laboratories do not have a standard of antimicrobial susceptibility testing, and when they have one, they do not strictly comply with standard recommendations. Moreover, the importance of the strict and correct realization of antibiogram has not been well integrated by the technicians.

11:50

Annette Donnelly, Ellen HopeKearns

Walking With Angels, Inc. Champaign IL, United States

The Need for Genotypic Antiretroviral Resistance Testing for Children in Developing Countries

Background: The rapid scale-up of antiretroviral therapy (ART) has dramatically reduced HIV-related morbidity and mortality. Scale-up of ART will inevitably lead to the emergence of HIV drug resistance (HIVDR), which is of particular concern in children. HIVDR leads to more rapid virological failure and reduces treatment options. Moreover, the need for second and third-line treatments may be associated with greater toxicity, adverse effects, poor adherence and higher treatment costs. In developed countries, the use genotypic antiretroviral resistance testing (GRT) to screen for HIVDR is routinely used to guide treatment protocols. Walking with Angels, Inc. supports innovative communities, including Nyumbani in Kenya. Nyumbani serves over 4,000 HIV affected children through holistic medical and social programs.

Methods: Nyumbani manages an ISO 15189 accredited diagnostic laboratory providing HIV services and other general diagnostic tests for Nyumbani children and the general community. Nyumbani Diagnostic Laboratory was the first, and currently the only, diagnostic facility offering GRT in Kenya. GRT for 4 non-nucleoside reverse transcriptase inhibitors (NNRTIs) and 7 nucleoside reverse transcriptase inhibitors (NRTIs) were completed for 21 treatment-naïve children, ages 3 months to 7 years using an Applied Biosystems 3130 genetic analyzer.

Results: Sixty-two percent of treatment-naïve children demonstrated intermediate or high-level resistance to two or more NNRTIs. One out of three of the children showed significant resistance to all 4 NNRTIs. Ten percent of treatment-naïve children showed a high level of resistance to 2 or more NRTIs.

Conclusion: Universal access to GRT is needed not only to provide critical information to guide effective treatment options for patients but can provide important insights on the performance of HIV treatment and prevention programs generally.

ORAL SESSION 3.2 ADVANCES IN CD4 TESTING

DATE: **Wednesday, 3 December**

TIME: **11:00 – 12:45**

LOCATION: **Room 1.6**

CO-CHAIRS: **Larry Westerman**, Centers for Disease Control and Prevention, United States of America
Matilu Mwau, Kenya Medical Research Institute, Kenya

11:00

Nathan Ford¹, Andrew Hill²

¹ World Health Organization, Geneva, Switzerland, ² Liverpool University, United Kingdom

Can CD4 Monitoring be Stopped Among Virologically Suppressed Patients: a Systematic Review and Meta-analysis

Background: Recent studies have shown that CD4 changes are rare in patients who are virologically suppressed, suggesting that CD4 monitoring adds little to virological monitoring. Until recently, most studies were carried out in Europe and the USA, and data have not been systematically assessed.

Methods: Two databases and three conference sites were systematically reviewed from September 2008 to April 2014 for studies reporting CD4 changes among virologically suppressed patients. Point estimates and 95% confidence intervals were calculated for the proportion of patients who experienced a decline in CD4 cell count despite being virologically suppressed, and these estimates were pooled using random-effects meta-analysis.

Results: 9 studies reporting outcomes on 16,758 patients were included for review. While most studies (6/9) were carried out in Europe and the USA, the majority of data came from Africa (3 studies, 13,463 patients); these studies and was reported in the last 12 months. The pooled proportion of virologically suppressed patients who experienced a decline in CD4 was 3.6% (95%CI 1.9-5.4%). There was no difference according to age, study design or location, or CD4 or viral load threshold. Where reported, the majority of CD4 declines were transient or explained by the use of concomitant immunosuppressive therapy.

Conclusion: Across a range of settings, CD4 declines are rare among patients who are virologically suppressed. These finds support recent policy moves to reduce or stop CD4 monitoring in settings where routine virological monitoring is available.

11:10 **CANCELLED**

Mihiretu Molla

Department of Health Informatics, College of Medicine and Health Sciences, Institute of Public Health, University of Gondar, Gondar, Ethiopia

Predictors of CD4 Count Changes after Initiation of Antiretroviral Treatment in University Gondar Hospital, Gondar, Ethiopia

Background: The effort for preventing HIV/AIDS ranges from behavioral intervention to the introduction of antiretroviral treatment program. The WHO recommends the optimum time for initiating ART should be guided by a patient's CD4 count and clinical staging. Predictors of CD4 count change after initiation of ART are important for patient monitoring and AIDS prognosis prediction. This study investigated factors associated with CD4 count change among patients on ART in University of Gondar Hospital, northwest Ethiopia.

Methods: The investigators conducted a cross sectional study among HIV/AIDS patients enrolled in an ART program. 2935 adults having at least two CD4 count values were considered. The researcher used the ART database and reviewed patient charts. The primary outcome measure was CD4 count change. Multiple linear regression analysis was used to identify factors associated with CD4 count change.

Results: The median CD4 count increased from 139 cells/ μ l at the initiation of ART to 356 cells/ μ l at the most recent visit. A median CD4 count change of 208 (IQR 224) cells/ μ l was observed after 194.4 (IQR 148.6) weeks on ART. The median rate of CD4 cell increase was 1.06 cells per week on ART. Age ($\beta = 97.59$, $p=0.000$), baseline hemoglobin level ($\beta = 4.029$, $p=0.000$), and baseline CD4 count ($\beta = 0.222$, $p=0.000$) were significant predictors of CD4 count change. The patients' functional status when commencing ART, WHO clinical stage, ART adherence, cotrimoxazole adherence, educational, and marital statuses were also found to be significant predictors of CD4 count change.

Conclusion: Age when starting ART, educational and marital status, WHO clinical staging, baseline hemoglobin level, baseline CD4 count, ART adherence, cotrimoxazole adherence, and functional status, and recent follow up CD count are significant predictors of CD4 count change. Clinicians need to monitor patients who initiated ART at a lower baseline hemoglobin level, and/or CD4 count level.

11:20

Francois-Xavier Mbopi-Keou^{1,2}, Florence Tanghu Mimo³, Hortense Gonsu Kamga¹, Pierrette Omgba Bassega⁴, Martin Samuel Sosso⁵, Joseph Mindimi Nkodo^{1,4}, Alexis Ndjolo^{1,5}, Côme Ebana Mvogo¹, Maurice Aurelien Sosso¹, Laurent Bélec^{6,7}

1 University of Yaoundé I, Yaoundé, Cameroon, 2 Department of Laboratories & Blood Safety, Ministry of Public Health, Yaoundé, Cameroon, 3 Université des Montagnes, Bangangté, Cameroon, 4 Hôpital de District de la Cité Verte, Yaoundé, Cameroon, 5 Centre International de Recherches Chantal BIYA, Yaoundé, Cameroon, 6 Hôpital Européen Georges Pompidou, Paris, France, 7 Université Paris Descartes, Paris, France

Validation of Muse[®] Auto CD4/CD4% Assay to Determine the Absolute Number and Percentages of CD4 T Cells Using Cameroonian Children and Adult Patients' Samples

Background: The study evaluated the simplified, robust, single-platform Muse[®] Auto CD4/CD4% Assay (EDM Millipore, Merck KGaA, Darmstadt, Germany) for CD4 T cell enumeration in absolute count and in percentage, compared against the reference CE IVD-qualified Guava auto CD4/CD4 percent system[®] (EDM Millipore) flow cytometry method.

Methods: A total of 101 K3-EDTA-blood samples from 59 adults and 42 children were collected after informed consent from patients or guardians. All patients received free biological follow-up. Samples were tested in parallel at CIDM Laboratory, University of Yaoundé I.

Results: Absolute CD4 T cell counts of Muse[®] and Guava[®] were highly correlated when using the non-parametric Passing–Bablok regression analysis ($r^2=0.97$) with a slope of 0.98 and an intercept of +6.4. The mean absolute bias between Muse[®] and Guava[®] cells results was -2.5 cells/ β l (95% CI: -18.7-13.7) with limits of agreement from -356 to 185 cells/ml, as assessed by Bland-Altman analysis. CD4 T cell count in percentage of Muse[®] and Guava[®] were also highly correlated when using the Passing–Bablok regression analysis ($r^2=1.07$) with a slope of 1.07. The mean absolute bias between Muse[®] and Guava[®] CD4 T cells results in percentage was +9.75 %CD4 (95% CI: -19.9-39.4). Differences between both techniques were observed at low CD4 T cell count (<150 cells/ml). CD4 T cell counting by Muse[®] allowed identifying the majority of individuals with CD4 T cells <500 cells/ μ l, with a sensitivity of 97% and a specificity of 96%.

Conclusion: Taken together, these findings demonstrate that the Muse[®] Auto CD4/CD4% Assay analyzer is a reliable alternative flow cytometer for CD4 T lymphocyte enumeration to be used in routine for immunological monitoring according to the WHO recommendations in HIV-infected adults as well as children living in resource-constrained settings.

11:30

Matilu Mwau^{1,2}, Silvia Kadima³, Joy Mwende⁴, Maureen Adhiambo⁴, Catherine Akinyi⁴, Marta Prescott⁵, Judi Lusike³, Jackson Hungu³, Lara Vojnov³

1 Kenya Medical Research Institute, Nairobi, Kenya, 2 Jomo Kenyatta University of Agriculture and Technology, Juja, Kenya, 3 Clinton Health Access Initiative, Nairobi, Kenya, 4 Kenya Medical Research Institute, Busia, Kenya, 5 Clinton Health Access Initiative, Boston, United States

Technical Performance Evaluation of the ZymoMyx MyT4 Point of Care Technology for CD4+ T Cell Enumeration

Background: Though absolute CD4+ T cell enumeration is the primary gateway to antiretroviral therapy initiation for HIV-positive patients in all developing countries, patient access to this critical diagnostic test is relatively poor. We technically evaluated the performance of a newly developed point-of-care CD4 technology, the ZymoMyx MyT4, compared with conventional CD4+ T cell testing technologies.

Methods: Over 250 HIV-positive patients were consecutively enrolled and their blood tested on the ZymoMyx MyT4, BD FACS Calibur[™], and BD FACS Count[™].

Results: Compared with the BD FACS Count[™], the ZymoMyx MyT4 had an r^2 of 0.7269 and a mean bias of -23.37 cells/ μ l. Compared with the BD FACS Calibur[™], the ZymoMyx MyT4 had an r^2 of 0.5825 and a mean bias of -46.58 cells/ μ l. Kenya currently uses a CD4+ T cell test threshold of 350 cells/ μ l to determine patient eligibility for antiretroviral therapy. At this threshold, the ZymoMyx MyT4 had a sensitivity of 95.3% (95% CI: 88.4 – 98.7%) and a specificity of 87.9% (95% CI: 82.3 – 92.3%) compared with the BD FACS Count[™] and sensitivity and specificity of 88.2% (95% CI: 79.4 – 94.2%) and 84.2% (95% CI: 78.2 – 89.2%), respectively, compared with the BD FACS Calibur[™]. Finally, the ZymoMyx MyT4 had a coefficient of variation of 12.80% compared with 14.03% for the FACS Calibur[™].

Conclusion: We conclude that the ZymoMyx MyT4 performed well at the current 350 cells/ μ l ART initiation eligibility threshold when used by lower cadres of health care facility staff in rural clinics compared to conventional CD4+ T cell technologies.

11:40

Jason Williams

Supply Chain Management System

Geospatial Analysis: A CD4 Referral Network Optimization and Strategic POC Integration Model

Background: An in-depth evaluation of existing CD4 networks is critical to contain costs and improve diagnostic coverage. Current challenges: many countries continue scaling up access to CD4 services; referral networks remain inefficient; access to CD4 services is increasing with instrument proliferation to the detriment of optimizing cost-effective network performance.

Under the direction of PEPFAR and EHNRI, SCMS partnered with LLamasoft to develop an optimal CD4 referral network design and point-of-care (POC) integration approach for Ethiopia using optimization software with geospatial capabilities.

Methods: ART referral (n=666) and laboratory (n=155) locations were geo-coded. Referral linkages, functionality and age were established for all CD4 instruments. Laboratory and referral test numbers were collected to determine instrument utilization rates. Costs of maintenance, sample transport, unit price per test and commodity stock level requirements were established. Supply Chain GuruTM was used to analyze existing CD4 referral sites to establish an optimal referral network.

Results: In 2012, 732,588 CD4s were performed in Ethiopia, with 381,042 (52%) constituting referrals. Approximately 180 CD4 instruments were believed to be in use, with 138 instrument site linkages established during the exercise, with 37% deemed inoperable through site reports during data collection. Instrument utilization was calculated at 19%, with >50% accounted for by referrals. Following initial optimization of the referral network, 12 instrument locations were suggested as excess. From current coverage, 54 referral sites, accounted for only 6% of the sample referral network, were identified as potential POC candidates. Current referral network distance traveled was reduced by an average of 50 km following optimization, with a potential of 60% savings in annual sample transport costs (\$1.023 million).

Conclusion: Optimizing CD4 referral networks is an ideal opportunity to enhance CD4 coverage, assist in scale-up efforts and establish cost saving measures to advance efficient use of novel POC technologies and the scale-up of viral load capabilities.

11:50 **CANCELLED****Oriel Mahlatsi¹, Naseem Cassim¹, Lindi Marie Coetzee¹, Deborah K. Glencross¹**¹ National Health Laboratory Service (NHLS), National Priority Programme, Johannesburg, Gauteng, South Africa**Using Open Source Spatial Software to Analyze and Optimize Inter-laboratory CD4 Referral Patterns in South Africa**

Background: The National Health Laboratory Service (NHLS) operates 262 laboratories across South Africa, of which 61 (23%) offer CD4 testing. CD4 samples are transported from referral (n=226) to CD4 testing laboratories, using an extensive national courier network. Current inter-laboratory referral patterns were analyzed to assess travel distances, while proposing optimized referral patterns where alternative referral patterns would benefit pre-analytical turn-around-times (TAT).

Methods: CD4 data was extracted from Corporate Data Warehouse (CDW) for the 2013 calendar year. The extract identified both the referring (n=226) and testing CD4 laboratories (n=61). To assess Euclidian distances (ED), spatial coordinates were sourced and included for both the referring and testing laboratories. The inter-laboratory ED was calculated using Microsoft Excel and displayed on a map using Google fusion tables. Using the calculated ED, the best spatially placed CD4 testing laboratory was proposed for each referral laboratory. Data was analyzed using Stata and MS excel.

Results: The current inter-laboratory referral ED ranged from 0 km (testing performed on-site) to a 431km (furthest CD4 laboratory). With the proposed referral patterns, the maximum ED reduced to 303km. 83% (n=188) of the referring laboratories were within 100km of a CD4 testing laboratory, increasing to 88% (n=198) with the new referral patterns. Currently, 9 laboratories (4%) reported an ED over 200km, which reduced to 4 (2%). Current referral patterns reported a median ED of 37km compared to 27.5km when 18 referral routes were redirected to closer testing sites.

Conclusion: The desktop analysis demonstrates that some current referral patterns are not optimal (n=18). Inter-laboratory travel times can be reduced significantly if the proposed referral patterns are utilised, which will direct CD4 samples to the closest testing facility, irrespective of regional or institutional boundaries.

ORAL SESSION 3.3

ADVANCES IN EARLY INFANT DIAGNOSIS

DATE: **Wednesday, 3 December**

TIME: **11:00 – 12:45**

LOCATION: **Auditorium 1**

CO-CHAIRS: **Wendy Stevens**, National Health Laboratory Service, South Africa
Charles Kasipo, Clinton Health Access Initiative, Malawi

11:00

Charles Kiyaga¹, Helen Lee²

1 Ministry of Health, Uganda, 2 University of Cambridge UK

Adherence to Early Infant HIV Diagnosis (EID) Testing Algorithm – Uganda's Experience

Background: Early Infant Diagnosis (EID) in resource-limited settings is a multi stage process that begins at identification of exposed infants at 6weeks to the final exit test at 18 months. Being a multi stage process that happens over time, a testing algorithm is required to ensure that it happens as expected with the right final diagnosis. Below is the testing algorithm:

Exposed infants do a 1st PCR beginning at 6weeks, or any earliest opportunity there after. If the 1st PCR is positive, a repeat PCR is taken off on the day of treatment initiation. If the 1st PCR is negative, a 2nd PCR is done 6 weeks after cessation of breastfeeding. For all who were tested with PCR, whether positive or negative, an exit rapid HIV test is required at 18 months.

This study was done to assess adherence to this testing algorithm.

Methods: This was a cross-sectional study, where retrospective data on EID testing was collected for the year 2012 at 16 health facilities, covering the entire tier of the health system, from Health Center IIIs to Regional hospitals.

Results: A total of 2425 exposed infants were tested from the 16 study sites in 2012, out of which 221 were found to be HIV positive (9.1%). However, of the 221 positive infants only 131 (59.3%) were ever initiated on ART (40% lost). Of the total 2,204 negative infants by 1st PCR, only 868 (39.4%) did a 2nd PCR (60% lost). Of the total 2,425 who did 1st PCR, only 667 (27.5%) did a final exit rapid test at 18 months (72% lost).

Conclusion: According to the data above, adherence to testing algorithm is generally poor. With this poor adherence to testing algorithm, there may be cases of misdiagnosis that go unchecked. Many of the tested infants are being lost through the EID cascade.

11:10

Rogers Kisame¹, Sindisiwe Susan Dlamini²

1 University Research Co., LLC (URC), Mbabane, Swaziland, 2 Swaziland Health Laboratory Services (SHLS) Mbabane, Swaziland

Selection and Evaluation of a Third Rapid HIV Assay as a Tie Breaker to Enhance Early HIV Diagnosis and Linkage to Care in the Kingdom of Swaziland

Background: With an HIV prevalence of 31% among adults, Swaziland emphasizes the scale-up of combination HIV prevention strategies including rapid HIV testing. Rapid HIV tests provide instant results for early diagnosis and linkage to care. The current Swaziland serial HIV testing algorithm includes a highly sensitive test (Determine[®]HIV-1/2, Alere), followed by a highly specific test (Uni-Gold[™] HIV-1/2, Trinity Biotech). If both rapid tests yield discordant results, retesting and referral for ELISA is conducted. The introduction of a third rapid HIV test as a tie breaker would boost early diagnosis and linkage to care in the country.

Methods: Evaluation of 4 WHO-prequalified and USAID approved test kits: DPP[®] HIV 1 / 2 (Chembio Diagnostic Systems, Inc), HIV 1 / 2 STAT-PAK[®] Assay (Chembio Diagnostic Systems, Inc), Clearview[®] COMPLETE HIV1/2 (Alere) and SD Biotline HIV 1/2 3.0 (Standard Diagnostics) will be done in 2 phases; phase 1 evaluated cost per test, utility on different blood samples, ease of use, packaging, storage requirements, availability in the region, post marketing evaluation and ISO certification. Phase 2 will evaluate sensitivity, specificity and positive and negative predictive values against a reference method. Results from phase 1 evaluation will be presented here.

Results: Based on phase 1 evaluation criteria, DPP[®] HIV 1/2 was not easy to use, had unsatisfactory packaging and high cost per test. SD Biotline HIV 1/2 though easy to use with low cost per test had unsatisfactory packaging and poor post marketing evaluations. HIV 1/2 STAT-PAK[®] Assay met all criteria except had unsatisfactory packaging. Clearview[®] COMPLETE HIV 1/2 met all criteria except had high cost per test.

Conclusion: For Swaziland, Clearview[®] COMPLETE HIV 1/2 and HIV 1/2 STAT-PAK[®] Assay are ideal candidates for HIV rapid test tie breaker. Results from phase 2 will determine which should be included in the national testing algorithm.

11:20

Sekesai Mtapuri-Zinyowera¹, Douglas Mangwanya², Raiva Simbi², Neha Goel³, Jose Paolo Magbanua⁴, Peter Gumbo¹, Ellen Munemo¹, Lourdes M. Nadala⁴, Angella Mushavi², Vasco Chikwasha⁵, Helen Lee³

1 National Microbiology Reference Laboratory, Harare, Zimbabwe, 2 Ministry of Health and Child Care, Harare, Zimbabwe, 3 Diagnostics Development Unit, University of Cambridge, United Kingdom, 4 Diagnostics for the Real World Ltd. Sunnyvale, California, USA, 5 Department of Community Medicine, University of Zimbabwe, Harare, Zimbabwe

Task Shifting Training for Point-of-Care Technologies: The SAMBA Experience in Zimbabwe

Background: Zimbabwe with its population of 12.9 people, is one of the HIV high-burden countries with 1.4 million living with HIV and AIDS. Due to shortage of health staff in the country and in order to ensure universal access to ART, there has been task shifting activities on rapid HIV testing and ART initiation. Essential point-of-care technologies for viral load tests and early infant diagnosis (EID) for HIV, such as SAMBA II, are coming into the market and appropriate health cadres who can operate these technologies need to be assessed.

Methods: This was a descriptive cross-sectional study organized by the Ministry of Health and Child Care whereby, 40 medical staff and source locations from all over the country were randomly selected by lot casting to avoid bias. Eight participants from each of the 5 following health practitioners joined the study: nurses, laboratory scientists, laboratory technicians, microscopists and primary care nurses. They were divided into 2 groups with 4 members of each health practitioner being in either of the 2 groups. Group 1 participants were trained by the assay developers on how to run the SAMBA II test, and then were given masked proficiency panels to run independently of the Cambridge trainers. After running the tests, the participants wrote an exam and answered a questionnaire. Group 2 participants that came in 2 days later were trained by two from each Group 1 and went through the same exercise as Group 1. Data was analyzed by the MOHCC using routine statistical tools.

Results: All participants had a 100% pass rate on the proficiency panel testing whilst there was a 95% pass rate on the written exam for both groups. Responses to the questionnaire showed that 75% of the participants in Group 1 and 40% in Group 2 indicated that the SAMBA II instrument was very easy to use whilst 25% from Group 1 and 60% from Group 2 found it easy to run. None indicated that SAMBA II was not easy, nor difficult to run. Concerning the suitability to non-lab staff, the responses from Group 1 and Group 2, respectively, were as follows: a) very suitable- 45% and 40%; b) suitable - 35% and 50%; and c) with reservations- 20% and 2%, respectively.

Conclusion: The SAMBA II instrument system and assay is easy to use and can be operated by lower health practitioners such as primary care nurses and microscopists. The Group 1 health practitioners who were trained for two days were able to train others and gave equally good results.

11:30

Collins Odhiambo¹, Clement Zeh², Kenneth Ouma¹

1 Kenya Medical Research Institute, Kenya, 2 Centers for Disease Control and Prevention, Kenya,

Evaluation of the Simple Amplification-Based Assay (SAMBA) Qualitative Point-of-Care HIV-1 Viral Detection Assay on Whole Blood Among HIV-exposed Infants in Western Kenya

Background: There has been considerable progress in reducing new HIV infections among infants worldwide with a 58% decrease in 2013 compared with 2002, bringing prevention efforts a step closer to eliminating new perinatal infections. Despite this progress, challenges remain in universal testing of infants and initiating treatment for all HIV-infected infants, with only about 28% of all HIV-infected infants initiating treatment. Point-of-care testing (POC) represents a new frontier in HIV care and management. Currently, no device is marketed for early infant diagnosis. A new nucleic acid-based assay (simple amplification-based assay - SAMBA) developed by University of Cambridge for rapid POC detection of HIV-1 at the long terminal repeats was evaluated for its performance on HIV-exposed infants.

Methods: Venous whole blood samples were obtained from infants of age \leq 18 months from patient support centers within Nyanza region in western Kenya between November 2013 and April 2014. Testing occurred at the Kenya Medical Research Institute HIV Research laboratory in Kisumu, Kenya. Roche Cobas Ampliprep/Cobas Taqman (CAP/CTM) was used as the reference platform for HIV DNA PCR with the Abbott m2000 as a tie-breaker test in case of discordance between the two platforms. All tests were performed according to manufacturer's specifications. Data analysis for standard performance parameters for qualitative tests with accompanying 95% confidence intervals (CI) was performed on STATA v.13.

Results: 335 whole blood samples were tested on SAMBA and CAP/CTM platforms. SAMBA had 4 (3 negative and 1 positive) tests with discordant results against CAP/CTM. Following further analysis of the four discordant samples by the Abbott m2000 assay, 3 SAMBA negative samples were confirmed negative while the positive remained discordant. Against the reference standard-of-practice PCR assays, SAMBA had a final sensitivity of 100% (95% CI: 98.2-100), specificity of 99.3% (95% CI: 95.9-99.9), positive predictive value of 99.5% (95% CI: 97.3-99.9), negative predictive value of 100% (95% CI: 97.3-100) and an overall agreement of 99.7% (95% CI: 99.1-100).

Conclusion: SAMBA had high sensitivity and specificity compared with CAP/CTM and Abbott m2000 making it suitable for rapid POC testing and near patient HIV diagnosis among infants in resource limited settings. Using SAMBA would expand access to early infant diagnosis services, prompt initiation of therapy and reduced loss to follow up in these settings.

11:40

Robert Luo¹, Sergio Carmona², Stefanie Templer¹, Britta Seiverth¹, Paul Baum¹, Carole Devaux³, Wendy Stevens²

¹ Roche Molecular Systems, USA, ² University of the Witwatersrand, South Africa, ³ Centre de Recherche Public de la Santé, Luxembourg

Improved Sensitivity of a Dual-probe HIV-1 Qualitative Test for Plasma and Dried Blood Spots

Background: HIV-1 nucleic acid detection is an established tool in the diagnosis of HIV-1 infection and is particularly important for early diagnosis of infants ≤ 18 months in whom serologic tests are unreliable. This study evaluated the performance of a second-generation real-time PCR assay, the COBAS[®] AmpliPrep / COBAS[®] TaqMan[®] HIV-1 Qualitative test, version 2.0 (CAP/CTM HIV-1 Qual Test v2.0), which uses a dual-probe approach to detect total HIV-1 nucleic acid in human plasma and dried blood spot (DBS) samples.

Methods: The limit of detection of the CAP/CTM HIV-1 Qual Test v2.0 was determined by testing the 2nd International HIV-1 RNA WHO Standard (NIBSC Code 97/650), diluted in HIV-1-negative human EDTA plasma or whole blood for DBS. Patient specimens (n=169 HIV-1 positive EDTA Plasma, n=272 HIV-1 positive DBS, n=1298 HIV negative EDTA Plasma and n=1000 HIV negative DBS) were tested to determine the assay's clinical specificity and sensitivity. The HIV-1 positive specimens included Group M (Subtypes A-H, CRF01_AE), O and N. The specimens were also analyzed on the Abbott Real Time HIV-1 Qual assay to determine the correlation between the two assays.

Results: The new assay demonstrated a limit of detection of 20 copies/mL in plasma and 300 copies/mL in DBS. A specificity of 99.8% in plasma and 99.9% in DBS was demonstrated with 1298 HIV-1 negative plasma specimens and 1000 HIV-1 negative DBS specimens, respectively. Correlation to the Abbott Real Time HIV-1 Qual assay in human plasma showed 100% agreement (n=169 positive HIV-1 clinical specimens; n=100 HIV-1 negative individual donors). In DBS, all HIV-1 negative specimen (adult: n=100; infant: n=200) and all (n=100) confirmed HIV-1 positive infant DBS showed 100% agreement on both systems. Out of 172 confirmed HIV-1 positive adult DBS, all could be confirmed positive with the new CAP/CTM assay while the Abbott RealTime HIV-1 Qual assay missed five low-titer DBS.

Conclusion: The new CAP/CTM HIV-1 Qual Test v2.0, shows improved sensitivity compared to current on-market products. Additionally, the DBS sample matrix minimizes the logistical efforts in sample collection and transport and grants patients living in rural areas access to testing.

11:50

Nei-yuan Hsiao¹, Lorna Dunning², Catherine Clary², Max Kroon³, Landon Myer²

¹ Division of Medical Virology University of Cape Town, South Africa, ² School of Public Health University of Cape Town, South Africa, ³ Department of Paediatrics and Child Health University of Cape Town, South Africa

Evaluation of the Alere q Point-of-Care System for Early Infant HIV Diagnosis

Background: Early diagnosis and prompt linkage to treatment of infants exposed to maternal HIV improves their survival, health and development. Current policies of centralised laboratory testing for early infant diagnosis (EID) often have prolonged turn-around times and consequently delay definitive management. An accurate point-of-care (POC) diagnostic system with results available in less than two hours potentially improves the time to initiation of antiretroviral therapy and retention in care with improvements in infant outcomes.

Methods: We investigated the analytic performance of the Alere q HIV1/2 POC assay in the laboratory setting, using the standard-of-care (SOC) Roche CAP/CTM HIV-1 qualitative PCR as gold standard. Parallel testing of both assays was conducted on samples received in the National Health Laboratory Service virology laboratory for infant HIV PCR between Dec 2013 and August 2014.

Results: A total of 1057 samples from 1004 unique infants (median age 47 days) were tested as part of the study. Of the samples tested, 885 (84%) tested negative, 161 (15%) tested positive and 11 (1%) were equivocal on the SOC assay. There was high concordance (99%) between the two assays. The sensitivity and specificity of the POC assay were 97% (95% CI: 92-99%) and 99% (95% CI-99-100%), respectively. However, 6% of the samples (n=65) tested had error results in the first Alere q attempt. Of these, 66% were resolved on the second attempt. Errors were significantly more common among infants <10 days of age (p=0.002). When these errors were considered as incorrect results, the concordance rate dropped to 93%.

Conclusion: Results from the Alere q assay have a high concordance rate with the current gold standard. The sensitivity and specificity were excellent given that postnatal infant prophylaxis may have reduced the sensitivity of EID in this setting. However, the relatively high error rate related to the POC assay is of concern and the source of these technical errors needs to be addressed before the assay can be used widely.

ORAL SESSION 3.4 DIAGNOSTIC INNOVATIONS

DATE: **Wednesday, 3 December**

TIME: **11:00 – 12:45**

LOCATION: **Room 2.4**

CO-CHAIRS: **Emmanuel Fajardo**, Medecins Sans Frontieres, South Africa
Daniela Maria Cirillo, San Raffaele Scientific Institute, Italy

11:00

Shihai Huang¹, Sergio Carmona², Brian Erickson¹, John Salituro¹, Chadwick Dunn¹, Livhuwani Nxumalo², Jeffrey Wuitschick¹, Jens Dhein¹

¹ Abbott Molecular Inc., IL, USA, ² University of the Witwatersrand Medical School, Johannesburg, South Africa

Improved Performance of the New Prototype Automated Abbott RealTime HIV-1 DBS Viral Load Assay*: Potential Use in Expanded Viral Load Testing in Resource Limited Setting (*For Research Use Only)

Background: Quantitative measurement of HIV-1 levels in peripheral blood is an essential parameter to determine disease prognosis and the course of antiretroviral therapy for infected patients. Due to limited viral RNA stability, conventional HIV-1 viral load testing from plasma imposes restrictive requirements for sample collection, handling and shipment, which can hamper further expansion of VL testing in resource limited settings. Dried blood spots (DBS) represent a feasible option that bypasses these logistic and technical limitations. This study evaluates the performance of the new prototype Abbott RealTime HIV-1 DBS VL assay.

Methods: EDTA whole blood was spotted (70 µL) on DBS cards and air dried. A single spot was used per specimen and submerged in a new DBS treatment buffer. After incubation at room temperature for 20 minutes with intermittent mixing, the DBS sample tubes were directly loaded on the m2000sp and processed through the automated Abbott RealTime HIV-1 DBS VL procedure.

Results: The prototype Abbott RealTime HIV-1 DBS VL assay detected HIV-1 RNA at 1,000 copies/mL with >95% probability. Assay was linear from 250 to 1,000,000 copies/mL. Assay precision in SD (log₁₀ copies/mL) was between 0.05 and 0.15 at >2,000 copies/mL, and between 0.11 and 0.28 in 400 to 1,000 copies/mL range. Viral load measurements from DBS showed good correlation with those from plasma. Up to 93 DBS specimens can be processed within 8 hours.

Conclusion: The new Abbott RealTime DBS VL assay demonstrated improved sensitivity (LoD=1,000 copies/mL). The assay exhibited good precision and linearity, and correlated well with the plasma assay. Workflow improvements (i.e. one spot each test, elimination of manual eluate transfer) allow seamless integration of DBS testing in the laboratory, thereby enabling expansion of VL testing. Further assay evaluation in large scale is required, using routine field capillary blood collected as DBS.

11:20

Kathleen Tietje¹, Carmen Forsman¹, Heather White¹, Mitra Singhal¹, David Fredricks², Daisy Ko², Tina Fiedler², Katrien Vermeiren³, Erwin Sablon³, Rudi Rossau³

¹ PATH, Seattle, WA, USA, ² Fred Hutchinson Cancer Research Center, Seattle, WA, USA, ³ Biocartis N.V., Mechelen, Belgium

Demonstration of the Idylla™ System for Rapid, Multiplexed Molecular Diagnosis of Infectious Diseases

Background: A host of infectious diseases disproportionately affect poor and marginalized communities. Accurate and timely diagnosis of infections is often hampered by lack of facilities and trained personnel, and by prolonged time to results using current methods. An automated (sample-in/result-out) diagnostic device with fast turnaround time would be very beneficial at the point of need. The molecular diagnostics system Idylla™ is designed to detect and quantify multiple DNA or RNA-based biomarkers in a wide variety of sample types.

Methods: To demonstrate the utility of Idylla™, real-time PCR assays for 4 common sexually transmitted infections (*Neisseria gonorrhoeae*, NG; *Chlamydia trachomatis*, CT; *Trichomonas vaginalis*, CT; and bacterial vaginosis, BV) were developed and multiplexed onto a Idylla™ research prototype. A laboratory study with human samples from two cohorts compared results of the multiplexed test to single PCR assays and to gold standard clinical diagnostics for the respective pathogens.

Results: A single vaginal swab introduced into the Idylla cartridge was able to concurrently detect the presence of four pathogens with high sensitivity and specificity. Operator time for the test was less than 5 minutes, and total time to results was less than 2.5 hours.

Conclusion: Idylla™ is a fully integrated system that has sample-in result-out functionality and can test a wide range of sample types. This flexible platform can be used to develop and tailor assay panels according to local diagnostic priorities.

11:30

Lesley Scott¹, Natasha Gous¹, Sergio Carmona^{1,2}, Wendy Stevens^{1,2}¹ University of the Witwatersrand, Faculty of Health Science, School of Pathology, Department of Molecular Medicine and Haematology, Johannesburg, South Africa,² National Health Laboratory Service, National Priority Program, Johannesburg, South Africa**Performance of Xpert[®] HIV-1 Quant Compared to Roche CAP/CTM v2 and Abbott RealTime HIV-1 on a Prequalification Plasma Validation Panel**

Background: HIV viral load (VL) testing is critical for monitoring patient's response to antiretroviral treatment. VL is a laboratory based test and quality testing services rely on good specimen transport logistics. In South Africa where >2million VL's are performed annually, relevant services will need expansion through centralised high-throughput or decentralized lower-throughput testing platforms. The latter is being investigated with the GeneXpert(Cepheid) system, currently in 207 smear microscopy laboratories in NHLS for use in diagnosing pulmonary tuberculosis. We investigated the performance of the Xpert[®] HIV-1 Quant assay for VL.

Methods: A 42 member plasma HIV-1 subtype C panel used to validate the CAP/CTMv2 (Roche) and RealTime HIV-1 (Abbott) during implementation of these platforms in NHLS was tested on the GeneXpert HIV-1 Quant assay. GeneXpert HIV-1 Quant is a fully automated real time molecular cartridge based test with two internal quantification standards, requiring 1ml plasma with a VL detection range 40-10million copies/ml and can detect HIV Group M,O,N and recombinants. Frozen plasma was shipped to Cepheid, Sweden, where testing was performed and results analysed in Johannesburg. CAP/CTMv2 and RealTime HIV-1 were reference methods used for statistical analysis.

Results: All HIV negative samples were correctly identified by Xpert[®] HIV-1 Quant, with no carry over and only 1 result was not generated due to instrument error. Xpert[®] HIV-1 Quant's intra-variability (standard deviation [SD]/coefficient of variation [CV]) is log0.16copies/ml/36.8%CV compared to log0.15copies/ml/36%CV for CAP/CTMv2 and log0.15copies/ml/35.9%CV for RealTime HIV-1. Xpert[®] HIV-1 Quant generates lower values than CAP/CTMv2 (log0.18copies/ml [SD log0.1copies/ml]) and higher values than RealTime HIV-1 (log-0.17copies/ml [SD log 0.08copies/ml]). Xpert[®] HIV-1 Quant has overall good agreement (similarity CV)/concordance correlation) of 1.5%CV/0.922 with CAP/CTMv2 and 0.9%CV/0.918 with RealTime HIV-1.

Conclusion: The GeneXpert HIV-1 VL assay shows good performance on a plasma validation panel compared to existing reference methods. A full clinical validation is worth investigating.

11:40

Emmanuel Fajardo¹, Racheal Shamiso Mandishora², Oscar Tapera², Elton Mbofana³, Sekesai Mtapuri-Zinyowera²¹ Médecins Sans Frontières, Southern Africa Medical Unit, Cape Town, South Africa,² National Microbiology Reference Laboratory (NMRL), Harare, Zimbabwe,³ Médecins Sans Frontières, Harare, Zimbabwe**Rapid Plasma Separation Device for Point-of-Care Viral Load Testing: A Proof-of-Concept**

Background: Plasma remains the preferred sample type for quantitative viral load (VL) testing. However, obtaining plasma entails centrifuging whole blood samples, storing it in cold chain and rapidly transporting it to the testing laboratory. This is problematic in remote sites where electrical centrifuges and cold-chain storage are usually unavailable. Simpler devices able to separate plasma from whole blood without mechanical centrifugation would greatly simplify plasma sample preparation for the use with new POC VL technologies. We assessed the feasibility of a rapid plasma separation device (RPSD) to generate liquid plasma.

Methods: Remnant EDTA-whole blood samples used for CD4 testing at the National Microbiology Reference Laboratory in Harare were used for this experiment. We evaluated an Indian manufactured disposable device (Advanced Microdevices Pvt, Ltd, India) which separates plasma based on the principle of membrane filtration. 350 ÅµL of blood sample was applied to the device and the amount of liquid plasma was measured and tested for VL testing using the NucliSENS easyQ HIV-1 V2.0.

Results: Out of ten devices tested, 9 generated valid results with an average volume of 65 ÅµL of plasma (range: 40 – 80 ÅµL). The average filtration time was 21 minutes (range: 10 – 35). The average haematocrit level was 35.7% (range: 10.1 – 48.6). 100% of the plasma samples derived from the device generated valid VL results.

Conclusion: Although the disposable device was simple to use, it required EDTA whole blood, precise pipetting and the filtration time was longer than claimed by the manufacturer. Despite this, liquid plasma was successfully obtained in 90% of the devices. This novel collection device simplifies plasma collection and could be potentially used in combination with new POC VL technologies that require small amounts of plasma. Future studies with a larger sample size are needed to confirm these initial findings.

11:50

Abiodun Ogunniyi¹, David Dairo², Femi Ajumobi³, Patience Ogunjobi⁴, Busola Ojo⁴, Oyetunde Oyebeami⁵, Olufunmi Fawole², Hanna Dada-Adegbola⁴, Oyibo Wellington⁶

¹ Nigeria Field Epidemiology and Laboratory Training Program, Nigeria, ² Epidemiology and Medical Statistics Department, University of Ibadan, Nigeria, ³ National Malaria Elimination Program, Nigeria, ⁴ Medical Microbiology Department, University College Hospital, Nigeria, ⁵ Oyo State Ministry of Health, Nigeria, ⁶ College of Medicine, University of Lagos, Nigeria

Validation and Comparison of Cyscope Microscope, Quantitative Buffy Coat and Rapid Diagnostic Kit for Malaria Diagnosis among Clinic Attendees in SouthWest Nigeria

Background: The unavailability of accurate, rapid, reliable and cost-effective diagnostic instruments compels many laboratories to depend on the labour-intensive and time-consuming light microscopy for diagnosis. Alternative instruments like Cyscope fluorescent microscope (Cyscope), Quantitative Buffy Coat fluorescent microscope (QBC) and CareStart™ Rapid diagnostic kit (CareStart™) with the potential to address these challenges have been developed but their validity and cost effectiveness have not been determined in Nigeria, an endemic and resource limited setting. This study was designed to validate these instruments and assess their comparative cost-effectiveness

Methods: Blood samples collected from 502 patients who were systematically randomly selected from 1800 patients at three hospitals in southwestern Nigeria, were tested for malaria parasites using the diagnostic tools mentioned above, with Light Microscopy as the gold standard. For each instrument, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), turn around time and cost-per-hour of use were assessed. Statistical analysis included McNemar chi-square and Kappa statistics at 0.05 significance level.

Results: Malaria prevalence in the samples was 19.5% (CareStart™), 21.7% (light microscopy), 30.7% (Cyscope) and 32.7% (QBC) respectively. Sensitivity of the instruments compared with light microscopy was 76% (CareStart™), 95% (Cyscope) and 98.1% (QBC) while specificity was 85.5% (QBC), 87.3% (Cyscope) and 96% (CareStart™). PPV for the instruments was 65.2% (QBC), 67.5% (Cyscope), and 84.7% (CareStart™) with NPV of 93.6% (CareStart™), 98.6% (Cyscope) and 99.4% (QBC). Inter instrument agreement index, Kappa value (Ka) were 0.71 (OR=28.5; CI=7.54 - 241.01) (QBC), 0.72 (OR=10.0; CI= 4.01 - 32.13) (Cyscope) and 0.75 (OR=0.6; CI= 0.3 - 1.13) (CareStart™). Average cost per hour of use for the instruments was \$2.04 (Cyscope), \$5.61 (RDT), \$5.89 (QBC) and \$10.77 (light microscopy). The turnaround time per result output was 5minutes (Cyscope), 10minutes (QBC), 20minutes (CareStart™) and 45 minutes (light microscopy).

Conclusion: All the instruments tested were valid for laboratory diagnosis of malaria. Cyscope fluorescent microscopy was found to be comparatively accurate, most rapid and cost-effective for malaria diagnosis in this resource-limited setting and is therefore recommended for routine diagnosis for control and elimination of malaria.

ORAL SESSION 3.5

THE JOURNEY TO LABORATORY ACCREDITATION

DATE: **Wednesday, 3 December**

TIME: **11:00 – 12:45**

LOCATION: **Terrace Meeting Room**

CO-CHAIRS: **Talkmore Maruta**, African Society for Laboratory Medicine, Ethiopia
Thomas Gachuki, National HIV Reference Laboratory, Kenya

11:00

Jean-Bosco Ndiokubwayo¹, Talkmore Maruta², Ngobile Ndllovu², Sikhulile Moyo³, Teferi Mekonen², Ali Ahmed Yahaya¹, Sheick Oumar Coulibaly¹

¹ World Health Organization Regional Office for Africa, Brazzaville, Congo, ² African Society for Laboratory Medicine (ASLM), Addis Ababa, Ethiopia, ³ Botswana-Harvard AIDS Institute Partnerships, Gaborone, Botswana

Progress Made in the Implementation of the Stepwise Laboratory Improvement Process

Background: The World Health Organization Regional Office for Africa (WHO/AFRO) and its partners, including the African Society for Laboratory Medicine (ASLM) and the United States Centers for Disease Control and Prevention (CDC) established the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) framework for improving the quality of public health laboratories in developing countries. Since 2012, the implementing partners have continued to incorporate the lessons learned to strengthen the SLIPTA process.

Methods: It is a descriptive reporting of SLIPTA implementation in the African Region.

Results: Key results to up to December 2013 include: Twenty (42.5%) of the African countries in the WHO AFRO region, have nominated a SLIPTA focal person who are responsible for ensuring its national implementation and 29 ASLM SLIPTA auditors have been certified. As of 2013, 41 laboratories across 11 countries were audited, with the majority of the laboratories (90%) being Ministry of Health public health laboratories. The mean score for these laboratories was 71% (median 72.1; SD 11.1; interquartile range 65.5–77.1) with 25% of the labs receiving below 65.5% (2 Star rating). Results varied based on sections of the SLIPTA checklist with Sections 6 of the checklist (Internal auditing) and Section 10 (Corrective actions) the laboratories achieved mean scores below 50%. Section 2 (Management reviews), Section 6 (Internal Auditing) and Section 11 (Occurrence Management) showed the greatest variability with interquartile ranges of 47.1–76.5, 20.0–60.0 and 41.7–91.7 respectively. Although Section 10 (corrective actions) had less variability in performance, its median score was low (41.7).

Conclusion: The WHO/AFRO SLIPTA has been well received as a tool to assess and facilitate improvements in the quality of laboratory services across. In fact, following the assessments, 3 laboratories to date have been recommended for international accreditation. However, the areas of budgeting, inventory management, corrective actions, root cause analysis and validation of methods still remain a challenge in most laboratories and will continue to be areas of continued focus for the laboratories in the African Region.

11:10

Lawrena Okoro, Anthony Emeribe

Medical Laboratory Science Council of Nigeria, Abuja, Nigeria

Using Scores in Checklist Sections to Identify Gaps in SLIPTA Implementation

Background: Medical Laboratory Science Council of Nigeria carries out baseline and follow-up audits of medical laboratories using the National Laboratory Audit Checklist, an adopted SLIPTA checklist. Amongst these are ART laboratories receiving support from different PEPFAR implementing partners in Nigeria. This paper examines the performance of 13 laboratories in Nigeria audited between 2012 and 2013.

Methods: Baseline assessment was conducted in a cohort of 16 public laboratories offering ART services, after which the laboratory managers, quality officers and safety officers were trained on the 12 Quality System Essentials. Certified mentors supported these laboratories for two weeks. The follow up audit was conducted in 13 out of 16 laboratories.

Results: One laboratory improved from 0 to 3 stars, one from 0 to 2 stars, one from 0 to 1 star and 3 from 1 to 2 stars. One laboratory maintained 2 Stars status while 6 maintained 0 star statuses. 11 laboratories showed improvement in Documents and Records, 8 in Management review, 9 in Organization and Personnel, 9 in Client Management and Customer Service, 4 in Equipment, 4 in Internal Audit, 1 in Purchasing and Inventory, 8 in Process Control and Internal & External Quality Assessment, 2 in Information Management, 10 in Corrective Action, 9 in Occurrence Management, and 10 in Facilities and Safety.

Conclusion: These laboratories showed improvement in the baseline scores in sections where the requirements is within staff influence or control, the exceptions being Purchasing & Inventory, Internal Audit and Information management suggesting that there may be need for targeted capacity building in these areas. It is however difficult to demonstrate stepwise improvement in Internal audit as a laboratory can only score 0, 1 or 10.

11:20

Nqobile Ndlovu

African Society for Laboratory Medicine, Addis Ababa, Ethiopia

High-level Advocacy to Build Support for Laboratory Accreditation

Background: Political and management commitment within Ministries of Health (MOH) is critical for laboratories to achieve international accreditation. ASLM directly advocates to high level MOH representatives and implementing partners, advancement of laboratory accreditation through the stepwise laboratory quality improvement process towards accreditation program (SLIPTA).

Methods: Advocacy meetings were held with countries after completion of SLIPTA audits. These meetings included closed sessions and open events covered by the local media. The meetings included discussion on the accreditation performance of the national laboratories, with a focus on systems-level gaps and challenges. Invitations to attend the meetings were sent to MOH and partners.

Results: During the period May – December 2013, a total of 11 advocacy meetings were conducted in 11 countries, including Cameroon, Côte d'Ivoire, Ethiopia, Ghana, Lesotho, Mozambique, Namibia, Nigeria, Rwanda, Tanzania and Zambia. The highest MOH representations included a Minister of Public Health (Cameroon), a Deputy Minister of Health (Mozambique), and a Permanent Secretary of Health (Zambia). Of the 11 meetings, 10 were attended by national Laboratory Services Directors, four by representatives from WHO-AFRO (Cameroon, Zambia, Lesotho and Mozambique), and three by local laboratory professional associations (Ghana, Zambia and Ethiopia). All the meetings were attended by representatives from in-country US-CDC and partners. Actions taken as a result of these meetings included staff from laboratories that performed well, being sent by MOH to visit accredited laboratory (Zambia). In two countries, the laboratories received MOH support to submit applications for international accreditation (Mozambique, Ghana). There was commitment and prioritisation to support the TB Laboratory in Mozambique to apply for accreditation, preparation of application documentation for accreditation for seven laboratories in Nigeria, and support of three laboratories in Cameroon for international accreditation.

Conclusion: Presentation of SLIPTA results including systems level gaps and challenges that need to be addressed to high level MOH and partner representatives can enhance institutional support to laboratories preparing for accreditation.

11:30

Thomas Gachuki, Mamo Umuro

Kenya Ministry of Health, National Public Health Laboratories (National HIV Reference Laboratory), Nairobi, Kenya

ISO Accreditation of First Public Laboratory in Kenya: Benefits and Experiences

Background: The National HIV Reference laboratory (NHRL) commenced the process of establishing a quality management system (QMS) to ensure analytical and service quality in 2010 and attained ISO accreditation 2013.

Methods: Gap analysis established areas of improvement. The laboratory then undertook improvement projects on all areas of the QMS. Quality indicators were established to monitor all aspects of the analytical process and quality of service. These are equipment downtime, specimen turnaround time, specimen rejections, service interruptions, stock-outs, customer surveys, corrective actions, occurrence management and proficiency test performance. Reports were presented to management for regular reviews. Procedures for all the processes were set in place

Results: Specimen turnaround time reduced by up to 95%. Specimen rejections reduced by 93%. No service interruptions in 2013 down from 15 days in 2010. Stock-outs reduced to zero due to enhanced inventory control. Equipment downtime reduced to zero attributable to engagement of service contracts and regular preventive maintenance. Customer surveys complaints reduced by 90%. Services quality improved due to increased responsiveness, drawing up customer contracts and adoption of email communication. Corrective actions and occurrences reduced by 70%. Proficiency test performance improved to 100%. Benefits: Increased technologist productivity as a result of more efficient systems. Enhanced patient confidence and international recognition which has seen rise in test volumes (50%) and expanded test menu now for example HIV drug resistance testing. Success story has stirred other public laboratories in the country to seek accreditation. The government has now mandated the NHRL serve as a center of excellence and mentor other facilities to attain accreditation

Conclusion: International accreditation is attainable even for public laboratories in limited resource settings. Quality of services and reliability of analytical results in public laboratories can be improved by implementing QMS.

11:40

Cathy Robinson^{1,2}, Wendy Arneson^{1,3}

1 ASCP Institute for Science, Technology, and Policy, Chicago, IL, USA, 2 Louisiana State University Alexandria, Alexandria, LA, USA, 3 University Texas Medical Branch, Galveston, TX, USA

Customer Service and Corrective Action Top List of Sustained Laboratory Improvements In Resource-Limited Countries Striving to Earn International Accreditation

Background: Resource-limited countries requesting PEPFAR funding to improve medical laboratory services were tasked with setting goals to qualify for international accreditation beginning with the second round of funding in 2008. A series of workshops, the Strengthening Laboratory Management Toward Accreditation (SLMTA) Initiative, were delivered in laboratories to assist implementation of laboratory improvements. The SLIPTA checklist was developed as a tool to guide laboratories implementing quality management systems. The sections of the checklist correlate with quality system standards in the Clinical and Laboratory Standards Institute guidelines. This study monitored 31 laboratories in three developing countries between 2010 and 2012. Baseline and post-SLMTA assessments were conducted at each lab; scores from each of the sections were analyzed.

Methods: This study used a quasi-experimental design with a (retrospective) mixed study. Data was derived from on-site laboratory assessments by trained SLIPTA assessors using the WHO-AFRO SLIPTA Checklist. The checklist is comprised of 12 sections, 334 questions, and a maximum score of 250 points. Each of the 12 sections relates to the quality essentials utilized to measure laboratory quality. Both baseline and post-SLMTA workshop scores of each laboratory were analyzed to determine frequencies and descriptive statistics.

Results: A review of checklist scores in these laboratories indicate sections 4 (customer service), and 10 (corrective action) demonstrated the largest increase (56.3%) between baseline and post-workshop scores. Sections 6 (internal audit) and 8 (Information management) demonstrated the smallest increase in compliance at 11.7% and 12.3% each. The other 8 sections showed from 17.1% to 44.3% improvement. As laboratories continue to improve they move closer to ISO 15189/17025 accreditation.

Conclusion: The data suggests SLMTA workshops assist in improving laboratory services. As laboratories continue implementing quality management systems patient results become more accurate, clinicians more confident in results, and patient care improves. Increasing knowledge also ensures a productive workforce.

11:50

Kyle Bond¹, Cuong Duong¹, Hien Bui¹, Nhan Dang¹, Nhanh Bui²

1 U.S. Centers for Disease Control and Prevention (CDC), Hanoi, Vietnam,
2 Hai Duong Preventive Medicine Center, Hai Duong, Vietnam

Rapid Ascent from Zero Quality to ISO Accreditation in 18 Months: A Case Study from Vietnam

Background: Strengthening Laboratory Management Toward Accreditation (SLMTA), a structured quality improvement program, was piloted in 12 sites in Vietnam in 2012. This study describes the remarkable achievement of one laboratory that rose from the lowest performer in the group to international accreditation in 18 months.

Methods: The standard SLMTA implementation process was followed, including site selection, baseline and exit audits, 3 installments of training workshops, improvement projects, and mentoring. Management from all participating laboratories was engaged from the beginning. Laboratory directors and quality managers were trained; mentorship (lasting, on average, one day) was provided to all sites twice monthly during the 12-month implementation period. Improvement projects were conducted; all laboratory staff dedicated themselves to quality improvement.

Results: At baseline audit, Hai Duong Preventive Medicine Center (HDPMC) scored the lowest (29% on the quality checklist) among the 12 laboratories enrolled. During exit audit, HDPMC scored the highest (86%). These results gave laboratory management and staff the confidence to pursue ISO accreditation despite a lack of additional support from external organizations. In January 2014, just 6 months after completing the SLMTA program, HDPMC was awarded ISO 17025 accreditation.

Conclusion: This notable accomplishment will inspire other low-scoring laboratories in the developing world to set high goals and achieve excellence through commitment, resolve, creativity, and team work despite limited resources.

ORAL SESSION 3.6 THE ROLE OF LABORATORY IN OUTBREAK RESPONSE

DATE: **Wednesday, 3 December**

TIME: **11:00 – 12:45**

LOCATION: **Auditorium 2**

CO-CHAIRS: **Amadou Sall**, Institut Pasteur, Senegal
Peter Nsubuga, Global Public Health Solutions,
United States of America

11:00

Tsidiso Gugu Maphanga, Thokozile G. Zulu, Nelesh P. Govender

Centre for Opportunistic, Tropical and Hospital Infections, National Institute for Communicable Diseases, a Division of the NHLS, Johannesburg, South Africa

Genetic Diversity of Sporothrix Species Isolated From Clinical and Environmental Sources from an Outbreak among Gold Miners in Barberton, Mpumalanga

Background: Lymphocutaneous sporotrichosis is acquired following traumatic implantation of organic matter contaminated with the thermally-dimorphic fungus, *Sporothrix schenckii*. This species-complex comprises 6 cryptic species including 4 well-described pathogens: *S. schenckii sensu stricto*, *Sporothrix brasiliensis*, *Sporothrix globosa*, *Sporothrix luriei* as well as *Sporothrix mexicana* (an emerging human pathogen) and *Sporothrix albicans* (a non-pathogenic species). We aimed to genotype clinical and environmental isolates obtained from an outbreak at a South African gold mine.

Methods: We sequenced the calmodulin (CAL) gene of isolates obtained from an outbreak at a gold mine in Barberton in 2011. All isolates were initially confirmed as *S. schenckii* species-complex by phenotypic assays and sequencing of the internal transcribed spacer region of the ribosomal gene. Following PCR amplification using the CL1 and CL2A primers, we sequenced 800-850bp of the CAL gene and performed pairwise sequence alignment using Genbank/ CBS-KNAW databases. The CAL gene of a control strain, *S. schenckii* ATCC 6243, was sequenced in parallel. A phylogenetic tree was constructed using the CAL gene sequence dataset.

Results: While 17 clinical cases of sporotrichosis were identified, only 9 cases were culture-confirmed (yielding 11 isolates). In addition, 5 *S. schenckii* isolates were cultured from underground environmental samples. All clinical isolates were identified as *S. schenckii sensu stricto* by CAL sequencing and all environmental isolates were identified as *S. mexicana*. Phylogenetic analysis revealed two separate trees with 100% bootstrap support with sequences from isolates of each species clustered together. The ATCC strain sequence clustered with those of the clinical isolates.

Conclusion: Sequencing of the CAL gene identified cryptic species within the *S. schenckii* species-complex in an outbreak setting. Although the clinical and environmental isolates belonged to different species, we cannot exclude the possibility that the miners acquired infection from an underground source because environmental samples were not collected systematically.

11:10

Samuel Badung¹, Gbenga Ajani¹, Okeke A. Lilian², Elmina A. Abiayi², Ndadinasiya E. Waziri³, Elisha Pede⁴, Peterside Kumbish², Tony M. Joannis², Adebola T. Olayinka⁵, Philip A. Okewole², Patrick Nguku¹

¹ Nigerian Field Epidemiology and Laboratory Training Program, Asokoro, Abuja, Nigeria, ² National Veterinary Research Institute, Vom, Nigeria, ³ African Field Epidemiology Network, Asokoro, Abuja, Nigeria, ⁴ Plateau State Ministry of Health, Jos, Nigeria, ⁵ Ahmadu Bello University teaching Hospital, Zaria

Cholera Outbreak in Plateau State, Nigeria, 2011

Background: In developing countries, cholera outbreaks cause a high burden of disease and rapidly overwhelm health care services. On 6th June, 2011 an outbreak of diarrhoea and vomiting was reported by the Epidemiology unit of Plateau State Ministry of Health, Nigeria. Nine Local Government Areas (LGAs) were affected. We investigated to describe the outbreak, identify the etiologic agent and institute control measures.

Methods: We conducted a descriptive study. A case was defined as any person with acute watery diarrheal with or without vomiting or died from acute watery diarrheal, between 7th May and 15th August, 2011 in Plateau State. We reviewed medical records to identify cases. Stool specimens from suspected cases, water from reservoir drinking pots and corn food were analyzed. Descriptive analysis was carried out using epi-info and MS Excel.

Results: Of the 651 identified cases, thirteen died (Cases Fatality Rate = 2%), with an overall attack rate of 21.7 per 100,000; 351 (53.9%) were males, median age was 25 (range 2 – 84). Of the 9LGAs affected, Jos North LGA had the highest number of cases; 237 (36.4%). A total of 391 (60.1%) cases were in-patients. Fifteen (51.72%) of the 29 stool specimen tested using dip stick rapid test method were positive for *V. cholerae*. Pure cultures of *V. cholerae* were isolated from 2 stool samples (13.3%), 2 water samples from different reservoir drinking pots (66.7%) and 2 samples of corn food (100%).

Conclusion: The likely cause of the outbreak was faecal contamination of water and corn food. Health education campaigns on good hygiene practices, treatment of drinking water, early detection of cases and oral rehydration therapy were carried out in affected communities. Proper disposal of sewages was recommended. Keywords: Outbreak, Diarrhoea, *V. cholerae*, Nigeria.

11:20

Sow Abdourahmane¹, Abdourahmane Sow^{1,2}, Yamar Ba³, Diawo Diallo³, Oumar Faye¹, Rubin Chen³, Kathryn A Hanley⁵, Scott C Weaver⁴, Mawlouth Diallo³, Amadou A Sall¹

¹ Institut Pasteur Dakar, Arbovirus and viral Hemorrhagic Fevers Unit, Dakar, Senegal, ² Institut de Santé Publique d'Epidémiologie et de Développement, Centre de recherche INSERM U 897 Epidémiologie-Biostatistique, Université Bordeaux II, France, ³ Institut Pasteur Dakar, Medical entomology Unit, Senegal, ⁴ Center for Tropical Diseases and Department of Pathology, University of Texas Medical Branch, Texas, ⁵ Department of Biology, New Mexico State University, New Mexico

Re-emergence of Yellow Fever in Kedougou Southeastern Senegal in 2010-2011

Background: Yellow fever (YF) is an acute infectious viral disease transmitted by *Aedes* mosquitoes. Human cases follow periodic emergence YF virus (YFV) from its sylvatic cycle in non-human primates. In Senegal, the Kedougou region is an emergence zone where amplifications of sylvatic YFV have been reported at 4 to 6 years interval. Since 2007, the development of gold mining has led to increased urbanization, more activity in the forest and massive immigration of non-immune populations. In association with these disruptions, a YF outbreak occurred in Kedougou in 2010. In this paper we report epidemiological, virological and entomological information about this outbreak.

Methods: From January 2010 to December 2011, 9,213 patients including 6,763 (73.4%) acute cases were enrolled at 7 clinics in Kedougou region. Among these cases, 13 were confirmed as YF (0.14%), including 12 IgM antibody positives, and 2 PCR positive and 10 probable cases. Three thousand four hundred and seventy seven (3,477) and 1,793 mosquito pools were respectively collected and tested for YFV by PCR and virus isolation in 2010 and 2011. YFV was detected in 67 pools of mosquitoes (1.9%). Additionally, 378 monkeys were screened for anti-YFV IgM and neutralizing antibody; one monkey sample presented anti-YFV IgM, 40.47% of adult monkeys showed neutralizing antibody responses to YFV, and seroprevalence of YF neutralizing antibodies among juvenile monkeys increased from 4 to 42% between 2010 and 2011. Entomological investigations during the YF outbreak revealed that *Ae. aegypti* was present in all localities; however, *Aedes furcifer* was the predominant species and Breteau indexes were well above the epidemic threshold

Results: Results are included in Methods.

Conclusion: Increased urbanization and migration of susceptible populations may favor adaptation of *Ae. Aegypti* to domestic context and the presence of infected *Aedes furcifer* that would lead to intermediate or urban transmission of YFV.

11:30

Joseph Asamoah Frimpong^{1,2}, Gershon Kobla Anthony^{1,3}, Abdulai Marijanatu^{1,3}, Culbert Nuolabong^{1,3}, Iddrisah Florence^{1,3}, Kofi Mensah Nyarko^{1,3}

1 Ghana Field Epidemiology and Laboratory Training Programme (GFELTP), Ghana Health Service, Accra, Ghana, 2 Noguchi Memorial Institute for Medical Research, Accra, Ghana, 3 Ghana Health Service (GHS), Accra, Ghana.

An Outbreak of Measles in Techiman Municipality, Brong-Ahafo Region – Ghana, 2014

Background: Measles is a vaccine preventable disease that is targeted for elimination in Ghana. On the 13th January, 2014 a report was received from Techiman Municipal Health Directorate indicating four suspected cases of measles. We investigated this outbreak to determine the source of the outbreak, extent of the outbreak, identify risk factors and recommend control and preventive measures.

Methods: We conducted a 1:2 unmatched case-control study. A case was any person between the ages of 6 months to 15 years with a history of fever and maculopapular rash with or without cough, redness of the eyes and running nose within the period, 1st October, 2013 to 13th February, 2014. A control was a person of same age group without the above symptoms within the same period. We reviewed medical records, interviewed community members, collected blood for laboratory diagnosis and assessed the environment of facilities and communities. We performed descriptive analysis and assessed risk factors using fisher-exact test at 95% confidence level.

Results: We identified 33 patients; 8 were laboratory confirmed and 25 were epidemiological linked. Cases ranged from 6 months to 13 years. Attack rate was 5/10000 with no fatalities. 29% and 79% of the cases and controls were vaccinated respectively. Females were mostly affected, 58% (19/33). The index case was one year old female, who presented to the facility on the 4th December, 2013. No measles vaccination ($p < 0.05$) and recent admission to paediatric ward prior to onset of illness ($p < 0.05$) were significantly association with measles infection.

Conclusion: There was a propagated outbreak of measles in Techiman municipality. Paediatric ward was the likely source. Setting up an isolation ward to manage cases and education of parents and guardians played a significant role in containing the outbreak. We recommended national measles immunization mop-up exercise to the Ghana health service.

11:40

Cynthia Semá Baltazar¹, Cátia Taibo², Jahid Sacarlát², Lorna Gujral¹, Eduardo SamoGudo¹

1 National Institute of Health Ministry of Health, Maputo, Mozambique, 2 Faculty of Medicine Eduardo Mondlane University Maputo, Mozambique"

Mozambique Field Epidemiology and Laboratory Training Program (FELTP) – Strengthening Disease Detection through Laboratory Confirmation

Background: The Mozambican Field Epidemiology and Laboratory Training Program (FELTP) is a competency-based, post-graduate training and service program, establish in 2010 with two tracks (Epidemiology and Laboratory Management Track). The program aims to build applied epidemiology and laboratory capacity through joint training and field activities involving both epidemiology and laboratory trainees. Public health laboratories are a critical component of global communicable disease detection, prevention, and control in the country and the Mozambican FELTP is the most advanced-level training program that combines epidemiology with public health laboratory management training.

Methods: Program data on FELTP Mozambique were reviewed and analyzed. We analyzed the role of the laboratory track on field investigation from the three cohorts enrolled in the program. The curriculum includes four modules and one is public health laboratory management. The residents have an approximately 20-month field placement focused on service and public health practice in national references laboratories.

Results: Since the program began 41.6% (15/36) of laboratories from the public health sector have enrolled one or more technicians in the laboratory track of the training program. Of the 22 outbreak investigations conducted by trainees in the FELTP, 21 involved laboratory confirmation of an etiologic agent (measles, cholera, PFA, poisons, malaria, and Dengue). So far, 11 laboratory surveillance systems have been evaluated. The residents develop 8 databases for laboratory information systems and 27 standard operating procedure guidelines as part of their outputs. Two residents participated in a Molecular Epidemiology of Emerging Infectious Diseases week-long course. Four residents have defended their master's degree thesis in a laboratory component (antimicrobial resistance and analysis of drinking water quality data).

Conclusion: The FELTP in Mozambique demonstrates a model for joint training of epidemiologists and laboratory scientists to address the challenges faced for integrating epidemiologic data, and diagnostic testing for better routine surveillance systems and outbreak investigations.

11:50**Ali Elbireer**

Johns Hopkins University-NGO – Uganda MU-JHU Care Ltd Infectious Diseases Institute

Ebola Epidemic: Laboratory Lessons Learned in Uganda – Are You Ready?

Background: There has been several outbreaks of viral hemorrhagic fever (VHF) – mostly Ebola infections - in West Africa recently this years, in Uganda we had 3 VHF outbreaks during the past 2 years. Clinical and research Laboratory in VHF outbreak countries such as in Uganda typically receive samples from large numbers of patients with infections presenting with non-specific symptoms every day. Whilst most laboratories are Bio-safety Level two (BSL-2) and these laboratories are expected to adhere to and follow universal precaution practices for general infectious disease, we were unable to find specific guidance for processing, testing, and shipping of Ebola suspected samples.

Methods: During the VHF outbreaks experience we created tools and procedures to help with communication to laboratory staff, infection control and processing of samples with suspected VHF infection during the outbreaks in Uganda.

Results: During these VHF/Ebola outbreaks, enhanced infection control and communication procedures were implemented within 24 hours of the WHO/Ministry of Health announcement of the outbreaks. During the course of these outbreaks our laboratory received an average of 300 samples daily from different locations in Uganda of which we got few samples from patients suspected of Ebola infection. The laboratory staff followed additional precautions implemented to process all samples received during the outbreak period, and implanted additional processing and shipping protocols for processing EBOLA' suspected samples and were referred and transported to the Ugandan Virus Research Institute (UVRI) for testing.

Conclusion: Use of simple communications tools and preparing the laboratory staff for VHF outbreaks can help laboratory professional confidently deal with these outbreak and provide adequate diagnostic and public health services in Uganda, and can raise laboratory staff awareness of VHF outside of the epidemics area.

THURSDAY, 4 DECEMBER 2014

ORAL SESSION 4.1 IMPACT OF SURVEILLANCE

DATE: **Thursday, 4 December**

TIME: **11:00 – 12:45**

LOCATION: **Room 1.4**

CO-CHAIRS: **Fausta Mosha**, National Public Health Laboratory, Tanzania
Alash'le Abimiku, Institute of Human Virology, University of Maryland School of Medicine

11:00

Miriam Matonya^{1,2}, Vida Mmbaga^{1,2}

¹ Tanzania Ministry of Health and Social Welfare, Tanzania, ² National Health Laboratory Quality Assurance and Training Center, Tanzania

Surveillance of Seasonal Influenza in Tanzania: Five years of Sentinel Surveillance 2009-2013

Background: Seasonal influenza surveillance in Tanzania is conducted with the aim of describing the epidemiology, seasonality and burden of influenza in Tanzania and to identify the type of circulating influenza strains. We summarized reports of influenza laboratory results to create awareness of circulating influenza viruses in the country.

Methods: Nasal and oral pharyngeal swab specimens collected from patients meeting standard World Health Organization case definition for influenza like illnesses (ILI) and Severe Acute Respiratory Illness (SARI). The first two patients per day for ILI and all SARI cases are taken specimen, placed into a single cryovial containing viral transport media and transported to the National Influenza laboratory within 72 hrs by a local Courier Service provider. Total RNA purified by QIAamp[®] viral RNA mini kit and tested by PCR. A set up involved CDC real time reverse transcriptase-polymerase chain reaction (rRT-PCR) protocol which include Oligonucleotide primer and dual labeled hydrolysis Taqman[®] probe for detection and characterization of influenza, optimized using One step probe rRT-PCR Invitrogen SuperScript[™]III Platinum[®] or Ambion Ag Path-ID[™] kits. Applied Biosystems 7500 thermocycler was used. Appropriate negative and positive control specimens were run alongside each reaction. The results were recorded as cross-over threshold (CT) values; ≤ 39.9 was recorded as positive, > 40 as negative. A subset of positive samples was sent to WHO Collaborating Center, CDC Atlanta for further testing and feedback report received.

Results: A total of 10,125 influenza specimens were tested. 887(8.7%) were positive for influenza type A and B. Among the positive samples, 635(71.2%) were positive for influenza A and 252 (28.8%) influenza B. Out of the influenza A positives, 317(49.9%) were pandemic H1N1, 308(48.5%) H3 and 6 (0.6%) seasonal H1 subtypes whereby the later was lastly detected in Sept 2009. None of the samples tested positive for Influenza A/H5 and A/H7. Out of the 491 samples shipped to WHO CC, 147 (30%) was

unable to recover in cell culture. Identified strains of circulating viruses included; A/CALIFORNIA/07/2009-LIKE (H1N1)2009pdm, A/PERTH/16/2009-LIKE H3N2, A/VICTORIA/361/2011-LIKE(H3N2), B/BRISBANE/60/2008-LIKE, B/VICTORIA/02/87, A/TEXAS/50/2012-LIKE (H3N2), B/Yamagata/16/88, B/WISCONSIN/01/2010-LIKE, and B/Massachusetts/02/2012-like.

Conclusion: The national influenza sentinel surveillance is effective in monitoring the circulating influenza viruses which have major impact when there introduction of a new pandemic strain. Continued surveillance is, however needed to define the disease burden in Tanzania.

11:10

Eshetu Lemma¹, Beniam Feleke², Abebaw Kebede¹, Muluwork Getahun¹, Zelalem Yaregal¹, Ribka Fantu², Yetnebersh Fiseha¹, Abyot Meaza¹, Zekarias Dagne¹

¹ Ethiopian Public Health Institute, Addis Ababa, Ethiopia, ² Centers for Disease Control and Prevention, Addis Ababa, Ethiopia

Second Round National Anti Tuberculosis Drug Resistance Surveillance – Ethiopia

Background: The first round national anti tuberculosis drug resistance surveillance was carried out in 2003-2005 and showed multi drug resistant tuberculosis (MDRTB) level of 1.6% and 11.5% in new and treated cases respectively. As a follow up to this, this second round surveillance was started in mid- December 2011 to demonstrate the current level of drug resistant TB in Ethiopia. Objective: To assess the magnitude of anti tuberculosis drug resistance of tubercle bacilli in Ethiopia.

Methods: Cross sectional survey in newly diagnosed TB patients with target sample size of 1614 recruited from 32 diagnostic centers throughout the country has been performed from mid December 2011. Treated TB patient identified during this study period were also included for the intended surveillance purposes. Sputum samples were collected at the study sites and transported to EPHI for culture on Lowenstein–Jensen medium and drug sensitivity testing was done by proportion method on INH, SM, RMP, and EMB. Regular laboratory quality assurance procedures, linkage to supranational laboratory, monthly data quality monitoring, supportive site supervision and site level patient interview assessment were measures taken to ensure the quality of the expected result of the project. Furthermore, reporting of laboratory results to the sites and linkage of MDR TB patients to appropriate treatment centers have been strictly followed.

Results: There result shows that MDRTB of 2.7% (33/1205) in new TB cases and 17.9% (39/217) among retreatment patients. In the total number of 72 detected MDR TB cases 19 were from HIV positive subjects while 17 were from individuals receiving isoniazid preventive therapy IPT.

Conclusion: The result shows increasing proportion of MDRTB in both new and treated patients when compared to the first round study. MDR TB cases observed in HIV positive patients and in patients receiving IPT require further attention with potential implementation of rapid molecular testing in this category of patients to rule out or to rule in MDRTB before initiation of treatment. Acknowledgment: The project was financially and technically supported by CDC and WHO.

11:20

Winfrida Cheriro¹, James Brooks², Ben Liang², Ji Hezhao², Raphael Lihana³, Michael Kiptoo³, Simeon Mining⁴, Wilfred Emonyi⁵, Elijah M. Songok³

1 Moi Teaching and Referral Hospital (MTRH), Eldoret, Kenya, 2 National HIV and Retrovirology Laboratories (NHRL), Ottawa, Canada, 3 Kenya Medical Research Institute (KEMRI), Nairobi, Kenya, 4 Moi University School of Medicine, Eldoret, Kenya, 5 Moi University School of Medicine and USAID-AMPATH Partnership, Eldoret, Kenya

Drug Resistance Testing in HIV Infected on Treatment and Naïve: Implications on Treatment Outcome

Background: Access to antiretroviral therapy (ART) is increasing in resource-limited settings (RLS) and can successfully reduce HIV-related morbidity and mortality. However, due to the high mutation rate of HIV and the lifelong treatment, it is expected that HIV drug resistance will occur in persons not on treatment due to transmitted drug resistance mutation and those on treatment in Kenya as well even if appropriate regimens are provided and good adherence is supported. The main objective was to evaluate inter subtype reverse transcriptase, and protease gene mutations of viral isolates obtained from HIV infected patients attending Moi Teaching and referral Hospital (MTRH) clinics and to determine the proportion and characteristics of patients who develop resistance to drugs in ARV naïve and in ARV experienced patients failing therapy.

Methods: In 2009, we consecutively collected plasma samples from patients attending the study site who were ARV naïve according to chart review and those who were on ART for more than 12 months and were failing therapy according to WHO guidelines. We performed genotypic drug resistance using well established in-house population based Sanger sequencing methods.

Results: We successfully extracted and sequenced 83 samples. Median age was 36.7 years. Majority were women 50/83. ARV naïve patients were 49 and experienced group were 33. 3 out of 49 naïve patients had drug resistance mutations (DRMS). Out of the 33 ARV experienced group who were failing therapy according to WHO guidelines, only 3 did not harbor any DRMS, 27 harbored resistance mutations to nucleoside reverse transcriptase inhibitor (NRTI), thirty harbored resistance mutations to non nucleoside reverse transcriptase inhibitor (NNRTI), and two harbored resistance mutations to NNRTI only.

Conclusion: The information observed in our study can serve as an indicator of ARV program efficiency in patients still on treatment, those who are to start treatment and those who are to be changed therapy due to failure. Drug resistance testing would be necessary before initiating ART in order to achieve a better clinical outcome. Thus, assessment of the proportion of HIV-infected persons who are naïve and those who have developed ARV resistance and characterization of the causes and factors associated with resistance development are critical steps in modifying treatment guidelines and regimens to improve their effectiveness.

11:30

Awa Ba Diallo¹, Pape. A Niang Diallo, Maimouna Diakhaté-Touré¹, Aissatou Gaye-Diallo¹, Ndeye Coumba Touré-Kane¹, Halimatou Diop-Ndiaye¹, Astou Guèye-Gaye¹, Souleymane Mboup¹

1 Laboratoire de Bactériologie-Virologie, Dakar, Sénégal, 2 Comité National de Lutte contre le Sida, Dakar Sénégal

Supervision of Sexually Transmitted Infections in Senegal: a National Survey Conducted in 2006 and 2010 Respectively on 596 and 570 Femal Sex Workers in Different STIs Centers of Senegal

Background: This work aimed to determine the prevalence of STI in the group of Femal Sex Workers in Senegal. We have done a behaviour survey combined to a biological investigation.

Methods: The vaginal specimen collection was done by the FSW herself and blood was collected. The vaginal secretion was used for the diagnosis of vaginal candidiasis, *Trichomonas vaginalis* vaginitis and bacterial vaginosis; blood was analyzed for diagnosis of syphilis and HIV infection.

Results: On a total of 1166 women, 596 were tested in 2006 and 570 in 2010. The age varied from 15 to 62 years. All were Femal Sex Workers registered in a national medical centre or working as clandestine. *T. vaginalis* was found in 11.2% of the cases in 2006 and 14, 9% in 2010 with a non-significant difference whereas the prevalence of vaginal candidiasis was 7.6% in 2006 and 11.1% in 2010. The bacterial vaginosis affected 38.9% in 2006 and this STI has affected more than the half of the FSW in 2010 (52.3%). Bacterial vaginosis was almost always associated with a local inflammatory reaction. The rate of Syphilis went from 12.9% to 4.0% in 2010. The HIV prevalence was 19.9% among the FSW in 2006 and 11.9% in 2010 whereas the pregnant women tested in 2006 gave only a rate of 0.8% (0.6 to 4.3% according to area), thus confirming the HIV concentrated epidemic in Senegal. Among the FSW, HIV co-infection with bacterial vaginosis were noted in 57% and 61.8% respectively in 2006 and 2010.

Conclusion: This work shows the stability of HIV infection in Senegal but also suggests some future orientations in care, support, prevention and research on STIs. It shows that the microbiological part of the national survey and monitoring of STIs must be conducted in a sentinel manner.

11:40

Angela Amayo¹, John Mwihi², Benard Muture³, Jedida Wachira¹, Matilu Mwau⁴, Judy Mwangi¹

1 Management Sciences for Health, Nairobi, Kenya, **2** National Public Health Laboratory Services, Ministry of Health, Nairobi, Kenya, **3** Ministry of Health, Nairobi, Kenya, **4** Jomo Kenyatta University of Agriculture and Technology, Nairobi, Kenya

Use of Clinical Laboratory Data to Determine Disease Prevalence and Diagnostics Services Provided in Kenya

Background: Clinical laboratories provide reports that are used for diagnosis and treatment monitoring of individual patients. When pooled, this clinical laboratory data reflects disease patterns in populations and can be used for disease surveillance and inform policies on measures for disease control. This resource is underutilized in developing countries. The Ministry of Health has established a Laboratory Monitoring and Evaluation (M&E) Unit which regularly collates national clinical laboratory data. The aim of this review is to describe the population disease patterns and laboratory analytical capacity through analysis of the data submitted to the Unit.

Methods: Laboratory data from all 172 districts which were aggregated by the District Medical Laboratory Technologists every quarter and submitted to the Laboratory M&E Unit at the Ministry of Health were reviewed. Laboratory tests requested and results obtained from July 2010 to June 2011 were analysed. Data analysis was done using Stata 10 I/C.

Results: During the review period, laboratory data were received from 155 districts (90.1%). Of the 688 total reports expected, 451 (65.6%) reports were received. The total tests captured were 9.75 million. The most common tests reported were malaria smears at 3.5 million (35.9%), while the lowest were bacterial culture examinations at 30,448 (0.001%). The positivity rates for key diseases/conditions were: hyperglycaemia, 24.9% (95%CI:14.5-65.6%); malaria, 23.2% (5.0-38.9%); anaemia, 18.8% (5.2-39.2%); Amoebiasis, 15.8% (3.4-18.9%); tuberculosis new cases, 12.7% (9-18%); HIV, 7.6% (2-14.5%); and positive syphilis serology 2.1% (0.9-5.6%).

Conclusion: The prevalence of HIV and malaria correlates with other national reports for these conditions during review period. The low rate of bacterial culture examinations indicates weak systems for microbiological examinations nationally. The findings show that clinical laboratory data can be a cost-effective passive disease surveillance tool. Analysis of scope of laboratory tests can also inform on gaps in laboratory systems which can be addressed systematically.

11:50

Trevor Shoemaker¹, Stephen Balinandi², Alex Tumusiime², Joseph F. Wamala³, Luke Nayakarahuka⁴, Barbara Knust², Ilana Schafer², Julius Lutwama⁴, Ute Ströher², Pierre Rollin², Stuart Nichol²

1 Viral Special Pathogens Branch, Centers for Disease Control, Uganda, **2** Centers for Disease Control, USA, **3** Ministry of Health, Uganda, **4** Uganda Virus Research Institute, Uganda

Uganda Viral Hemorrhagic Fever Surveillance, Laboratory, and Outbreak Response Program, 2010-2014: A Model for Early Detection and Effective Outbreak Control

Background: Uganda is endemic for viral hemorrhagic fevers (VHFs) and other zoonotic diseases. Beginning in July 2010 the Centers for Disease Control (CDC), the Uganda Virus Research Institute (UVRI), and the Ministry of Health (MOH) established a first of its kind national VHF surveillance program. In addition, a permanent national VHF diagnostics laboratory was established at UVRI in Entebbe.

Methods: The program established a standardized, integrated, viral hemorrhagic fever surveillance system in Uganda that was able to detect the first instances of suspect VHFs, rapidly report them to the national level, submit samples and perform rule-out testing within 24 hours of sample receipt. Training on VHF case definitions, data collection, clinical case identification, safe sample collection, and shipping has been carried out at over 20 sentinel sites.

Results: Since 2010, 23 sentinel surveillance sites were established and over 250 clinical and laboratory staff were trained on case identification, reporting, and sample collection for suspect VHF cases. The program has tested over 2800 clinical samples from surveillance activities, serosurveys, and VHF outbreaks. Between 2011 and 2012 the laboratory confirmed 4 separate Ebola hemorrhagic fever (EHF) outbreaks and one Marburg hemorrhagic fever (MHF) outbreak. In 2013, the laboratory confirmed 3 independent outbreaks of CCHF. These were the first human CCHF cases confirmed in Uganda in 36 years. The VHF surveillance program continues to receive suspect VHF case reports from Uganda and the East African region.

Conclusion: The Uganda VHF program is one of the most successful infectious disease programs, confirming 8 independent VHF outbreaks since 2011. Rapid identification and lab confirmation has led to effective response and containment of VHF outbreaks in Uganda and DRC. The program serves as a model for countries across Africa. Lessons from this program should be used to build programs capable of preventing large VHF outbreaks from occurring in the future.

ORAL SESSION 4.2 INFLUENZA AND RESPIRATORY INFECTIONS

DATE: **Thursday, 4 December**

TIME: **11:00 – 12:45**

LOCATION: **Room 1.6**

CO-CHAIRS: **Michael Owusu**, Kumasi Centre for Collaborative Research in Tropical Medicine, Ghana
Mpho Seleka, National Institute for Communicable Diseases, South Africa

11:00

Catherine Kapperich¹, Natalia Rodriguez^{1,2}, Andy Fan¹, Jacqueline Linnes¹, Christopher Chen¹

¹ Boston University, Boston, MA, USA, ² Wyss Institute for Biologically Inspired Engineering, Boston, MA, USA

A Fully Integrated Paper-Based Assay for the Extraction, Isothermal Amplification, and Detection of Pandemic (H1N1) Influenza A RNA

Background: The 2009 Influenza A H1N1 Pandemic (pH1N1) caused 284,500 deaths worldwide, 51% of which occurred in developing countries in southeast Asia and Africa. This disproportionate number of deaths suggests that efforts to prevent future Influenza pandemics need to more effectively target these developing regions. Remaining the predominant strain even this 2014 flu season, an inexpensive, portable, rapid and sensitive diagnostic for pH1N1 is needed to facilitate clinical care and infection control. Laboratory sample preparation followed by RT-PCR is currently the standard molecular diagnostic method for pH1N1, but it requires highly skilled technicians and expensive equipment that make this method unsuitable for use in limited-resource settings. Here, we present an instrument-free, paper-based assay for the extraction, isothermal amplification and detection of pH1N1 RNA from clinical nasopharyngeal swab and aspirate samples that will enable rapid diagnosis at the point-of-care.

Methods: We developed paper extraction supports using compressed cellulose chromatography paper to extract precipitated RNA from lysed nasopharyngeal samples. A reverse-transcription loop-mediated isothermal amplification (RT-LAMP) assay was designed to specifically target and amplify pH1N1 RNA at a constant temperature of 65°C within the paper matrix. Loop primers were tagged with FITC and biotin to enable immediate downstream detection of the amplified products on lateral flow strips containing streptavidin-coated beads, an anti-FITC test line, and a biotin control line to indicate whether the assay functioned correctly.

Results: We achieved extraction and precipitation of RNA in paper matrices with yields of 60-90%, which were sufficient for downstream amplification and detection. Our RT-LAMP assay specifically amplified pH1N1 RNA in clinical samples with titers as

low as 10⁵ cp/mL within 20min at 65°C. Amplified products were eluted from the paper matrices and immediately detected on the anti-FITC lateral flow detection paper strips.

Conclusion: We demonstrate successful pH1N1 RNA extraction, isothermal amplification, and detection in a fully integrated, rapid and inexpensive paper-based assay for point-of-care applications. The simplicity, rapidity, sensitivity, and cost-effectiveness of this method make it well suited for use in primary care or low-resource settings.

11:10

Mpho Seleka¹, Marietjie Venter^{1,2,3}, Florette K Treurnicht¹, Amelia Buys¹, Johanna McAnerney¹, Terry Besselaar^{1,4}, Orienka Hellferscee¹, Cheryl Cohen¹, Shabir A Madhi^{1,5}

¹ Centre for Respiratory and Meningitis, National Institute for Communicable Diseases, National Health Laboratory Services, Johannesburg, South Africa, ² Zoonosis Research Unit, Department of Medical Virology, University of Pretoria, ³ Global Disease Detection, US-CDC, South Africa yds8@cdc.gov, ⁴ Global Influenza Surveillance Network, WHO, Geneva, Switzerland, ⁵ Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa

Molecular Epidemiology of Influenza B Viruses and Antigenic Profiles in South Africa: 2005-2013

Background: Data on molecular epidemiology of influenza B in South Africa are limited and was previously described for the period of 1998-2001. We investigated the circulation, molecular epidemiology and antigenic profiles of influenza B from 2005 to 2013, in South Africa.

Methods: Influenza virus positive samples identified through the Viral Watch (VW) surveillance program for influenza-like illness during 2005-2013 were primarily used for describing seasonal circulation and antigenic profiles of influenza B. These viral samples, together with those from individuals hospitalized for severe acute respiratory illness (SARI; 2009-2013) were used for molecular characterization of influenza B. The hemagglutination inhibition (HAI) assay was used for antigenic strain typing and molecular characterization was by phylogenetic analysis of the hemagglutinin (HA) HA1 region.

Results: During 2005 to 2013 Influenza B virus never circulated as the dominant influenza strain when compared to influenza A, however both strains occurred at almost the same frequency of about 50% in 2010 and 2012. Over the study period, all influenza B cases identified in 2007, 2010 and 2012 had the highest frequencies (34-39%) and B/Victoria lineage viruses dominated at frequencies of 57% (159/280), 95% (101/106) and 79% (153/194), respectively. A total of 162 influenza B viruses were characterized by phylogenetic analysis during the study period of which 109 (67%) belong to the B/Victoria lineage and 53 (33%) to the B/Yamagata lineage. Influenza B vaccine strains were mismatched to the dominant circulating lineage in 2005, 2008, 2009 and 2011. Influenza B/Yamagata lineage viruses from 2011 are mainly in clade 3, whereas all 2013 B/Yamagata viruses are in clade 2 which is characterized by B/Massachusetts/2/2012 which is the 2014 vaccine strain.

Conclusion: Although influenza B viruses never circulated as the dominant influenza strain various degrees of dominance for either of the two lineages could be seen over the study period.

11:20

Michael Owusu¹, Augustina Annan¹, Yaw Adu-Sarkodie²

¹ Kumasi Centre for Collaborative Research in Tropical Medicine, Kumasi, Ghana, ² Department of Clinical Microbiology, Kwame Nkrumah University of Science and Technology

Human Coronaviruses Associated with Upper Respiratory Tract Infections in Rural Areas of Ghana

Background: Acute respiratory tract infections (ARI) are the leading cause of morbidity and mortality in developing countries, especially in Africa. This study sought to determine whether Human coronaviruses (HCoV) are associated with upper respiratory tract infections among older children and adults in Ghana.

Methods: A case control study among older children and adults in three rural areas of Ghana using asymptomatic subjects as controls was conducted from September 2010 to October 2013. Nasal/Nasopharyngeal swabs were tested for Middle East Respiratory Syndrome Coronavirus (MERS-CoV), HCoV-229E, HCoV-OC43, HCoV-NL63 and HCoV-HKU1 using Reverse Transcriptase Real-Time Polymerase Chain Reaction.

Results: Out of 1,213 subjects recruited, 150 (12.4%) were positive for one or more viruses. Of these, single virus detections occurred in 146 subjects (12.0%) and multiple detections occurred in 4 (0.3%). Compared with control subjects, infections with HCoV-229E (OR = 5.15, 95%CI = 2.24 – 11.78), HCoV-OC43 (OR = 6.16, 95%CI = 1.77 – 21.65) and combine HCoVs (OR = 2.36, 95%CI = 1.5 – 3.72) were associated with upper respiratory tract infections. HCoVs were found to be seasonally dependent with significant detections in the harmattan season (mainly HCoV-229E) and wet season (mainly HCoV-NL63). A comparison of the obtained sequences resulted in no differences to sequences already published in GenBank.

Conclusion: HCoVs could play significant role in causing upper respiratory tract infections among adults and older children in rural areas of Ghana.

11:30

Ebenezer Foster-Nyarko¹, Brenda Anna Kwambana¹, Jessica Mclellan¹, Ifedayo Adetifa², Odutola Aderonke¹, Fatima Ceesay¹, Abdoulie Bojang¹, James Jafari¹, Olatunde Ogundare¹, Martin M. O. Ota³, Martin Antonio¹

¹ Vaccinology Theme, Medical Research Council Unit, The Gambia, Banjul, The Gambia, ² Disease Control and Elimination Theme, Medical Research Council Unit, The Gambia, Banjul, The Gambia, ³ Regional Office for Africa, World Health Organization, Brazzaville, Republic of Congo

Co-colonization of Group B Streptococci and Other Respiratory Pathogens during Early Infancy in West Africa

Background: Nasopharyngeal (NP) carriage of Group B Streptococci and other β -haemolytic Streptococci (BHS) during early infancy in sub-Saharan Africa is poorly understood. Given the increasing coverage of vaccines targeting pathogens co-inhabiting the pharyngeal mucosae, surveillance of BHS carriage and disease is important.

Methods: 1200 nasopharyngeal swabs collected from infants between 2 – 3 months old were cultured using standard microbiological methods to estimate the prevalence of Streptococci Groups A (GAS), B (GBS), C (GCS) and G (GGS). Resistance to penicillin, chloramphenicol, tetracycline and macrolide-lincosamide-streptogramin (MLSB) was ascertained for BHS isolates by the E-test agar diffusion and D-test methods respectively. We also assessed NP carriage of Streptococcus pneumoniae, Haemophilus influenzae, Staphylococcus aureus and Moraxella catarrhalis.

Results: The overall prevalence of BHS was 20.0%, dominated by GBS (69.2%); predominantly of serotypes V (38.6%) and II (34.9%). *S. pneumoniae* was most prevalent in carriage (62.3%), then *S. aureus* (49.8%), *M. catarrhalis* (32.1%) and *H. influenzae* (31.5%). GBS colonization positively associated with *S. aureus* (OR 1.89 [95%CI: 1.33-2.69], $P < 0.001$) and negatively associated with *S. pneumoniae* (OR 0.47 [95%CI: 0.33-0.67], $p < 0.001$) and *M. catarrhalis* (OR 0.61 [95%CI: 0.40-0.92], $p = 0.017$). GGS colonization positively associated with *H. influenzae* (OR 2.06 [95%CI: 1.08-3.92], $p = 0.027$). >99% BHS isolates were susceptible to penicillin and chloramphenicol. Tetracycline resistance ranged from 25% in GAS to 91% in GBS. Macrolide-lincosamide-streptogramin (MLSB) resistance was 1.3%.

Conclusion: There is significant NP carriage of BHS, and particularly, GBS in Gambian infants beyond the neonatal period and this data serves as baseline data for monitoring changes in carriage prevalence post PCV and Hib introduction.

11:40

Mbayame-Ndiaye Niang¹, Chris Victor², Aldiouma Diallo³

1 Institut Pasteur de Dakar, Dakar, Senega, 2 PATH, Seattle, Washington, United States, 3 Institut de Recherche pour le Développement, Dakar, Senegal

Role of the Laboratory in a Cluster-randomized Trial: Effectiveness of Seasonal Influenza Vaccination of Children in Africa (Senegal)

Background: In tropical developing populations, the pattern of influenza circulation and the role of children in transmission may differ markedly from those in temperate settings. The effects of wide-spread influenza vaccination of children have also not been extensively studied. Therefore, we initiated a multi-year project in rural Senegal to evaluate these effects after vaccination of children with seasonal trivalent inactivated influenza vaccine (TIV)

Methods: Twenty villages of the Niakhar area were randomized 1:1 for vaccination of children 6 months through 10 years of age with TIV formulated for the 2008-2009 northern hemisphere influenza season or inactivated poliovirus vaccine (IPV). After immunizations were completed, surveillance for laboratory-confirmed febrile acute respiratory illness was conducted using active, community-based and enhanced, passive health post-based surveillance. Individuals reporting symptoms were assessed clinically, and nasal swab and throat swab specimens were collected for virologic testing.

Results: During year one surveillance, beginning mid-July 2009 and ending June 2010, 1465 cases laboratory-confirmed as seasonal influenza were identified. A total of 1445 (99%) of these cases were A/H3N2, and nearly all occurred from July through November 2009. Antigenic characterization of a subset of specimens indicated with high probability that at least 90% were A/Perth/16/2009 (H3N2)-like infections. Among age-eligible children participating in vaccinations, 812 A/H3 cases were detected, among age-eligible children not participating in vaccinations 238 were detected, and among the rest of the population 395 were detected.

Conclusion: To our knowledge, this is the largest influenza vaccine trial conducted in sub-Saharan Africa. Our cluster randomized design allowed for the measurement of total, indirect, and overall vaccine effectiveness. These data provide evidence that current inactivated influenza vaccines can provide benefit to developing country populations. This kind of study emphasizes the crucial role played by the national reference laboratory in the confirmation of influenza cases.

ORAL SESSION 4.3 HIV PROFICIENCY TESTING

DATE: Thursday, 4 December

TIME: 11:00 – 12:45

LOCATION: Room 2.4

CO-CHAIRS: **Umuro Mamo**, National Public Health Laboratory, Kenya
Nadia Siteo, Ministry of Health, Mozambique

11:00

Shon Nguyen¹, Artur Ramos¹, Joy Chang¹, Bin Li², Vedapuri Shanmugam¹, Debrah Boeras¹, John Nkengasong¹, Chunfu Yang¹, Dennis Ellenberger²

1 Division of Global HIV/AIDS and Division of HIV/AIDS Prevention-Surveillance & Epidemiology, Centers for Disease Control and Prevention (CDC), Atlanta, GA, USA,

Monitoring the Quality of HIV-1 Viral Load Testing through Proficiency Testing Program using Dried Tube Specimens in Resource-Limited Settings

Background: HIV-1 RNA viral load (VL) is used for monitoring disease progression and antiretroviral therapy outcomes in HIV-infected patients. To assess the performance of laboratories conducting VL testing in resource-limited settings, the US Centers for Disease Control and Prevention (CDC) implemented a voluntary, free-of-charge, external quality assurance program using dried tube specimens (DTS).

Methods: DTS proficiency test (PT) panels consisting of 5 coded specimens were prepared and shipped 3 times in 2010 and 2011, and twice in 2012 at ambient temperature to participating laboratories. The results for laboratories (N ≥ 6) using the same VL assay were grouped, analyzed, and graded as acceptable if within a group mean ± 3SDs. Overall PT scores were analyzed using a linear regression model.

Results: Between 2010 and 2012, the number of countries and laboratories participating in the PT program increased from 16 to 44 and 32 to 114, respectively. Of the 665 PT panels shipped, 520 (78.2%) results were reported and 10 different VL assays were used. The frequency at which graded participants reported acceptable results were Abbott (96.6%), Roche COBAS (96.3%), Roche Amplicor (94.5%), Biocentric (93.0%), and NucliSENS (89.3%). A temporal analysis of the overall proficiency scores showed improved performance over time (p = 0.024); higher PT scores were observed for laboratories that participated in more test cycles.

Conclusion: DTS are an effective and practical alternative specimen type to the traditional plasma specimens for VL PT programs as they do not require cold chain transportation and storage. Our data suggest that the CDC HIV-1 VL PT program positively impacts the testing performance of the participating laboratories, which may translate into better and more accurate VL testing services for patients. Work count: 277 Key words: external quality assurance, Proficiency Testing, HIV-1 RNA viral load

11:10

Bashir Farah, Robert Langat, Jackton Indangasi, Simon Ogola, Omu Anzala
KAVI-Institute of Clinical Research, University of Nairobi, Nairobi, Kenya

Inter-operator Comparison of the Elispot Assay Proficiency Testing in HIV-1 Clinical Trials in Kenya

Background: The ELISPOT assay is used for immunogenicity assessments of HIV-1 vaccine candidates in clinical trials. As part of the quality management systems, KAVI laboratory participates in monthly external quality assurance proficiency panels that assess and monitors laboratory performance in ELISPOT over time.

Methods: Frozen PBMC samples isolated from HIV-1 seronegative individuals with previously-characterized IFN- γ ELISPOT responses to CMVpp65, FEC (Flu, EBV and CMV) and mock peptide pools were provided by IAVI from blood packs obtained from the South African National Blood Transfusion Service. Sufficient vials were provided to test the same 6 PBMC samples per month for 6 months. Two such PBMC panels were provided each year. Monthly testing was rotated amongst three laboratory staff. Cell viabilities and recoveries were also analyzed.

Results: Mock data were less than 50 SFU per million PBMC for all sets of PBMC tested over 12 months. 213 out of a total of 216 data points (98.6%) for mock, FEC and CMVpp65 responses were in the expected ranges for PBMC samples tested over 12 months. Intra-operator analysis showed that there were no statistically significant differences in the mock ($p=0.35$), FEC ($p=0.99$) and CMVpp65 ($p=0.99$) responses for PBMC tested over 12 months. Cell recovery was in the range of 3.0-13.1 x 10⁶/ml with viability of above 92%.

Conclusion: Three operators have demonstrated competence in ELISPOT testing of multiple batches of frozen PBMC over 12 months. Responses were within the expected ranges for mock, CMVpp65 and FEC among different operators. The Elispot proficiency therefore remains a robust and reproducible tool for the assessment of immunogenicity of HIV-1 and other vaccine candidates in clinical trials.

11:20

Muchiri Njogu¹, Frankline Kitheka¹, Sophie Mwanyumba¹, Kipkerich Bera², Umuro Mamo²

¹ National HIV Reference Laboratory, Nairobi, Kenya, ² National Public Health Laboratory Services, MOH, Kenya

Rapid HIV Testing, Going Beyond Numbers in the Era of Task Shifting to Non Laboratory Personnel While Maintaining Quality Through Individual Based Proficiency Test Monitoring – The Kenyan Successful Experience

Background: Use of HIV rapid testing has expanded worldwide in response to the call for universal access to prevention, care, and treatment by UNAIDS and WHO 3 by 5 initiative of 2003. Kenya initiated task shifting programs which has seen rapid HIV testing being performed by people with varied skills in laboratory and in

non-laboratory settings. This resulted in to massive number of people being tested for HIV and the concern was on the quality of testing being offered hence need for close monitoring. Accurate HIV diagnosis is the first step to identifying infected persons for follow-up referral and care. The laboratory should take the center stage in ensuring Quality in HIV testing while the government strive to achieve the 3 by 5 goal.

Methods: The Ministry of Health in Kenya through the National HIV reference laboratory introduced an EQA program in 2005 that now captures the whole system of HIV testing. Kenya runs different HIV programs: PMTCT, PITCT, VCT, Laboratory and Home based testing. All these programs other than laboratory are run by non laboratory personnel. The HIV Proficiency testing EQA scheme targets 10,000 plus individuals performing HIV testing of whom 7,000 (70%) are enrolled. Over 5,500 (78.5%) of the enrolled are non-laboratory personnel. Six blinded dry tube specimens (DTS) are sent to each enrolled person, who performs the test, submit results for assessment and then feedback is shared. Assessment is based on, Correctness and interpretation of results, Adherence to procedures and algorithm etc. This scheme runs three times per year to ensure constant and regular monitoring.

Results: Trends of performance in these programs has shown tremendous improvements in the quality of results being generated, creating confidence in the whole testing and program set-ups.

Conclusion: Individual based Proficiency testing is an effective tool in assessing the quality of testing

11:30

Nadia Siteo

Instituto Nacional de Saude, Eduardo Mondlane

The Performance of POC CD4 Technologies in Quality Assurance Systems is Comparable to the Performance of Conventional Technologies, in Mozambique

Background: In resource-limited settings, many patients do not have reliable access to essential diagnostic tests for the management of major diseases such as tuberculosis, HIV and malaria. The implementation of POC technologies can significantly decentralize the CD4 testing network and provide greater patient access to critical diagnostic tests. It is necessary, therefore, to monitor the performance of POC technologies to ensure device and operator performance are adequate and comparable to conventional technologies.

Methods: In 2010, Mozambique began implementing POC CD4+ T cell testing for HIV disease staging and treatment monitoring. Three times a year, all sites that have (do) CD4 testing devices receive a panel composed of two specimens with low and normal level of CD4 T cells. The results obtained are sent to INS for submission to the quality assessment and standardization for immunological measures (QASI) external quality assurance program. The performance of POC CD4 devices was compared with conventional FACSCalibur (Becton Dickinson, USA) and FACSCount (Becton Dickinson, USA) and based on reports for QASI and the national EQA program for CD4 testing (PNAEQ).

Results: We monitored the performance of five panels, from February 2012 to June 2013. During this period, there were 97 PIMAs, 16 FACSCaliburs and 25 FACSCount, that participated in both EQA programs. The performance of the POC CD4 devices in QASI was consistently comparable or better than conventional laboratory CD4 instruments and remained higher than 85% in both EQA programs.

Conclusion: These results improve the confidence of results that are produced by POC CD4 devices. A coordinated program of monitoring and follow-up of health care facilities with POC devices is essential to the success of the national testing program.

11:40

Larry Westerman¹, Nichole Arnett¹, Sehin Birhanu¹, Karen Chang², Mary Schmitz², Katie Tucker¹, Omotayo Bolu¹, John Nkengasong¹, Luciana Kohatsu¹, and Fausta Mosh^{3,4}

¹ Division of Global HIV/AIDS, Center for Global Health, U.S. Centers for Disease Control & Prevention, Atlanta, GA, USA, ² ASPH/CDC Allan Rosenfield Global Health Fellow, ³ National Health Laboratory Quality Assurance and Training Center, Tanzania Ministry of Health and Social Welfare, ⁴ African Field Epidemiology Network

Quality Assurance Monitoring of Pima CD4 Testing: Operator Errors Attributing to Higher Invalid Test Rates

Background: Pima CD4 is a point-of-care test (POCT) used to provide CD4 counts for HIV/AIDS care. Like all laboratory tests, it is important to monitor the quality of POCT to ensure accurate and reliable results. When performed correctly, the Pima CD4 can provide accurate and reliable results. If an error occurs during Pima testing, an invalid test will result. Invalid tests are either due to failures of the analyzer or reagent, suboptimal specimens, or incorrect testing procedure. Monitoring of invalid test rates can provide data and information for Quality Assurance (QA) of Pima CD4 POCT and indicate corrective actions necessary to improve the quality and reliability of the CD4 results.

Methods: HCWs performed Pima CD4 testing at 5 HIV Healthcare Sites around Dar es Salaam. All Pima CD4 tests were analyzed by a QA team to determine the rate of invalid Pima CD4 tests performed per site, per HCW, and per Pima Analyzer.

Results: Between September and October 2011, 3517 Pima CD4 tests were performed by 13 HCWs with a total invalid test rate of 9% (309) and ranged from 2%-15% between the HCWs. The invalid test rate between sites ranged between 5-12%. Eleven Pima Analyzers were used with an invalid test rate for each individual analyzer ranging between 4-16%. At one site 4 Pima Analyzers were used and 2 HCWs performed testing on each of the Analyzers. The invalid test rate on each Pima Analyzer for HCW #1 was 13, 12, 9 and 15% and for HCW #2 was 6, 2, 4, and 4%.

Conclusion: By reviewing Pima invalid tests rates, training and supervision could be targeted to HCWs with higher than normal invalid test rates, as observed at one site in this study. Also, when indicated corrective action could be taken to troubleshoot faulty analyzers or reagents

11:50

Oluwaseun Aladesanmi¹, Eric Lugada¹, Olusegun Busari², Olumide Okunoye², Okechukwu C. Nwanyanwu³, Ali Onoja³, Jelpe Tapdiyel³

¹ Axios Foundation, Abuja, Nigeria, ² National External Quality Assessment Laboratory, Zaria, Nigeria, ³ Centres for Disease Control and Prevention, Nigeria

Does Laboratory Participation in EQA Programs Have an Impact on Laboratory Performance? Results of Two Years Evaluation of Laboratories Performances in the National Proficiency Testing Scheme, Nigeria

Background: An evaluation of the performance of laboratories participating in the National Proficiency Testing Scheme (NPTS) in Nigeria from between April 2011 and February 2013 was conducted to determine if the act of participation of laboratories in an external quality assurance program will likely improve laboratory performance.

Methods: In order to evaluate effectiveness of participation in proficiency testing (PT), an assessment of the outlier percentage per parameter per trial was carried out. Correlation of participation in proficiency testing with percentage outlier and Linear Regression value for the trend of percentage outlier through all trials of immune monitoring CD4 PT scheme was determined. Statistical analysis was carried out using SPSS 18.0 and significance is considered at $P < 0.05$ at 95% Confidence Interval (CI). For HIV serology PT, effectiveness of participation in the PT Scheme was assessed based on acceptable performance and compliance with the national testing algorithm.

Results: Percentage Outlier Decline for CD4: For the CD4 Absolute Count, a declining outlier percentage from Trial 7 (42.2%) through to Trial 18 (14.6%) was noted with a correlation value of -0.460 and a statistically significant regression value of 0.410 ($P=0.025$) was observed. Increase in Compliance with National Algorithm for HIV Serology: Increase in cumulative percentage compliance with national testing algorithm per cycle went from 62.2% of laboratories complying in the first cycle to a progressive increase in compliance noted with each subsequent panel event: 80.6%, 84.3% and 95.1 % for Cycle 37, 38 and 39 respectively.

Conclusion: Improvement in performance in CD4 and HIV serology proficiency testing by participating labs in Nigeria suggests that the quality of routine testing of CD4 immune monitoring and HIV serology performed by these laboratories has improved as well, with positive implications for patient care. It is recommended that all laboratory participate in EQA programs for all testing parameters as they potentially have a significant impact on the quality of laboratory services and thus on patient care.

ORAL SESSION 4.4 SUSTAINABLE LABORATORY INFORMATION SYSTEMS

DATE: **Thursday, 4 December**

TIME: **11:00 – 12:45**

LOCATION: **Terrace Meeting Room**

CO-CHAIRS: **Ralph Timperi**, Association of Public Health Laboratories, United States of America
Amitabh Adhikari, Centers for Disease Control and Prevention, United States of America

11:00

Beth Skaggs^{1,2}, Janise Richards¹, Mark DeZalia¹

¹ Centers for Disease Control and Prevention, Atlanta, Georgia, USA,

² Centers for Disease Control and Prevention-Mozambique, Maputo, Mozambique

Review of Laboratory Information Management Systems in Mozambique: Quality Indicators

Background: A laboratory information management system, whether paper-based (LIMS) or electronic (eLIMS), is a critical tool for the management of a service laboratory. As in many countries, most laboratories in Mozambique use separate logbooks for specimen registration and test results. Data critical for laboratory quality, such as specimen rejection rate, quality control results, reagent lot numbers, and reference ranges are rarely captured. Beginning in 2006, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) funded efforts to standardize the LIMS and to implement an eLIMS in laboratories at the reference and provincial levels.

Methods: A review of the six eLIMS and six comparable LIMS sites was conducted through structured interviews with 42 healthcare workers, including hospital administrators, clinicians, laboratory managers, and technicians. Laboratories were assessed for the presence of quality systems or processes to: 1) track turnaround time of laboratory testing; 2) monitor specimen rejection; 3) run, record, and analyze internal quality controls; and 4) use laboratory information to produce reports for decision making and laboratory management.

Results: Results indicated that eLIMS improved turnaround time for laboratory testing compared to laboratories using LIMS. No quantitative differences in the remaining indicators were observed between eLIMS and LIMS laboratories, including no improvement in the ability of eLIMS users to demonstrate laboratory quality processes assessed. eLIMS users did report an increased ability to provide a quality service; improved timeliness, completeness, and legibility of laboratory test results; increased ability to track specimens, and ease of tracking and reporting the number and types of tests performed.

Conclusion: These findings reinforce that laboratory quality improvement is driven by policy, training, and behavior change rather than by systems and tools, though the latter can reinforce the former. Since this assessment, Mozambique MOH has implemented in earnest the step-wise laboratory quality improvement program that reinforces implementation and monitoring of quality management systems.

11:10

Thomas Gachuki, Mamo Umuro

Kenya Ministry of Health, National public Health Laboratories(National HIV Reference Laboratory), Kenya

Successful Utilization of Laboratory Information Systems in Establishing Quality Management Systems Leading to ISO Accreditation

Background: The National HIV Reference laboratory (NHRL) embraced the use of a robust laboratory information management system (LIMS) in the process of establishing a quality management system (QMS) leading to ISO accreditation.

Methods: Quality indicators were used to monitor all aspects of the analytical process and quality of service. LIMS was utilized in monitoring these quality indicators, managing data, and increase efficiency. Workflow was developed and LIMS configured to match. Configurations include: Automatic off site daily data backups. Three levels of results review and approval electronically before release. Electronic signatures for each personnel Standard request /report form format. Use of barcodes and mechanism of double data entry. The instant and direct email of results/feedback from LIMS to customers. Email alerts to users and management on failures of any of the indicators. Inventory control and specimen archival system. Daily and weekly reports on all indicators prepared and emailed to laboratory management from the system. System was then validated. Roles and responsibilities were defined and users trained. System ticketing mechanism was developed to report and track errors. Regular review of the system logs and its effectiveness was done in monthly meetings between management and LIMS administrator

Results: There was 90 % reduction in data entry errors. Specimens turnaround time reduced by up to 95%. Service interruptions reduced by 100%. Stock-outs reduced to zero. Customer complaints reduced by 90%. Service quality improved due to increased responsiveness and email communication. Timely interventions in case of failure. Increased system security due to use of electronic signatures. Increased technologist productivity as a result of more efficient systems.

Conclusion: Proper utilisation of LIMS aids in the development of QMS laboratory. It is important to involve everyone on configuring the system, which should also be guided by laboratory needs.

11:20

Philip Boakye¹, Bernard Nkrumah², Anthony Ofosu³, Beatrice van der Puije¹, Samuel Duh¹, Ava Onalaja⁴, Amitabh Adhikari⁵, Reshma Kakkar⁶, Celia Woodfill²

1 Global Health Systems Solutions, Accra, Ghana, **2** Centers for Disease Control and Prevention – Ghana, Accra, Ghana, **3** Ghana Health Service, Accra, Ghana, **4** The Association of Public Health Laboratories, Silver Spring, MD, USA, **5** Muon Technology, Inc., Northrop Grumman CIMS Contractor, Centers for Disease Control and Prevention, International Laboratory Branch, Division of Global HIV/AIDS (DGHA), Atlanta, GA, USA, **6** The St. John Group, Atlanta, GA, USA

Rapid Scale up of the Basic Laboratory Information System (BLIS) in Ghana

Background: In HIV programs, laboratories provide key testing information used to make clinical decisions. However, laboratories in Ghana are challenged with keeping pace with program growth and data management. Strengthening Laboratory Management toward Accreditation (SLMTA) was introduced in Ghana in 2009, with the aim of improving the quality of laboratory services. Data management is a key component of SLMTA, and in 2011 we piloted an open source laboratory information system called Basic Laboratory Information System (BLIS) in laboratories undergoing SLMTA.

Methods: A Technical Working Group (TWG), under the leadership of the Ghana Health Service, was set up to spearhead the launch of BLIS. The TWG selected four laboratories for a pilot based on specific criteria including infrastructure and testing volume. Assessments were conducted prior to and after implementation of BLIS. A local partner conducted the implementation, configuration, training, supportive supervision and troubleshooting. The TWG had regular meetings to inform and advise on implementation.

Results: BLIS was successfully installed and validated at 4 pilot sites within 6 months. After the pilot, BLIS was rapidly scaled up to 8 additional sites in 3 months and 120 laboratory staffs were trained on BLIS. One laboratory technologist was designated at each laboratory to serve as an Administrator for managing BLIS use and minor troubleshooting. BLIS was successfully integrated into SLMTA at 9 sites. Post-implementation assessments and monitoring visits showed greater efficiency, reduced turnaround time by 50%, decreased patient wait time by 30% and increased ability to assess workload at all sites.

Conclusion: Strong leadership, careful planning, local partnership, a robust information system, and a standard approach were key factors that enhanced the implementation of BLIS in Ghana. BLIS has streamlined laboratory processes, enabled appropriate storage of data and reduced turnaround time.

11:30

Edwin Ochieng¹, Rufus Nyaga¹, Michael Mwangi², Winnie Migwi², Osborn Otieno³

1 Association of Public Health Laboratories (APHL), Silver Spring, Maryland, USA, **2** Ministry of Health-Kenya, Nairobi, Kenya, **3** CDC/DGHA-Kenya Nairobi, Kenya

Rift Valley Provincial General Hospital in Kenya Goes Paperless: Achieving 100% Automation of Laboratory Data in Developing Countries

Background: Rift Valley Provincial General Hospital (RVGPH) laboratory in Nakuru, Kenya, handles numerous requests from various departments within the hospital. The requests were being logged into a Hospital Management Information System (HMIS) by the clinicians then accessed in its laboratory through the HMIS. The laboratory staff had to key the requests into the Laboratory Information Management System (LIMS), process them then feed the results both into LIMS and HMIS for access by the clinicians. The lack of data exchange functionality between the systems meant duplication of work by the laboratory staff. As a result, the use of LIMS declined and the laboratory lost the capability of the LIMS for tracking and quality control of testing results. In order to achieve the advantages of information systems for both laboratory and clinical needs, integration of the systems was planned. APHL, a PEPFAR-funded organization, worked closely with the Ministry of Health (MOH)-Central data unit (CDU), CDC -Kenya and other stakeholders to implement this project.

Methods: An intersystem communication mechanism was developed for data exchange between HIMS and LIMS. This enabled laboratory results to be automatically posted to clinicians after they have been validated.

Results: The automation has reduced patients waiting time for results by 50%, The dynamic dashboard at the reception enables patients to track status of their laboratory results. Transcription errors have reduced and quality of laboratory data improved. There is ease of tracking samples and reduced turnaround time. Laboratory cash collection has also increased by 30%

Conclusion: It is important for countries to develop standards and specifications at national level for procurement of Health Information systems and interoperability. Additionally, Collaboration of stakeholders is important in ensuring success of the project.

11:40

Emmanuel Kweyu¹, Roy Rutto¹, Emmanuel Kitsao¹, Brian Kiprof¹, Edwin Ochieng², Osborn Otieno³, Amitabh Adhikari⁴, Ralph Timperi²

¹ Strathmore University iLabAfrica, Nairobi, Kenya, ² Association of Public Health Laboratories, Silver Spring, Maryland, USA, ³ CDC/GAP/Kenya, Nairobi, Kenya, ⁴ CDC/GAP/ILB, Atlanta, Georgia, USA

Towards Providing an Affordable and Sustainable Laboratory Information System for Developing Countries: Successful Implementation of BLIS-Kenya Open Source Laboratory Information System In Public Health Hospital Laboratories In Kenya

Background: The challenges including the high cost of Laboratory Information System (LIS) implementation in developing countries are well documented. Laboratories in developing countries, have high demand for test services but are under equipped and understaffed. We modified an open source basic laboratory information system (BLIS) that was configured primarily for sample management to introduce functionalities such as data exchange interfaces and electronic transmission to a hospital electronic medical records system (EMRS) to reduce manual workload, decrease turn-around times, and improve quality control documentation to meet internationally-recognized laboratory standards and improve quality of laboratory testing.

Methods: A gap analysis for implementation of LIS was conducted in the Bungoma and Kapsabet District Hospital Laboratories. Modifications to BLIS were programmed. Extensive staff training was conducted on the new application, BLIS-Kenya. Needs of users and stakeholders (laboratory staff, hospital management, Ministry of Health (MoH) and donor partners) were captured in small group meetings.

Results: Six month's post-development, successful implementation of BLIS-Kenya was achieved in two district hospital laboratories. The system is fully integrated to the hospitals' EMRS, automatically receiving laboratory test requests from and returning results to clinicians. The system tracks the movement of specimens providing turn-around-times; is interfaced with laboratory instruments; and provides individual workload monitoring, test reporting and quality control documentation. Efficiencies gained from BLIS enable staff to increase test services and allot more time to quality procedures. Test results are transmitted to patient's EMR as soon as results are verified providing clinicians with more timely information for patient management.

Conclusion: BLIS-Kenya is a technical model that can support LIS implementation in developing countries through active user participation. This application is appropriate for introduction to district level laboratories and can support laboratory accreditation. We propose BLIS-Kenya as a proven option for maintenance by local capacities such as university computer science departments.

ORAL SESSION 4.5 IMPROVING BIOSAFETY AND LABORATORY EQUIPMENT

DATE: **Thursday, 4 December**

TIME: **11:00 – 12:45**

LOCATION: **Auditorium 2**

CO-CHAIRS: **Maureen Ellis**, International Federation of Biosafety Associations, Canada
James Olweny, Medical Access Uganda Limited, Uganda

11:00

James Olweny¹, Eric Nabuguzi¹, Henry Oundo¹, Paul Lotay¹, Sheba Nakimera¹, Wilson Nyegenye², Rashid Settaala¹, Sowedi Muyingo¹

¹ Medical Access Uganda Limited, Kampala, Uganda, ² Ministry of Health – Central Public Health Laboratories, Uganda

The Maputo Declaration on Strengthening of Laboratory Systems: Where is Uganda on Equipment Harmonization and Standardization Six Years Down the Road?

Background: Harmonization and standardization in laboratory networks can improve access to essential diagnostics. In developing countries like Uganda, efficient management of Laboratory supply systems has been mired by a complex range of equipment and reagents from which to select. This is worse among private-not-for-profit (PNFP) health facilities receiving donations from partners without consideration of policy framework. In line with the Maputo Declaration on Strengthening of Laboratory Systems (2008), Uganda developed the National Health Laboratory Services Policy (2009), draft National Health Laboratory Strategic Plan (2010-2015), standardized equipment, recommended tests by level of care (2011) and VEN classified list of laboratory supplies (2011). This paper describes the extent of equipment harmonization and standardization among Ugandan private-not-for-profit health facilities.

Methods: In April 2014, we reviewed CD4, hematology and chemistry testing platforms in 190 MOH Anti-retroviral Therapy accredited facilities focusing on primary platforms. We compared CD4, chemistry and hematology testing capacity by level of care against the MOH recommended test menu and harmonized equipment list.

Results: Facilities included 111 HCIIIs, 37 Hospitals, 33 Specialized HIV clinics and 9 HCIVs. We reviewed 63 facilities with laboratories namely; 6 HCIIIs (10%), 31 Hospitals (49%) 23 Specialized HIV clinics (37%) and 3 HCIVs (5%). Fifty-one facilities had CD4 platforms, 33 had Clinical chemistry and 33 had hematology platforms. All facilities had approved MOH CD4 testing platforms 100% (51). Clinical chemistry and hematology

platforms were 70% (23) and 82% (27) adherent to MOH approved guidelines respectively. Twenty-five (40%) of sites were HCIIIs and Specialized HIV clinics performed CD4 and chemistry testing not recommended by MOH.

Conclusion: PNFP health facilities in Uganda are on track towards achieving laboratory equipment harmonization and standardization six years down the road of streamlining the laboratory supply chain. Policy direction should recognize and utilize capacity of lower level health facilities to improve access to diagnostics in Uganda.

11:10

Thomas Stevens, David Bressler, Shanna Nesby, John Nkengasong
US Centers for Disease Control and Prevention (CDC), Atlanta, GA, USA

Development of a New Laboratory Safety Evaluation Tool to Build Robust Safety Programs and Achieve QMS Accreditation

Background: In 2009, the WHO-AFRO and African Society of Laboratory Medicine (ASLM) launched the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA). Laboratory safety is a significant part of the SLIPTA process, composing more than 30% of the evaluation criteria. WHO-AFRO also encourages countries to integrate laboratory safety and security into their daily operations and patient diagnostic activities. To complement the SLIPTA process, CDC has developed a companion tool to assist laboratories with building complete safety programs and achieving quality management systems (QMS) and accreditation.

Methods: Similar to SLIPTA, this new tool provides a stepwise approach to developing laboratory safety programs. It outlines 14 basic programs required to safely work with patient specimens and infectious agents. The tool provides a road map of core criteria (competencies) for implementing specific safety programs such as employee infection control, the handling of chemicals and infectious waste, and principles for maintaining laboratory facilities and equipment. The tool also incorporates safety citations from several references and standards, to include the SLIPTA checklist, ISO-15189, ISO 15190, CWA 15793/16393, and the WHO-Laboratory Biosafety Manual, 3rd edition.

Results: This tool will assist countries with protecting laboratory personnel as they perform basic diagnostic activities associated with HIV, TB and other infectious diseases. It will simplify the self-assessments process and facilitate the development of strategies and budgets that measure progress towards QMS-accreditation. It will also help build indigenous capacity to sustain laboratory programs, operations, equipment and facilities.

Conclusion: PEPFAR-supported countries are encouraged to implement QMS to support accurate test results and appropriate patient care. This safety tool will help institutions develop robust safety programs that protect employees, the environment and fulfill requirements for QMS leading to accreditation.

11:20

Wilson Nyegenye¹, Christina Mwangi², Ida Namakula¹, Eileen Burke², Steven Aisu¹, Sunday Izidoro³, Victor Bigira⁴, Sam Wasike², Sitra Mulepo⁵, Philip Kasibante¹

¹ Central Public Health Laboratory, Ministry of Health, Kampala, Uganda, ² Centres for Disease Control and Prevention, Kampala, Uganda, ³ National Medical Stores, Entebbe, Uganda, ⁴ Clinton Health Access Initiative, Kampala, Uganda, ⁵ Infrastructure Division, Ministry of Health, Kampala, Uganda

Laboratory Equipment Maintenance using Reagent Markup and Reagent Rental Strategy in Uganda

Background: Ensuring laboratory equipment functionality is an often overlooked component in the supply chain system. Uganda has labored to keep track of status of equipment service and maintenance (S&M) catarracts and warranty due to fragmented procurement of contacts by the Ministry of health (MOH), donors and implementing partners, leading to relatively long machine downtime resulting into ineffective services delivery. MOH streamlined laboratory equipment maintenance through reagent markup and rental strategy.

Methods: The status and functionality of laboratory equipment was assessed, and quantification was conducted to determine national laboratory supply needs, thresholds for each commodity category and funding commitment from different development partners. Based on the commitments and thresholds, MOH opted to streamline S&M through reagent markups. In addition, the regional equipment maintenance workshops were revamped to coordinate S&M of lab equipment. With technical support from CHAI and CDC a number of supplier sensitization workshops and negotiations were conducted. with individual suppliers to agree on the reagent markup.

Results: MOH recruited 8 biomedical engineers to coordinate equipment S&M at the central and regional levels through the equipment maintenance workshops, with equipment suppliers doing the S&M based on the agreed markups. As a result, the number of functional CD4 equipment has increased from 60 to 140, reducing equipment downtime from 3 months to 2 weeks on average and CD4 testing increasing from 750,000 tests in 2012 to ~1,000,000 in 2013. 250 lab staff have been trained in routine lab equipment maintenance and all suppliers have started training the biomedical engineers to level 2 certification.

Conclusion: Incorporating reagent markups into the prices of laboratory reagents and strengthening regional maintenance workshops has improved the coordination and functionality of laboratory equipment for the provision of quality laboratory services.

11:30

Mouslihou Mohamed¹, Howoro Loua², Sophie Ouvrard¹, Etienne Guillard

1 Solthis-Guinée, Guinée, 2 Comité national de lutte contre le sida, Guinée

Suivi des Stocks de Réactifs et Consommables de Laboratoire de Biologie Médicale : Développement d'un Outil de Calcul de la Couverture en Guinée

Background: Les programmes de lutte contre le VIH sida ont besoin d'un suivi régulier des stocks pour éviter toute rupture qui mettrait en péril la qualité de la prise en charge des patients. Dans ce cadre, un effort est fourni pour les médicaments notamment les antirétroviraux. Par contre, pour les réactifs et consommables de laboratoire, peu d'initiatives sont rapportées pour assurer un suivi des niveaux de stocks prenant en compte la dynamique des flux de stocks. Pour répondre à ce besoin, un outil prenant en compte ces différents éléments a été développé et testé par Solthis en Guinée. Il permet de prévenir les ruptures de stocks en les anticipant grâce à une estimation rapide et simple des périodes de disponibilités.

Methods: L'outil est une application informatique. Ses paramètres tiennent compte de la date de mise à jour des données, de la quantité de stocks disponibles, de la date de péremption des produits, de leurs coûts et des quantités consommées. Il est également paramétrable en fonction de la nature des examens : dépistage, charge virale, mesure des CD4, hématologie, biochimie.

Results: L'outil produit automatiquement non seulement des tableaux et des représentations visuelles des périodes de disponibilités mais aussi un tableau de bord valorisé des péremptions. Ceci permet de communiquer avec les acteurs et institutions concernées et les alerter si nécessaire sur des disponibilités critiques (risque de rupture et surstock). Cet outil est utilisé mensuellement par la cellule de suivi des approvisionnements en Guinée.

Conclusion: L'approche méthodique et structurée de cet outil permet de standardiser l'analyse du risque de rupture de stocks et a un effet positif dans le suivi des approvisionnements et des stocks

11:40

Mary Ann Sondrini

Eagleson Institute, Maine, USA

Biological Safety Cabinet Training for African Countries at Eagleson Institute U.S.A.

Background: WHO encourages laboratories to implement quality management programs that facilitate accurate test results and safe work practices. Biological safety cabinets (BSCs) are one of the most important pieces of laboratory equipment used in diagnosing TB, HIV and other dangerous diseases, while providing protection to laboratorians and the surrounding environment. To provide this protection, laboratory workers must safely and effectively perform work within the BSC and the cabinet must be maintained and certified annually. However, this has not occurred in many African countries, due to lack of trained personnel. Eagleson Institute's goal is to assist countries with developing a cadre of trained individuals who can service African BSC's, which are from multiple global manufacturers and often have complex repair issues. At the same time, these individuals can instruct laboratorians in the safe use of the cabinets.

Methods: Over the past 10 years, Eagleson has developed a multi-phase BSC technician training program, which includes U.S. based training, followed by in-country mentoring and evaluation. As part of the program, participating countries are provided guidance on candidate selection criteria; assistance in purchasing BSC testing equipment; two sessions of U.S. based training; help preparing for the mentor's in-country visit to validate student skills according to a 10-level scale designed by the Institute; and support in implementing a national BSC certification program.

Results: To date, 31 students from 16 countries have been trained, with 14 having been mentored. This includes 21 individuals from 9 PEPFAR countries. Additionally, one country has now included BSC certification in their national health plan.

Conclusion: Developing a country-wide BSC certification program is a step-wise process that requires training, validation, resources and national endorsement. Several countries in Africa have made great strides in this direction, and can serve as models to others. Continuing to develop skilled technicians is critical, and their importance must be acknowledged.

11:50

Maureen Ellis¹, Tubi Abiola²¹ International Federation of Biosafety Associations, Ottawa, Ontario, Canada,² African Biological Safety Association, Microbiologist/Laboratory Consultant, National TB and Leprosy Control Program, Abuja, Nigeria

Partnering with Biosafety Associations in Africa to Strengthen Laboratory Biosafety

Background: The International Federation of Biosafety Associations (IFBA), together with the African Biological Safety Association (AfBSA) are collaborating with the ASLM to strengthen biosafety across the African lab community. Such activities involve equipping laboratorians with the skills and tools they need to conduct reliable diagnostics in safe manner and minimizing risks to them and the surrounding community. ASLM's collaboration with IFBA and AfBSA will directly support ongoing efforts to strengthen the laboratory workforce and quality laboratory services in Africa.

Methods: Through their regional network of biosafety professionals, the IFBA and AfBSA set up a focused approach for "local risk and needs" assessments to ensure facilities, equipment and biosafety practices are cost-effectively maintained (e.g. not relying on highly complex engineering solutions for laboratory infrastructure & HVAC systems; using materials & equipment that are locally sourced; and tailoring biosafety practices to the risks presented by each laboratory activity). To complement these efforts, activities are also developed to build biosafety competencies among the laboratory workforce through the provision of training programs and workshops tailored to each institute and local need.

Results: The collective actions within the network of biosafety professionals in the last four years have resulted in an increased competent laboratory workforce, safe work practices and cost-effectively maintained infrastructure. These achievements have been made possible through support of multiple stakeholders including Biosafety Associations which act as a complement to the efforts of governments and multilateral agencies.

Conclusion: Over the next year, the IFBA and AfBSA will enhance their efforts to strengthen biosafety in laboratories across Africa. As a new member of the Stop TB Partnership, the IFBA is also calling for closer collaboration between national biosafety associations and their respective national Stop TB Partnerships in implementing national TB control strategies.

ORAL SESSION 4.6 RETURN ON INVESTMENT IN LABORATORY

DATE: Thursday, 4 December

TIME: 11:00 – 12:45

LOCATION: Auditorium 1

CO-CHAIRS: **Edwin Shumba**, Zimbabwe National Quality Assurance Programme (ZINQAP) Trust, Zimbabwe
Alaine Umubyeyi Nyaruhirira, Management Sciences for Health, South Africa

11:00

Lee F. Schroeder¹, Ali Elbireer², Timothy K. Amukele³

¹ Stanford University School of Medicine, Stanford, CA, USA, ² Makerere University-Johns Hopkins University, Clinical Core Laboratory at Infectious Diseases Institute, Kampala Uganda, ³ Department of Pathology, Johns Hopkins University School of Medicine, Baltimore, Maryland, USA

Laboratory Tests Use and Laboratory Test Costs in Sub-Saharan Africa: A Comprehensive Survey of Clinical Laboratory Test Menus, Test Volumes, and Test Complexities in Kampala, Uganda

Background: Which of the 4000-plus known medical laboratory tests are available in sub-Saharan African communities? How much do they cost? This information is critical for policymakers, healthcare researchers, industry, and the public. We present a report on test availability and costs for all laboratories in Kampala city (population 1.7 million).

Methods: All laboratories in Kampala city were identified and surveyed in person. Surveyors collected test menus and self-reported laboratory-wide testing volumes at each laboratory. Individual tests were grouped into disease-related test-types. Test availability was calculated as the percentage of laboratories offering a given test-type weighted by the total daily testing volume of those laboratories. We refer to this metric as Test Accessibility.

Results: Laboratory testing volumes and menus were available for 95% (907/954) of laboratories. 110 different test-types were identified. These test-types clustered into 3 groups in terms of Test Accessibility: group one (10 test-types; offered in POC and complex labs), group two (33 test-types; offered in complex labs only), and group three (67 test-types; rarely offered). Tests available in POC laboratories (group one tests) had the greatest Test Accessibility. The most commonly offered test-types, in decreasing order, were urinalysis, syphilis, malaria, HCG, HIV, stool analysis, typhoid, glucose, ABORh, and CBC. The median test menu size for POC labs was 6, and for complex labs was 10. Average cost of the 10 most commonly offered test-types in POC labs was \$2.3 (range \$1.6 – \$4.4) and in complex labs was \$4.0 (range \$2.0 – \$13.2).

Conclusion: This work introduces a new measure of test availability, which accounts for both the number of laboratories offering a test as well as the testing capacities of those laboratories. We call this measure Test Accessibility. In Kampala, Uganda, tests fall into 3 categories in terms of accessibility. Test-types offered in POC labs were most accessible.

11:10

Farouk Umaru, Fales Mwamba

Supply Chain Management System (SCMS), Arlington, VA, USA

Cost Effective Mix of Point-of-Care (POC) and Conventional Instrument Deployment in Zambia

Cost-efficient laboratory networks are essential to high quality patient care. WHO's recommended 500 CD4 counts threshold substantially increased demand for CD4 tests. Advocates called for the rapid deployments of point-of-care (POCs) to compensate for insufficient capacity of laboratory instruments. Zambia delayed the implementation of POC technology to understand the existing laboratory capacity in order to strategically integrate POC in its network. This study aimed to test the hypotheses that there is: 1.) insufficient laboratory instrument capacity to respond to CD4 demand; and 2.) Existing instruments are over utilized to meet increased demand. Five years' worth of CD4 test data on standardized conventional laboratory instruments of FACS Count, FACS Calibur and GUAVA was collected and analyzed. HIV patient care and treatment data was used to calculate CD4 demand using WHO recommended threshold. Instrument capacity was calculated using manufacturers' recommended output of tests per day. Tests conducted on each machine per year were used to determine instrument utilization. Total CD4 capacity for conventional testing platforms was compared to the annual demand. The annual CD4 tests demand increased by over 50% from 852,000 tests in 2009 to 1.8 million tests in 2013 as threshold changed from 350 to 500 counts. Conventional instrument capacity increased from 1.9 million tests in 2009 to 3.5 million tests in 2013, an increase of 47% in response to service demand. Similarly, conventional instrument utilization averaged 32% over the same period. Hence conventional instruments adequately responded to increased tests demand without adversely affecting utilization. Conventional instruments can adequately respond to increased CD4 tests demand. Field deployment of POC technology must consider the capacity of existing conventional laboratory instruments. Evidence-based implementation ensures the appropriate mix of POC and conventional instruments to achieve cost-effective laboratory networks for quality patients' care.

11:20

Edwin Shumba¹, Phoebe Nzombe¹, Absolom Mbinda¹, Raiva Simbi², Douglas Mangwanya², Peter H. Kilmax^{3,4}, Elizabeth T. Luman⁵, Sibongile N. Zimuto¹

1 ZINQAP Trust, Harare, Zimbabwe, 2 Ministry of Health and Child Care, Harare, Zimbabwe, 3 U.S. Public Health Service, 4 U.S. Centers for Disease Control and Prevention, Harare, Zimbabwe, 5 CDC International Laboratory Branch Division of Global HIV/AIDS, US Centers for Disease Control and Prevention, Atlanta, GA, USA

Weighing the Costs: Implementing the SLMTA Program in Zimbabwe

Background: In 2010 Zimbabwe's Ministry of Health adopted the Strengthening Laboratory Management Toward Accreditation (SLMTA) program as a tool for laboratory quality systems strengthening. We evaluated costs to conduct SLMTA using 2

models (external facilitators, and internal local or MoH facilitators) from the perspective of the implementing partner, and estimate resources needed to scale up the program nationally.

Methods: Average expenditure was calculated based on accounting records; calculations included implementing partner expenses but excluded in-kind contributions and salaries of local facilitators and trainees. We also estimated theoretical cost, keeping all contextual variables constant across the two models. Resource needs for future national expansion were estimated based on a 2-cycle implementation plan, in which 12 laboratories in each of 5 provinces would implement SLMTA per cycle; for the internal facilitator model, 20 facilitators would be trained at the beginning of each cycle.

Results: The total expenditure to implement SLMTA 11 laboratories using external facilitators was approximately US\$64,000 (\$5810/laboratory); expenditure in 19 laboratories using internal facilitators was \$116 000, including \$89,000 to train facilitators (\$6105/laboratory). Theoretical expenses of implementing a 12-laboratory round of SLMTA keeping all contextual variables constant is \$57,000 using external facilitators and \$96,000 using internal facilitators. The expenses for subsequent SLMTA rounds using the previously-trained internal facilitators would drop to \$15,000, yielding a break-even point of 2 rounds (\$114,000 using external facilitators and \$111,000 using internal facilitators). Estimated average resources required for national implementation in 120 laboratories would therefore be \$570,000 using external facilitators (\$57,000 per province) and \$312,000 using internal facilitators (\$96,000 for the first province and \$15,000 for the subsequent 4 provinces in each of the 2 cycles).

Conclusion: Investing in training of internal facilitators will result in substantial savings. Our study provides information to assist policy makers to develop strategic plans for investing in laboratory strengthening. Keywords: Cost, SLMTA, internal facilitators, external facilitators

11:30

Kilian Songwe, Maryanne Otieno

A Global Healthcare Public Foundation (the Foundation), Gaithersburg, MD, USA

SLMTA Return On Investment for Finance Managers

Background: When a hospital invests in its diagnostic medicine through SLMTA the Laboratory's Return on Investment (LROI) can be valued in a number of key measureable points such as; 1. Improved quality, 2.Streamlined operations, 3.Reduced cost and, 4.Serving a larger population with less. This abstract seeks to present gains that the laboratory (hospital cash cow) has made that improves the clinical quality and streamline operations without necessarily changing current technology.

Methods: A retrospective review of actual data collected after the implementation of a QMS implementation over two years in comparison with data from just before the implementation of the QMS.

Results: ROI has traditionally been measured as a ratio of financial gains divided by improvement investment cost (ROI = FG/IC). In this review, qualitative benefits such as i) improved patient safety, ii) improved relationship between the clinicians and laboratory staff and iii) streamlined operations were noted. Implementation of a QMS as a result of SLMTA participation initially showed a very low ROI however, over time (two years) a ripple effect in secondary, financial returns was noticed with fewer repeat test and increased reportable test. These benefits has allowed for a larger population to be served as TAT for testing reduced. At "A'gnarum", laboratory over two years, reportable test went up by 25,106 from 107,639; full time employees reduced by two and rejected samples drop by 82 from 213 registered at the onset of the QMS. A revenue flow of USD \$76,537.87 from USD \$53,643.42. A critical balance needs to be achieved between clinical technological additions i.e new equipment, versus program investments and trained personnel.

Conclusion: Strong ROI could be seen from better relationship between the clinicians and the laboratory staff thus resulting in a streamlined operation yielding better service to a larger population in a quality and patient safe environment.

11:40

Alaine Umubyeyi Nyaruhirira¹, S Chutima², F Matovu³, M Gasana⁴, C Mundy⁵

1 Management Sciences for Health, Pretoria, South Africa, 2 USAID, Washington, USA, 3 Makerere University, Kampala, 4 TB Division, Rwanda Bio-Medical Center, Kigali, Rwanda, 5 Management Sciences for Health, Medford, USA

Financing the Introduction of New TB Diagnostics and Treatment: Reflections from Rwanda and Uganda

Background: Successful uptake of TB interventions will require viable financing strategies and mechanisms. The approach was developed to assess financing of new TB diagnosis and treatment interventions, and identify financing gaps and barriers to maintaining existing TB interventions and introducing new one.

Methods: We carried out case studies in Rwanda and Uganda from July to September 2012 to develop the assessment approach. A desk review of the National TB Program (NTP), MOH documents and budgets, and consultations with key stakeholders involved in TB control on decision-making and planning processes, resources requirements for diagnosis and treatment, introduction plans of new TB interventions, and challenges to TB financing were conducted

Results: The Uganda national tuberculosis and leprosy program planned to roll out MDR-TB treatment and GeneXpert machines to reach 100 machines by financial year 2014. The incremental cost of implementing GeneXpert diagnostics is about US\$ 29.65 per test and installing each GeneXpert machine is approximately US\$ 45,400 The Rwanda national tuberculosis program planned to roll out the GeneXpert in 2 phases and reach 16 Machines in the country by financial year 2014. The National technical working group develops criteria of placement of the machines and a budget for 2012-2017 was developed and submits for funding through the

TB National strategic plan. The cost of implementing and installing each GeneXpert GX4 machine is approximately US\$ 48,070

Conclusion: Determining and ensuring adequate financing for TB diagnostics and treatment interventions will be a recurring challenge, as governments are increasingly expected to contribute financially to health care in an environment of competing needs.

11:50

Teri Roberts, Jennifer Cohn

Medecins Sans Frontieres, Access Campaign, Geneva, Switzerland

A Market Assessment of HIV Immunological and Virological Testing Across Low- and Middle-Income Countries

Background: While the supply-side of the viral load testing (VLT) market has been fairly well mapped, country-specific, demand-side information requires more in-depth study.

Methods: A qualitative market assessment was conducted across five countries (South Africa, Zimbabwe, Malawi, Kenya, and India), with a primary focus on VLT, and additional inclusion of CD4 testing, infant diagnostics, genotyping and second-line ART. The assessment evaluated the current market for products in-country as well as an evaluation of likely future changes to the market. A semi-structured questionnaire was used as a guide to interview respondents who included heads of national HIV programs, procurement managers and laboratory directors. Questions covered areas such as procurement, pricing, funding, country guidelines and the extent to which they are being implemented, testing targets, impact and implications of scaling up VLT, challenges or obstacles, and stakeholder input.

Results: Our findings reveal that, for the most part, while countries have limited access to VLT at national level, universal access to routine VLT is only a reality in South Africa. Only South Africa and Malawi have guidelines recommending the use of routine VLT. Future changes to the market include plans by several countries for VLT scale-up and, for some countries, discontinuation of CD4 for those who are virologically undetectable and stable (e.g. South Africa). Pricing both within and between countries varied greatly. Those benefitting from competition and economies of scale (South Africa) or CHAI negotiated prices (Kenya) achieved much lower prices. Donor funding was available for VLT (except for South Africa, where VLT is state-funded), however countries only applied to fund a very limited number of tests and pooled procurement was not used to negotiate better prices. Due to increased automation and simplicity of both laboratory-based and point-of-care testing, countries cited cost as the main challenge to scale-up, along with sample transport and expedient results delivery.

Conclusion: Reliable, up-to-date, comparable, standardized and transparent information on market dynamics, diagnostic characteristics and testing costs are critical to decide on the best technologies for a given context and health system level, and to ensure access to these tools.

MONDAY, 1 DECEMBER 2014

ORAL POSTERS 1.1 EVALUATING NOVEL TESTS

DATE: **Monday, 1 December**

TIME: **13:00 – 14:10**

LOCATION: **Ballroom East/West**

CO-CHAIRS: **Moses Joloba**, Makerere University, Uganda
George Alemnji, Centers for Disease Control and Prevention, Barbados

13:00

Nassim Cassim¹, Lindi Marie Coetzee¹, Deborah K. Glencross²

¹ National Health Laboratory Service (NHLS), National Priority Programme, Johannesburg, South Africa, ²University of the Witwatersrand, Johannesburg, South Africa

Using Laboratory Data to Predict Which Districts to Prioritize the Implementation of Cryptococcal Antigenaemia Detection Using a Combination of Automated EIA and a Manual Lateral Flow Assay South Africa

Background: Cryptococcal meningitis (CM) is a major cause of HIV-related morbidity and mortality in Africa and could be prevented by screening patients for sub-clinical cryptococcal antigenaemia (CRAG) using either a lateral flow (LFA) (IMMY, Norman, OK) or enzyme immunoassay (EIA) assays followed by fluconazole treatment. These assays would be performed as a reflex test in remnant CD4 samples (<100 cells/μl). It was essential that Health districts be identified to pilot cryptococcal screening, in the absence of national cryptococcal prevalence data.

Methods: CD4 data for the 2013 calendar year (n=3.8m) was extracted from the Corporate Data Warehouse (CDW) at the National Health Laboratory Service (NHLS). Samples with a CD4 count below 100 cells/ul were analyzed (n=362k 10%). The data analysis for each district (n=52) included the percentage of CD4 samples below 100 cells/ul, median CD4 and average number of cryptococcal samples per day. Data was analyzed using Stata and MS Excel.

Results: The percentage of CD4 samples below 100 cells/ul per district varied between 5.7 to 12.5%. An analysis of categorized percentages identified that 92% of the districts were between 8 and 12%. Three health districts reported a percentage greater than 12%. The median CD4 varied from 44 to 59 cells/ul. Daily district volumes varied significantly, ranging from 10 to 1420. Only 15% (n=8) performed less than 50 tests per day, with 29 districts (59%) reporting a daily test volume in excess of 200.

Conclusion: The percentage of samples below 100 cells/ul and median CD4 identified the same priority districts for pilot implementation in a phased approach, e.g. Vhembe. Additionally the high daily test volumes indicates that the integrated tiered service delivery model (ITSDM) developed for CD4 testing should be replicated for cryptococcal testing.

13:10

Filimon Mitiku Haile¹, Elsa Hagos², Nega Berhe¹, Bjørn Myrvang³, Svein G. Gundersen⁴

¹ Akilu Lemma Institute of Pathobiology, Addis Ababa, Ethiopia, ² Semera University, Ethiopia, ³ Institute for International Health, University of Oslo, Oslo, Norway, ⁴ Sorlandet Hospital HF and Agder University College, Kristiansand, Norway

Serum Hyaluronic Acid as a Non-Invasive Tool to Diagnose Schistosomal Periportal Fibrosis In Schistosoma Mansonii Endemic Areas of Ethiopia

Background: Among parasitic infections, *Schistosoma mansoni* induced infection is the most prevalent infection worldwide with a significant public health and economic outcome. Morbidity and mortality associated with *S. mansoni* is mainly the result of periportal fibrosis (PPF) which can be diagnosed using ultrasonography. As ultrasound equipment are not readily available in *S. mansoni* endemic areas, serum markers like hyaluronic acid (HA) have been used as an alternative means of diagnosing PPF.

Methods: A cross sectional study was conducted from November 15-25, 2011, with the aim of determining the importance of serum HA as a marker for schistosomal PPF in patients found in *S. mansoni* endemic areas situated in Northeastern Ethiopia. The study involved 55 individuals from Kemise town and surrounding *S. mansoni* endemic villages, and 20 controls from *S. mansoni* non-endemic area (Addis Ababa). PPF was determined using portable ultrasound equipment and graded according to the 'Niamey protocol'. Serum HA concentration was determined using commercially available ELISA kit.

Results: The mean concentration of HA in the sera of the cases was significantly higher than the controls ($p < 0.001$). The concentration of HA also increased significantly as the pattern of PPF became severe while serum HA concentration positively correlated with PPF scores ($\mu\text{g} = 0.6438$, $p < 0.001$). An HA concentration of 27.9 μg/liter of serum differentiated moderate cases of PPF from advanced cases with a sensitivity, specificity, positive predictive value and negative predictive value of 85.71%, 75.61%, 60.5 %, 93.9%, respectively ($p < 0.001$).

Conclusion: In conclusion, serum HA concentrations could be used as an alternative, noninvasive potential marker for schistosomal PPF and to assess its severity in patients found in *S. mansoni* endemic areas.

13:20

Natasha Gous¹, Lesley Scott¹, Tintswalo Mavutani¹, Norma Bosman^{2,3}, Wendy Stevens^{1,4}

¹ Department of Molecular Medicine and Hematology, University of the Witwatersrand, Johannesburg, South Africa, ² Department of Clinical Microbiology and Infectious Diseases, University of the Witwatersrand, Johannesburg, South Africa, ³ National Health Laboratory Service, Johannesburg, South Africa, ⁴ National Health Laboratory Service National Priority Program, Johannesburg, South Africa

Laboratory Validation of SD BIOLINE HIV/Syphilis Duo Rapid Test

Background: Maternal syphilis affects approximately 1.3million women worldwide and causes adverse pregnancy outcomes if left untreated. Screening for both HIV and syphilis simultaneously could potentially integrate and strengthen maternal healthcare services in high prevalence settings. The HIV/Syphilis Duo (abbreviated Duo) (Standard Diagnostics, Inc., Korea), a strip-based rapid test, provides simultaneous detection of HIV-1/2 and/or *Treponema pallidum* from finger prick blood within 20minutes. We determined the laboratory performance of the HIV/syphilis Duo versus laboratory predicate [HIV ELISA; syphilis TPHA and Rapid Plasma Reagin (RPR)].

Methods: The Duo was tested on the following randomly selected residual specimens from NHLS Serology laboratory, JHB: 1.) plasma tested for HIV on 4th generation ELISA (Advia Centaur, Siemens); 2.) plasma screened for syphilis with Architect Syphilis TP (TPHA) (Abbott). HIV specimens were also tested on the HIV-1/2/0 Tri-line (ABON BioPharm Co, Ltd) and Determine HIV-1/2 (Alere). The HIV/syphilis Duo was further validated on: 3.) a panel of ELISA HIV+/- specimens; 4.) a panel of TPHA and 5.) RPR syphilis+/- specimens; tested by an independent lab.

Results: For HIV detection: 100% sensitivity/specificity was observed for patient specimens (n=201) and HIV panel (n=20) versus ELISA [of which n=38/201 (19%) were syphilis+]. Determine and ABON also achieved 100% HIV sensitivity and specificity on same specimens. Syphilis detection: Sensitivity of 94.5%, specificity of 96% (n=207) versus TPHA residual specimens. 100% sensitivity/specificity versus TPHA panel (n=40); 100% sensitivity and 95% specificity versus RPR panel (n=40).

Conclusion: The HIV/syphilis Duo, demonstrated 100% HIV concordance with ELISA technology and 94-100% concordance with TPHA and RPR on plasma specimens. A clinical evaluation to determine performance within a PMTCT program is planned.

13:30

Emmanuel Okunga¹, Waqo Boru¹, Gura Zeinab¹, Galgalo Tura¹, Amwayi Samuel¹, Wences Arvelo²

¹ Kenya Field Epidemiology and Laboratory Training Program, Ministry of Health, Nairobi, Kenya, ² US Centers for Disease Control and Prevention-Kenya, Nairobi, Kenya

Malaria Test Performance During an Outbreak in Kenya, 2012

Background: In July 2012, a malaria outbreak was confirmed in Pokot North district of Kenya. This was based on an upsurge of confirmed malaria cases above surveillance action thresholds, and increased malaria test positivity rates. Blood smears (BS) and rapid diagnostic tests (RDT) were used to detect *Plasmodium falciparum* infection. We conducted a descriptive study to assess testing rates, result documentation rates and test positivity rates.

Methods: We retrospectively reviewed outpatient, inpatient and laboratory records for all patients treated for malaria at five health facilities in the district during the period 29th May to 9th July 2012 (6 weeks). Patients were exclusively tested by either BS or RDT. We extracted the data into a Microsoft-Excel database and analyzed the data. We calculated malaria testing rates, documentation of results rates and test positivity rates for each testing method. We performed a chi-square test to compare positivity rates by BS and RDT.

Results: Records for 1537 patients with suspected malaria were reviewed. Of these, 1057 (69%) had been tested, 730 (69%) were by BS and 327 (31%) were by RDT. For 78% (827/1057) of patients that had documented results, 628 (76%) tested positive for malaria. Of these, 321 (51%) were by BS and 307 (49%) by RDT. Test positivity by BS was 64% (321/501) and by RDT was 94% (307/326) [chi sq. 97.92, df=1, p<0.001].

Conclusion: Presumptive treatment for malaria is high due to low testing rates and poor documentation of results. There is wide discrepancy between RDT and BS results. Though BS is the predominantly used method, better documentation of RDT results and higher positivity rate favor the adoption of RDT during outbreaks.

13:40

Iryna Gerilovych, Borys Stegny, Andrii Zavgorodnii, Anton Gerilovych, Vasyl Arefiev

National Scientific Center "Institute of Experimental and Clinical Veterinary Medicine", Kharkiv, Ukraine

Validation of Multiplex PCR for Detection and Differentiation of Salmonellas

Background: Salmonellosis is the zoonotic disease caused by Salmonella bacteria. These are food-borne pathogens, which require improvement of diagnostics and surveillance measures. For this purpose, prior to implementation of PCR-based system for monitoring Salmonella, presence and differentiation of the agent was validated under O.I.E. requirements. This study aimed to perform interlaboratory testing and clarification of the PCR-based test for its implementation in Ukraine.

Methods: The PCR-based detection technique for Salmonella species detection has been tested under O.I.E. requirements, using determination of specificity, sensitivity and repeatability.

Results: Testing was performed on the panel for five basic agents Salmonella enterica ser. Enteritidis, Salmonella ser. Typhimurium, Salmonella ser. Typhi, Salmonella ser. Dublin, Salmonella ser. Gallinarum-Pullorum. The specific panel included positive samples with containment 10¹-10⁷ PFU/ml (n = 5 for each species). Also the artificially contaminated clinical materials were used (n = 5). The negative panel involved non-polluted clinical materials (n = 20). The heterological samples involved a panel of E.coli, Proteus spp., Mycobacteria spp. and Mycolpasma spp. Samples were marked by commission and blinded for the tested stuff. Testing characterized protocol as 89 % sensitive, 98 % specific (artificial reactions were observed) and repeatable. These characteristics allowed recommending the technique implementation in the laboratory practice in Ukraine. Specific guidelines for performing the test have been developed.

Conclusion: We have validated the PCR-based protocol for indication of Salmonella genus agents and identification of its basic agents S. Enteritidis, S. Typhimurium, S. Typhi, S. Dublin, S. Gallinarum-Pullorum that recognized it to be sensitive, specific, and repeatable and able to be implemented in the laboratory practice for food safety control.

13:50

Irith De Baetselier¹, Lambert Mwambarangwe², Vicky Cuylaerts¹, Viateur Musengamana², John Rusine³, Claude Mambo Muvunyi³, Agrippine Mukaruranga³, Janneke van de Wijgert^{2,4}, Evelyne Kestelyn^{2,4}, Tania Crucitti¹

¹ Institute of Tropical Medicine, Clinical Department, HIV/STI Reference Laboratory, Belgium, ² Rinda Ubuzima, Kigali, Rwanda, ³ National Reference Laboratory, Kigali, Rwanda, ⁴ University of Liverpool, Liverpool, UK

Implementation and Evaluation of the Presto Combined Qualitative Real Time CT/NG Assay in Rwanda

Background: Nucleic acid amplification assays for the detection of Chlamydia trachomatis/Neisseria gonorrhoeae (CT/NG) were not available at the National Reference Laboratory (NRL) in Kigali, Rwanda. We implemented the Presto combined CT/NG real time amplification DNA assay (Goffin Molecular Technologies, The Netherlands) at NRL in the context of an EDCTP funded reproductive health study (RING-PLUS).

Methods: Prior to study start, the assay was evaluated at the Institute of Tropical Medicine (ITM). A training and subsequent validation run were performed at NRL. Bi-monthly external quality control testing was implemented throughout the study. All endocervical swabs were tested at NRL and the results were evaluated against an extended gold standard at ITM (Abbott RT CT/NG assay with confirmation of positive results by a CT or NG in-house RT-PCR assay).

Results: The results of the validation run were 100% concordant. All study samples (n=192) were retested using the gold standard algorithm at ITM, returning five CT/NG dual-positive, eleven CT-positive and nine NG-positive results. Two samples were excluded from analysis as they contained PCR inhibitors. The Presto kit detected all NG-positive samples, missed 1 CT-positive sample although this was equivocal in the assay. It falsely detected 3 NG's and 1 CT. The latter CT sample was positive by the Abbott assay but could not be confirmed using the in-house PCR. Sensitivity and specificity of the Presto assay were 93.8% (95%CI: 62.7%–99.0%) and 99.4% (95%CI: 96.8%-99.9%) for CT and 100% (95%CI: 76.7-100.0%) and 98.3% (95%CI: 95.1-99.6%) for NG.

Conclusion: The Presto kit is an appropriate assay for the detection of CT/NG in Kigali, Rwanda. The established RT-PCR platform in Kigali provides faster results and considerably reduces the risk of contamination compared to traditional PCR. The quality control procedures and retesting of samples at ITM will contribute to the method validation that is required for accreditation.

ORAL POSTERS 1.2 HIV AND CO-INFECTIONS

DATE: **Monday, 1 December**

TIME: **13:00 – 14:10**

LOCATION: **Ballroom East/West**

CO-CHAIRS: **Charles Kiyaga**, Ministry of Health, Uganda
Teri Roberts, Médecins Sans Frontières,
South Africa

13:00

Kepher Otieno¹, Ernest Makokha², Caleb Ogada¹, Grace Bartonjo¹, Mamo Umuro¹, Jane Mwangi²

1 National HIV Reference Laboratory, Ministry of Health, Nairobi, Kenya, 2 Division of Global HIV/AIDS (DGHA), US Centres for Disease Control and Prevention (CDC), KEMRI, Nairobi, Kenya

CD4 Point of Care Testing (POCT) at Household Level in Kenya: an Added Novelty from a Nationally-Representative Based Cross-Sectional Survey

Background: Kenya conducted an AIDS Indicator Survey in 2012. This involved HIV testing for participants aged 18 months to 64 years in 9300 households. The availability of CD4 point of care testing (POCT) afforded a unique opportunity to determine persons eligible for ART in rural settings.

Methods: Fifty POC PIMA (Alere PIMA CD4, USA) were first validated in our Central Laboratory and distributed to 372 survey clusters across the country. Consenting participants provided 5mL of venous whole blood into K3 EDTA anticoagulated vacutainers. Participants who tested HIV positive on rapid HIV testing were offered opportunity to know their CD4 count immediately through CD4 POCT using an aliquot of 25µL. HIV Counselors used the results to counsel and refer participants to the nearest health facilities providing anti-retroviral therapy services. Left-over samples were shipped to the Central Laboratory for CD4 Testing using FACSCalibur (BD, Biosciences, San Jose CA, USA). The results obtained at central level were used to validate the CD4 POCT testing and confirm eligibility for ART.

Results: Of 361 participants who tested HIV positive, 339 (94%) were offered CD4 POCT but 22 participants declined home testing. Of these, 68 (21%) met the CD4 threshold for ART initiation and HBTC counselor received results within 20-30 minutes, where participants were counseled and referred to the nearest ART facility. However, 180(53%) of samples tested at HBTC and transported to the Central Laboratory were found to have lost integrity due to transportation challenges.

Conclusion: CD4 POCT is feasible at household level and can be adapted as a routine component of HIV Testing and Counseling (HTC) services to achieve timely linkage to care and treatment in resource limited settings.

13:10

Daive Brambilla¹, Richard Luhanga², Haswel Jere³, Susanna Ceffa¹, Zita Sidumo⁴, Tatiana Aidé⁴, Erasmo Fernando⁵, Remigio José Mugunhe⁵, Fulvio Erba⁶, Leonardo Palombi⁶

1 DREAM Program, Rome, Italy, 2 DREAM Program, Mandala, Blantyre, Malawi, 3 DREAM Program, Mtengo Wa Nthenga Hospital, Lilongwe, Malawi, 4 DREAM Program, Maputo, Mozambique, 5 DREAM Program, Beira, Mozambique, 6 Tor Vergata University, Rome, Italy

Dried Blood Spot (DBS) Validation in Viral Load Measurement using Abbott System m2000 in HIV Positive Patients Under Antiretroviral Treatment in DREAM Malawian and Mozambican Cohorts

Background: DBS use could improve the accessibility to HIV viral load in Africa. The aim of this study is to evaluate HIV-VL from DBS using Abbott m2000 system identifying the lower detection limit (LDL). A comparison of 5 different VL ranges LOG results was performed.

Methods: 300 DBS (50 µl WB per spot, air dried overnight and stored at RT) were collected from HIV-positive patients on ARV treatment at 3 DREAM health centers: Blantyre (Malawi), Beira and Maputo (Mozambique). Abbott 0,6ml HIV-1 RNA and 1,0 ml HIV-1 RNA DBS protocol has been used respectively for plasma and DBS eluate, Bland-Altman and Krouwer plots have been used for comparison analysis.

Results: The Bland-Altman plot [(plasma-DBS)/2 vs (plasma-DBS)] show a good agreement in the range from 3 to 7log(VL), whereas between 1 and 3log(VL) several outliers are present. All the ND-results are ND both in plasma than in DBS. The mean is 0.12log(VL), SD is 0.55log(VL), the UL and LL are respectively 1.199log(VL) and -0.956log(VL). The Krouwer plot [plasma vs (plasma-DBS)] display the same behavior. Cutting off the ND-results and VL from 1 to 3log, both the Bland-Altman than the Krouwer plot show a good correlation among the two methods. All the values are within the CI and are well dispersed around the mean. The mean is reduced at -0.05log(VL), SD is 0.23log(VL), the UL is 0.401log(VL) and the LL -0.493log(VL).

Conclusion: Affordability of DBS for HIV-VL testing was assessed with Abbott Molecular m2000 System. DBS give comparable results with respect to plasma in the range from 3 log(VL) up to 7(VL) log with a little overestimation of the VL from the DBS, whereas the two methods show a complete disagreement in the range 1-3log. Thus a threshold of 3log must be considered when DBS is used with this device.

13:20

Lucy Mupfumi¹, Madisa Mine², Mulamuli Moyo¹, Timothy Matsuokwane¹, Tuelo Mogashoa¹, Kenneth Mugisha³, Lesedi Tsalaiile³, Lesego Busang³, Frank Mwangemi³, Tendani Gaolathe¹

¹ Botswana Harvard AIDS Institute, Gaborone, Botswana, ² Botswana Harvard HIV Reference Laboratory, Gaborone, Botswana, ³ African Comprehensive HIV/AIDS Partnerships, Gaborone, Botswana

Evaluation of CD4 Enumeration by Non-Laboratory Personnel Using PIMA Point of Care (POC) Instruments in Rural Clinics in Tutume Sub-district in Northern Botswana

Background: Reliance on centralized CD4 testing which requires trained technicians has hampered the successful roll out of antiretroviral therapy (ART) in rural and remote clinics in Botswana. The study assessed the performance of the PIMA POC CD4 technology used by lay counselors at six rural clinics as part of the Treatment Optimization Strategy.

Methods: Lay counselors from 6 remote clinics received a three-day standardized training on the PIMA technology at a central facility, followed by onsite training and competence assessment. Consenting HIV-infected patients provided both venous and finger prick blood samples. The lay counselors performed CD4 enumeration on the PIMA instruments using both finger prick and venous blood samples at the clinic. Venous blood was sent for testing at the centralized laboratory. Linear regression, student t-tests and Bland Altman plots were used to assess agreement of PIMA with the BD FACSCalibur as the gold standard for CD4 enumeration.

Results: A total of 272 paired venous and fingerprick samples were collected between August and October 2013. The median CD4 count was 458 cells/ μ l (IQR, 320-596) with the FACSCalibur. There was a strong correlation between the FACSCalibur CD4 cell counts and both PIMA fingerprick ($r=0.75$) and venous blood ($r=0.89$). We observed a mean bias with the PIMA of -32.3 cells/ μ l (95% CI, -47.9 to -16.7; $p<0.001$) and -48.1 cells/ μ l (95% CI, -60.2 to 36.0; $p<0.001$) for fingerprick and venous samples respectively. The bias for fingerprick was small (+7.2, 95% CI, -11.8 to +26.1; $p=0.45$) for CD4 counts <350 cells/ μ l compared to (-47.2, 95% CI, -67.6 to -26.9; $p<0.001$) for CD4 counts >350 cells/ μ l.

Conclusion: The PIMA POC CD4 machines operated by trained non-laboratory personnel are suitable for decentralization of CD4 testing to small and remote clinics. The bias in CD4 enumeration with PIMA POC needs further investigation.

13:30

Cleophas Kalala, Eddy Sokolua, Viviane Munyemba Kasende, Huguette Kabulo Nday Lilas Kongolo Mwamba, Pacifique Misingi Aye, Jean Baptiste Shuli Tchomba, Sylvain Yuma Ramazani

Centre National de Transfusion Sanguine (CNTS), Cliniques universitaires de Kinshasa, République Démocratique du Congo

Taux de Séroconversion au VIH, VHB, VHC et Syphilis Chez les Donneurs Bénévoles Fidélisés de Sang de 2012 à 2013 au Centre National de Transfusion Sanguine, à Kinshasa/ République Démocratique du Congo

Background: Le Centre National de Transfusion sanguine (CNTS), pour une réduction radicale du risque de transmission des marqueurs infectieux, procède à la recherche des donneurs bénévoles en ciblant les groupes à bas risque. Ceux qui sont indemnes des marqueurs infectieux sont sensibilisés en vue de leur fidélisation. La présente étude a pour but d'évaluer le taux de séroconversion dans ce groupe des donneurs bénévoles fidélisés de sang (DBFS).

Methods: De 2012 à 2013, 13292 donneurs bénévoles fidélisés de sang (DBFS) se sont présentés au CNTS pour réaliser leurs dons. Pour chaque DBFS, 10 millilitres de sang ont été prélevés pour la mise en évidence des anticorps de quatre marqueurs par la technique ELISA manuel. Pour chaque résultat positif, l'échantillon était soumis à l'ARCHITECT i 1000sr (ELISA automatisé)

Results: Parmi ces donneurs, 108, soit 0.8%, ont présenté une séroconversion à l'un des marqueurs recherchés dans le cadre de la stratégie nationale de transfusion. Cette séroconversion est observée lors du troisième don au plus tôt. Le taux de séroconversion au VIH était de 0.1 %, au VHB de 0.3 %, au VHC de 0.3 %, à la syphilis de 0.1 %. Quatre cas de co-infections ont été notés ; il s'agit de VIH-VHC, VHC-syphilis, VHC-VHB, VHC-VHB-syphilis.

Conclusion: Le taux de séroconversion aux différents marqueurs est faible chez les DBFS.

13:40

Natasha Gous¹, Lesley Scott¹, Wendy Stevens^{1,2}

¹ Department of Molecular Medicine and Haematology, University of the Witwatersrand, Johannesburg, South Africa, ² National Health Laboratory, Service National Priority Program, Johannesburg, South Africa

Can Dried Blood Spots or Whole Blood Liquid Transport Media Extend Access to HIV Viral Load Testing?

Background: Plasma viral load (VL) for monitoring HIV patients receiving ART has limitations in RLS where logistical constraints often prevent storage/ transport of plasma. Dried Blood Spots (DBS) are being investigated as they can be transported at ambient temperature and remain stable for longer periods of time compared to plasma but have reduced sensitivity due to small volumes collected. Thus alternative blood transport media are being investigated for more accurate VL estimation. We compared the performance of VL using different whole blood (WB) transport media against existing plasma methodology on a single specimen.

Methods: HIV+ patients presenting at Themba Lethu for ART monitoring were consented and enrolled to provide 4xEDTA tubes. The following volumes of WB were added to different media and tested on the Abbott RealTime HIV-1 assay: 105µl Hemaform (SpotOn Sciences); 500µl Primestore (LHNVD); 300µl 18mm and 500µl 22mm Hastings DBS (Abbott Molecular); 50µl duplicate pre-perforated DBS (Munktell) (in-country predicate). Remaining plasma tested on Abbott RealTime (gold standard).

Results: Median plasma VL for 96 specimens=log 4.2cp/ml (range: log1.6 – log6.3); target not detected (TND) in: 4/96 (4.2%) plasma; 20/87 (23%) Primestore; 29/95 (30.5%) 18mm DBS; 31/96 (32.3%) 22mm DBS; 32/96 (33.3%) Munktell DBS and 32/96 (33.3%) Hemaform. Among these TNDs, 79% (103/130) were <log3 (overall range log1.6- log 5.7) and minimum VL detected was log 2.8 (by Hemaform, 18mm and 22mm DBS). Precision (SD of the bias/%Similarity CV) of media compared to plasma VL at >3log: 22mm SD=0.2/2.6%CV; 18mm SD=0.3/3.2%CV; DBS SD=0.3/3.1%CV; Hemaform SD=0.4/3.8%CV Primestore SD=0.4/5.1%CV.

Conclusion: Plasma VL remains the most sensitive and accurate method for monitoring patients' response to ART. Up to 33% of patient's VL results could not be detected by WB media, majority of which were <log3.0. VL results >log3.0 for all WB media showed increased variability versus plasma testing.

13:50

Isaac Ssewanyana¹, Proscovia Nambuya¹, Meghan Wareham², Victor Bigira², Grace Kushemererwa¹, Christine Namulindwa¹, Iga Tadeo¹, Steven Aisu¹, Charles Kiyaga¹

¹ Central Public Health Laboratories, Ministry of Health, Kampala, Uganda, ² Clinton Health Access Initiative, Kampala, Uganda

HIV Passivity Rate Among Vertically Exposed Infants in Uganda is Steadily Declining and is Associated with the Increased Percentage of Mothers on ART During Antenatal

Background: HIV remains a major challenge in Uganda, with an estimated 100,000 newborn babies exposed to vertical HIV transmission each year. Since 2000 when Uganda's PMTCT program started, the program largely relied on intermittent use of ARVs for prophylaxis during pregnancy and/or breast-feeding period. Very few mothers then were taking ARVs for their own health. It was not until 2012 when Uganda adopted the WHO Option B+ strategy, which puts the woman on complete ART for life for both her own health and for PMTCT. Since then, the number of pregnant and lactating women on ART has increased. This study tries to show the correlation between the increased number of women on ART and HIV positivity of the children born overtime.

Methods: Data from the EID data-base was analyzed for the period between August 2011 to December 2013. The parameters assessed were; 1) HIV positivity rate among exposed infants, 2) proportion of mothers on ART during antenatal, and 3) the Correlation between 1, and 2. Mothers whose ART status at antenatal was unknown were excluded from the analysis.

Results: National HIV positive rate has steadily declined from the peak of 9.8% in September 2011 to 6.1% by December 2013. The proportion of mothers on ART has grown from 44% in August 2011 to 62.6% (59/134 – 2478/3068) by December 2014. Mothers' data that missed ART information was eliminated from the analysis. HIV positive rate has a significant inverse correlation with the proportion of mothers on ART (Spearman $r = -0.7969$, CI $-0.9026 - -0.6008$, $p < 0.0001$).

Conclusion: Mother to child transmission in Uganda is steadily declining as more mothers are put on ART. The option B+ strategy will likely enable us to achieve virtual eMTCT by 2015 as planned.

14:00

Gizachew Tadesse Akalu¹, Kassu Desta Tulu², Addis Tamire Woldemariam³, Abate Bane Shewaye⁴

¹ Ethiopian Medical Laboratory Association (EMLA), Ethiopia, ² Addis Ababa University, College of Health Sciences, School of Allied Health Sciences, Department of Clinical Laboratory Sciences, ³ Office of the Ministers, Federal Ministry of Health of Ethiopia, ⁴ Addis Ababa University, College of Health Sciences, School of Medicine, Department of Internal Medicine

Determination of the Magnitude of Hepatitis B Viral Infection in Healthcare Workers; Addis Ababa, Ethiopia

Background: H Hepatitis B virus infection is a serious global health problem, with 2 billion people infected worldwide, and 350 million suffering from chronic HBV infection. About 3 million healthcare workers face occupational exposure to bloodborne viruses each year in which about 2 million to hepatitis B virus infections. This study was conducted to determine the magnitude and associated risk factors of Hepatitis B viral infections in healthcare workers.

Methods: Data were obtained from a cross-sectional study conducted in St Paul Hospital Millennium Medical College, among healthcare workers from November 2013 – May 2014. A convenient sampling method was utilized to get the required sample size. A structured questionnaire was used to capture individual socio-demographic characteristics and associated risk factors. Five ml blood was collected, centrifuged and the serum was analyzed for the serologic markers of HBsAg, anti-HBc and anti-HBs using Chemiluminescent Microparticle Immunoassay. Descriptive and logistic regression models were used for analysis.

Results: Among the 313 healthcare workers, the seroprevalence of current hepatitis B viral infection was 2.6%; while prevalence of life time exposure was 25.6%. Prevalence of needle stick and sharp injuries were 33.9% and 35.5% respectively. While, exposure to blood and body fluids were 57.2% and 44.4% respectively. Consistent use of gloves was reported by 49.8% of HCWs. Doctors practiced 71.4% of consistent use of glove, while laboratorians were the least likely to consistently use gloves (40.0%). Only 1.6% of HCWs had completed scheduled vaccination against HBV and 73.8% of HCWs were susceptible to infection. Exposure to blood (COR: 9.351, 95% CI: 1.164 – 75.095, $p < 0.012$), jaundiced and diagnosed liver disease (COR: 3.096, 95% CI: 1.051 – 9.120, $p < 0.032$), and HBV vaccination ($c2 = 11.145$, $p < 0.002$), were independent risk factors that were potentially associated with hepatitis B viral infections.

Conclusion: The prevalence of current hepatitis B virus infection and life time exposure to hepatitis B viral infection among health care workers was high. Exposure to potentially infectious body fluids, needle stick and sharp injuries was also high. Whereas a small proportion of healthcare workers are vaccinated against hepatitis B virus infection. Besides the doctors, nurses and medical laboratory professionals; cleaners, porters and general service providers were also at a comparably high or more risk of HBV infection as they interact with patients and clinical wastes. Emphasis to continuous medical education and training on infection prevention and safety precautions, vaccination package to HCWs, compliance with universal precautions, access to safer injection technologies and post-exposure management are strongly recommended to improve safety of HCWs and quality of patient care.

ORAL POSTERS 1.3 LABORATORY QUALITY IMPROVEMENT

DATE: **Monday, 1 December**

TIME: **13:00 – 14:10**

LOCATION: **Ballroom East/West**

CO-CHAIRS: **Lynne Galley**, American Society for Microbiology, United States of America
Varough Deyde, Centers for Disease Control and Prevention, South Africa

13:00

Humphrey Musuluma, Ndubueze Eigbe

FHI360, Abuja, Nigeria

Remarkable Reduction in Downtime Following Implementation of Laboratory Equipment Maintenance Strategy in FHI-360- Supported Hospitals in Nigeria

Background: FHI360 Nigeria is currently implementing the Strengthening Integrated Delivery of HIV/AIDS Services project to assist the Government of Nigeria to reduce the burden of HIV/AIDS by building local capacity to deliver sustainable, high-quality, comprehensive treatment and care. Supported hospital's system strengthening included deployment of 441 testing equipment for CD4, hematology and chemistry. Lack of appropriate strategy of laboratory equipment maintenance inevitably leads long downtimes hence leading to provision of inefficient and suboptimal patient care. We describe findings of a strategy implemented during the past two years which has remarkable increased equipment functionality.

Methods: A four prong strategy was developed aimed at decreasing downtime through outsourced service maintenance for laboratory equipment coupled with capacity building of operators for sustainable efficient utilization. The strategy set out specific terms of reference for the vendor service provision with reporting template, requirement of sharing of biweekly reporting of functionality and tracking of downtime based of first report to vendor, annual vendor performance customer service assessment by equipment operators and pegging quarterly payment for preventive maintenance and repairs on complete verifiable service records.

Results: Equipment downtime reduced drastically from over 30% to the current sustained average of 5 to 8% over two year period which is indicative of over 90% testing equipment functionality for improved patient care through diagnosis and patient monitoring.

Conclusion: Strict monitoring of service providers and increasing operator capacity led to sustained improvement in functionality hence contributing to improved patient care.

13:10

Lambert Mwambarangwe¹, Vicky Cuylaerts², Viateur Musengamana¹, Stephen Agaba¹, Evelyne Kestelyn¹, Tania Crucitti², Irith De Baetselier², Jennifer Van Nuij¹, Janneke van de Wijgert³, Ndagijimana J. Claude¹

¹ Rinda Ubuzima, Kigali, Rwanda, ² Institute of Tropical Medicine, Belgium, ³ Institute of Infection and Global Health, University of Liverpool, Liverpool, UK

Building Effective Onsite Laboratories in Developing Countries: A case Study of Rinda Ubuzima

Background: Rinda Ubuzima (RU) is a research center in Rwanda conducting clinical trials that rely on quality laboratory sciences. Sending samples to laboratories outside the organization is costly and inefficient. Further, offsite laboratories in developing countries do not always adhere to Good Clinical Laboratory Practices (GCLP). We examine the development strategies and effectiveness of the RU onsite laboratory.

Methods: The laboratory performed the following tests for the Ring-Plus Study, a clinical trial on the safety and acceptability of NuvaRing: HIV and pregnancy rapid testing, wet mount microscopy, Nugent scoring, Ison and Hay grading, HSV-2 and syphilis testing. Cervical and vaginal swabs, urine samples, and vaginal rings were processed, stored and shipped to the Institute of Tropical Medicine (ITM) for further testing. ITM established internal and external quality systems to ensure activities were done in accordance with GCLP. ITM and RU collaborated and developed standard operating procedures, analytical plans, assay and equipment validation, external quality assessment, and equipment calibration. ITM held monitoring visits to confirm proper conduct of laboratory procedures including GCLP compliance. Trainings and courses were organized for laboratory staff.

Results: RU demonstrated high levels of competency, with 99-100% concordance in external quality testing. The assessment reports showed that the laboratory attained GCLP standards required for clinical trials. Three of the staff members upgraded their academic levels and two attended a Quality Management System course.

Conclusion: The RU onsite laboratory is capable of producing reliable and timely data offering an alternative to shipping samples outside the organization for laboratory analyses. Regular assessments and trainings are important to increase data reliability and staff competencies. We recommend that onsite laboratories are equipped with the necessary equipment and staff provided with necessary training to build local capacity. Adequate budgets to support GCLP activities should be foreseen.

13:20

Lynne Galley¹, Douglas Abbott¹, John Aldom¹, Janet Maleski¹, Lilian Shija²

¹ The American Society for Microbiology (ASM), Washington, DC, USA, ² Centers for Disease Control and Prevention (CDC)-Tanzania, Dar es Salaam, Tanzania

Quantification of Microbiology Laboratory Mentoring Progress in Tanzania

Background: The Microbiology Laboratory Mentoring Program in Tanzania trains local microbiologists as laboratory mentors, equips them with the ASM Microbiology Mentoring Package to standardize their mentoring approach, and assigns them to Regional hospitals to carry out structured visits. The program has trained twelve mentors to support twelve sites in as many regions; however, several more regions throughout the country are still in need of microbiology service strengthening.

Methods: The Mentoring Program, supported by ASM in partnership with Tanzania Ministry of Health and Social Welfare and CDC-Tanzania, includes tools to quantify the progress of mentored laboratories towards provision of quality service in the diagnosis of common and HIV-related opportunistic infections of public health significance. Mentors measure a laboratory's successful implementation of technical and quality systems using a scored microbiology assessment checklist based on international laboratory standards. Mentors also report routine monitoring of standard operating procedure (SOP) implementation, quality control (QC) compliance, and external quality assessment performance on standardized forms until all targets are met.

Results: The twelve laboratories supported by the Tanzanian mentors have advanced towards ASM-established criteria for program completion: a score of at least 75% on the checklist; implementation of more than 50 SOPs and 20 QC procedures; and performance of at least 80% over two successive bacteriology-specific proficiency tests. Each is at a different stage in the process. By using this approach to measure improvement, mentors have also drawn attention to laboratory system challenges negatively affecting progress, such as supply stock outs and staff transfer.

Conclusion: The local mentor model implemented in Tanzania supports country ownership, increases geographical coverage of Regional microbiology laboratory service strengthening, and sustains capacity building efforts long-term. Clear benchmarks for laboratories to meet and tools to measure progress, allow mentors to complete current efforts and move on to other sites in need of support.

13:30

Stephina Nyoka¹, Nodathini Nazo², Tebogo Tjale², Richard Mareletse², Mankwana Titus², Frederick Lwanga²

1 National Health Laboratory Service, Johannesburg, South Africa, **2** NHLS Mafikeng Laboratory C/o Mafikeng Provincial Hospital, Mafikeng, South Africa

Improvement of the Quality Management System at Mafikeng Laboratory: Benefits of SLMTA Improvement Projects

Background: Implementation of quality management systems poses a critical challenge in various laboratories within the NHLS. Mafikeng laboratory was selected for enrollment into the Strengthening Laboratory Management Towards Accreditation (SLMTA) pilot project. The main objectives for enrolling were to identify key gaps in the quality management system (QMS) as well as achieve measurable improvements while preparing for accreditation.

Methods: The laboratory was audited using the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) checklist to identify gaps and obtain a baseline score. A total of 8 improvement projects (IPs) were issued to laboratory staff to implement, with 6 IPs focusing on technical requirements of ISO 15189 such as quality indicator monitoring, monitoring of internal quality control, staff competency assessment, external quality assurance (EQA) monitoring, validation of methods, and monitoring of referred tests. The other IPs focused on management requirements such as management of customer complaints and document control. To determine the extent of QMS improvement attained through SLMTA, a SLIPTA exit audit and ASLM audit will be conducted.

Results: The SLIPTA baseline audit result was 44% with a 0 star rate. A total of five IPs were completed within the acceptable time frame of 12 weeks resulting in several improvements. All staff were subjected to competency assessments and records were available by the end of 16 weeks. Improvements in the Microbiology and Chemistry sections were also noted at 16 and 12 weeks, respectively. In addition, improvement in terms of enrollment of outstanding methods on EQA was observed. The SLIPTA exit and ASLM audits have been scheduled for May and July 2014, respectively.

Conclusion: A significant improvement was observed from seven of the eight IP's completed in this laboratory, mainly meeting "technical requirements" of ISO 15189. The results obtained from this project indicate that the use of improvement projects is effective in implementation of QMS requirements.

13:40

Angela Amayo, Doris Bota¹, Albert Bunyasi², Mamo Umuro², Jedida Wachira², Jacob Okello¹

1 Management Sciences for Health, Nairobi, Kenya, **2** National Public Health Laboratory Services, Ministry of Health, Nairobi, Kenya

Innovative Improvements in Biosafety Practices Following Biosafety Skill-Based Trainings in Kenya

Background: Risks of laboratory-acquired infections in clinical laboratories has led to national efforts to increase awareness of better practices through biosafety trainings. Some modern biosafety equipments are costly and not affordable for primary care laboratories where workers and patients are exposed to biorisks. Understanding biosafety principles enables laboratory workers to apply innovative approaches to improvise some of the equipments, using readily available materials. The aim of this paper is to describe the biosafety improvements in primary health care laboratories following skills based biosafety training.

Methods: Baseline audits were conducted before training in 34 facilities from 18 counties in Kenya using the Kenya National Safety checklist. The checklist captures the 14 biosafety core elements. Trainees developed workplans for biosafety improvements during the biosafety training. Follow-up mentorship visits were conducted at least 4 months after the training and laboratories were re-assessed. Improvements made were documented.

Results: From June 2012 to March 2014, workers from 216 facilities were trained. Baseline assessments in 34 facilities showed poor waste segregation in 33 facilities (97%), lack of standard safety equipment in 29 (86%), poor laboratory access control in 24 (71%), absence of staff Hepatitis B vaccination in 22 (65%) and poor chemical management in 19 facilities (56%). Follow-up visits to 6 of the 34 facilities showed improvements including improvised eye wash stations and spill kits (n=5), innovative separation of patient waiting and testing areas (n=4), improvised accidents and incidents documentation (n=5) and Hepatitis B vaccination of staff (n=3). Effective management advocacy was evidenced by facility-initiated procurement of bin liners and counter books in all six facilities.

Conclusion: Notable improvements in biosafety practices, including innovations, indicate that the training approach enabled the learners to understand biosafety principles, and motivated them to apply the same to address biosafety challenges.

13:50**Talkmore Maruta**¹, Katy Yao², Sikhulile Moyo³, Nqobile Ndlovu¹

1 African Society for Laboratory Medicine, Addis Ababa, Ethiopia, **2** International Laboratory Branch, Division of Global HIV/AIDS, Center for Global Health, Centers for Diseases Control and Prevention, Atlanta, GA, USA, **3** Botswana-Harvard AIDS Institute Partnerships, Botswana-Harvard HIV Reference Laboratory, Gaborone, Botswana

Training-of-Trainers: A Strategy to Build Country Capacity for Effective SLMTA Expansion and Sustainability

Background: The Strengthening Laboratory Management Toward Accreditation (SLMTA) program uses a training-of-trainers (TOT) model to build capacity for program scale-up. It is designed to maximize utilization of its TOT graduates while minimizing inconsistencies and ensure high program quality during global expansion.

Methods: The 2-week SLMTA TOT enables participants to facilitate the SLMTA curriculum effectively and implement the process authentically. The TOT follows the teachback methodology where participants practice teaching the curriculum while learning its content. Master trainers lead the TOT and coach participants on their teachback assignments. A trainer's toolkit provides all the materials necessary to teach each of the 44 activities in the SLMTA curriculum as well as preparation instructions and teaching protocols. Incoming TOT participants are carefully screened to ensure future availability to execute program activities. Two surveys were conducted to assess the effectiveness of the TOT strategy: one sent to 316 TOT graduates in 25 countries and the other sent to the program leads in 10 countries that have hosted a local TOT workshop.

Results: By the end of 2013, the SLMTA TOT program has produced 433 SLMTA trainers; they in turn have trained more than 1,600 people to implement SLMTA in 501 laboratories in 39 countries. Ninety-seven percent (97%) of the 433 TOT graduates and 87% of the 38 master trainers are based in developing countries. In a survey sent to all TOT graduates as of March 2013, 92% have been utilized at least once in program implementation, and as of August 2013 87% of them were still actively involved in program activities. Ninety-seven percent (97%) of the surveyed TOT graduates stated that the TOT workshop prepared them well for training or other program tasks.

Conclusion: The SLMTA TOT strategy is effective in building local capacity for global program expansion while maintaining program quality.

TUESDAY, 2 DECEMBER 2014

ORAL POSTERS 2.1 LABORATORY INFORMATION MANAGEMENT SYSTEMS

DATE: **Tuesday, 2 December**

TIME: **13:00 – 14:10**

LOCATION: **Ballroom East/West**

CO-CHAIRS: **Amitabh Adhikari**, Centers for Disease Control and Prevention, United States of America
Matilu Mwau, Kenya Medical Research Institute, Kenya

13:00

Chioma Nwuba^{1,2}, Ogbuikpe Inmpey¹, Vincent Ihaza¹, Okechukwu Agbo¹, Sunday Aguora³, Innocent Ibegbunam³, Elvis Okafor³, Theophilus Faruna³

1 Supply Chain Management System, John Snow Incorporated, Enugu State, Nigeria, 2 Texila American University, Guyana, 3 Supply Chain Management System, John Snow Incorporated, Abuja, Nigeria

Strengthening Laboratory Supply Chain Management Systems for Improved Uptake of Prevention of Mother to Child Transmission Services in Six States in Nigeria

Background: Availability of HIV laboratory commodities in sufficient quantities at service delivery points is key to achieving the ambitious target set for prevention of mother-to-child transmission (PMTCT) of HIV in Nigeria. This is, however, impeded by commodity distribution challenges and late submission of consumption reports, coupled with low commodity delivery coverage for rural clinics, resulting in frequent stock-outs of essential commodities and the need for many pregnant women to travel long distances to access antiretroviral therapy at urban clinics.

Methods: To improve access to HIV testing services and PMTCT drugs for pregnant women with HIV, USAID funded SCMS project implemented the following interventions at 377 rural clinics in six focus states: • Integrated 10 existing parallel HIV/AIDS commodity management systems in the region to form a unified system for commodity storage and distribution. • Unified the collection of logistics management information reports with existing data collection systems, facilitating timely report submission to inform resupply decisions. • Introduced simplified commodity reporting forms to aid community health workers in the collection and timely submission of accurate consumption reports. • Initiated bi-monthly cluster review meetings which provides a forum for service providers and state supply chain management teams to have access to continuing education on HIV commodities management and to share best practices in patient and commodity management.

Results: With improved availability of test kits, the number of pregnant women tested for HIV increased from 39,044 pre-intervention to 79,384 post-intervention. Subsequently, quantity of test kits ordered increased by 98.5% post-intervention. After

six months, reporting rate for PMTCT drugs and HIV test kit consumption increased from 54.0% to 78.6% and 60.5% to 77.5%, respectively. Introduction of cluster review meetings and simplified commodity reporting forms in rural clinics has improved the quality and timely submission of consumption and requisition reports for resupply decision making.

Conclusion: Strengthening existing supply chain management systems to prevent stock-outs of essential laboratory commodities is crucial for preventing new HIV infections among children and for improving the lives of pregnant women with HIV in Nigeria.

13:10

Meghan Wareham¹, Victor Bigira¹, Brian Ngwatu¹, Betty Mirembe¹, Charles Kiyaga², Isaac Sewanyana², Peter Elyanu³, Eleanor Magongo³, Jeff Grosz¹

1 Clinton Health Access Initiative, Kampala, Uganda, 2 Central Public Health Laboratories, Ministry of Health, Kampala, Uganda, 3 AIDS Control Programme, Ministry of Health, Kampala, Uganda

Tracking ART Initiation with Laboratory Information Systems: the Implementation of HIV-Positive Infant Follow-Up Forms for Improved Retention in Care at Health Facilities in Uganda

Background: The Central Public Health Laboratories (CPHL) in Uganda operates an efficient, high-volume centralized national laboratory and accompanying database for Early Infant Diagnosis (EID) testing, with more than 88,000 tests run in 2013. The EID database records all public sector test results; however, no feedback mechanism exists between facilities and the Ministry regarding the outcome of positive infants.

Methods: To address this loss, CPHL in partnership with the Clinton Health Access Initiative (CHA) and the Ministry of Health (MOH) has developed a tool, the HIV Positive Infant Follow-Up Form, to track the receipt of positive EID test results by caregivers and ART initiation. These forms are automatically generated by the EID database and sent with EID test results to health facilities. The forms are completed at facilities and returned to CPHL, where the results are entered into the database. The follow-up form addresses whether the caregiver received test results, whether the child was initiated on ART, and whether the child was referred to another facility. Follow-up forms are sent to facilities on a monthly basis. The Ministry began rolling out this system nationally in April 2014.

Results: To date, follow-up forms have been sent to over 130 health facilities. From preliminary analysis of facility-level data for 932 infants, some 49% of positive infants were initiated on ART. The major causes of loss-to-follow-up were failure of the caregivers to retrieve results (8.7%) and child deaths (6.5%). Initial impact assessment for the follow-up forms is due after six months of implementation, and additional data will be available by October 2014.

Conclusion: The follow-up forms offer a means of tracking ART initiation among positive infants and identifying the key causes of loss. This system offers a model for improving laboratory information systems beyond diagnosis to address patient outcomes and foster retention in care.

13:20 CANCELLEDMark DeZalia^{1,2}, Janise Richards¹, Beth Skaggs^{1,3}

¹ Centers for Disease Control and Prevention, Atlanta, GA, USA, ² The St. John Group, Atlanta, GA, USA, ³Centers for Disease Control and Prevention – Mozambique, Maputo, Mozambique

Review of Laboratory Information Management Systems in Mozambique: Implementation Successes and Challenges

Beginning in 2006, the President's Emergency Plan for AIDS Relief (PEPFAR) funded standardization of paper-based laboratory information management systems (LIMS) at all laboratory levels and implementation of an electronic LIMS (eLIMS) in selected reference and provincial hospital laboratories in Mozambique as part of efforts to strengthen the national laboratory network. Implementation of the eLIMS occurred over many years and involved international and local stakeholders. To understand the successes and challenges of the eLIMS implementation process, a review was conducted that focused on 1) infrastructure improvement and facility readiness, 2) training LIMS users to incorporate it into daily workflows, 3) coordination with health information stakeholders, and 4) planning for local ownership and sustainability. Methodology consisted of planning documentation and training activities reviews; structured interviews with informants at six eLIMS and six comparable paper-based sites, MOH stakeholders, and key implementing partners; technology reviews at eLIMS sites; and laboratory workflow observation. The review revealed that many factors affected the eLIMS implementation process. Among these were: 1) lack of comprehensive project planning that coordinated eLIMS implementations with other laboratory improvement activities, 2) frequent staff rotations within laboratories in which eLIMS had been implemented that made eLIMS training challenging, 3) a vendor without a local presence, 4) lack of a change management process, and 5) no clear plans for transition of LIMS support and maintenance to MOH. Findings suggest that the eLIMS implementation was complicated by an unintentional programmatic separation of technology implementation from general laboratory quality improvement activities. Implementation preceded PEPFAR's stepwise laboratory quality improvement program that defines a laboratory documentation and records management standard and builds laboratory technicians' capacity to analyze and use laboratory information to manage and improve laboratory services. These findings highlight that technology alone does not improve laboratory efficiency; technology can enhance or detract from efforts to improve laboratory quality.

13:30Claude Muvunyi¹, Wangeci Gatei², Edouard Ntagwabira¹, John Rusine¹, Eugene Habiymbere², Janvier Seromundo¹, Laetitia Gahimbare³, Baptiste Mazarati¹

¹Rwanda Biomedical Center, National Reference Laboratory, Rwanda, ²Centers for Disease Control and Prevention, Rwanda Country Office, ³USAID/DELIVER Project, John Snow, Incorporated (JSI), Rwanda

Scale-up of Laboratory Network in Support of HIV/AIDS Prevention Care and Treatment: Rwanda Experience

Background: In 2004 donor funding increased, allowing Rwanda to respond emphatically to the HIV/AIDS epidemic by expanding access to care and treatment for all. A situational analysis of the laboratories showed 70% failed to meet basic standards of clinical laboratories. This process and outcome monitoring describes some of the results from the scale-up of laboratory services.

Methods: The National Reference Laboratory (NRL) heads a tiered laboratory system coordinating all laboratory services in the country and provided the results presented. Data on number of testing facilities, test packages and infrastructure at each site is collected routinely. NRL reports on annual PEPFAR progress reports for clinical care indicators including HIV rapid tests, CD4, viral load (VL) and other routine clinical tests. Additionally, NRL participated in an overall laboratory network assessment in 2011 and in 2013.

Results: The number of sites testing for HIV in both VCT and Provider Initiated Testing Centers increased from 129 in 2004, to 493 by 2013 with a cumulative total of over 16,000,000 HIV rapid tests. The scale-up of ARVs required testing for clinical staging and monitoring virological failure. In 2006, only seven sites had CD4 capacity, increasing to 27 by 2010 and 74 by 2013 including 22 point of care CD4 sites. Initially VL and EID were tested only at NRL. The number of VL done increased from 14,426 in 2010 to 67,264 by 2013 which warranted decentralization. Presently, 7 other sites have capacity to do VL in each province and 15 sites have GeneXpert equipment for TB diagnostic support.

Conclusion: Over the last 10 years, Rwanda has expanded laboratory capacity significantly. Major challenges include inadequate human resources, inefficient procurement process and equipment management, and inadequate infrastructure. However Rwanda has laid the ground work for a strong laboratory system to ensure accessible, affordable and reliable services nationwide

13:40

Abdoulaye Ouattara¹, E.V. Adjogoua¹, A V Akran¹, M Kamagaté², G Elia³, G T Gueu¹, M. Dosso¹

¹ Pasteur Institute, Côte d'Ivoire, ² Service de Pharmacologie clinique, UFR Science médicale, Université Felix Houphouët Boigny, Côte d'Ivoire, ³ Sanofi Pasteur, Côte d'Ivoire

Burden of Febrile Illness in Côte d'Ivoire: When Clinical Diagnosis Mismatched with Laboratory-Confirmed Cases in Malaria Control

Background: Fever is a commonly presenting complaint among persons seeking healthcare in low resource areas. Presumptive treatment of febrile illness patients for malaria remains the norm in endemic areas of West Africa, and malaria remains the top source of health facility outpatient visits in many West African nations. But many other febrile illnesses, including bacterial and viral infections, share a similar symptomatology as malaria and are routinely misdiagnosed as such; yet growing evidence suggests that much of the burden of febrile illness is often not attributable to malaria. To address this problem, the World Health Organization (WHO) malaria treatment guidelines moved away from clinical diagnosis of malaria to treatment based on the results of a malaria diagnostic test such as blood smear or malaria rapid diagnostic test. We sought to highlight comprehensively the gap between syndrome-based diagnosis and malaria laboratory-confirmed cases into two hospitals in Abidjan to enhance the interest of biological confirmation in out or inpatient management.

Methods: We prospectively studied a cohort of 812 pediatric and adult febrile admissions to two hospitals in Abidjan over the period of one year using thick blood smear for malaria and IgM ELISA or real-time RT-PCR for Dengue Fever. The clinical signs and the initial diagnosis after patient examination have been specified during the data collection.

Results: Malaria was identified in 234 of the 807 blood samples proceeded. Among the 406 febrile cases where malaria was retained as clinical diagnosis at the end of consultation, thick blood smear was negative for 246 (60.6%) of them. For the 401 febrile cases with other syndrome-based diagnosis, malaria was detected in 74 cases (18.5%). Two patients with initial clinical diagnosis of malaria were really Dengue Fever cases after laboratory confirmation.

Conclusion: Malaria clinical misdiagnosis could be avoided now in resource-limited areas because malaria rapid diagnostic test are available.

13:50

Clement Ndongmo¹, Esther de Gourville¹, Victor Mudenda², Hamakwa Mantina², Edward Mwabuka², Charles Nyambe³, Clement Phiri⁴, Kenneth Langraaf⁴

¹Centers for Disease Control and Prevention Country Office, Lusaka, Zambia, ² University Teaching Hospital, Lusaka, Zambia, ³ Ministry of Health, Lusaka, Zambia, ⁴ Association of Public Health Laboratories, USA

Modernization of Laboratory Information Management System At the University Teaching Hospital, Zambia

Background: The University Teaching Hospital (UTH) is a 1,863 bed national referral hospital in Zambia with a comprehensive laboratory service testing over 40,000 samples per month in ten technical units housed in separate buildings on the UTH campus. In 2012 UTH implemented a project and upgraded from manual to electronic Laboratory Information Management System (LIMS) to improve testing efficiency, sample tracking and reduce delays in obtaining results.

Methods: The Association of Public Health Laboratories (APHL) was contracted by the United States (US) Centers for Disease Control and Prevention (CDC) to provide oversight for LIMS implementation at UTH, in collaboration with Ministry of Health (MOH). An on-site gap analysis identified and summarized the scope of work and financial implications, resulting in a Request For Proposals (RFP) to select a vendor. Three potential vendors presented their LIMS at a joint stake-holders' meeting. Laboratory System Technologies Proprietary software, Disa*Lab was selected and LIMS implementation spanned March to November 2013. LIMS impact is being evaluated through monitoring trends within laboratory turnaround time (TAT) for key laboratory analytes.

Results: LIMS implementation required establishment of: a centralized sample registration centre; a Local Area Network to link laboratories; 65 computer work stations; 25 interfaced automated analyzers; 162 trained users; and communication capacity for results delivery. TAT times for indicator analytes of alanine amino transferase, full blood/differential count, and malaria parasite microscopy were 96, 54 and 24 hours, respectively, in December 2013 and 22, 8, and 5 hours by April 2014, representing an 80% average improvement in TAT.

Conclusion: The impact of the LIMS was quickly evident in faster results for patient care. Observed, though not measured, were improved operational efficiency, decongestion of the out-patient department, improved biorisk management and reduction of laboratory work interruptions because non-laboratory personnel no longer deliver samples and collect results within laboratory areas.

ORAL POSTERS 2.2

ROLE OF LABORATORY IN EPIDEMIOLOGY

DATE: **Tuesday, 2 December**

TIME: **13:00 – 14:10**

LOCATION: **Ballroom East/West**

CO-CHAIRS: **Namita Singh**, Clinton Health Access Initiative, India
Tura Galgalo, Field Epidemiology Laboratory Training Program, Kenya

13:00

Catherine Okoi, Martin Antonio

Medical Research Council(MRC) Unit, The Gambia Vaccinology Theme, Banjul, The Gambia

Non-tuberculous Mycobacteria (NTM) in The Gambia – A Pilot Study

Background: In sub-Saharan Africa, the contribution of non-tuberculous mycobacteria (NTM) to the aetiology of pulmonary TB-like disease is uncertain. The aim of this pilot study was to generate data regarding the clinical relevance of NTM to pulmonary respiratory disease in the Gambian population making use of the platform provided by a nationwide TB prevalence survey.

Methods: Sputa from eligible participants who had abnormal chest X- ray and/or symptoms suggestive of pulmonary tuberculosis (PTB) were cultured using the MGIT 960 system. DNA was extracted from all culture positive isolates confirmed not to be *Mycobacterium tuberculosis* complex (MTBC) using the BD MGIT TBc identification test. These isolates were further characterized using 16S rRNA gene sequence analysis.

Results: 16S rRNA gene sequence analysis was performed on DNA isolated from suspected NTM cultures from 57 patients. Eight (14.8%) patients had NTM isolated from their sputa. (37.5%) of these patients had *M. kansasii* and 62.5 % had *M. avium* complex. One patient with *M. kansasii* was sputum smear positive and met the stringent American Thoracic Society (ATS) criteria for NTM lung disease.

Conclusion: The finding of 14% NTM in this study is significant and warrants further evaluation to identify characteristics and phenotypes of subjects with NTM as compared to those with MTBC and non-NTM.

13:10

Tadesse Menjetta¹, Serkadis Debalke², Daniel Dana²

¹ Hawassa college of Health Sciences, Hawassa, Ethiopia, ² Jimma University, Jimma, Ethiopia

Prevalence and Risk Factors Associated with Intestinal Helminthic Infections with Special Emphasis to *Schistosoma Mansoni* among Fishermen at Lake Hawassa, Southern Ethiopia

Background: Schistosomiasis and other intestinal helminthiasis are among the most common parasitic infections in developing countries and their impact on public health has been underestimated even if they cause considerable morbidity and mortality. Schistosomiasis like other neglected tropical diseases is a disease of poverty. It particularly affects agricultural and fishing populations. In Ethiopia, many surveys have shown that schistosomiasis and helminthes infections represent a major public health concern.

Methods: A community based cross-sectional study was conducted from April to June 2013 in Hawassa, Southern Ethiopia. A total of 243 study subjects were included and systematic random sampling method was applied. Data on socio demographic features and other predisposing factors were collected by using semi structured questionnaires. Stool samples were collected and processed using wet mount, Kato-Katz and formol-ether concentration techniques.

Results: Of the total 243 stool samples examined, 169 were positive for one or more of intestinal helminthes with an overall prevalence rate of 69.55 %. The overall prevalence rate of *S.mansoni* was 29.22%. The other most frequent intestinal helminthes were: *A. lumbricoides* 99 (40.74%), *T. trichiura* 87 (35.80%) and hookworm species 14(5.76%). The prevalence of *S. mansoni* was associated with factors such as swimming, frequency of swimming and frequency of water contact.

Conclusion: The prevalence of *S. mansoni* infection observed in this study indicates that the fishermen could become a potential source of infection and therefore are responsible for parasite transmission. This study had also identified risk factors like habit of hand washing after defecation and before meal and shoe-wearing habits that are associated with helminthes infections other than *S. mansoni*. Therefore, therapeutic intervention and health education are needed.

13:20

Adegboyega Oladipo¹, Adekunle Olowe², Saturday Udoh¹

¹ Medical Microbiology & Parasitology Department, Obafemi Awolowo University Teaching Hospitals Complex (OAUTHC), Osun State, Nigeria, ² Department of Medical Microbiology and Parasitology, Ladoké Akintola University of Technology (LAUTECH), Oyo State, Nigeria

TEM, CTX-M and SHV Beta-Lactamases in Clinical Samples of Klebsiella Pneumoniae Isolated in OAUTHC, Ile-Ife, Nigeria

Background: Extended Spectrum Beta Lactamases (ESBLs) that mediate resistance to 3rd generation cephalosporins are now observed worldwide. Numerous types of ESBLs exist and can be found in nosocomial infections with Klebsiella pneumoniae strains in hospitals. However, there is no information available on the detection and prevalence of beta-lactamases of Klebsiella pneumoniae in clinical samples in Obafemi Awolowo University Teaching Hospitals Complex, Ile-Ife, Nigeria.

Methods: In this analytical cross sectional study, between January 2012 and January 2013, 600 isolates were received from different clinical samples. Susceptibility of the isolates to different antibiotics was determined by disk diffusion method using NCCLS guidelines. The MICs of ceftazidime was determined using broth dilution assay. Isolates showing MICs \geq 4 μ g/ml for ceftazidime were phenotypically confirmed for ESBL production using double disc synergy method. The positive ESBL isolates were subjected to Polymerase Chain Reaction (PCR) to study the target genes.

Results: Patient's mean age was 65 \pm 26.36 year. Three hundred and twenty six (54.3%) cases were females and Two hundred and eighty two (45.6%) cases were males. Clinical presentation of infection were 189 cases of respiratory infection (31.5%), 129 cases of septicaemia (21.5%), 117 cases of wound infection (19.5%), 96 cases of UTI, (16%), 36 cases of STI (6%) and 33 cases of meningitis (5.5%). All the isolates were sensitive to imipenem. Resistance to ceftazidime and cefotaxime were 43.5% and 46.2 % respectively. Frequency of 375 (62.5%) cases of positive ESBL was recorded. The prevalence of SHV, CTX-M and TEM genes among these isolates were 32% (n=120), 36% (n=135) and 32% (n=120) respectively.

Conclusion: The incidence of ESBL producing isolates of Klebsiella pneumoniae is high in OAUTHC, Ile-Ife, Nigeria. Routine evaluation of ESBL producing pathogens in the hospital can help clinicians in empirical treatment of high risks patients with serious nosocomial and community acquired infections infection.

13:30

Seynabou Lo¹, Papa Amadou Niang Diallo², Awa Ba Diallo³, Ndèye Amy Diagne², Aicha Marceline Sarr⁴, Rokhaya Diagne⁵, Mamadou Lamine Dia³, Aissatou Gaye Diallo³

¹ Faculty of Health Sciences, University Gaston Berger of Saint-Louis, Senegal, ² Laboratoire de Bactériologie-Virologie CHU Le Dantec, Dakar, Sénégal, ³ Faculté de Médecine, Pharmacie et Odontologie, UCAD, Dakar, Sénégal, ⁴ Direction des Laboratoires du Sénégal, JUF Sciences de la Santé, Université de Thiès, Sénégal

Microbiological Investigation of the Risk of Nosocomial Infections in Four Services of Aristide Le Dantec Hospital, Dakar, Senegal

Background: Nosocomial infections (NI) or associated care infections are infections acquired in hospital or in a care facility. They are common and vary from country to country depending on the level of development especially in intensive care units as resuscitation. The environment, human resources and equipment play an important part in the transmission of NI. This work is an overview of risks related to NI in order to implement a control committee in Aristide le Dantec Hospital (HALD).

Methods: Samples from hands of personnel and equipment were made by swabbing then discharging into a thioglycollate broth and resazurin. Environmental samples were collected by exposing Mueller Hinton agar plates at different locations for 1 hour and then transported to the laboratory and incubated at 37°C for 18-24hours. Microscopic examination after Gram staining the colonies obtained and broths allowed to proceed in isolation in specific environments and identification algorithms with the laboratory. Antimicrobial susceptibility was performed according to the procedure of the Antibiogram Committee of the French Society of Microbiology (CA-SFM).

Results: Two hundred and forty four (244) bacteria strains were identified in the environment (110) hardware (79) and staff (56). For E. coli and Klebsiella spp, the activity of Aminoglycosides was better than Quinolones. Two strains of multiresistant Citrobacter spp were isolated. Strains of Enterobacter spp were isolated from personnel equipment and environment. Among staphylococci 49% of MRSA (Methicillin Resistant to Staphylococcus aureus) was noted.

Conclusion: Findings show a large diversity of bacteria into three sites and high contamination levels. The bacteria diversity identified in the four sites shows very high levels of contamination. The frequency of Gram-positive cocci was noted in the environment and Gram-negative bacilli on the equipment. High rates of resistance should be conducted to a surveillance and prevention of nosocomial infections by microbiology laboratories.

13:40

Patrick Malumba Kabitantshi

Institut National de Securite Sociale 'INNS', Kinshasa, République Démocratique du Congo(DRC)

Facteurs de Pronostic de l'Accès Pernicieux Palustre de l'Enfant à Kinshasa

Background: Cette étude a pour objectif de déterminer les facteurs de pronostic de l'accès pernicieux de l'enfant dans un hôpital pédiatrique, ultime niveau de référence dans la pyramide des soins.

Methods: Nous avons mené une étude transversale auprès des enfants âgés de 1 mois à 180 mois admis et hospitalisés pour accès pernicieux palustre selon la définition de l'OMS. Les variables suivantes ont été étudiées :l'âge,le sexe,les délais avant l'admission à l'hôpital,les motifs d'hospitalisation, Poids à l'admission, les différentes formes colligées,le traitement à la quinine avant l'admission,La Transfusion sanguine,L'évolution, la parasitémie,l'hypoglycémie,le standing familial. Les données ont été saisies à l'aide de logiciel Microsoft Excel et analysées avec le logiciel SPSS 10.0.7. Les variables prédictives de décès étaient recherchées en analyse bivariée par un test du Khi carré de Pearson ou par un test de Fisher exact, puis en analyse multivariée, pour les variables ayant un degré de signification inférieur à 0,30, par une régression logistique multiple selon le modèle pas à pas descendant. La valeur de $p \leq 0,05$ a été considérée comme significative.

Results: Plus de la moitié des enfants qui sont venus en consultations durant la période de notre étude étaient des garçons soit (63,9%), le sexe ratio de 1,7. 35,1% des enfants consultés avaient l'âge inférieur à 24 mois. Le délai entre le premier jour des manifestations cliniques et la consultation dans le service était en moyen de 6 jours avec intervalle de 1à15 jours. Le motif de l'hospitalisation le plus fréquemment était la prostration (46,3%) patients dès leur arrivée à l'hôpital. Des toutes les formes colligées, la forme digestive était la plus fréquente(39,8%),64,9% avaient reçu la quinine avant leur arrivée à l'hôpital. taux de létalité:10,2%, la forme cérébrale était la plus dominante. Parmi les variables étudiées, seule la forme cérébrale a une valeur significative. Nous pouvons remarquer que : l'âge, la forme digestive, le poids ont des valeurs faiblement significatives car leurs probabilité est < 10%.

Conclusion: Des résultats obtenus, il apparaît que l'âge inférieur à 24 mois, la prise en charge tardive, un coma initial, un collapsus cardiovasculaire, un état de mal convulsif sont des facteurs prédictifs du décès. Nous pouvons en définitive remarquer que la forme cérébrale de l'accès pernicieux est la plus mortelle de toutes les formes que présente l'enfant de Kinshasa. Ainsi, un diagnostic rapide et une bonne prise en charge de cette forme grave du paludisme de l'enfant par un personnel qualifié est susceptible d'aboutir à un pronostic favorable.

13:50 **CANCELLED****Louis Mujuwisha**¹, Elizabeth Karlsson², Judy Orikiiriza³, Johan Normark²

1 Department of Pediatrics and Child Health, School of Medicine, College of Medicine and Health Sciences, University of Rwanda,Rwanda, 2 Department of Molecular biology, Umea University Institute, Sweden, 3 Rwanda Military Hospital, Kigali, Rwanda

Sero-prevalence and Risk Factors of HBV Infection in Pediatric Patients Attending Rwanda Military Hospital (October -December 2013)

Background: In recent years hepatitis B virus (HBV) has become common as a single disease entity or as a co-infection. The commonest documented HBV routes of transmission in Low resource settings (LRSs) are mother to child (MTCT), sexual transmission and use of contaminated objects. Our main aim was to assess the sero-prevalence and risk factors of HBV infection in Pediatric patients attending Rwanda Military Hospital after widespread hepatitis B vaccination and early HIV antiretroviral treatment.

Methods: This was a prospective cross sectional study design carried out at Rwanda Military Hospital from October 2013 – December 2013. Children aged 3.5 months -18 years were recruited in the study after fulfilling the study criteria. A pre-coded and pretested questionnaire was administered to capture demographic characteristics and blood samples were removed to carry out HBsAg and HIV ELISA. Data was entered and analyzed using STATA version 10. Ethical clearance was received.

Results: Three hundred and four children were analyzed, with male: female ratio of 1.34:1, aged 3.5 months to 18 years with a mean age of 7.88 years (SD= ±5.5 years). Majority263/304(86.5%) were recruited from the Pediatric Outpatient department clinic with 214/304(70.4%) residing in Kigali Province and the commonest primary caretaker being a parent in 266/304(87.5%). The prevalence of HBV infection was 12/248(4.8%) with mean age of 12.7 years (age range: 2.75-18 years) with highest prevalence 9/12(75%) in >11-18 years and male: female ratio was 10:2. HIV prevalence was 1.6% with no HBV-HIV co-infection. Factors associated with HBV infection were male sex p -value <0.001; OR=9.1(CI: 8.5-9.9) and invasive traditional practices p -value <0.017; OR= 9.7(CI: 1-9.9).

Conclusion: 1. The high HB infection was in the older age thus there is need for providing HB vaccination boosters for the older age group to maximise HB prevention strategies 2. There is need to provide HB treatment beyond those who are HIV positive as our study clearly demonstrates that those infected by HBV were all HIV negative.

14:00

Jelili Ojodu¹, Lucy Maryogo-Robinson²¹ Newborn Screening and Genetics Association of Public Health Laboratories, ² Global Health Association of Public Health Laboratories**Newborn Screening Initiatives for Sickle Cell Disease in Africa**

Background: There is recognition of the importance of newborn screening (NBS) as a public health program in the US and worldwide. Each year thousands of newborns with severe genetic and congenital conditions are identified in the US from state NBS programs. With about 97% of the world's newborns born outside the US and Canada, there is a lot to be learned from interactions between NBS systems around the globe.

Methods: Sickle cell disease (SCD) affects about 100 million people worldwide, and 5% of the world's population are carriers. Over 250,000 infants are born yearly with SCD in Africa of which 60% will die as infants according to World Health Organization. Africa has the highest prevalence of sickle trait in the world with prevalence in Ghana and Nigeria estimated between 15-40%. Through NBS, newborns with SCD can be identified and treated early thus leading to better quality of life and a reduction in morbidity and mortality.

Results: The Association of Public Health Laboratories is currently working with Ministries of Health in several African countries to expand NBS programs and maximize the coverage of screened worldwide. Some African countries have expressed a desire to utilize NBS to improve the delivery of genetic health services.

Conclusion: This presentation will highlight current and future NBS initiatives in several African countries. The goal of these NBS initiatives is to reduce morbidity and mortality related to NBS conditions, using sickle cell disease as a model. At the end of the presentation, participants will be able to describe newborn screening initiatives in African countries.

ORAL POSTERS 2.3

HIV-RELATED DIAGNOSTICS

DATE: **Tuesday, 2 December**TIME: **13:00 – 14:10**LOCATION: **Ballroom East/West**

CO-CHAIRS: **Jackson Hungu**, Clinton Health Access Initiative, Kenya
Madisa Mine, Ministry of Health, Botswana

13:00

Nyasha Chin'ombe

Department of Medical Microbiology, University of Zimbabwe

Laboratory Evaluation of the Frequency of CCR2-V64I Polymorphism in an HIV-infected South African Population

Background: There is currently growing evidence that single nucleotide polymorphisms (SNPs) in some host genes encoding chemokine receptors such as CCR2 may influence susceptibility to HIV infection and/or HIV/AIDS disease progression. CCR2 is known to be minor co-receptor for HIV and is involved in the attachment and entry of the virus into the host cell. The CCR2 V64I polymorphism is found in the coding region of the gene and results in a change of valine to isoleucine (G-to-A transition at DNA nucleotide 190). The homozygous variant, CCR2 V64I-A/A has been associated with delayed AIDS disease progression. Data on the allele frequency of this polymorphism is scarce in African populations where the burden of HIV/AIDS is high. Objective: To investigate the frequency of CCR2-V64I SNP in a cohort of HIV-infected South African population.

Methods: DNA was isolated from blood of the subjects. Polymerase chain reaction and restriction fragment length polymorphism methods were used to evaluate the presence of CCR2-V64I genotypes (A/A, A/G and G/G). Frequencies of A and G alleles were calculated.

Results: Out of the 328 patients genotyped, 5 (1.5%) had A/A, 83 (25.3%) had A/G and 240 (73.2%) had G/G. The frequency of the A allele was 14% in this population. This was almost comparable to what has previously been found in African-Americans where the frequency was 15%. However, this frequency was higher than what has previously been found in Caucasians where it was 10%.

Conclusion: Our findings suggest that gene variants in chemokine receptors such as CCR2 may affect critical pathways in HIV infection in African populations. Acknowledgements: Claude Leon Foundation, Medical Research Council

13:10

Ebot Walter Ojong¹, Eric Akum Achidi², Anna Longdoh Njunda², Henri Lucien F Kamga³

¹ Department of Medical Laboratory Science, Faculty of Allied Medical Sciences, College of Medical Sciences, University of Calabar, Calabar, Nigeria, ² Faculty of Health Science, University of Buea, Cameroon, ³ Faculty of Health Science, University of Bamenda, Bamilli, Cameroon

Effects of Antiretroviral Therapy on Lipid Profile Levels of HIV Positive Patients at the Nylon District Hospital, Douala, Cameroon

Background: Although antiretroviral therapy (ART) substantially reduces morbidity and mortality in human immunodeficiency virus (HIV) positive patients, maintaining patients on ART for long term may be restricted by dysregulation of lipid metabolism which predisposes to an increased risk of developing cardiovascular diseases. The aim of this study was to investigate the effects of ART on lipid profile so as to provide useful data for better management of HIV patients who are placed on ART throughout life.

Methods: We carried out a cross-sectional study from March to August, 2012 at the Nylon District Hospital. Demographic data were collected using a well-structured questionnaire. Venous blood samples were collected from an equal number of ART-naïve patients, ART initiated patients and apparently healthy HIV negative control subjects (n = 100). Triglycerides (TG), total cholesterol (TC), high density lipoprotein cholesterol (HDL-C) and low density lipoprotein cholesterol (LDL-C) were determined using standard laboratory investigation methods. Independent sample t-test statistical analyses were carried out on the data using SPSS.17. P value <0.05 was considered as statistically significant.

Results: All subjects were between the ages of 3 to 63 years. The mean duration of treatment with ART was 20.77 ± 21.5 months. The mean serum HDL-C (43.44mg/dl) of ART-naïve patients was significantly lower than the control group (p<0.05). Mean serum TC and LDL-C of patients receiving ART were significantly higher compared to the control subjects (p<0.05). The mean serum TC, HDL-C and LDL-C of ART initiated group were 185mg/dl, 52.72mg/dl and 103.64mg/dl respectively and were significantly higher compared to the ART-naïve group (p<0.05).

Conclusion: Infection with HIV is characterized by a decrease in serum HDL-C levels. Treatment with ART significantly increases plasma concentration of TC, HDL-C and LDL-C. HIV patients on ART should therefore be closely monitored for alterations in lipid profile levels.

13:20

Chukwuemeka Kennedy Ikechukwu, Adeola Oluboyo, Charles Onyenekwe, Ejeatulu Chukwu Obi

Department of Medical Laboratory Science, Faculty of Health Sciences and Technology, College of Health Sciences, Nnamdi Azikiwe University, Nnewi campus Anambra state, Nigeria

Serum Levels of Bone Minerals and Alkaline Phosphate Activities in HIV-Seropositive Subjects in Nnewi, Nigeria

Background: The high prevalence of bone demineralization among HIV-infected patients in the current therapeutic era has been reported in multiple studies, thus this study was designed to investigate the serum levels of some bone minerals and alkaline phosphatase (ALP) activity in HIV-seropositive subjects.

Methods: This was a case-control (retrospective) study approved by the Nnamdi Azikiwe University Teaching Hospital Ethical Committee (NAUTHEC). A total of 100 subjects (80 HIV-seropositive and 20 HIV-seronegative which served as the control subjects) were investigated. 40 HIV-seropositive subjects were on highly active antiretroviral therapy (HAART) and the remaining 40 HIV-seropositive subjects were not on HAART. Laboratory analyses were carried out on subjects' blood samples with strict adherence to standard operating procedures.

Results: Results showed that there was no significant difference (p>0.05) in the mean serum calcium levels between the control and case groups. The mean serum magnesium level of the control group was significantly higher (p<0.05) than that of the HIV-seropositive patients on HAART, also the mean serum magnesium level of HIV-seropositive patients on HAART was significantly higher (p<0.05) than the naïve HIV-seropositive patients. A significant higher (p<0.05) mean serum phosphate level was observed in the control group than in the HIV-seropositive subjects on HAART, but significantly higher (p<0.05) mean phosphate level was found in naïve HIV-seropositive subjects than those on HAART. The mean serum ALP activity of both the naïve HIV-seropositive subjects and those on HAART was significantly higher (p<0.05) than the control subjects.

Conclusion: The findings from this research showed that there were significant pathologic alterations in the serum levels of the bone minerals and alkaline phosphatase activity in both the naïve HIV-seropositive subjects and those on HAART as compared to the HIV-seronegative control group. We therefore recommend the monitoring of the bone minerals and alkaline phosphatase activity in HIV-infected subjects.

13:30

Hylemariam Mihiretie¹, Asaye Birhanu², Bineyam Taye², Aster Tsegaye²

¹ Department of Medical Laboratory Sciences, Faculty of Medical and Health Sciences, Wollega University, Nekemte, Ethiopia, ² Department of Medical Laboratory Sciences, School of allied health Sciences, Addis Ababa University, Addis Ababa, Ethiopia

Intestinal Parasitosis in Relation to CD4+T Cells Levels and Anemia among HAART Initiated and Non-HAART Initiated Pediatric HIV Patients in Zewditu Memorial Hospital, Addis Ababa, Ethiopia

Background: Intestinal parasites (IPs) are a major concern in most developing countries where HIV/AIDS cases are concentrated and almost 80% of AIDS patients die of AIDS-related infections. In the absence of HAART, HIV/AIDS patients in developing countries unfortunately continue to suffer from the consequences of opportunistic and other intestinal parasites.

Methods: A comparative cross-sectional study was conducted among HAART initiated and non-HAART initiated pediatric HIV/AIDS patients of Zewditu Memorial Hospital (ZMH) between August 05, 2013 and September 25, 2013. A total of 180 (79 HAART initiated and 101 non-HAART initiated) children were selected by using consecutive sampling. Stool specimen was collected and processed using direct wet mount, formol-ether concentration technique and modified Ziehl-Neelson staining techniques. A structured questionnaire was used to collect data on Socio-demographic and associated risk factors. Data were entered and analyzed by using SPSS version 16 software and logistic regressions were applied to assess any association between explanatory factors and outcome variables. P values < 0.05 were taken as statistically significant.

Results: The overall prevalence of IPs was 37.8% where 27.8% of HAART initiated and 45.5% of non-HAART initiated pediatric HIV/AIDS patients were infected with IPs ($p < 0.05$). Cryptosporidium species (found only in non-HAART patients), *E. histolytica/dispar*, Hook worm and *Taenia* species were IPs associated with lower CD4+ T cell counts <350 cells/ μ L. The overall prevalence of anemia was 10% in HAART and 31.7% in non-HAART groups. Intestinal parasitic infection (IPI) was significantly associated with anemia in non-HAART patients [AOR, 95% CI: 4.5(1.3, 15.2), $P < 0.05$]. Hook worm, *S. stercoralis* and *H. nana* were IPs associated with anemia in non-HAART patients. The prevalence of IPs in non-HAART patients was significantly associated with Eating unwashed/raw fruit [AOR, 95%CI: 6.3(1.2, 25.6), $P < 0.05$], open field defecation [AOR, 95%CI: 9.3(1.6, 53.6), $P < 0.05$] and diarrhea [AOR, 95%CI: 5.2(1.3, 21.3), $P < 0.05$].

Conclusion: The overall prevalence of IPs differed by HAART status and opportunistic parasites like cryptosporidium species were found in HAART naïve patients with low CD4+ T cell counts. Anemia was also more prevalent and associated with IPs in

non-HAART patients. This study identified some environmental and clinical findings as determinant factors for intestinal parasitic infections. Therefore, Public health measures should continue to emphasize the importance of environmental and personal hygiene to protect infections with intestinal parasites to maximize the benefits of HAART.

13:40

Ekeh Evelyn, Mark Akindigh

AIDS prevention initiative in Nigeria, Jos University Teaching Hospital, Jos, Nigeria

Life Threatening Elevated Serum Alanine Amino Transferase and Creatinine Levels Among HIV-Infected Patients on Haart in Jos, North-Central Nigeria

Background: Highly active antiretroviral therapy (HAART) has increased the life expectancy of HIV infected individuals. However, drug induced liver and kidney damage has increased the risk of liver- and kidney associated mortality. In resource-limited settings (RLS), monitoring liver and kidney toxicities is carried out by estimating the serum levels of aminotransferases and creatinine respectively. We determined the prevalence of life-threatening elevated serum alanine aminotransferase and creatinine levels among HIV-infected patients on HAART at a HIV Clinic in Jos, North-central Nigeria.

Methods: This descriptive study was carried out at the HIV clinic of the Jos University Teaching Hospital from January 2009 to March 2014. The serum alanine aminotransferase (ALT) and creatinine levels of 15,118 patients were examined for life threatening elevation defined as ≥ 120 u/L and $\geq 260\mu$ Mol/L respectively.

Results: The prevalence of life threatening elevation of serum ALT was observed in 566(3.7%) and 78(0.5%) for elevated creatinine. The mean age of males with elevated ALT was 44.7 ± 8.9 years and 38.4 ± 9.6 years for female, median CD4 308 cells/ μ L (IQR 180,461 cells/ μ L) and mean BMI 19.7 ± 5.4 kg/m². Although no significant difference was observed between sex $p=0.887$ there was a significant difference in mean age between sexes ($p < 0.0001$). The mean age for males with elevated creatinine was 48.3 ± 15.4 years and 38.3 ± 8.5 years for females with significant difference for age ($p=0.0007$). The median CD4 was 125 cells/ μ L (IQR 53.5, 256), mean BMI 16.8 ± 3.4 kg/m² and no significant difference between sexes ($p=0.09$).

Conclusion: The prevalence of life-threatening elevation of serum ALT and creatinine was low among HIV-infected patients in Jos. The monitoring of serum ALT and creatinine levels for liver and kidney related toxicities among HIV infected individuals receiving HAART remains a useful tool in RLS. Further studies on risk factors associated with elevated serum ALT and creatinine levels among HIV-infected patients on HAART in Nigeria are needed.

13:50

Kwimatou Lekpa

Centre MURAZ, Laboratoire de Virologie, Bobo-Dioulasso, Burkina Faso.

Assessment of the “Biocentric” and “Nuclisens” assays using DBS for HIV-1 early Diagnosis and Viral Load Quantitation

Background: In Africa, special conditions of sampling process limit the pediatric HIV early diagnosis and viral load (VL) measurement in HIV-infected patients taking HAART. We have assessed two commercial RT-PCR systems using DBS as an alternative for blood collection in Burkina Faso.

Methods: Children born to HIV positive mothers (n=127) and HIV-1-infected patients receiving HAART (n=50) have been included. Plasma samples of all participants were firstly performed using the Biocentric RNA assay. Then, about 48 patients (n=28 with and n=20 without detectable HIV-1 ARN in plasma) have been randomly selected and tested by both Nuclisens and Biocentric RNA assays using paired plasma and DBS samples. Furthermore, PBMC obtained from patients receiving HAART with a plasma VL<5log10/ml were tested by the Biocentric DNA assay. Plasma results were considered as the Gold Standard for DBS test assessment.

Results: HIV prevalence among HIV-exposed children was estimated at 4.7% (CI95%, 1.8-10.0). The mean difference of HIV-1 RNA values obtained in DBS and plasma was estimated at +0.15 log10/ml for Biocentric and -0.36 log10/ml for Nuclisens. This value between Biocentric and Nuclisens assays using DBS was +0.30log10/ml. Good degrees of correlation were observed between the two techniques on DBS (R= 0.72 for the Biocentric and R=0.82 for the Nuclisens). When using Biocentric ARN assay, DBS generated higher values of VL in patients with plasma VL<4log10/ml and similarly plasma generated higher values of VL in patients with VL≥4log10/ml. Six from the 10 samples exhibiting discordant results (undetectable in plasma and detectable in DBS) by Biocentric ARN assay were tested positive using Biocentric DNA assay.

Conclusion: Excellent agreement between DBS and plasma samples with the two assays despite the under quantification in DBS. Proviral DNA contained in PBMC can slightly increase HIV-1 RNA VL values obtained by Biocentric if whole blood is used.

WEDNESDAY, 3 DECEMBER 2014

ORAL POSTERS **3.1** **TESTING AND HEALTH SYSTEM STRENGTHENING**

DATE: **Wednesday, 3 December**

TIME: **13:00 – 14:10**

LOCATION: **Ballroom East/West**

CO-CHAIRS: **Deborah Glencross**, University of the Witwatersrand, South Africa
Emmanuel Idigbe, Nigerian Institute of Medical Research, Nigeria

13:00

Samuel Kwame Opoku¹, Aparna Jha Ahuja²

¹ BD Diagnostics, Preanalytical Systems, Accra, Ghana, ² BD Diagnostics, Preanalytical Systems, Dubai, United Arab Emirates

Assessing Current Preanalytical Practices vs. Best Practices: A Benchmark for Improving Specimen Quality and Patient and Healthcare Worker Safety

Background: The preanalytical phase plays a major role in reliable laboratory testing. Despite the criticality of this phase, non-adherence to best practices in specimen collection continues to dominate current practices. Monitoring preanalytical practices may recognize process gaps and serve as a benchmark for improvement goals. A review of blood collection procedures was performed at three hospitals in Accra, Ghana, in collaboration with BD Laboratory Consulting Services. The objective was to identify areas that may compromise specimen quality, patient and healthcare worker safety.

Methods: Preanalytical observations were performed at each hospital, which included the number of blood collections, specimen collector and device type (safety or conventional needle). Patient safety was defined by identification confirmation, labeling, and gloves/disinfection and healthcare worker safety by the use and proper activation of safety devices, device disposal and needle recapping. Fill volume, hemolysis, and clotting were addressed for specimen quality.

Results: Most of the 362 specimen collections were performed by phlebotomists using a conventional needle or needle/syringe. At least 38% of patients were identified using the minimum identification criteria, 92% of specimen were labeled after collection. Gloves were worn properly 57% during all collections. Safety devices were seldom employed; however, the devices used were properly disposed. Recapping of needles was observed in 88% of phlebotomy procedures. Fill volume was noted to be adequate for most tubes with trace hemolysis identified in some chemistry specimens. All serum tubes were allowed to clot prior to centrifugation.

Conclusion: A range of preanalytical variables play a role in sample quality during phlebotomy and sample processing procedures. Quality control measures enabled the facilities to gain a better understanding of current practices versus best practices, identify opportunities for improvement and guide effective training for healthcare workers.

13:10

Lindi Marie Coetzee¹, Naseem Cassim¹, Deborah K. Glencross²

¹ National Health Laboratory Service (NHLS), National Priority Programme, Johannesburg, South Africa, ² University of the Witwatersrand, Johannesburg, South Africa,

Applying the Integrated Tiered Service Delivery Model (ITSDM) in KwaZulu- Natal (KZN) Province to Identify Optimal Placement of CD4 Testing Facilities

Background: The National Health Laboratory Service (NHLS) developed a six-tiered integrated tiered service delivery model (ITSDM) for accessible CD4 testing in 53 districts with suitable capacity to match test volumes. Historical placement of CD4 facilities evolved in the absence of optimized logistics, resulting in over-servicing. This study reports the application of ITSDM principles to ensure adequate CD4 service/ best-fit placement of testing facilities in the KwaZulu Natal province.

Methods: Test volume and in-laboratory turn-around-time (TAT) data for the 22 CD4 testing facilities were extracted from the Corporate Data Warehouse (CDW) between February 2013 and February 2014. Laboratories were categorized into ITSDM tiers based on test volumes, with instrument capacity and utilization calculated. Laboratories and referring clinics were mapped using ArcMap.

Results: 1.2 million tests were processed (31% of national test volume) across 11 health districts, currently comprising of 5 Tier 5 centralised metro laboratories, 9 Tier 4 district and 8 Tier 3 community laboratories. In-Lab TAT's for all 22 facilities were within 24 hours, with lab-to-lab transfer the biggest contributor to delayed TAT's (>48 hours). Combining test volumes, TAT, workflow data and spatial mapping, the ITSDM model proposed retaining 12 existing CD4 laboratories while consolidating 10 smaller laboratories into existing CD4 sites. Gaps in service were identified where 2 Tier 2 Point-of-Care Hubs were proposed for rural areas that fall out of the service coverage precinct.

Conclusion: Identifying over-/under serviced districts is the initial step towards streamlining CD4 services. By ensuring an appropriately tiered CD4 laboratory per district that can accommodate local test volumes, could potentially impacting positively on in-lab TAT through improved workflow and logistics. However, implementing the proposed changes to the current network is challenging and requires adequate assessment of available laboratory infrastructure, staff capacity, optimal transport

13:20

Nassim Cassim¹, Lindi Marie Coetzee¹, Deborah K. Glencross²

¹ National Health Laboratory Service (NHLS), National Priority Programme, Johannesburg, South Africa, ² University of the Witwatersrand, Johannesburg, South Africa

Assessing the Impact of Implementing a Community CD4 Laboratory in a Rural Health District in South Africa

Background: The CD4 Integrated Service Delivery Model (ITSDM) was developed to ensure equitable access to testing in South Africa. To address the lack of CD4 testing in the Pixley ka Seme health district, a Community laboratory (Tier 3) was established in De Aar. Due to the availability of in-district CD4 testing it was expected that test volumes would increase with a concomitant reduction in turn-around-times (TAT). De Aar laboratory was assessed 12 months after CD4 testing was introduced to assess the impact on local service delivery.

Methods: Using the Corporate Data Warehouse (CDW), CD4 data was extracted for the period April 2012 to July 2013 (n=11 964). Data for December 2012 was excluded as the Epics XLMCLTM/TQPrepTM Beckman Coulter platform was being installed. The mean in-lab TAT (in hours) was assessed for pre-lab (inter-laboratory referral time) and in-lab (testing time following registration). Data anomalies, such as incorrect dates, e.g. 1800/01/01, were excluded (n=36). Data was analyzed using Stata 12.

Results: Using the Corporate Data Warehouse (CDW), CD4 data was extracted for the period April 2012 to July 2013 (n=11 964). Data for December 2012 was excluded as the Epics XLMCLTM/TQPrepTM Beckman Coulter platform was being installed. The mean in-lab TAT (in hours) was assessed for pre-lab (inter-laboratory referral time) and in-lab (testing time following registration). Data anomalies, such as incorrect dates, e.g. 1800/01/01, were excluded (n=36). Data was analyzed using Stata 12.

Conclusion: This study demonstrates that the deployment of in-district CD4 testing substantially reduces in-lab TAT. This was achieved through shorter travel times to the CD4 laboratory. The analytical testing TAT remained unchanged. It is therefore recommended that additional Community CD4 laboratories are established in under serviced areas. Where this is not feasible, logistics/pre-analytical processes should be improved.

13:30

Barry Kosloff^{1,2}, Ingrid Terlouw³, Gregers Chalker³

¹ London School of Hygiene and Tropical Medicine, Department of Infectious and Tropical Diseases, London, UK, ²ZAMBART Project, UNZA School of Medicine, Lusaka, Zambia, ³ Air Filter Maintenance Services, Johannesburg, South Africa

Modular Containment Laboratory-Hybrid (MCL-H): A Novel Design Combining BSL3 Infectious Disease and BSL2 Molecular Laboratories in a Single, Transportable Unit

Background: Modular laboratories are cost-effective, sustainable alternatives to brick-and-mortar buildings for providing urgently-needed laboratory infrastructure in resource-limited settings. Over

the past five years, we have designed, constructed, delivered and commissioned a total of 19 BSL3 infectious disease laboratories and BSL2 molecular laboratories in 7 countries in Africa, South America and the Caribbean. These robust laboratories, constructed within 12-meter steel shipping containers, are transported via truck and ship to sites where traditional construction is too difficult or expensive and they can be relocated, as needed. Ideally, organizations conducting infectious disease research will possess both types of laboratories. Unfortunately, financial and space constraints often make this impossible.

Design: The Modular Containment Laboratory-Hybrid (MCL-H) is a 12-meter unit that combines the capabilities of infectious disease and molecular laboratories. The MCL-H is divided into three or four compartments: an optional office, an anteroom leading to a negative-pressure BSL3 laboratory, and a contiguous BSL2 molecular lab accessed via a separate entrance. The BSL3 is usually equipped with two Class II, Type A2 biological safety cabinets (BSC), centrifuge, MGI 960 and/or conventional incubator, autoclave, refrigerator and freezer. Culture and isolation of infectious organisms and extraction of nucleic acids for molecular assays is performed in the BSL3 laboratory. Amplification and detection of the nucleic acid extracts is performed in the BSL2 molecular laboratory.

Conclusion: The Modular Containment Laboratory-Hybrid (MCL-H) is a cost-effective, sustainable solution for organizations needing both a BSL3 infectious disease laboratory and a BSL2 molecular laboratory, but lacking the financial resources or space for separate facilities.

13:40

Joseph Mwangi, Joyceline Kinyua, Nancy Lagat

Kenya Medical Research Institute, Nairobi, Kenya

Country Based Testing Algorithms and Outcomes in a Blood Donation Setting; Implications on Cost and Future Testing

Background: Prevention of viral transmission by blood and blood products is the main goal of blood transfusion services. While false positive results are expected, high rate of false positivity result in waste of blood and increases cost of running blood programs. To determine the frequency of false-positive HIV-1, HBV and HCV in donated blood using local testing algorithm in Kenya, we re-screened donated blood for the three viruses.

Methods: 1200 samples were tested for HIV, HBV and HCV using two assays. The results obtained at the research laboratory were compared with those obtained at the testing site and two different testing methods used for each virus. Further testing was done using PCR with specific primers for the three viruses.

Results: Results of serological testing at the testing site showed 20 (2.5 %), 15 (1.9 %) and 24 (3 %) samples as positive for HIV, HBV and HCV respectively. Re-testing at the research laboratory showed that 7 (0.87%), 19 (2.3 %) and 0 samples were positive for HIV, HBV and HCV respectively. polymerase chain reaction detected additional 9 and 1, HBV and HCV infected samples respectively that second available sero- assays could not detect as well.

Conclusion: There is a significant number of false positivity in our donor testing system leading to wastage of blood and blood pints which is financial burden to budgets for AIDS programmes. Review of testing algorithm is required in order to mitigate wastage and identify test for improved diagnosis.

13:50

Stanley Kinge Waitthaka¹, Eliud N. Njagi², Joseph N. Ngeranwa², Daniel M. Muturi³, Wilfred K. Gatua³, Bernard M. Chiuri³, Leonard J. Njagi³

1 Mount Kenya University, Thika, Kenya, 2 Kenyatta University, Nairobi, Kenya, 3 Kenyatta National Hospital, Nairobi, Kenya

Quantitative Reference Ranges for Fasting Profiles and Oral Glucose Tolerance Test for Healthy Adults from Metropolitan Region (Nairobi) of Kenya

Background: To establish quantitative reference ranges for fasting profiles and oral glucose tolerance test for healthy adults from metropolitan region (Nairobi) of Kenya

Methods: A prospective study carried out on 871 healthy subjects from the metropolitan region of Kenya. Serum was analyzed using a clinical chemistry auto analyzer Olympus 640AU.

Results: The fasting profile parameters investigated were fasting blood glucose (FBG), total cholesterol (TC) triglycerides (TG), high density lipoprotein cholesterol (HDL), low density lipoprotein cholesterol (LDL) and TC/HDL ratio. In addition, oral glucose tolerance test (OGTT) was also investigated. Eight hundred and seventy one (871) healthy study subjects were involved in the study. Established reference ranges were as follows: FBG (venous whole blood) (2.1 – 5.7) mmol/L, TC (2.9 – 6.4) mmol/L, TG (0.44- 2.44), HDL C (1.1 – 2.1) mmol/L, LDL C (1.1 – 4.3) mmol/L, TC/HDL ratio (1.1 – 5.4). Established reference ranges for oral glucose tolerance test (OGTT) were as follows: baseline/fasting blood glucose capillary whole blood (3.2-5.4) mmol/L, half hour (4.7-8.9) mmol/L, one hour (4.4-9.8) mmol/L, one hour and half (4-8.1) mmol/L and two hours (3.4-7.2) mmol/L. Results for gender differences for the studied parameters were as follows: FBG (p=0.124), TC (p=0.205), TG (p=0.705) HDL C (p= 0.52), LDL C (p=0.417) and TC/HDL ratio (p=0.359). On the other hand, the gender results for timed OGTT were as follows: 0 hour (p=0.123), half hour (p=0.479), one hour (p=0.412), one hour and half (p=0.596) and two hours (p=0.630). Hence there were no gender disparities for the parameters in the studied adult Kenyan population.

Conclusion: Since the established reference ranges are a reflection of the Kenyan adult population our clinical chemistry laboratory reports interpretations will henceforth be independent of what has been quoted in literature. Likewise effective diagnosis and management of glucose and lipids pathological disorders will be achieved by the use of established adult Kenyan reference ranges.

14:00

Desalegn Tesema¹, Aster Tsegaye¹, Gonfa Ayana², Achameleh Mulugeta², Habtamu Asrat², Abnet Abebe²

1 Addis Ababa University, Addis Ababa, Ethiopia, 2 Ethiopian Public Health Institute, Addis Ababa, Ethiopia

Stability of Complete Blood Count and 3-part White Cell Differential Parameters with Storage Time and Temperature Variation Using Cell Dyn 1800 Automated Hematology Analyzer

Background: Complete blood count (CBC) and differential white cell counts are the most commonly ordered tests in clinical practice. These tests should be done within 8 hours based on the usual recommendations of instrument manufacturing companies. However, there is no clear-cut information whenever delayed arrival is unavoidable.

Methods: A total of 45 adult participants, 19 from ART clinic of Tikur Anbessa Specialized Hospital, Addis Ababa, and 26 apparently healthy Medical Laboratory Science students of Addis Ababa University were included in the study using convenient sampling methods. Cell-Dyn 1800 automated hematology analyzer was used for analysis. EDTA whole blood samples were analyzed at baseline before and after aliquoting. Each of six aliquots, for room temperature and 2-8°C storage, one each for transporting with and without an ice box were used. After the baseline analysis of the direct EDTA tube and an aliquot, all specimens were analyzed at 8, 24, 32, 56 and 72 hours of storage. Transported samples were analyzed within 8 hours and compared with baseline values.

Results: WBC, RBC, Hgb, MCH were stable for 72 hours regardless of storage temperature. These values were also unaffected during transportation. MCHC was relatively less stable. PLT counts remained stable in the direct EDTA tube samples stored at 2-8°C for 72 hours while aliquoted samples were less stable, showing a declining trend. MCV and RDW showed an increasing trend due to a change in the red cell size where differences were statistically significant (P<0.05) after 48 hours of storage. WBC Differential was the least stable of all where granulocytes showed a declining and monocytes an increasing trend.

Conclusion: Different CBC parameters showed different levels of stability due to storage, time, and handling conditions. Therefore, each parameter should be treated accordingly if delayance is unavoidable.

ORAL POSTERS 3.2 DRUG RESISTANCE

DATE: **Wednesday, 3 December**

TIME: **13:00 – 14:10**

LOCATION: **Ballroom East/West**

CO-CHAIRS: **Chunfu Yang**, Centers for Disease Control and Prevention, United States of America
Avelin Aghoken, Institut de Recherche pour le Développement, Cameroon

13:00

Aduigna Negussie¹, Gebru Mulugeta², Ahmed Bedru³, Ibrahim Ali², Damte Shimeles⁴, Tsehaynesh Lema⁵, Abraham Aseffa⁵

¹ Department of Public Health Officer, College of Health Sciences, Jigjiga University, Jigjiga, Ethiopia, ² Department of Medical Laboratory Sciences, Addis Ababa University, Addis Ababa, Ethiopia, ³ TB- Care Ethiopia, Addis Ababa, Ethiopia, ⁴ Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia, ⁵ Armauer Hansen Research Institute, Addis Ababa Ethiopia

Bacteriological Profile and Antimicrobial Susceptibility Pattern of Blood Culture Isolates among Septicemia Suspected Children at Tikur Anbessa Specialized Hospital and Yekatit 12 Hospital Addis Ababa, Ethiopia

Background: Blood stream infections are a major cause of morbidity and mortality in children in developing countries. The emerging of causative agents and resistance to various antimicrobial agents are increased from time to time and geography. This study aimed to determine the bacteriological profile and antimicrobial sensitivity patterns among children suspected of having septicemia.

Methods: A cross sectional study involved about 201 pediatric patients was conducted at pediatric units of Tikur Anbessa and Yekatit 12 Hospitals. Standard procedure was followed for blood sample collection. Samples were incubated in the BACTEC 9050 System, and followed by isolate identifications based on standard microbiological procedures and testing for their susceptibility to antimicrobial agents using the disc diffusion method.

Results: Among 201 study subjects 110 (54.7%) were males. Majority 147 (73.1%) of them were neonates. The mean length of hospitalization was 4.29 days. Out of the 201 tested blood samples, blood cultures were positive in 56 (27.9%). Gram negative and Gram positive bacteria constituted 29 (51.8%) and 26 (46.4%), respectively. The frequently found pathogen were *Staphylococcus aureus* 13 (23.2%), *Serratiamarcenscens* 12 (21.4%), Coagulase negative *Staphylococci* 11 (19.6%), *klebsiella* spp. 9 (16%), *Salmonella* spp 3 (5.4%) and *Enterobacter cloacae* 2 (3.6%). Majority of bacterial isolates showed high resistance to Ampicillin, Penicillin, Co-trimoxazole, Gentamicin and Tetracycline. Ciprofloxacin and Nalidixic acid were the most effective antimicrobial agents for Gram negative bacteria while

Vancomycin and Clindamycin to Gram positive bacteria. Deaths occurred in 25 (12.4%) of children out of which 13 (23.2%) of them had bacteremia.

Conclusion: The present study revealed that both Gram positive and Gram negative bacteria were responsible for blood stream infections. Majority of the isolates were multidrug resistant. The alarmingly higher percentages of multi-drug resistant emerged isolates urge us to take infection prevention measures and to conduct other large studies for appropriate empiric antibiotic choice.

13:10

Kodjovi Dodji Mlaga^{1,2}, Kodjovi D. Mlaga^{1,2}, Eugenie A. Anago³, Ségla Togossou⁴, Anoumou Y. Dagnra⁴, Ambaliou Sanni³

¹ Université de Lomé, Togo, ² Medical Research Council Unit the Gambia (MRC), ³ Institut Supérieure de Biotechnologie Appliquée (ISBA), ⁴ Laboratoire de Microbiologie, CHU Sylvanus Olympio

Drug Resistance Profile and Molecular Characterization of Extended Spectrum Beta-lactamase (ESBL) Producing *Escherichia coli* Isolated in Lomé

Background: Betalactam antibiotics belong to one of the families of antimicrobials widely used clinically against bacterial infections. Enterobacteria eventually develop a resistance mechanism by synthesis of beta-lactamase (enzymes) varied as TEM, SHV, and CTXM coded respectively by blaTEM, blaSHV and blaCTXM genes.

Methods: Isolates were from various biological samples such as pus (23), urine (20), vaginal samples (2), CSF (1), blood (2) anthers samples (5) from in and outdoor patients from 2009 to 2010. Susceptibility test was performed on all strains of Enterobacteria isolated using disc diffusion technique on agar plate (Muller Hinton). Biochemical test as well as PCR using specific primers for the detection of beta-lactamases producing was performed on the 53 *E. coli* EPI6 software was used for statistical analysis. The Chi2 values were calculated by the method of comparison of proportions.

Results: The overall prevalence of *E. coli* ESBL is 9.56% and majority of them isolated from pus. The resistance range from 94.34% to 100% among Betalactam group with exception of Imipenem. We observed an associated resistance with quinolone (statistical significance) and aminoglycoside groups. 52.08% of ESBL *E. coli* were resistant to chloramphenicol, 95.74% to trimethoprim – sulfamethoxazole and 95.56% to tetracycline. 98.11% of the *E. coli* isolates, has blaTEM genes and suggest a clonally expansion since ESBL genes are located on plasmids and 94.34% of patients were admitted at the hospital.

Conclusion: Multidrug resistance is related to the mode of circulation of the strain, and transmission can be done by plasmids between bacteria. A better understanding of the epidemiology of resistance will improve the therapeutic management of patients while reducing the prescription of broad-spectrum antibiotics

13:20

Michelle Bronze¹, Kim Steegen², Azwidowi Lukhwari¹, Maria A Papathanasopoulos³, Wendy Stevens^{3, 4}, Sergio C Carmona^{3, 4}

1 National Health Laboratory Service, Johannesburg, South Africa, **2** Wits Health Consortium, Johannesburg, South Africa, **3** University of the Witwatersrand, Johannesburg, South Africa, **4** National Health Laboratory Service, Johannesburg, South Africa

Optimization and Validation of an In-house HIV-1 Genotyping Protocol for Use on Dried Blood Spots in a South African Setting

Background: The Genotyping Laboratory at the Charlotte Maxeke Johannesburg Academic Hospital uses an accredited plasma-based in-house HIV-1 drug resistance (HIVDR) genotyping protocol. There is an imperative need to use dried blood spots (DBS) for HIVDR testing. This work evaluates an optimized version of the currently used protocol to work successfully on DBS.

Methods: Eighty-three (83) HIV-1 subtype C clinical DBS samples (viral load (VL): 400 – >10 000 copies/ml) and 7 VQA samples (VL: 2136 – 22912 copies/ml) were tested with the DBS-optimized protocol. Accuracy testing compared DBS and plasma genotypes. Inter- and intra- assay precision of DBS HIVDR was assessed. Optimization of reagent concentrations, thermocycling and extraction protocols was performed to increase the sensitivity of the DBS-protocol.

Results: Amplification success rates for samples with VL's 1000 – 3000 RNA copies/ml was 56% (18/32), whilst those with VL 3000 – 5000 copies/ml was 83% (24/29). Sequencing success rates for these samples was 95% (40/42). A 94% success rate for both amplification and sequencing of samples with a VL >5000 copies/ml (n=17) was observed. The VQA panel tested revealed that 86% (6/7) amplified, and all amplicons sequenced successfully. Average nucleotide similarities of 99.1% were noted between the two assays, and minor HIVDR and mutation profile differences were attributed to mixtures but had limited clinical implications. Intra-assay precision was more successful than inter-assay precision in terms of amplification success rates, but sequencing success rates were >90% for both sets of precision testing.

Conclusion: This DBS-optimized protocol was comparable with the currently used plasma-based protocol with respect to reaching amplification sensitivity of 1000 copies/ml, sequencing success rates, accuracy and precision. An acceptable genotyping success rate of 83% was observed for samples with a VL range of 3000 – 5000 copies/ml. This assay has been validated and can be implemented for routine HIV-1 genotyping in our laboratory.”

13:30

Aaron Aboderin¹, Iruka Okeke^{2, 3}, Eric Sumrall², Elizabeth Gallo², Adebayo Lamikanra⁴

1 Department of Medical, Microbiology and Parasitology, Obafemi Awolowo University, Ile-Ife, Nigeria, **2** Department of Biology, Haverford College, Haverford, PA, USA, **3** Faculty of Pharmacy, University of Ibadan, Ibadan, Nigeria, **4** Faculty of Pharmacy, Obafemi Awolowo University, Ile-Ife, Nigeria

Genetic Context for the Transmissible Quinolone-resistance Gene qnrS1 in Nigeria

Background: Resistance to fluoroquinolones in Enterobacteriaceae has become globally distributed with little data from West Africa. A study conducted in Nigeria that tracked fluoroquinolone resistance over three decades showed that quinolone resistance emerged in commensal *E. coli* after the 1990s and that qnrS1, is associated with low-level quinolone resistance. As commensals are important reservoirs of resistance genes that can be transferred to pathogens, understanding the genetic context and mechanism of spread of qnrS1 is necessary to conceive strategies for containment.

Methods: Purified plasmids from qnrS1-bearing *Escherichia coli* strain 09/22a from the Nigerian study were transferred to laboratory strains. Plasmid pEBG1 was sufficient to confer ciprofloxacin resistance and was shot-gun sequenced. Sequence annotation was performed using Artemis software the Basic Local Alignment Search Tool and Pfam. Conjugative ability was tested in solid and liquid mating experiments. Deletion analysis was performed to functionally characterize resistance to ciprofloxacin conferred by pEBG1

Results: pEBG1 is a 43,534 bp plasmid with an overall G+C content of 46.72%. Sequence annotation revealed that pEBG1 contains qnrS1 as well as dfrA14 and tetR with tetA genes conferring resistance to trimethoprim and tetracycline respectively. Mutational analysis confirmed that the ciprofloxacin resistance is derived exclusively from the qnrS1 gene harbored on the pEBG1 plasmid. In silico analysis determined the plasmid to belong to the X (subtype 2) incompatibility group and contained an IncX conjugation system. Conjugation experiments however showed that that pEBG1 is not self-transmissible but is mobilizable.

Conclusion: pEBG1 is a prototypical plasmid that has contributed to qnrS1 co-dissemination with resistance to other antimicrobials in Nigeria.

13:40

Emilia Enjema Lyonga¹, Michel Toukam¹, Celine Nkenfou³, Marie-Claire Okomo-Assoumou^{1,2}, Martha Mesembe², Agnes Eyoh¹, Georges Ikomey^{1,2}, Valentine Ngum Ndze¹, Sinata Koulla-Shiro¹

¹ Department of Microbiology, Haematology, Parasitology and Infectious Diseases, Faculty of Medicine and Biomedical Sciences, University of Yaoundé 1, Cameroon, ² Centre for the Study and Control of Communicable Diseases, Faculty of Medicine and Biomedical Sciences, University of Yaoundé 1, Cameroon, ³ Higher Teachers' Training College, University of Yaoundé 1, Cameroon

Resistance Pattern of Enterobacteriaceae Isolate from Urinary Tract Infections to Selected Quinolones in Yaoundé, Cameroon

Background: It is estimated that 150 million urinary tract infections (UTIs) occur yearly worldwide, resulting in more than 6 billion dollar in direct healthcare cost. The etiology of UTIs is predictable, with *Escherichia coli* an Enterobacteriaceae being the principal pathogen. Quinolones are the drug of choice. Just as with other antimicrobials, the extensive use or administration of these compounds led to the development of resistance by the bacteria. In this study, we report the resistance pattern in enterobacteriaceae isolates from urinary tract infections to quinolones in hospitalized and community patients at the Yaoundé Reference Hospital in Cameroon

Methods: A cross-sectional descriptive study was carried out for a ten-month period. Consecutive clean-catch mid-stream urine samples were collected from 207 in and out-patients. Identification was done using the Api 20E, antimicrobial susceptibility using the Kirby Bauer's disc diffusion method and the MIC was done using the E-test. Ethical clearance was obtained from the National Ethics Committee for Human Research in Cameroon.

Results: Out of the 207 isolates, 58 (28.0%) were found to be resistant to all the quinolones. The resistance observed by species were in the order: *Enterobacter* 4(30.8%); *Klebsiella* 19(29.7%); *Escherichia* 25 (29.4%); *Proteus* 2(11.8%); *Serratia* 4(25.0%); others 4(33.3%). Quinolone resistance for *Escherichia* was 42.9% for In-Patients (IP) and 16.3% for Out-Patient (OP) (P-value = 0.006); *Klebsiella* 35.9% for IP and 20% for OP (P-Value=0.13); *Proteus* 11.1% for IP and 12.5% for OP (P-Value=0.335); *Serratia* 18.2% for IP and 40% for OP (P-Value=1.0); *Enterobacter* 22.2 for IP and 50% for OP (P-Value 1.0)

Conclusion: High resistance rates to quinolones were observed not only for in-patients but also out-patients. These results should be considered during the administration of quinolones for UTIs. Guidelines for the use of these drugs should be instituted.

13:50

Enock Mulowa Mumbula¹, James C. L. Mwansa², Geoffrey Kwenda³, Chileshe Lukwesa-Musyani²

¹ The University of Zambia, School of medicine, department of Pathology and Microbiology, Lusaka, Zambia, ² Department of Pathology and Microbiology, University Teaching Hospital, Lusaka, Zambia, ³ Department of Biomedical Sciences, School of Medicine, University of Zambia, Lusaka, Zambia

Detection of Extended Spectrum β -Lactamases in Invasive *Klebsiella pneumoniae* Isolates from the University Teaching Hospital, Lusaka, Zambia

Background: *Klebsiella pneumoniae* is one of the major causes of blood-stream infections in hospitalised and community-based patients. Due to the development of multidrug resistant strains, treatment for these infections has been a challenge. Most studies demonstrate that this problem is mainly due to the ability of *Klebsiella pneumoniae* to produce extended spectrum β -lactamases, a group of plasmid-mediated enzymes that hydrolyse and confer resistance to second and third generation cephalosporins. This study aimed at detecting Extended Spectrum β -Lactamase production in invasive *Klebsiella pneumoniae* isolates at the University Teaching Hospital in Lusaka.

Methods: This was a laboratory-based cross-sectional study. Thirty-five blood culture isolates of *Klebsiella pneumoniae* were collected from a neonatal ward at the University Teaching Hospital in Lusaka. The production of the Extended Spectrum β -Lactamase was detected using the Combination Disc Method and by detecting the genes encoding them using Polymerase Chain Reaction. Drug resistance patterns were determined by the Kirby-Bauer Disc Diffusion Method against tetracycline, chloramphenicol, amikacin, gentamycin, co-trimoxazole, ciprofloxacin, cefotaxime, ceftazidime, cefpodoxime and imipenem.

Results: The results showed that 91.4% of the isolates produced Extended Spectrum β -lactamases. *Bla* genes were detected in 50% of the phenotypically confirmed Extended Spectrum β -lactamase-producers. The most prevalent genes were *BlaSHV* (75%), followed by *BlaTEM* (12.5%) and a combination of *BlaSHV* and *BlaTEM* (12.5%). No *BlaCTX* gene was detected. All the Extended Spectrum β -Lactamase-producing isolates were multidrug resistant but were sensitive to amikacin and imipenem.

Conclusion: There was a high prevalence of Extended Spectrum β -Lactamase-producing invasive *Klebsiella pneumoniae* in the neonatal ward of the hospital. Most of the isolates were multidrug resistant. However, all the isolates were sensitive to amikacin and imipenem. It is recommended that effective infection control measures against *Klebsiella pneumoniae* infection be instituted.

14:00

Oladipo Oladosu¹, Oyibo Wellington¹, Colin Sutherland²¹ ANDI Centre of Excellence for Malaria Diagnosis and Tropical Disease Research Laboratory College of Medicine, University of Lagos, Idiaraaba, Lagos, Nigeria,² Department of Infectious and Tropical Diseases, London School of Hygiene and Tropical Medicine, London School of Hygiene and Tropical Medicine, London, UK**Persistence of Chloroquine-resistant Plasmodium Falciparum Mutant Haplotypes in Children with Uncomplicated Malaria in Lagos, Nigeria Four Years After Change of Chloroquine as First-line Antimalarial Drug**

Background: In Nigeria, despite the change in National malaria drug policy to artemisinin combination therapy in 2005 due to widespread chloroquine (CQ) resistance, CQ still remains the most common antimalarial drug widely used in the treatment of malaria because it is cheap, affordable and accessible. Genetic markers to predict Plasmodium parasites' resistance especially for single nucleotide polymorphism (SNP) have the potential to provide information on P. falciparum resistance to antimalarial. This study aims to investigate the level of prevalence in Pfcr1 haplotypes and the point mutations in Pfmdr1 genes.

Methods: A cross sectional study was carried out with a total of 119 parasites DNA amplified from P. falciparum isolates in children with uncomplicated malaria in Lagos, Nigeria. The occurrence of haplotypes was investigated in Pfcr1 gene using probe-based qPCR and single nucleotide polymorphisms in pfmdr1 gene using nested PCR.

Results: The majority of the children with P. falciparum infection (91.6%) harboured parasites with the mutant Pfcr1 haplotype (CVIET). 4.2% comprised a mixture of genotypes encoding CVMNK and CVIET, while 4.2% only harboured the wild type (CVMNK). SVMNT was not seen in this study. Furthermore, the frequency of point mutations in Pfmdr1 was 62.2% and 69.0% for codons Y86 and F184 respectively. There were no mutations at codons 1034, 1042 and 1246 of the Pfmdr1 genes.

Conclusion: The high frequency of the resistant haplotypes (CVIET) and mutations in Pfmdr1 associated with CQ resistance seen among these children suggest that high CQ resistance P. falciparum parasites are still in circulation and it continuous use may continue to increase the level of mutations in Pfcr1 and Pfmdr1 genes. The return of CQ sensitive (wild type) parasites calls for effective legislation against the use, manufacture, importation and total withdrawal of CQ from the population. Hence, continuous monitoring of resistance pattern of CQ is imperative.

ORAL POSTERS 3.3

LABORATORY-BASED SURVEILLANCE AND EPIDEMIOLOGY

DATE: **Wednesday, 3 December**TIME: **13:00 – 14:10**LOCATION: **Ballroom East/West**CO-CHAIRS: **Omu Anzala**, University of Nairobi, Kenya
Richard Njouom, Centre Pasteur of Cameroon, Cameroon

13:00

Abebe Alemu¹, Hans-Peter Fuehrer², Gebeyaw Getnet¹, Belay Tessema³, Harald Noedl⁴¹ Department of Medical Parasitology, University of Gondar, Ethiopia, ² Department of Pathobiology, Austria, ³ Department of Medical Microbiology, University of Gondar, Ethiopia, ⁴ Institute of Specific Prophylaxis and Tropical Medicine, Austria**Plasmodium Ovale Curtisi and Plasmodium Ovale Wallikeri in North-West Ethiopia**

Background: In Ethiopia Plasmodium falciparum and Plasmodium vivax are the dominant species accounting for roughly 60 and 40% of malaria cases, respectively. Recently a major shift from P. falciparum to P. vivax has been observed in various parts of the country. The aim of this study was to assess P. ovale species in Gondar.

Methods: A health institution-based survey was conducted at Maksegnet, Enfranze and Kola Diba health centres and Metema hospital in North Gondar. Three-hundred patients with signs and symptoms consistent with malaria were included in this study and capillary blood was collected for microscopic examination and molecular analysis of Plasmodium species. Samples were collected on Whatman 903 filter papers, stored in small plastic bags with desiccant and transported to Vienna (Austria) for molecular analysis.

Results: Out of 300 study participants (167 males and 133 females), 184 samples were classified positive for malaria (133 P. falciparum and 51 P. vivax) by microscopy. By species-specific PCR 233 Plasmodium spp (95% CI: 72.6-82) were detected and the majority 155 (66.5%, 95% CI: 60.2-72.3) were P. falciparum followed by P. vivax 69 (29.6%, 95% CI: 24.1-35.8) and 9 (3.9%, 95% CI: 2-7.2) samples were positive for P. ovale. Seven of P. ovale parasites were confirmed as P. ovale wallikeri and two were confirmed as P. ovale curtisi. None of the samples tested positive for P. malariae. During microscopic examination there were high (16.3%) false negative reports and all mixed infections and P. ovale cases were missed or misclassified.

Conclusion: This study indicates that *P. ovale* malaria is under-reported in Ethiopia and provides the first known evidence of the sympatric distribution of indigenous *P. ovale wallikeri* and *P. ovale curtisi* in Ethiopia. Therefore, further studies assessing the prevalence of the rare species *P. ovale* and *P. malariae* are urgently needed.

13:10

Assah Nkohkwo^{1,2,3}, Nigel Talboys⁴

¹The Care Quality Commission, ²UK-National Health Service, ³Terumo BCT Europe-Africa, ⁴Terumo BCT, Belgium

Improving Blood Supply Safety & Adequacy in Developing Countries: Pan-African Blood Safety Perspectives

Background: Blood supply adequacy & safety in Africa present serious public health challenges. We examined whether these would be more effectively and responsively addressed through engagement of public health professionals, among other key stakeholders, into a pan-African Blood Safety Alliance.

Methods: Following a review of the literature, we engaged professional stakeholders and service user organisations across Africa during the years 2012-2014, through correspondences, direct discussions and seminars.

Results: Challenge (I): adequacy & safety of supply “Shortage of blood donations is a problem we faced constantly while working in Cameroon and we watched many children/adults die unnecessarily while at the CHU Yaoundé” (a Cameroonian Infectiologist based in the UK, June 2013). In sub-Saharan Africa: 3million whole blood (WB) collections are undertaken per year of which 2 million are still transfused as WB. Median overall risks of becoming infected with HIV, HBV, and HCV from a blood transfusion in sub-Saharan Africa were 1, 4.3, and 2.5 infections per 1000 units, respectively, projected by the WHO, to 28,595 HBV infections, 16,625 HCV infections, and 6,650 HIV infections every year. Public Health Challenge (II): There was an acute need for a robust and accessible African solution, a technology that exhibits: Effectiveness & Efficacy; Safety; Affordability Challenge (III): We identified a crying need for a meaningful user-focused professional alliance, including- patients & professional associations and biotechnology companies.

Conclusion: Going Forward: a Pan-African Blood Safety Alliance (PABSA) will promote the availability of adequate and the safest possible supply of blood or its products across the continent. It will not only instigate, but support the introduction through proper peer scrutiny of emerging potential robust solutions including Pathogen Reduction Technologies (PRT), such as Terumo BCT's Mirasol PRT system for whole blood

13:20

Mura Ngoi^{1,2,3}, Fausta Moshia², Ahmed Abade³, Mecky Matee¹

¹Muhimbili University of Health and Allied Sciences, Tanzania, ²Ministry of Health and Social Welfare, Tanzania, ³Field Epidemiology and Laboratory Training Program, Tanzania

Evaluation of Laboratory Based Multi Drug Resistant Tuberculosis (MDR-TB) Surveillance System in Muhimbili (NIMR-CTRL) Tanzania, 2012

Background: Globally Infectious disease accounts for over 25% of all deaths, TB being the fourth cause of mortality and seventh in developing countries. One active TB case has the potential of infecting approximately 10-15 people every year. An untreated MDR-TB case can also transmit MDR-TB strain to both infected and uninfected individuals. Tanzania is ranked 15th on the list of 22 high-burden tuberculosis countries in the world

Methods: A descriptive evaluation was conducted from November 2011 to January 2012. MMWR CDC guideline for evaluating surveillance system was used. Relevant records and reports from TB Laboratory were reviewed. 12 stakeholders from National to District level, in Dar es Salaam region were selected and interviewed using a semi structured questionnaire, MS Excel and Epi Info version 3.5.1 software was used to analyze data and establish frequencies and proportions

Results: From 2008 to June 2012 a total of 208 (11.6%) out of 1794 suspected MDR TB cases were laboratory confirmed. 75% of stakeholders accepted the system usefulness however 58.3% said the system is not simple with 58% missing data in request forms. The system accommodates both MDR and non MDR TB surveillance. There was 95% external quality assurance concordance meeting WHO standards. 91.7% of received specimen was in good condition. The system PVP is 11.6%. Specimen submission to TB Laboratory takes more than 5 days and results feed back to health facility takes more than 4 months. Full time employees operate the System

Conclusion: The system is useful, acceptable, flexible, and stable with good and representative data, regular internal quality control ensuring the good quality of laboratory results however complex. The system is highly sensitive with low PVP. The system should include laboratories at all levels

13:30

Julius Oyugi¹, Antar Munira², Mike Drebot³, Omu Anzala¹

¹ University of Nairobi, Nairobi, Kenya, ² Ministry of Health, Kenya,
³ National Microbiology Laboratory, Canada, University of Nairobi, Kenya.

Emerging Zoonotic Diseases in the Coastal and Nairobi regions of Kenya

Background: About 75% of recently emerging infectious diseases affecting humans are zoonotic diseases. In Kenya, it is anticipated that there may be an under-diagnosis and/or under reporting of zoonotic diseases. It is in this context that we seek to determine the prevalence of selected zoonoses in two regions in Kenya.

Methods: This was a cross-sectional study in which 182 patients were recruited from Coastal and Nairobi regions of Kenya between January and March 2011. Blood samples were collected from patients who presented with fever at the outpatient clinics. Seroprevalence of selected zoonotic agents was determined by an in-house Enzyme linked immunosorbent assay. A questionnaire was administered that included assessment of demographics, clinical presentations and history of recent travel. A complete blood count was also done for each patient. The data collected was entered into MS Excel and later analysed using SPSS.

Results: Sixty percent of all patients were antibody positive for a number of zoonotic diseases. Dengue fever virus, IgM prevalence was 8.2% and IgG prevalence was 35.2%. Overall Flavivirus (both WNV and Dengue) IgG prevalence was 63.7%. West Nile fever virus, IgM prevalence was 1.6%. Rift Valley fever virus IgG prevalence was 7.1% and Coxiella burnetii IgG prevalence was 5.5%. Rickettsia rickettsii IgG prevalence was 2.7% and Rickettsia typhi IgG prevalence was 0.5%. Leptospira IgM prevalence was 0.5%. History of recent travel ($p=0.010$), age ($p=0.004$), presenting symptoms ($p=0.004$) and region of residence ($p=0.000$) were found to be significantly associated with infection to zoonotic agents.

Conclusion: Dengue fever had the highest prevalence in both Mombasa and Nairobi while Leptospira and Rickettsia typhi had the lowest prevalence. Some of the Dengue IgM positive patients may have been ill due to dengue fever. It is reasonable to conclude that is a dengue virus an emerging zoonotic agent in Coastal region of Kenya.

13:40

David Bukbuk¹, Shuetsu Fukushi², Hideki Tani², Tomoki Yoshikawa², Satoshi Taniguchi³, Koichiro Iha³, Shigeru Morikawa³, Masayuki Saijo², Francis Kasolo⁴, Saka Saheed Baba¹

¹ Department of Veterinary Microbiology and Parasitology, Faculty of Veterinary Medicine, University of Maiduguri, Maiduguri, Nigeria, ² Department of Virology 1, National Institute of Infectious Diseases, Tokyo, Japan, ³ Department of Veterinary Science, National Institute of Infectious Diseases, Tokyo, Japan, ⁴ Disease Prevention and Control Cluster at the WHO Regional Office for Africa, Congo-Brazzaville

Rift Valley Fever Sero-surveillance using Recombinant Virus Nucleoprotein and Vesicular Stomatitis Virus Pseudotype-Based Assays Among Humans in Borno State, Nigeria

Background: Rift Valley fever virus (RVFV) is a zoonotic mosquito-borne virus belonging to the genus Phlebovirus in the Family Bunyaviridae. It causes severe diseases in humans and livestock throughout Africa and the Arabian Peninsula. The peculiar geographical location of Borno State in Northeastern Nigeria, which shares international borders with three other African countries (Cameroun, Chad and Niger), makes it vulnerable to the transboundary spread of various diseases, including viral hemorrhagic fevers (VHFs). The usefulness of recombinant viral nucleoprotein (rNPs)-based serological assays for the detection of antibodies against VHFs have been reported. In this study, the seroprevalence of RVFV infection in humans in Borno State, Nigeria was determined using the rNP-based IgG-ELISA. In addition, virus neutralization assay using VSV-pseudotype virus-bearing glycoproteins of RVFV was developed and its usefulness was determined for a high through-put screening of neutralizing antibodies against RVFV.

Methods: This is a cross-sectional study where 297 serum samples were collected from consenting subjects attending health facilities (government hospitals, private hospitals or clinics) in both rural/urban areas in Borno State in northern Nigeria. A recombinant baculovirus expressing rNP of RVFV, to produce recombinant His-tagged RVFV-rNP was developed and also a VSV-pseudotyped with RVFV-GP was generated and both used to test the serum samples in an IgG-ELISA and serum neutralization of the RVFV-GP-bearing VSV pseudotype (RVFV-pv) assays respectively.

Results: Of the 297 serum samples tested, 42 (14.1 %) were positive for the presence of RVFV IgG. Higher sensitivity and specificity of the RVFV rNP-based ELISA were observed when compared with the conventional neutralization assay using infectious RVFV (RVFV MP-12 strain) carried out on the same sera. Furthermore, the serum neutralization of the RVFV-GP-bearing VSV pseudotype (RVFV-pv) was determined. There was a positive correlation between the titers of neutralizing antibodies obtained using RVFV-pv and those obtained using the conventional neutralization assay with RVFV-MP12 strain. Therefore, RVFV rNP-based ELISA and RVFV-pv-based Nab assays developed in this study has the potentials to replace the traditional assays based on live viruses for the diagnosis and sero-surveillance studies of RVF.

Conclusion: The 14.1% (42 out of 297) seroprevalence of RVFV-IgG is very high which indicates that RVFV is endemic in Borno state. It also demonstrates the usefulness of the two assays which are both sensitive and specific as a sero-surveillance tool in this area without need for strict containment.

13:50

Mbayame Niang, David Kiori, Ousmane Kébé, Déborah Goudiaby, Ndongo Dia

Unité de Virologie Médicale, Institut Pasteur de Dakar, Dakar, Senegal

Caractérisation Génétique des Rhinovirus et Entérovirus Associés au Syndrome Grippal au Sénégal

Background: Les rhinovirus et les entérovirus sont responsables de la plupart des infections respiratoires aiguës. Au Sénégal, l'épidémiologie de ces virus reste mal connue. L'objectif de cette étude est d'étudier l'épidémiologie moléculaire des souches de rhinovirus et entérovirus respiratoires circulant au Sénégal.

Methods: La période de recrutement des cas de syndrome grippal s'étend entre 2012 et 2013. Au total 2515 patients répondant à la définition du cas ont été enrôlés et fait l'objet d'un prélèvement naso-pharyngé. La détection des virus a été faite par une technique RT-PCR en temps réel en utilisant le kit RV16 ciblant 16 types et sous-types de virus respiratoires. La caractérisation moléculaire des Rhinovirus et entérovirus a été faite par amplification et séquençage de régions discriminantes.

Results: Les résultats obtenus montrent que les Picornaviridae respiratoires (rhinovirus et entérovirus) constituent la première étiologie virale des IRA avec un taux de détection de 35%. Les enfants de moins de 5 ans sont plus vulnérables aux infections à rhinovirus avec une fréquence de 72% alors que celles à entérovirus montrent une distribution équilibrée à travers les différentes tranches d'Age. Le profil de circulation annuelle entre 2012 et 2013 révèle que les rhinovirus et les entérovirus circulent sur fond endémique avec des pics épidémiques dont l'intensité est plus importante pendant la saison des pluies. L'analyse phylogénique des rhinovirus révèle la présence des 3 types (Rhinovirus A, B et C) au Sénégal avec une prédominance des types A et C. La caractérisation des entérovirus montre exclusivement la présence de l'entérovirus 71 (EV71).

Conclusion: Nos résultats ont été confirmés dans plusieurs études, cependant il faudra continuer la surveillance sur une période plus longue afin de dresser un profil épidémiologique plus fin de ces virus au Sénégal mais aussi d'affiner la caractérisation pour avoir le profil des sérotypes circulant au Sénégal.

14:00

Joan Ejembi¹, Ronke Suleiman², Adebola Olayinka¹

¹ Ahmadu Bello University, Zaria, Kaduna State, Nigeria, ² Federal Medical Center Katsina, Katsina State, Nigeria

The Invitro Susceptibility Pattern of Candida Blood Stream Isolates to 3 Antifungal Agents at Abuth Shika, Zaria, Nigeria

Background: Candida is noted to be one of the most common opportunistic fungal pathogens, and Invasive candidiasis has become a public health problem due to the high associated rates of morbidity and mortality. Due to the burden of HIV and Aids and indiscriminate use of Antibiotics in this part of the world, Invasive fungal infections have increased in importance.

Methods: A cross-sectional study was done using a calculated minimum sample size of 385 patients. The study population comprised 390 patients with septicaemia and risk factors for Candidaemia. Blood samples were collected for blood culture with Brain heart infusion broth as the primary culture media. Subcultures were done onto Sabourauds dextrose agar, 7% Sheep Blood Agar and MacConkey agar. (Oxoid, UK) Positive yeast isolates were subjected to urea and germ tube test and species were identified using CHROMAgar Candida. (Oxoid, UK) Antifungal susceptibility test and MIC was determined using E-test strips for Amphotericin B 0.002 – 32µg/ml, Caspofungin 0.002 – 32µg/ml and Fluconazole 0.016 – 256µg/ml (Biomérieux, France).

Results: All the Candida isolates were found to be susceptible to Amphotericin B with MIC's ranging from 0.016 – 0.38 µg/ml. *C. parapsilosis*, *C. tropicalis* and *C. albicans* were susceptible to Caspofungin with MICs which ranged from 0.064 – 1.0 µg/ml. 2 (50%) isolates of *C. glabrata* and the only isolate of *C. krusei* were resistant to Caspofungin with MICs greater than 32µg/ml. *C. parapsilosis* and *C. tropicalis* demonstrated 100% susceptibility to Fluconazole with MICs which ranged from 1.0 – 8.0µg/ml. 2 (50%) isolates of *C. glabrata* and the only isolates of *C. albicans* (100%) demonstrated resistance to Fluconazole with MICs greater than 256µg/ml.

Conclusion: Resistance was demonstrated to Caspofungin and Fluconazole which is the first line in management of Candidaemia. Antifungal susceptibility testing is required to guide patient management. There is need for continued surveillance.

THURSDAY, 4 DECEMBER 2014

ORAL POSTERS 4.1 DIAGNOSTIC INNOVATIONS

DATE: **Thursday, 4 December**

TIME: **13:00 – 14:10**

LOCATION: **Ballroom East/West**

CO-CHAIRS: **Mark Ware**, Clinton Health Access Initiative, United Kingdom
Teferi Mekonnen, African Society for Laboratory Medicine, Ethiopia

13:00

Simon Walusimbi, Alfred Okeng, Edgar Kigozi, Samuel Kyobe
Makerere University, Department of medical microbiology, Kampala, Uganda

Comparison of SpeedOligo Test to Xpert MTB/Rif Test for Detection of Tuberculosis in Smear-Negative HIV-Infected Patients

Background: Laboratory diagnosis of Tuberculosis (TB) traditionally relies on smear microscopy and culture. However, recent advances in technology have seen the introduction of molecular tests for diagnosis of TB because they are more sensitive compared to microscopy and more rapid compared to culture. We compared a new molecular test called SpeedOligo[®] DIRECT Mycobacterium tuberculosis test (SpeedOligo) to Xpert MTB/Rif test (Xpert) for detection of TB in smear-negative HIV-infected patients. SpeedOligo is a PCR based test, attached to a dipstick used for the qualitative detection of Mycobacterium tuberculosis (MTB) and Non-Tuberculosis Mycobacteria (NTM). Xpert is an automated PCR test used for detection of TB and Rifampicin resistance in a one-off test giving results within three hours. Xpert was recommended by the World health Organization as the initial diagnostic for HIV-associated TB since 2010.

Methods: One hundred and nine (109) smear-negative sputum samples were tested with SpeedOligo. The SpeedOligo results were compared to the Xpert results which were not available until the final results of SpeedOligo were reported. The test results of both SpeedOligo and Xpert were then compared to a combination of liquid (MGIT) and solid (L-J) culture results.

Results: Of the 109 samples, 79% (86/109) had complete results including those of culture. The sensitivity and specificity of SpeedOligo compared to Xpert was 64% (95% CI: 35%-87%) and 83% (95% CI: 73%-91%) respectively. A substantial proportion of the tests 57% (12/21) which were positive on SpeedOligo were negative on Xpert and culture. We observed that when the SpeedOligo strips were incubated for longer than 3 minute background bands occurred which were misinterpreted as positive for MTB.

Conclusion: SpeedOligo has moderate sensitivity and high specificity for smear-negative TB when compared to Xpert. The visual interpretation of the test resulted into a substantial proportion of false positive results, which could limit its implementation in routine laboratory practice.

13:10

Muriel Meiring, Precious Setlai

Department of Haematology and Cell Biology, University of the Free State, Bloemfontein, South Africa

Development of an Enzyme-linked Immunosorbent Assay to Measure VWF Propeptide Levels in Plasma

Background: Von Willebrand disease (VWD) is the most common bleeding disorder in the world with a prevalence of 1% in the general population. The diagnosis of VWD is complex, thus patients with VWD are largely under-diagnosed or misdiagnosed. About 80% of VWD patients are diagnosed with type 1 VWD (a quantitative defect of von Willebrand factor (VWF)) and about fifty percent of them present with increased clearance of VWF. Patients with increased clearance of VWF do not respond well to the treatment of choice (DDAVP) because the efficacy of desmopressin treatment is reduced in these patients. The ratio between von the Willebrand factor propeptide (VWFpp) and the mature VWF antigen (VWF: Ag) can be used to diagnose these patients. The current commercially available assays that can be used to test the levels of VWFpp in plasma are still very expensive because the antibodies used in these assays are produced using animals. In this study, we developed an ELISA assay to determine the plasma levels of VWFpp.

Methods: Antibody fragments were selected against the VWFpp by using phage display technology. The VWFpp was first displayed on yeast, since no commercial preparation of the VWFpp exists. By using phage display technology, we selected two single chain variable antibody fragments (ScFv) from almost two-hundred phage colonies that bind specific to the VWFpp and not to the yeast on which it was displayed. The antibody fragments were then purified on protein A columns and tested for specific binding to the VWFpp.

Results: The purified ScFv were able to detect VWFpp in normal plasma. By comparing our assay to commercial assays, our antibody fragments showed a higher binding affinity for VWFpp in plasma at especially lower plasma concentrations than an assay using commercial antibodies to the VWFpp. Our assay is also more cost-effective than commercial antibodies, since it was not necessary to use expensive infrastructure as in the case with the development of antibodies using experimental animals. The production of ScFv is also not an expensive process, since it can be amplified in E.coli cells.

Conclusion: We speculate that the combination of yeast- and phage display could be the reason why the 2 ScFv were selected successfully without alterations in specificity as both technologies are known to produce antibodies with the highest binding affinity. The next step is to validate our assay and possibly commercialise it as a cost-effective assay for the determination of VWFpp in plasma.

13:20

Felix Botchway¹, Cecilia Lekpor², David Dosoo³

1 Pediatric Department, Korle Bu Teaching Hospital, University Of Ghana Medical School, Accra, Ghana, 2 Pathology Department, Korle Bu Teaching Hospital, Accra, Ghana, 3 Kintampo Health Research Centre, Kintampo, Brong Ahafo, Ghana

Quantitative Detection of Plasmodium falciparum Histidine Rich Protein 2 in Saliva

Background: Malaria is a global health priority with a heavy burden of fatality and morbidity. Improvements in field diagnostics are needed to support the agenda for malaria elimination. Saliva has shown significant potential for use in non-invasive diagnostics, but the development of off-the-shelf saliva diagnostic kits requires best practices for sample preparation and quantitative insight on the availability of biomarkers and the dynamics of immunoassay in saliva. This study measured the levels of the PfHRP2 in patient saliva.

Methods: Matched samples of blood and saliva were collected between March and August, 2013 from forty patients at the ER and OPD of the pediatric unit of Korle Bu Teaching Hospital. Parasite density was determined from thick-film blood smears. Concentrations of PfHRP2 in saliva of malaria-positive patients were measured using a custom chemiluminescent ELISA in microtitre plates. Forty negative-control patients were enrolled. Saliva samples were stabilized with protease inhibitor

Results: Of the forty patients with microscopically confirmed *P. falciparum* malaria, thirty seven tested positive for PfHRP2 in the blood using rapid diagnostic test kits, and forty for PfHRP2 in saliva. All negative-control samples tested negative for salivary Pf HRP2. The ELISA agreed with microscopy with 100 % sensitivity and 100 % specificity. Salivary levels of PfHRP2 ranged from 15 to 1,162 pg/mL in the malaria-positive group.

Conclusion: Saliva is a promising diagnostic fluid for malaria when protein degradation and matrix effects are mitigated. Systematic quantitation of other malaria biomarkers in saliva would identify those with the best clinical relevance and suitability for off-the-shelf diagnostic kits.

13:30

Basan Motawi¹, Dalia Salem¹, Zeinab Mostafa², Yasser Mostafa³, Randa El-Harizy⁴

1 Department of Medical Microbiology & Immunology, Faculty of Medicine, Ain Shams University, Cairo, Egypt, 2 Tuberculosis research Unit, Faculty of Medicine, Cairo University, Egypt, 3 Department of Chest diseases, Faculty of Medicine, Ain Shams University, Cairo, Egypt, 4 Department of Medicine, Faculty of Medicine, Cairo University, Cairo, Egypt

Evaluation of Mycobacteria Growth Indicator Tube (MGIT) for Drug Susceptibility Testing of Mycobacterium Tuberculosis Isolates from Egypt

Background: The importance of rapid availability of Mycobacterium tuberculosis (*M. tuberculosis*) antimicrobial susceptibility testing results is universally acknowledged. Aim of the Work: This study aimed to evaluate the performance and practicability of manual Mycobacteria Growth Indicator Tube (MGIT) in performing indirect susceptibility testing of *M. tuberculosis* isolated from Egyptian tuberculosis (TB) patients.

Methods: The reliability of manual MGIT for testing susceptibilities of 318 *M. tuberculosis* isolates to first line anti-tuberculosis drugs; streptomycin (SM), isoniazid (INH), rifampin (RIF) and ethambutol (EMB) were evaluated in comparison with conventional indirect method of proportion (MOP).

Results: MGIT detected drug resistance rates of 28%, 23.7%, 24.8% and 21.7% among new TB cases, and resistance rates of 28%, 32.7%, 24.8%, and 21.7% among treated TB cases for SM, INH, RIF, and EMB respectively. Multi-drug resistance (MDR-TB) were detected in 3.3% and 12.4% among new and treated TB cases respectively. MGIT showed very good agreement with MOP susceptibility testing results (Kappa ranged from 0.7 to 0.82). There is 100% agreement between results of MGIT and MOP regarding MDR-TB detection. The turnaround times (TAT) "from specimen processing to reporting of drug susceptibility test results" ranged between 10 to 30 days (mean=17.4) for MGIT and 3- to 73 days (mean=48.9) for for MOP.

Conclusion: Manual MGIT can be utilized as a rapid and practical mean for drug susceptibility testing of *M. tuberculosis* in routine Laboratories with poor resources

13:40

Keshendree Moodley¹, Lindi-Marie Coetzee², E. Shimp³, B. Neary³, B. Crider³, D.K. Glencross¹

¹ Department of Molecular Medicine and Haematology, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa, ² National Health Laboratory Service (NHLS), Department of Haematology, Charlotte Maxeke Johannesburg Academic Hospital, South Africa, ³ IMMY, Oklahoma, USA

Preliminary Data on a New Flow Cytometry Assay for the Early Detection of Cryptococcal Antigenaemia

Background: Reflex cryptococcal antigen (CrAg) testing in HIV+ patients, with CD4 counts <100 cells/ μ l, was proposed for early detection of cryptococcal infection. This test is labor intensive and not suited for high volume testing. Consequently, a Flow Cytometric Assay (FCA) is under development by IMMY. The aim of this study was to compare performance of the FCA to the lateral flow assay (LFA) and assess the impact on CD4 reporting.

Methods: Patient samples were tested for CrAg with LFA and retested with FCA. Different methods of sample preparation was assessed, i.e. incubation with FCA reagent pre- (n=129) or post whole blood lysis (n=34). Analysis was done on CrAg/PLG protocols on the Beckman Coulter (BC) cytometer. CrAg results were compared with IMMY LFA and CD4 results to the reference PLG/CD4 method. GraphPad Prism was used for statistics.

Results: CrAg results revealed 100% sensitivity and specificity for post lysis vs. 100% sensitivity and 99% specificity for pre lysis compared to LFA. Comparison of absolute CD4 count and CD4 percentage of lymphocytes showed p values >0.05 (t-test, not significant) for both FCA preparation methods. Bland Altman showed a negligible bias (2-4 cells/ μ l) for absolute CD4 count and <1% for CD4% for both preparation methods. Reproducibility of whole blood control (ImmunotrolTM) and ImmunotrolTM/CrAg+ control showed CV's of <5%, as did patient samples (CV's of <7%). Mean Fluorescence Intensity (MFI) of CrAg positive samples were <10 compared to CrAg negative MFI values of >60.

Conclusion: The FCA showed comparable CrAg results to LFA, without compromising CD4 parameters. The FCA is easy-to-use and can be performed on existing technologies without impacting workflow/staff requirements. Results can be standardized across laboratories with quality control measures to ensure accurate definition of CrAg positivity, whilst simultaneously reporting CrAg and CD4 results.

13:50 **CANCELLED**

Mulualem Tadesse Jano

Jimma University, Department of Medical Laboratory Science and Pathology, Jimma, Ethiopia

Concentration of Lymph Node Aspirate Improves the Sensitivity of Acid Fast Smear Microscopy for the Diagnosis of Tuberculous Lymphadenitis in Jimma, Southwest Ethiopia

Background: Tuberculous lymphadenitis (TBLN) is the most common form of extrapulmonary tuberculosis. The cytomorphological features of lymph node smears have reduced specificity for the diagnosis of tuberculosis. The diagnosis of tuberculous lymphadenitis with direct smear microscopy lacks sensitivity due to the limited number of the bacilli in lymph node aspirate. Therefore, we aimed to assess whether the concentration of lymph node aspirate improves the sensitivity of acid fast smear microscopy for the diagnosis of tuberculous lymphadenitis.

Methods: A cross-sectional comparative study was conducted on 200 patients clinically suspected for tuberculous lymphadenitis in Jimma, Ethiopia. Lymph node aspirate was collected and the first two drops were used for cytomorphological study and direct acid fast staining. The remaining aspirate was treated with N-acetyl-L-cysteine (NALC) and concentrated by centrifugation at 3000g for 15 minutes. The sediment was used for acid fast staining and culture. Identification of mycobacterial species was done by para-nitrobenzoic acid susceptibility test.

Results: Complete data were available for 187 persons with presumptive TBLN, of which 68% (127/187) were positive for M. tuberculosis on culture. Four isolates, 2.0% (4/187), were identified as non-tuberculosis Mycobacteria (NTM). The detection rate of direct smear microscopy was 25.1% and that of the concentration method 49.7%. Cytomorphologically, 79.7% of cases were classified as TBLN. Using culture as the gold standard, the sensitivity of direct smear microscopy was 34.6%, for concentrated smear microscopy 66.1%, and for cytomorphology 89.8%. The majority (76.4%) of positive cases on concentration method showed grades of AFB positivity that were above scanty, making the bacilli easily visible within a shorter screening time. Two AFB positive cases on concentration method were non-tuberculosis mycobacteria (NTM). The concentration method yielded a positive result from seven cases diagnosed as suppurative abscess by cytology. Both for the direct and concentration method the highest rate of AFB positivity was observed in smears showing caseous necrosis alone and the smear positivity rate decreased with the appearance of epithelioid cell aggregates.

Conclusion: The concentration of lymph node aspirates for acid fast smear microscopy had significantly higher sensitivity and higher grades of AFB positivity.

14:00

Mpho Maphayio¹, Jaya George¹, Braimoh Bello²

¹ Department of Chemical Pathology, University of the Witwatersrand and National Health Laboratory Services, Johannesburg, South Africa, ² Centre for Statistical Analysis and Research, Johannesburg, South Africa and School of Public Health, University of the Witwatersrand, Johannesburg, South Africa

Modalities of Prostate Specific Antigen Testing in Gauteng Clinics and Hospitals, South Africa

Background: The Prostate Cancer Foundation of SA has issued guidelines on the use of Prostate Specific Antigen (PSA) in prostate cancer screening, diagnosis and management. We do not know how this test is used in our healthcare facilities. This study aims to describe modalities of prostate specific antigen testing in terms of number of PSA requests, patient demographic characteristics, type of health care facility (clinic vs. hospital), prostate biopsy uptake and PSA level.

Methods: A descriptive retrospective study of PSA tests done at the National Health Laboratory Services laboratory at Charlotte Maxeke Johannesburg Academic Hospital from January 2013 to December 2013.

Results: 17,498 subjects had PSA tests. Of these 13,795 (78.9%) were done in Black African men (BA) while 3703 (21.2%) in other racial groups (Others). More requests (62%) were from clinics vs. 38%, from hospitals. The mean age for BAs (55.5±13.3) was significantly lower than that of Others (62.9 year±12.6, p<0.01), and median PSA in BAs was lower, 0.95(IQR 0.54-2.26) compared to 1.07 (IQR 0.53-2.81, p=0.02) in Others.

Only 17.2% of all men had a PSA above 4µg/L, which is the cut off used in our laboratory. This proportion was lower in BAs (16.8%) than in Others (18.8%, p=0.005). More BAs aged 60 and above had PSA level above 4µg/L than Others of the same age category (32.2% vs. 26.1% p=0.01).

Of the four hundred and twenty men who underwent prostate biopsy, 213 (50.5%) had cancer. Fewer prostate biopsies were done in BAs than Others (2% vs. 4% p=0.01), although they were more likely to be diagnosed with prostate cancer on biopsy than Others (54.3% vs. 43.2%, p=0.03).

Conclusion: Numbers of PSA tests done varied by age and race of patients. There were also racial differences in the rate of biopsy testing and prostate cancer diagnosis on biopsy.

ORAL POSTERS 4.2 POLICY AND NETWORKING

DATE: **Thursday, 4 December**TIME: **13:00 – 14:10**LOCATION: **Ballroom East/West**

CO-CHAIRS: **Charles Massambu**, National Public Health Laboratory, Tanzania
Jackson Amone, Ministry of Health, Uganda

13:00

Ritu Shrivastava¹, Andy C Wilson², Christina Mwangi³, Renuka Gadde⁴, John N. Nkengasong¹

¹ Centers for Disease Control and Prevention, Atlanta, Georgia, USA, ² Abbott Fund, ³ Centers for Disease Control and Prevention, Kampala Uganda, ⁴ Becton Dickinson & Company, New Jersey, USA

An Essay on the Critical Role of Public Private Partnerships in Strengthening Laboratory Medicine in Developing Countries

Background: Despite the enormous progress in the HIV/AIDS arena, the global recession has precipitated a funding crisis that threatens to undermine the hard-fought gains to meet the Millennium Development Goals (MDG). Reliable laboratory systems are critical for better patient management and therefore to meet the MDGs. Innovative solutions are needed to enable and sustain the advances in laboratory systems. Former U.S. Secretary of State Hillary Rodham Clinton, emphasized that governments cannot solve these problems alone, but partnerships can.

Methods: We explored public private partnerships (PPP), as a model for laboratory system strengthening and present two case studies.

Results: The Abbott Fund invested \$10 million modernizing 23 regional-level laboratories and \$100+ million strengthen Tanzania's health system in a PPP between Ministry of Health and Social Welfare (MOHSW) and U.S. Centers for Disease Control and Prevention (CDC). Results show a ten-fold increase in the number of tests processed within five years (109,071 tests in 2004 to 1,157,839 tests in 2009). In 2007, Becton Dickinson and Company (BD) implemented the BD-PEPFAR PPP in Uganda along with MOH, CDC team and local partners to fortify the specimen referral and result reporting system. Referrals from persons with presumptive multi-drug resistant tuberculosis increased by 10-fold and 94% of specimens reached the national laboratory, within the established target of 72 hours. It's estimated that by 2013, BD-PEPFAR PPP may have contributed to improved quality of care and treatment for nearly 500,000 patients enrolled in HIV/AIDS and TB treatment program.

Conclusion: These case studies illustrate the power and potential of PPPs to harness their collective strengths towards a shared goal. Under the flagship of African Society of Laboratory Medicine such innovations can play a critical role to maximize support for essential laboratory systems to meet MDGs. We encourage governments to foster new relationships with private-sector companies.

13:10

Faith Nawagi¹, Samuel George Okech², Cheryl Robertson³, Samuel Majalija⁴

¹ Makerere University, College of Health Sciences, Department of Nursing, Kampala, Uganda, ² Makerere university, College of Veterinary Medicine, Kampala, Uganda, ³ University of Minnesota Minnesota USA, ⁴ Makerere University, School of Biomedical Sciences, Department of Bio-medical Laboratory Technology, Kampala, Uganda

One Health; An Approach to Strengthen the Future of Laboratory and Clinical Health Systems to Solve Health Challenges in Africa

Background: Strengthening health systems to effectively respond to local and global health concerns has for long time been a challenge most especially in developing countries. This has seen the birth of many capacity building programmes in the various health sectors with minimal emphasis on multisectoral and multidisciplinary collaboration in training and health service delivery. To address this gap Makerere University in collaboration with university of Tufts and Minnesota through One Health central and East Africa network made it possible for the nursing, veterinary and environmental health students to undertake a joint field attachment in 2013 which I participated in.

Methods: This led to collaborative, innovative and multidisciplinary interventions aimed at disease prevention, laboratory diagnosis, health promotion and improved health seeking behaviours among others in the various sites and timely diagnosis of diseases. This caused remarkable impact in the communities despite the limited time frame with community involvement in designing and prioritization of interventions. Health concerns were solved in a very short period of time making it possible for the students to appreciate the power of collaboration in solving complex health problems that would not have been easily solved through intervention by individual disciplines. Knowledge gaps were identified thus providing a platform for collaborative research.

Results: Preventing disease at the human-animal-ecosystems interface requires deliberate strategic approaches that target the advancement of policies, structures and processes, the reinforcement of those skills and capacities critical for minimizing health risks and limiting their social, economic and public health impact. Most of the current health challenges in Africa need to be solved through multidisciplinary and multisectoral collaborations, strategic partnerships and collective decision making.

Conclusion: In this regard one health approach possess a great opportunity to strengthen the future of laboratory and clinical health systems to solve complex health challenges through improved diagnosis, timely response to outbreaks and efficient surveillance.

13:20

Emmanuel Okunga¹, Oluoch David¹, Wako Boru¹, Gura Zeinab¹, Galgoro Tura¹, Amwayi Samuel¹, Wences Arvelo²

¹ Kenya Field Epidemiology and Laboratory Training Program, Ministry of Health, Nairobi, Kenya, ² US Centers for Disease Control and Prevention-Kenya, Nairobi, Kenya

Probable Human Rabies Death in an Urban Hospital in Kenya, August 2013

Background: Rabies is an endemic, notifiable disease in Kenya; however the prevalence is unknown due to poor surveillance. In August 2013 we received an informal community report of a probable rabies death in Busia County.

Methods: We visited Busia County Hospital and, using a case report form adopted from the California Department of Public Health, extracted patient information from the patient's file. We used the World Health Organization case definition. We traced the patient's home and interviewed household members.

Results: The patient was 20 years old and expectant at 30 weeks gestation. She lived in Bukalama, Busia County. She presented to Khunyangu Sub-County Hospital on 2/08/2013 with complaints of headache, anxiety, hydrophobia, hallucinations and abdominal pain following a dog bite on the medial malleolus of the left ankle joint one month prior to symptom onset. She was referred to Busia County Hospital on 3/08/2013. She had not received rabies vaccination and had no significant medical history. A diagnosis of rabies in pregnancy was made. Local wound treatment was performed and diazepam (10 mg) was given 8 hourly. No rabies immunoglobulin was given. She remained lucid, however died on 6/08/2013. No specimens were collected. The domestic dog had died within 10 days of biting the patient and had no known contact with another rabid animal. The patient had not traveled; there were no ill contacts and no history of occupational exposure.

Conclusion: The patient died of symptoms consistent with rabies. There was no laboratory confirmation of the animal and human cases. There was no notification of the death to the higher health system or veterinary department. The patient did not receive post-exposure prophylaxis (PEP). Dog death and dog bite notification, community education on PEP, canine population vaccination and collaboration between human and veterinary health services should be strengthened.

13:30

Julien Nzeze¹, Giovanni Guidotti², Stefano Capparucci², Anna Maria Doro Altan², Ceffa Susanna², Dirk Shaka¹, Leonardo Palomb³, Essenge Freddy⁴, Jacques-Devos Kabemba⁵

1 Community of Sant'Egidio, DREAM Programme, Kinshasa, RDC, 2 Community of Sant'Egidio, DREAM Programme, Rome, Italy, 3 "Tor Vergata" University, Rome, Italy, 4 Community of Sant'Egidio, DREAM Programme, Mbandaka, RDC, 5 Medecin chef de Zone de N'sele, Ministère de la santé, RDC

Partenariat Public/Privé en RDC Pour l'Implémentation de l'Option B Plus Chez les Femmes Enceintes HIV Positives: le Cas du Programme DREAM

Background: L'infection du VIH/SIDA est un problème de santé publique majeure aussi en RDC, où la prévalence chez la femme enceinte est de 3.5% (2011). Un protocole pour la prévention de la transmission de la mère à l'enfant a été élaboré en 2012 selon l'option B+. DREAM (Drug Resource Enhancement against Aids and Malnutrition), un programme de prise en charge des personnes infectées par le VIH/SIDA, de la Communauté de Sant'Egidio, est intégré dans les programmes nationaux et travaille avec les différents acteurs nationaux et internationaux. Lancé en 2002 au Mozambique, est implanté dans 10 pays d'Afrique, dont la RD Congo. (Mbandaka 2009, Kinshasa 2011).

Methods: Avec l'adoption d'un partenariat public/privé de longue durée entre le Ministère de la Santé et DREAM, un laboratoire de biologie moléculaire de référence et une unité DREAM MOBILE ont été mis à disposition, pour le renforcement de la PTME en appui de 10 structures de maternités publiques pour une couverture d'environ 100 km². Les points de force sont la gratuité complète et totale, la centralité et l'engagement actif du patient, la prise en charge intégrée VIH / Nutrition, l'Informatisation du parcours clinique et le fort réseautage avec les structures impliqués.

Results: Renforcement en capacités des structures de maternité avec séances de counselling et dépistage (4352 femmes dépistées) à l'occasion de la normale activité prénatal (CPN). Augmentation de la rétention des femmes (86%), avec l'assistance technique de la structure/paire éducation. Facilité d'accès à la cellule familiale. Pourcentage de nouveaux nés testés à 6 semaines avec DBS : 64%, résultats consignés en 24 jours. Taux de transmission mère – enfant enregistré : 1,3%.

Conclusion: L'adoption d'un choix sérieux et responsable des stratégies thérapeutiques et un réseau de laboratoires peuvent assurer suivi, contrôle et surveillance des femmes à coté de leur zone de résidence.

13:40

Ariane Nzouankeu, Marie-Christine Fonkoua, Gaëlle Tchouwa, Genevieve Tsobnang, Marcelle Abanda, Esther Sokeng, Antoinette Ngandjio

Centre Pasteur du Cameroun, Laboratory of Bacteriology, Yaoundé, Cameroon

Improving Surveillance of Neisseria Gonorrhoea Antimicrobial Drug Resistance Based on Efficient Laboratory Network: Case of Cameroon-GASP

Background: Gonorrhoea remains a public health concern worldwide. Resistance of *N. gonorrhoeae* (NG) to third generation cephalosporins and quinolones has recently emerged. In 2011, WHO launched in Africa, a sentinel program for gonococcal antimicrobial surveillance (GASP), aimed at strengthening laboratories capacities for identification of NG and monitoring antimicrobial resistance. In Cameroon, the GASP net work is coordinated by "Centre Pasteur du Cameroun" (CPC), in this study, we present GASP activities and the impact of the network on data collection from november 2012 to april 2014.

Methods: GASP network in Cameroun groups hospitals laboratories with capacities of bacterial culture and identification, and health centers laboratories able to afford Gram staining only. CPC, in charge of confirmation and antimicrobial susceptibility testings received either isolates or smears couple to culture dishes depending on the lab capacities. Minimal Inhibitory Concentrations (MIC) of ceftriaxone, cefixim and ciprofloxacin were determined according to CASFM guidelines.

Results: After training supported by WHO, 20 laboratories were enrolled in Yaoundé. Only 10 participated actively and provided data. A total of 102 NG isolates were collected in 2012 and 2013, representing a three fold increase, compared to data obtained in CPC alone during the 2 previous years. 83.3% of isolates produced beta-lactamases according to nitrocephine test. No resistance was observed to Cefixim., Resistance to Ceftriaxone and Ciprofloxacin was respectively observed in 3.92% and 16 % of strains, with respective MICs of 0.002 to 0.25µg/ml and 0.002 to 32 µg/ml.

Conclusion: These results highlight the importance of GASP Network in surveillance activities. Moreover, the resistance data obtained and notified to Ministry of Public Health will help for treatment schemes revision.

13:50

Abdul Mwanja, Fausta Mosh, Charles Masambu, Dickson Majige, Angelika Luguru, Jacqueline Mumba, Lawrence Lekashingo, Lugano Kyando

Ministry of Health and Social Welfare, Dar es salaam, Tanzania

On Site Sensitization Meeting to Hospital Management Teams Enhance Implementation Laboratory Quality Systems through SLMTA Program to 5 Laboratories Funded Under East Africa Public Health Laboratories Network Project (EAPHLNP) in Tanzania

Background: Strengthening Laboratory Management Toward Accreditation (SLMTA) program to improved Laboratory Quality System has been implemented to 5 satellite laboratories of Sumbawanga, Kigoma and Musoma Regional Hospitals as well as St. Benedict's Ndanda Mission and Kibong'oto TB Special Hospitals. The Laboratories are supported by East Africa Public Health Laboratories Network Project (EAPHLNP) under World Bank funds. Although technical and financial support was provided there was no remarkable improvement on implementation of Quality Systems. On site sensitization meeting on importance of Quality Management Systems to Hospital Management Team was conducted to address this challenge.

Methods: December 2011 Baseline Assessment conducted by trained laboratory Quality Assessors, all laboratories scored star zero. Early 2012 satellite laboratories enrolled into SLMTA program, project target is to achieve at least 2 stars as per WHO-AFRO – SLIPTA scheme. December 2012 peer assessment conducted, its objective was to measure progressively level of improvement. The result was star zero again from all 5 laboratories. After this Project Coordinating Unit (PCU) team decided to conduct on site sensitization meeting on importance of Laboratory Quality Management Systems to Hospital Management team. Specific agenda and special Laboratory Quality Assessment tool were developed, the meetings conducted between April and May 2013.

Results: September 2013 ASLM certified auditors audited satellite laboratories and scores are from 1 to 3 stars. Sumbawanga (2), St. Benedict's Ndanda Mission (3), Maweni – Kigoma (1), Musoma Regional (2), Kibong'oto TB (3).

Conclusion: On site sensitization meetings create and opportunity to Hospital Management teams to understand better the accreditation process and their responsibilities resulted to quality improvement and better scores.

ORAL POSTERS **4.3**
EXTERNAL QUALITY ASSURANCE PROGRAMMES

DATE: **Thursday, 4 December**

TIME: **13:00 – 14:10**

LOCATION: **Ballroom East/West**

CO-CHAIRS: **Henry Mbah**, FHI 360, Nigeria
Lawrena Okoro, Medical Laboratory Science Council of Nigeria, Nigeria

13:00

Alaine Umubyeyi Nyaruhirira¹, Catherine Mundy², Rhehab Chimzizi³, Bismarck Adusei³, Francesca Dzata⁴, Sebaka Molabo⁵, Lesly Scott^{5, 6}, Pedro Suarez², Frank Bonsu⁴

1 Management Sciences for Health, Pretoria, South Africa, 2 Management Sciences for Health, Medford, USA, 3 TB CARE I, Accra, Ghana, 4 National TB Control Program, Ghana, 5 Laboratory Health Service (NHLS), Johannesburg, South Africa, 6 University of the Witwatersrand, Johannesburg, South Africa

Initiating an Innovative External Quality Assurance Programme for Xpert MTB/RIF Instrument in Ghana (Pilot Phase)

Background: Internationally approved external quality assurance (EQA) programs are well-defined for TB microscopy, culture, and susceptibility testing. However, EQA has not yet been evaluated or demonstrated as feasible and useful for Xpert MTB/RIF testing. Consequently, countries have not initiated an EQA program for regularly measuring the technical performance of staff using Xpert MTB/RIF. In 2011, the National Health Laboratory Service (NHLS) in South Africa addressed this gap by developing a program that uses EQA to evaluate Xpert MTB/RIF testing of dried culture spots (DCS). Ghana's National TB Program, with support from TB CARE I, pilot tested the NHLS' program at four sites in Ghana.

Methods: Four study sites each received four spot panels that included a DCS of a MTB-positive Rifampin-sensitive strain, a MTB-positive Rifampin-insensitive strain, non-TB mycobacteria, and a negative control. The NTP conducted one-day training on EQA implementation at each facility before launching the EQA program. Participating facilities sent data reports to the NHLS for analysis through email or tbgxmonitor.com and received annual certificates of completion. The NTP conducted supervision and corrective action to the implementing sites, as they routinely do for microscopy.

Results: Three DCS batches with 48 DCS were shipped to Ghana for 4 GX4. Results on three panels were 100% accurate. At the four study sites, 100% of laboratory staff participated in the process.

Conclusion: This pilot project demonstrates that the use of inactive M. Tuberculosis coupled with easier transportation of DCS material can be safely evaluated for an EQA program that highlights expected staff error and site non conformities. Cost needs to be established for global participants (currently \$135/panel by module), but the use of a DCS format allows the material to be shipped as non-biohazardous and at one tenth the cost of transporting then other EQA material. Monitoring of the GeneXpert instrument and cartridge performance should be complemented with monitoring of the complete testing process. The NHLS' DCS test proved to be an appropriate vehicle for pilot testing the use of EQA for Xpert technology. The World Health Organization should endorse the dissemination of this approach, and thus, the cost reduction.

13:10

Franklin Kitheka, Sophie Mwanyumba, Mamo Umuro

National HIV Reference Laboratory, Nairobi, Kenya

Improving Quality of Rapid HIV Testing Services in HIV Testing and Counseling Settings: Impact of Hands-On Refresher Training

Background: In Kenya, the bulk of testing for diagnosis of HIV infection is primarily performed by non-laboratory personnel using Rapid HIV tests, thereby necessitating the need for close monitoring by laboratory practitioners to ensure the reliability of testing services.

The National HIV Reference Laboratory (NHRL) provides Dried Tube Specimen (DTS) technology based proficiency testing (PT) programs for Rapid HIV Testing. The program sends DTS-based Proficiency Testing panels three times a year to individually enrolled HIV testers with aim of assessing the quality of their performance. This helps in the identification of performance deficiencies and areas that require improvement at the individual HIV tester level. Targeted technical quality intervention strategies are implemented on identified PT participants following each PT survey. One such intervention strategies is refresher training.

Methods: In 2012, 198 individual HIV testers with unsatisfactory PT performance were offered refresher training with emphasis on quality assurance and hands on sessions on rapid HIV testing. The training was conducted by skilled, experienced HIV testing laboratory practitioners. Close monitoring and guidance were accorded during the training sessions. PT panels were administered on the trained testers in the next round and the impact of the refresher training monitored through their performance.

Results: 3.5% (7/198) of the trained PT participants did not return results to NHRL for performance evaluation. 98% (188/191) of those who returned results obtained satisfactory PT performance. Of the three (3) with unsatisfactory performance, none of them obtained incorrect results in their PT performance.

Conclusion: Refresher training, if done by skilled and experienced trainers is an effective quality improvement tool in Rapid HIV testing services.

13:20

Emmanuel Ojo, Henry Mbah, Humphrey Musuluma, Olufunmilayo Ojo, Sunday Ashaolu, Michael Dada, Uche Okudo, Olunmi Negedu-Momoh, Kwasi Torpey

Family Health International (FHI 360), Abuja, Nigeria

Use of Dried Tube Specimen Technology for Quality Assurance in Remote HIV Testing Sites Supported by FHI360 in Nigeria

Background: Dry tube specimen (DTS) technology is a cost-effective method used especially for Proficiency Testing (PT) of HIV rapid testing services for multipoint testing outside the laboratory in resource constrained settings in Africa. Here we report the implementation of DTS technology as PT methods to assess the quality of HIV serology testing in some remote FHI360 supported HCT & PMTCT sites in Nigeria.

Methods: In January 2013, FHI360 in collaboration with CDC Nigeria trained FHI360 and government technical staff on the preparation and use of DTS technology. Panels were produced in General Hospital Badagry, Lagos and Nnamdi Azikwe University Teaching Hospital, Nnewi, Anambra. Through lessons learnt in the initial production, existing SOPs and tools were reviewed. Five characterized PT panels were sent to each testing unit. This involved 15 sites in Lagos for the pilot phase in August 2013 and 41 sites (31 Lagos & 10 Anambra) for the scale up phase in February 2014. The evaluation was based on the following weighting, 80% for accuracy of testing results and 20% on reporting following the national algorithm. A score of $\geq 80\%$ was considered satisfactory.

Results: In the pilot phase, 14 sites (93.3%) returned their results, nine sites (60%) scored a 100%, five (33.3%) scored between 80% and 99%. In the scale up phase, involving 41 sites, there was no return from four sites (12.9%), all in Lagos. Twenty five sites (67.5%) scored 100%, 10 (27%) scored between 80% and 99%. Poor performance of less than 80% score was observed in two sites (5.7%) in Lagos. However many participating sites do not follow the national algorithm.

Conclusion: DTS technology can be easily use to monitor the quality of HIV rapid testing. The result of testing is satisfactory in most sites.

13:30

Oluwaseun Aladesanmi¹, Eric Lugada¹, Olusegun Busari², Olumide Okunoye², Sulieman Aminu³, Okechuku Oguer³, Gregory Uchuno⁴, Tosan Erhabor⁴, Eruona Etubi⁵, Jelpe Tapdiyel⁶, Okechukwu C. Nwanyanwu⁶

1 Laboratory, Health Systems Strengthening and Logistics, Axios Foundation, Abuja, Nigeria, 2 National External Quality Assessment Laboratory, Zaria, Nigeria, 3 Department of Defense, Nigeria, 4 Medical Laboratory Science Council of Nigeria, Nigeria, 5 Federal Ministry of Health Nigeria, Nigeria, 6 Centres for Disease Control and Prevention, Nigeria

Causes of Proficiency Testing failures in CD4 Immune Monitoring in Nigerian Laboratories: Outcomes of Investigation and Corrective Action Onsite Visits to Unsatisfactory CD4 Proficiency Testing Laboratories in Nigeria

Background: After 8 rounds of events in the National Proficiency Testing Scheme (NPTS), a Proficiency Testing Corrective Action Team (PT-CAT) was formed to conduct root cause investigation (RCI) into the causes for failure and recommend corrective action (CA) for unsatisfactory performing laboratories.

Methods: A criteria for classifying unsatisfactorily performing labs into groups A, B and C was developed. Labs grouped in C were ranked critical and intervention recommended was site visit for RCI and CA. Each critical lab was visited and RCI was conducted using the developed PT-CAT Investigation checklist to track and investigate testing through pre-analytical, analytical and post-analytical stages by reviewing PT documentation, observing testing, and interviewing lab staff.

Results: Weaknesses noted among laboratories visited included problems with documentation such as lack of standard operating procedures (16.7%), clerical errors in filing results (8.3%), lack of registration of PT panels (41.7%) and missing equipment printouts (33.3%). Gaps in knowledge of PT processes were also observed in all laboratories (44.4%) as well as lack of PT failure investigation (55.6%). Technical issues observed include no pipette calibration (38.5%) and weak or non-existent internal quality control measures (30.8%). Other technical issues observed were, non-monitoring of environmental and storage temperature and non-review of PT results before submission accounting for 15.4% of technical issues each. Personnel (83%), equipment (50%), electricity (33%) and reagent related issues (67%) were found in the laboratories visited. Personnel issues include high workload and inadequate staff (29%), non-availability of trained staff (14%) and lack of competency assessment (57%). Faulty and malfunctioning equipment was responsible for all the equipment issues observed. Reagent related issues, including poor storage, accounted for 33% while non-validation of reagents was observed in 67% of the labs visited.

Conclusion: The findings revealed a cataract of reasons why laboratories failed CD4 proficiency testing that are similar to previous studies conducted elsewhere. Laboratories with a proactive knowledge of these pit falls can implement preventive action to prevent reoccurrence and lead to improvements in CD4 testing and proficiency tests performance.

13:40

Schifra Uwamungu¹, Anthony Kebira Nyamache², Florance Masaisa³, Serah Njoki Kaggia⁴, Swaibu Katare⁵

1 University of Rwanda, College of Medicine and Health Sciences, Biomedical Laboratory Sciences Department, Kigali, Rwanda, 2 Kenyatta University, Microbiology Department, School of Applied Sciences, Nairobi, Kenya, 3 Department of Medicine, University of Rwanda, Hematologist Butare University Teaching Hospital, 4 Medical Laboratory Sciences Department, Jomo Kenyatta University of Agriculture and Technology, 5 National Center for Blood Transfusion, Rwanda

Coagulation Factors Level in Fresh Frozen Plasma in Rwanda

Background: Fresh Frozen Plasma is used in transfusion medicine and is associated with many risks if used inappropriately. There are limited studies conducted in Sub-Saharan Africa including Rwanda despite the limited known shelf life and storage condition of FFP that varies across many countries¹ transfusion guidelines. The aim of this study was to determine the level of coagulation factors in fresh frozen plasma in subsequent period of routine storage conditions.

Methods: A cross section study was designed to determine the level of coagulation factors and inhibitors over the time comparing baseline results and up to three months of storage based on both age, sex, weight and blood group of blood donors. A total of seventy two, fresh frozen plasma, have been collected from three blood transfusion sampling centers in Rwanda in three days after scientific review and ethical approval. The samples have then been analyzed using a full automated machine ACL 7000, using turbidimetric clot and chromogenic methods for factors assays and Prothrombin time and activated partial thrombin time tests.

Results: We found significant decrease of fibrinogen (-10%), FII (-8%), FV (-15%), FVII (-13%), FX (-15%), FXIII (-5%), PC (-7%), and ATIII (-5%), show a decrease from baseline up to three months, whereas FVIII (-8%), F IX (-4%), FXI (-6%), FXII (-3%), FPS (-3%), and VWF-Ag (-7%) have been constant without significant change (+/-0%) from baseline to one month then changed also significantly over time and decreased up to three months.

Conclusion: Our findings revealed that all coagulation factors and inhibitors in plasma could still be retained in fresh frozen plasma stored under -18 °C for three months. Such plasma would be acceptable product for most patients requiring fresh frozen plasma. However, the existence of labile factors including APTT and PT should be confirmed before transfusing.

13:50

Cheryl Johnson

World Health Organization, Switzerland

Are We Delivering the Wrong Results?: Examining Misclassification of HIV Status and False Positive Test Results

Background: There has been a scale-up in HIV testing globally, particularly with rapid diagnostic tests (RDTs). Such growth, however, has exceeded some national systems for ensuring the quality of rapid HIV testing. Recent reports suggest misclassification of HIV status is happening in resource-limited settings. Possible factors include: test kit failures, clerical errors, not following standard operating procedures, cross-reactivity between assays, misapplication of testing algorithms, and others. There are concerns about how misclassification, particularly false positive diagnosis, could undermine HIV programmes. Thus, we conducted a systematic search to assess misclassification of HIV status.

Methods: We conducted an electronic systematic search of peer-reviewed, abstracts and grey literature published from January 1990- July 2014. Eligible studies included laboratory-, facility- and community-based settings, using RDTs within a diagnostic testing algorithm. Focus was on actual misclassification, particularly false positive diagnoses. Studies reporting on factors related to potential misclassification or quality of HIV testing in programmatic setting were also included. No geographic limitations on search.

Results: 43/828 studies met inclusion criteria. Nearly all studies (40/43) were in low- middle income countries, in Africa (30/43) and in facility-based settings (40/43). Only 2 studies report actual rates of HIV status misclassification, ranging from 2.6%-10.5%, in 3 countries. Additionally, 4 studies evaluating testing algorithms in research settings report false positive rates as high as 48.2%; of which, 3/ 4 used a "tie breaker" strategy. Identified factors that could lead to greater number of false positives and misclassification include: inappropriate testing strategies (use 3rd assay as a "tie-breaker" result), test procedure errors, clerical errors, and use of inappropriate testing algorithms including effect of population characteristics resulting in cross-reactivity between assays.

Conclusion: Evidence on rate of misclassification is alarming, but limited due to few published reports, small sample sizes and ad-hoc investigations. Nevertheless, efforts are needed to examine magnitude of misclassification and its determinants. The use of "tie breaker" strategies, as well as human error, lack of training and supervision, population characteristics, test kits, among others, may contribute to greater number of false positive results. Urgent attention needs to be paid to global guidance on testing strategies, efforts to validate national testing algorithms, and to address frequent and re-occurring operator errors.

14:00

Esther Gathinji¹, Jennifer Anderson², Janvier Serumondo³, Emmy Rusanganwa³, Claude Muvunyi³, Anicet G. Dahourou⁴, Sally Liska¹

¹ Association of Public Health Laboratories, Silver Spring, Maryland, USA, ² Oneworld Accuracy, Vancouver, Canada, ³ Rwanda Biomedical Center/National Reference Laboratory, Kigali Rwanda, ⁴ CDC/DGHA/Rwanda, Kigali Rwanda

Implementation of a National EQA Program for the Rwanda Hospital Laboratory Network

Background: External quality assurance (EQA) is a recommended component for a laboratory's Quality Management System and a good indicator of laboratory operations such as equipment maintenance and inventory control. While there are advantages to a national EQA program provided by the national laboratory, material and human resources are often limited and a commercial system could be utilized.

Methods: Through a PEPFAR cooperative agreement with CDC/DGHA/ILB and CDC-Rwanda; APHL established a contract with Oneworld Accuracy to provide EQA panels for hematology, basic chemistry, CD4 and HIV rapid test to the National Reference Laboratory (NRL) and the national hospital laboratory network, comprised of 49 laboratories. The NRL receives and distributes the panels; each laboratory reports results electronically through the Oneworld Accuracy System (OASYS). The laboratory staff received training on OASYS before the initial test event. Additional training included review of results and feedback with guidance for corrective action and improvement.

Results: The laboratories successfully completed two EQA events (July and October 2013) with 100% participation.

The results were evaluated on an international level. 76% of the results submitted and evaluated were within the acceptable range set by the Centers for Medicare and Medicaid services in the U.S.

The laboratories showed remarkable improvement in the quality of their results in just one event. CD4, hematology and chemistry results respectively improved by 16%, 4% and 6% from the first test event to the second event, with respectively 90%, 80% and 64% of the results within the acceptable range at the second test event."

Conclusion: Participation in an EQA program with electronic reporting can be successfully implemented for a national laboratory network. Program success depends on a well-organized supply chain. In Rwanda, the NRL has centralized operations and oversight of the national hospital laboratory network, including a distribution and communication system.

POSTER 1

Richter Razafindratsimandresy

Virology Unit, Institut Pasteur de Madagascar BP1274, Antananarivo, Madagascar

Molecular Comparison and Diversity of Human Enteroviruses Circulating Between North and South Regions of Madagascar

Background: The live attenuated strains used in the oral poliovirus have been the main tool in the WHO polio eradication program. However, in rare cases, the attenuating mutations in the vaccine strains can rapidly revert and may cause vaccine-associated paralytic poliomyelitis or generate a transmissible and neurovirulent circulating vaccine-derived poliovirus (cVDPV) strains. In Madagascar, several VDPVs outbreaks have been reported during the last decade in the southern province. In all cases, the viral strains involved were recombinant between Sabin strains and Coxsackievirus A (CV-A) strains. Nevertheless, little is known about the enteroviruses circulation and epidemiology in the regions where these outbreaks occurred.

Methods: To explain factors that may determine circulation and emergence of VDPVs, we investigated and characterized the Human enteroviruses (HEVs) isolated from healthy children in four sites from two different regions (South and North) of Madagascar.

Results: Analysis of 1,309 stools showed a detection rate 26.8% of non-poliovirus enteroviruses (NPEVs). Amongst NPEVs detected, the phylogenetic analysis with the VP1 capsid region allowed to identify 51.3% (180/351) of HEV-C, 40.2% (141/351) of HEV-B, and 8.5% (30/351) of HEV-A species. Interestingly, the HEV-C species predominated in the southern sites (68.3%: 123/180) compared to northern sites 31.7% (57/180) ($p < 10^{-3}$); and the HEV-B species predominated in the northern sites (63.8%: 90/141) compared to southern sites 36.2% (51/141) ($p = 0.002$). We also showed that amongst HEV-A species, CV-A7 and CV-A10 were the most detected (36.7% and 30.0% respectively); while for HEV-B species, the CV-B4 (16.3%) was the predominant serotype detected. Amongst HEV-C species, CV-A13 and CV-A11 predominated in the southern sites (94.7% and 69.1%, respectively) ($p < 10^{-3}$).

Conclusion: The high circulation of Coxsackieviruses A associated with the low polio vaccine coverage as observed in the southern region of Madagascar, could result in increasing recombinant events amongst human population and thus contribute to the emergence of recombinant VDPVs.

POSTER 2

Inocencio Mate

National Institute of Health, Mozambique

Investigation of Dengue in Nampula City, Nampula Province, Mozambique, 2014

Background: Dengue is a febrile illness caused by dengue viruses belonging to Flaviviridae family and transmitted by Aedes mosquitoes. The first report of dengue (DENV-3) in Mozambique was in 1984-1985. In March 2014, an outbreak of dengue serotype 2 was reported in Pemba in Northern Mozambique. Transmission was also detected in Nampula, a neighboring province. The aim of this activity was to investigate the occurrence of dengue in Nampula City (NC) and to compare results between dengue rapid diagnostic tests (RDT) and ELISA.

Methods: Laboratory based surveillance was conducted between April 25 and May 6 at Nampula Central Hospital. Suspect cases were defined as patients with unexplained fever, Plasmodium negative result, and at least 2 of the following symptoms: headache, retro-orbital pain, myalgia, arthralgia, rash, or hemorrhagic signs. Suspected cases were tested using a combined dengue RDT to detect NS1 antigen and IgM/IgG antibodies. ELISA IgM antibody capture testing was also performed.

Results: Of 55 suspect cases from 10 neighborhoods of NC, 29 (52.7%) were positive for at least 1 marker of dengue infection by RDT. Of these, 15 (51.7%) were female. The mean age was 25.1 years, range 11-51 years. Main groups affected were students (30.9%) and health professionals (16.4%). From suspected cases, 49 were tested by ELISA for dengue IgM antibody and 14 (28.6%) were positive. Compared to ELISA, the sensitivity, specificity, positive- and negative-predictive value of RDT IgM were 57.1%, 100%, 100% and 85.3%, respectively. The concordance between RDT and ELISA IgM results was 87.7% and kappa value was 0.66 (95%CI: 0.41-0.89).

Conclusion: The results demonstrate the occurrence of dengue in NC. Positive RDT results highly suggest a dengue infection but a negative RDT result doesn't rule out a dengue infection. National and local health authorities developed activities to respond to and control the outbreak.

POSTER 3

George Sowayi, Evelyn Khabukwi Mulunji, Gabriel Wanyama Mukoya

Department of Medical Laboratory Sciences, School of Public Health, Biomedical Science and Technology, Kakamega, Kenya

Role of Selected Hematopoietic Micronutrient Status in Anemia Among Pregnant Teenagers Attending Antenatal Clinic at Two Healthcare Facilities in Bungoma County in Western Kenya

Background: Anemia in pregnancy is major problem globally, but especially in developing countries. This is bound to be particularly pronounced among teenagers, owing to increased O₂ demand, occasioned by the combined metabolic needs of a rapidly growing girl and her developing fetus. This has been found to increase risks of feto-maternal as well as child mortality and morbidity. Adequate intake of certain micronutrients promotes hematopoiesis thereby, making related nutritional status crucial to prevention of anemia in this population. The study aimed to establish possible contribution of hematopoietic micronutrient nutritional status towards anemia in teenage pregnancy in the target population. It is objectives were to determine the prevalence of anemia, status of selected hematopoietic micronutrient intake and the association of hematopoietic micronutrient nutritional status with anemia.

Methods: Descriptive, cross-sectional survey was done in 2009 at Bungoma County Hospital and Bumula Health Centre antenatal clinics, using 384 consecutively sampled teenagers. Micronutrient status was estimated as dietary intake using the Food Frequency Questionnaire; and anemia as hemoglobin concentration, categorized on basis of erythrocyte morphology and size, using Leishman-stained peripheral blood film (PBF) microscopy. SPSS version 12 computer program was used for data analysis, and inference based on 5% significance level.

Results: Overall anemia prevalence was 61% (Hb <100g/L); severe anemia (Hb <60g/L) 20%, moderate (Hb ≤90g/L) 31.2%, mild (Hb >90 <110g/L) 48.3%. One sample Students t-test revealed significantly prevalent nutritional deficiency anemia: Macrocytic, hypochromic anemia, 42.4%; microcytic, hypochromic anemia 49%. One sample Student's t-test showed inadequate micronutrient intake (p=0.001)—mean intakes: Folate, 364.4μg Vs the RDA of 400μ (55.2%); Ascorbate, 63.03mg vs 700mg (56.8%); and Iron, 16.8 mg vs 30mg (68.5%). Anemia prevalence and association with micronutrient intake was high (Chi Square=27.3 df9, p<0.05).

Conclusion: Anemia prevalence was significantly high, with microcytic hypochromic anemia slightly more prevalent than macrocytic, hypochromic anemia. Deficiency of the selected three hematopoietic micronutrients was significantly high with iron being affected most. The findings suggest a significant role for ascorbate, folate and iron nutritional status in the etiology of anemia in teenage pregnancy in the study population. This underscores need for inclusion of relevant interventions in antenatal care for pregnant teenagers in this target population in this study setting.

POSTER 4

Paul LaBarre, Kathy Tietje, Kenneth Hawkins, Christine Clerk, Kelly Ebels, Chris Crudder, Robert Burton

PATH, Seattle, Washington, USA

Progress Toward Development of a Low-Density Infection-Detection Test to Support Active Detect-and-Treat Interventions Aimed at Regional Malaria Elimination

Background: As successful malaria control programs dramatically reduce malaria prevalence, strategic and programmatic changes are required to eliminate malaria transmission altogether. Development of new, game-changing, and possibly disruptive malaria infection-detection (ID) technologies can enable more efficient elimination interventions in the most challenging malaria-endemic environments.

Methods: Phase I activities are oriented toward development of a robust target product profile (TPP) for a new, elimination-focused diagnostic product. Foundational activities in this phase include development of a use-scenario taxonomy, an analysis of elimination markets, a five-country field investigation of user requirements, a landscape analysis of technologies in the product development pipeline, and a review of elimination epidemiology and elimination tactics.

Results: Phase I activities support development of an infection-detection test (IDT) for qualitative detection of low-density *Plasmodium falciparum* (Pf) infections.

Conclusion: Phase II activities will support development of an IDT intended for qualitative detection of Pf infections. Specifically, the test is intended for use in active ID interventions aimed at identifying and treating subclinical, low-parasite-density populations that serve as reservoirs of parasite biomass. The proposed IDT will use human blood from a finger-stick sample on a rapid diagnostic test assay format and include histidine-rich protein 2 (HRP2) and one other Pf antigen as targets.

POSTER 5

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Factors Affecting Survival of HIV Positive Children Taking Antiretroviral Therapy at Adam Referral Hospital and Medical College, Ethiopia

Background: The aim of this study is to explore factors affecting survival of children living with HIV/AIDS after initiation of ART. In which it highlights the need for local evidence to promote interventions that optimize survival among HIV-infected children on ART in Ethiopia.

Methods: Institution based retrospective cohort study was employed on 560 children enrolled on ART from January, 2006-December, 2010. Information on relevant variables was collected from patients' medical cards and registries. Univariate analysis was used to describe the baseline characteristics of the patients'. Life table was used to estimate survival after initiation of ART. Log rank test was used to compare survival between different categories of independent variables. Multivariable Cox proportional model was fitted to identify factors affecting survival after initiation of ART.

Results: Children on ART were followed for a median follow up period of 47 months (IQR= 29, 62). At the end of follow up, 364 (65%) were alive and 43 (7.6%) were reported dead. More than three fourth of the deaths occurred within the first sixth months of starting ART. The estimated cumulative survival probabilities were 0.939, 0.928, 0.926, 0.923, 0.920, and 0.916 at 6, 12, 18, 36, 48, and 60 months, respectively. Anemia (hemoglobin level < 10gm/dl) (AHR=2.60, 95% CI=1.41, 4.84), absolute CD4 cell count below the threshold for severe immunodeficiency (AHR=3.55, 95% CI 1.48, 8.46), advanced WHO staging (stage IV) (AHR=3.08, 95% CI=1.27, 7.47), and underweight (AHR=2.49, 95% CI 1.27, 4.88) have found to be predictors of mortality after ART initiation.

Conclusion: Mortality was high especially during the first sixth months following ART initiation. Therefore, close follow up of HIV exposed children to make early diagnosis and treatment initiation before the development of severe immune deficiency and advanced clinical stage is important.

POSTER 6

Isah Adagiri Yahaya

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Distribution of Plasma C-Reactive Protein Measured by High-Sensitivity Assay in Apparently Healthy Adult Nigerians

Background: The plasma levels of C-reactive protein (CRP) within the reference interval have been shown to be a strong predictor of coronary heart disease (CHD) and is being considered in cardiovascular disease risk assessment. And for effective utilization of CRP in this regard, its distribution among apparently healthy individuals in the general population must be established, using the high-sensitivity method of analysis. Aim: The aim of this study was to describe the plasma distribution of C-reactive protein concentration in apparently healthy adult Nigerians and to estimate the proportions of those at high risk for cardiovascular disease.

Methods: C-reactive protein, glucose and lipid profile parameters were measured in one hundred and twenty apparently healthy adult Nigerians free of features suggestive of cardiovascular disease and not on any form of hormonal therapy. The blood pressure, height and weight of the participants were also measured. CRP was measured by synthron C-reactive protein ultra-sensitive Eliza method, while glucose and lipid profile parameters were measured by routine methods.

Results: CRP concentration ranged from 0.62-11.64 mg/L (mean, 1.3 mg/L, mean, 2.3 mg/L, 95% confidence interval(CI), 0.75-11.0 mg/L). About 81.7%, 15% and 3.3% of the participants had CRP concentration of <3 mg/L, 3-10 mg/L and >10 mg/L respectively. The plasma levels of glucose and lipid profile parameters were within the reference limits of our laboratory. None of the participants was obese.

Conclusion: This study describes the plasma distribution of C-reactive protein in healthy adult Nigerians. The results obtained would be useful in the risk assessment of individuals for future cardiovascular disease in our setting.

POSTER 7

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West Virginia University, School of Medicine – Pathologists' Assistant Program, WV, USA

The Role of Pathologists' Assistants: Young Profession with Great Potential to Improve Anatomic Pathology in a Pathologist Limited Continent-Africa

Background: The American Association of Pathologists' Assistants defines Pathologists' Assistants as highly trained allied professionals who provide various pathological services under the direction and supervision of pathologists. They are practically and academically trained in gross anatomy, lab management, anatomic techniques, and post-mortem examination.[AAPA website] PAs perform specimen processing such as gross dissection, post-mortem examinations, frozen sections and prepare tissue for various other examinations. In the U.S and other countries such as Canada, PA programs were established to improve pathological services in a cost effective manner. The creation of a PA program in Africa can help improve anatomic pathology departments by transferring grossing responsibilities and lab administration duties from pathologists to PAs. This will increase the availability of pathologists to provide faster diagnosis and improve quality management in clinical laboratories. Train the trainer programs sponsored by PEPFAR and in collaboration with ASCP have addressed the shortage of Pathologists. In December 2013, a team of three consultants visited the country of Swaziland to address a pathology backlog. The week session focused on training and building capacity by training lab technicians to prevent a future pathology backlog.

Methods: Literature Review of the cost-effectiveness of PAs in the U.S and case study of the National Lab in Swaziland where anatomic pathology principles were taught to the staff.

Results: PAs have improved patient care and lowered healthcare costs in the United States. Similar results can be obtained in Africa. With limited training and assistance, the staff at the National Health Lab in Swaziland was able to apply grossing principles and recover from an 18-month pathology backlog.

Conclusion: The creation of a PA certification program in Africa can help address the shortage of pathologists. If a two-year program cannot be readily established, shorter intense training can be of immediate value to anatomic pathology labs in Africa.

POSTER 8

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Implementing Laboratory Equipment Back-up Program: A Strategy to Minimize Service Interruption in APIN Laboratory Program

Background: One of the benefits of a good laboratory equipment management program is the reduction in interruption of services due to equipment breakdowns and failures. Service interruption resulting from equipment failure has grave consequences, especially client dissatisfaction. Laboratories are required to develop and implement back-up plans and procedures such as the use of back-up equipment or back-up laboratories for testing in the event of equipment repair or breakdown. It was in this realization that the management of APIN established back-up equipment plan at major supported health facility laboratories in Nigeria. This study seeks to review the effectiveness of the equipment back-up program.

Methods: Major facility laboratories with high patient load and sample volume were considered for provision of back-up equipment. The location of the facilities was also considered such that they could serve as back-up laboratories to other neighbouring health facilities. Both major and minor analytical and non-analytical equipment required for HIV/TB diagnosis and monitoring of treatment were backed-up with either similar or alternative equipment platforms.

Results: Out of 25 facility laboratories that received support for a complete back-up procedure, none of them experienced any service interruption. This represented 100% successful implementation of the back-up strategy. Though they were cases of equipment failure, but these did not result in service interruption. The back back-up equipment were used to support service provision in instances where equipment breakdown was recorded.

Conclusion: A well-managed laboratory equipment back-up program, coupled with a good equipment management program, is an effective strategy for eliminating service interruption resulting from equipment failures. Laboratories should therefore be encouraged to implement an equipment back-up program as part of their equipment management strategies.

POSTER 9

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HBV Co-infection and Its Predisposing Factors among HIV Positives at Karamara Hospital: A Comparative Cross Sectional Study between Pre-ART and ART Initiated

Background: Hepatitis B virus (HBV) infection is one of the major diseases of mankind that has shown to cause serious public health problem. HBV and HIV share common transmission pathways, and

the prevalence of hepatitis B surface antigen (HBsAg) reactivity in HIV co-infected patients is much higher than the population prevalence. HBV/HIV infected individuals are 6 times more likely to develop chronic hepatitis B than HIV negative individuals. Objective: to assess HBV co-infection and its predisposing factors among ART naïve and ART-initiated HIV positives attending at Karamara Hospital in Jigjiga city, capital of Ethiopian Somali Regional State.

Methods: A comparative cross sectional study was conducted from March to September 2013. Questionnaire, clinical and laboratory based data were collected. All the 350 blood samples collected were examined using immuno-chromatographic HBsAg test. Data was entered into Epi Data and analyzed using SPSS 17 computer software. Chi-square (χ^2) and logistic regression tests were used and p-value of less than 0.05 was considered as cut off value for statistical significance.

Results: An overall 4.6% (95% CI: 2.7-7.1%) prevalence rate of HBV co-infection was observed. Higher prevalence of HBV co-infection was found among ART naïve HIV positives which was 6.4% (95% CI: 3.3-11%) as compared to 3.1% (95% CI: 1.3-6.3%) prevalence among ART-initiated HIV infected individuals. Of the predisposing factors, only history of surgery had a statistically significant association with HBV co-infection among HIV positives (p-value=0.02, AOR=32, 95% CI=1.7-62).

Conclusion: The overall prevalence of HBV co-infection lies under intermediate epidemicity (2 to 7%) according to WHO classification. This underscores the importance of HBsAg Screening, which was not routinely done, for HIV infected individuals prior to HAART initiation in order to effectively manage co-infection and hepatitis. Key words: Co-infection, HBV, HIV, Pre-ART/ART naïve, ART-initiated, predisposing factor

POSTER 10

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Asymptomatic Oral Yeast Carriage among HIV and Non-HIV Individuals in Benin City, Nigeria

Background: Candidiasis is the commonest opportunistic fungal infection in patients infected with human immunodeficiency virus. CD4+ lymphocytes counts have been found to be a marker of HIV disease progression. This study was conducted to determine the prevalence of candidiasis among HIV patients, to evaluate Candida species diversity in the infected patients and to determine the association between CD4+ cell count and the prevalence of candidiasis.

Methods: A total of 300 subjects comprising of 100 each from those on highly active retroviral therapy (HAART), those not on HAART (HAART-naïve) and non HIV subjects were used for this study. Three samples comprising of urine, stool and oral swab were collected from each subjects.

Results: The overall prevalence of candidiasis among HIV patients was 52.5%. HAART naïve patients have significantly higher prevalence (OR=3.650; 95%CI=2.029, 6.564; P<0.0001) than their counterpart on HAART (OR=1.991; 95%CI=1.133, 3.497 ; P=0.0232). It was observed that the female gender was a significant risk factor for acquiring candidiasis (OR=3.400; 95%CI=1.141, 10.130; P=0.0289). The effect of age on prevalence of candidiasis was observed in HIV patients on HAART (P=0.0161). CD4+ counts >200c/µl was a significant risk factor for acquiring candidiasis only among HAART naïve patients (OR=4.368; 95%CI=1.597, 11.946; P=0.0042). The five species of *Candida* recovered from this study are *C. albicans*, *C. krusei*, *C. parapsilosis*, *C. tropicalis*, and *C. glabrata* respectively.

Conclusion: This study show that there was a significant relationship between antiretroviral therapy, CD4+ counts, and the prevalence of candidiasis.

POSTER 11

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Impact of Management Commitment towards Implementation of Quality Management System: Our Experience from Federal Capital Territory Administration (FCTA) Hospitals' Laboratories

Background: There are twelve (12) General Hospitals in the Federal Capital Territory (FCT) of Nigeria. The laboratory Units of these hospitals are managed by the Medical Laboratory Services Unit of the FCT Hospitals Management Board. Over the years, the laboratories had operated with little or no understanding of Quality Management System (QMS). As a result of this, many irregularities such as missing tests results, prolonged turnaround time, reagents out-of-stock, and transcription errors were common. With support from FHI 360 in 2012, baseline assessment of the laboratories was conducted using WHO/AFRO SLIPTA Checklist. The result was shared with the FCTA Hospitals Management. Therefore we evaluated Management's commitment towards implementation of Quality Management System in FCTA Hospitals' laboratories.

Methods: Firstly, a Medical Laboratory Scientist was designated with a sole responsibility of coordinating QMS efforts for all the FCTA Laboratories. Management sponsored 13 Medical Laboratory Scientists to a training on Laboratory Quality Management System. Thereafter, a workshop on SOPs Writing and laboratory documents development was organized for those set of laboratorians. Mentoring and supervisory visits were carried out to correct the nonconformities observed during the baseline assessment and to ensure compliance with the laboratory documents that were developed.

Results: Quality Manual, Laboratory Handbooks, Safety Manual, SOPs, templates, logs and worksheets were developed; staff are beginning to comply with these documents. There is improvement

in documentation and records keeping. Infrastructural upgrade of most of the facilities was carried out to enhance effective workflow. The laboratories have witnessed improvement in service delivery – turnaround time has been reduced. Laboratory test results retrieval has become easier.

Conclusion: Three out of the twelve labs have been selected for ISO 15189 accreditation process. Our experience has clearly shown that management commitment is an effective tool towards an effective implementation of laboratory QMS in a setting like ours.

POSTER 12

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Research Methodology and Scientific Writing Course: Transforming Laboratory Personnel to Research Scientists

Background: The East Africa Public Health Laboratory Networking (EAPHLN) Project which is being implemented in Kenya, Uganda, Tanzania, Burundi and Rwanda has several components which include Operational Research. The Operational Research component has two strategic objectives namely: – (i) to provide oversight and guidance in carrying out operational research activities under the regional project; and (ii) to facilitate local and regional capacity to carry out operational research and evaluation of medical diagnostics. In order to facilitate the local and regional capacity to carry out operational research, there is need to build human capital at the study sites.

Methods: A training needs assessment was carried out among healthcare personnel at the World Bank-funded EAPHLN facilities which are being implemented in Kenya, Rwanda, Tanzania and Uganda. We developed a short training in Research Methodology and Scientific Writing to support the implementation of operational research activities at the health facilities in Kenya. The course content was delivered through lectures, self-directed learning, group discussions, individual and group assignments.

Results: The curriculum was developed and piloted in April 2012. A total of nineteen participants from Kenyan sites were trained in Mombasa for two weeks. Six concept proposals were developed. The proposals are at different stages of scientific review process. The training curriculum was reviewed in October 2012 and packaged into three manuals namely: – Facilitators, Participant and Exercise. The curriculum was adopted by the East, Central and Southern African Health Community (ECSA-HC) to train participants from the region.

Conclusion: Strengthen capacity building in operational research at the centres of excellence in order to adequately address public health related issues. Capacity build other facilities country wide and regionally by rolling out the training. Develop structured mentorship programs in the facilities.

POSTER 13**Gladys Esendi Chunge**

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Survey, Isolation, and Characterization of Pathogenic Micro-organisms in the Outdoor Hospital Environment of Thika District Hospital, in Kenya

Background: The aim of the study was to isolate and characterize pathogens implicated in nosocomial infections which may be recovered within the outdoor hospital environment. It highlights the need to strengthen infection prevention practices in hospital in order to maintain good hospital environmental hygiene and thus safeguard the health of hospital staff, patients and visitors who frequent the hospital environment.

Methods: Descriptive cross-sectional study. This study reviews 7 microbiological soil sampling events from 7 different sites of Thika District Hospital. Fungi were recovered and enumerated by plating and incubation on Sabouraud's Dextrose Agar, Malt Extract Agar and Potato Dextrose Agar. Bacteria were recovered and enumerated after plating on Nutrient Agar, Potato Dextrose Agar and MacConkey agar. Bacterial characterization was performed using biochemical tests, microscopic evaluation the use of Bergey's manual of Systematic Identification. Raw data was analyzed using Excel software and trends were displayed in bar charts.

Results: The results show there are pathogenic bacteria and fungi in present in large numbers in the outdoor environment Thika District Hospital. The pathogens are highly sensitive to antibiotics with the exception of *Pseudomonas aeruginosa* which showed high resistance to antibiotics.

Conclusion: The outdoor environment of Thika District hospital is highly contaminated by bacterial and fungal isolates that cause severe infections in humans. The hospital's public health department must take measures to step up infection control measures in order to prevent transfer of infections from the outside environment to inside the hospital. The high sensitivity of the majority of the isolates to antibiotics indicates that many of the organisms under test have not been exposed to the effects of the antibiotics and intervention measures at this time would be highly effective and beneficial. However, isolates of *Pseudomonas aeruginosa* are the worst threat because they showed high resistance to antibiotics.

POSTER 14**John-Moses Uwanduoma Maduabuchi**¹, Eusebius Sunday Ugwu², Ivy Ifeoma Ogb³¹ Medical & Research Centre (MRC), Enugu, Nigeria, ² Isi-Uzo District Hospital, Enugu, Nigeria, ³ Trans-Ekulu Medical Centre, Enugu, Nigeria**Setting up a Quality Management System in a Community-based Clinical and Research Facility: Experiences and Challenges in a Rural Nigerian Setting**

Background: Medical & Research Centre – MRC Ikem is a community-owned hospital, managed by ZETA-12. Ikem is a rural part of Enugu, Nigeria, with peculiar poor health indices. The facility

is an innovation designed to provide managed healthcare services including a pilot community-based health insurance scheme – GOODLIFE Policy, operated by the Ikem Community Health System. MRC Ikem is also a member of a regional network of clinical trial sites created under the auspices of the Eastern Nigeria Research Ethics Forum (ENREF).

Methods: At MRC, frameworks were put in place to provide good hospital services with adequate and reliable clinical laboratory support. Quality policy, manual and objectives were developed as the basis for setting up a QMS, with the aim of getting certification within 3 years. The basic facility requirements were provided, and series of sequential training (online and onsite) designed for hospital staff. These include training on Bioethics, ISO Systems and GxPs, some of which are ongoing. Faculty and training resources are from the academia, private consulting, the Nigerian Regulatory Authorities and WHO.

Results: Site training were conducted on ISO 9001 requirements using both online resources and those from Standards Organisation of Nigeria (SON). Trainees were also exposed to ISO 15189 requirements for Medical Laboratory Standards. In addition to the IQC, and the available EQA/PT programs for the laboratory, we designed GCP/GCLP – Quality System in accordance with the Research Quality Association Quality System Workbook. Efforts were made(as required in our Quality Policy), with variable outcomes to encourage other partnering hospitals to develop similar Quality Systems in a bid to ensure optimal adequate care with referrals.

Conclusion: This paper discusses our on-going efforts, the interim outcomes, including the setting up of Isi-Uzo Ethics Committee, the new QA/QI program in the ENREF Network and also showcases the challenges encountered.

POSTER 15**Ayodeji Olayanji**, Richard Akele

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Comparative Study of Haematological Parameters in HIV Positive Individuals on Different HAART Regimen

Highly active antiretroviral viral therapy (HAART), a combination of three antiretrovirals from at least two drug classes for optimization of hindrance to HIV replication has greatly increased life expectancy. HAART combinations in the present study include Combivir(NVP), Combivir(EFV), Truvada(NVP), Truvada(EFV), Lanten(NVP) and Lanten(EFV). These combinations may independently, or in interaction with the disease process elicit haematotoxicity. To compare the effects of various HAART on blood cells, two hundred and thirty one blood samples were collected from clients attending a public hospital on six different HAART combinations, at least six months after commencement of HAART. Samples were assayed for CD4 counts and some haematological parameters. The difference between baseline (pre- HAART) and values after HAART were statistically compared. All HAART combinations used induced good immunological (CD4 count ranging from 154cellmm⁻³ to 262 cellmm⁻³) responses and thrombocytopenia (P<0.05). Anaemia (P<0.05) was more

prominent in Zidovudine based combinations while the Nevirapen based drugs showed Eosinopenic ($P<0.05$) tendencies. The data generated suggests that the haematological profile of the client must be well assessed before and during HAART to manage these effects.

POSTER 16

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Assessment of the Temperature Monitoring Systems in Public Health Laboratories in Kenya

Background: Laboratory equipment must be run within specified temperature ranges in order to operate according to the required specifications. By monitoring temperature in accordance with the manufacturer's instructions the laboratory protects the integrity of the materials. If temperature control is not maintained for reagents and specimens, then the laboratory cannot have confidence in the results obtained.

Methods: The temperature monitoring systems of three Public health laboratories and one faith based laboratory were evaluated. The temperature was monitored manually using mercury thermometers and staff took recorded temperatures manually on a paper log sheet at designated times during the day. One of the laboratories employed the use of maximum and minimum thermometers.

Results: 4/4 (100%) did not monitor the temperature electronically and used mercury thermometers. None of the thermometers used were traceable to National Institute of Standards and Technology (NIST). There was 4/4(100%) error observed for off-shift hours as temperatures were not monitored during weekends and public holidays and the overall transcription error was 40% for the past one year.

Conclusion: Manual monitoring is labour-intensive and requires the lab staff to spend some time taking and recording temperature. Charts and logs need to be collected, reviewed, filed, and stored for future audits. The manual monitoring does not provide a comprehensive view of storage conditions during off-shifts and does not alert staff of any temperature excursions. It is therefore critical that public health laboratories invest in automated computerized systems that increases the accuracy by providing continuous monitoring, centralized data collection, and simplified reporting.

POSTER 17

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Smear Conversion Rates on New Smear Positive Pulmonary Tuberculosis Patients in Adama District, Ethiopia

Background: Examining sputum smear and monthly follow up is one of the strategies of the directly observed treatment program which maximizes the chance of early detection of failure cases.

Methods: Patient records of Tuberculosis clinic at Public health facilities found in Adama district, Ethiopia were studied. Sputum smear conversion rates, treatment adherence, treatment outcomes and associated factors were retrospectively assessed in newly diagnosed and treated smear positive pulmonary tuberculosis patients of known HIV status enrolled in the directly observed treatment program from August 2007 – March 2011.

Results: Among the 458 enrolled study participants, 32.8% were HIV positive. Adherence of patients to the full course dose was observed to be 92% among 350 patients. Sputum smear conversion rates of 95.3%, 96.6% and 99.4% were observed on the 2nd, 5th, and 7th month interval of the follow up respectively. HIV positivity, age, sex and residence were not found to be associated with higher sputum conversion rates. An adjusted hazard ratio of 2.67 (95% CI=1.10-6.52, df=1, p=0.031) of dying were observed in HIV co-infected tuberculosis patients.

Conclusion: Higher rate of sputum conversion rates and good adherence are encouraging results in the tuberculosis control program implementation of the district.

POSTER 18

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Comparative Analysis of Putative Genes Mediating Invasion of Vertebrate Hosts by Plasmodium falciparum Parasite of Malaria

Clinical malaria is associated with the proliferation of Plasmodium parasites within the human erythrocytes. The coordinated processes of the merozoites' egress, recognition, attachment and ultimate invasion into host's erythrocytes are rapid and tightly regulated by the parasite proteases during the erythrocytic stage of parasite's life cycle. Using comparative genomics and bioinformatics tools I was able to identify and characterize some of the homologous sequences i.e. paralogs and orthologs of the putative genes involved in the erythrocytic invasion in Plasmodium falciparum compared to the other Apicomplexan parasites.

Using EupathDB resource, the BLAST application, Markov Clustering Algorithm (OrthoMCL) and the InterPro protein signatures/domains, I managed to identify the relatedness of the divergent proteases involved in the merozoite invasion. The study involved the determination of the functional and evolutionary similarities through sequence alignments, and clustering patterns analysis of the four classes of proteases involved in the merozoite invasion and propagation of Malaria disease. These sequences are information from the comparative genomic analysis across the Apicomplexa genomes provided critical information in the designing, synthesis and development of viable, successful and broad spectrum inhibitors/drugs which would control the spread of Human Malaria and wide range of other infectious diseases affecting both humans and livestock.

This project will serve as an information resource and a gateway in providing lasting solutions to complement the ongoing efforts in the development of an effective and viable Malaria vaccine and drugs. The availability of strong therapeutic strategies against these tropical infectious diseases would ease the financial and disease burden to the endemic nations particularly in Africa which would result in increased productivity, double-digit economic growth and improved health outcomes.

POSTER 19

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Utilisation des Tests de Diagnostic Rapide du VIH dans le Cadre de la Délégation des Tâches: Quel Contenu pour la Formation des Agents de Dépistage?

Background: La délégation du dépistage du VIH aux agents communautaires ou de santé qui n'ont pas une formation de base en biologie médicale interpelle sur la qualité de leurs dépistages. C'est pourquoi le contenu de la formation qu'ils reçoivent occupe une place importante surtout dans un contexte où les ressources ne permettent pas de réaliser des évaluations externes de la qualité. Pour ce motif, Solthis, en collaboration avec le programme sida et le Laboratoire national de santé publique, Guinée a développé un module de formation adapté aux agents non professionnels en laboratoire.

Methods: Au préalable, chaque personne ciblée est évaluée pour identifier les besoins en formation. La formation se déroule en deux étapes : une en salle (dans un laboratoire) pendant 2 jours puis l'autre dans le site en 1 jour, les 3 à 4 semaines suivant la première. La formation en salle contient 5 heures de modules théoriques (épidémiologie, biologie, algorithme de dépistage, utilisation des outils de gestion, gestion des stocks, contrôle de qualité et hygiène) et 9 heures de travaux pratiques (prélèvement, utilisation des tests, remplissage des outils). L'approche est participative. Les principaux supports sont des exercices, des vidéos et les modes d'emploi fournis par les fabricants de tests.

Results: Cette approche a été utilisée pour la formation de plus de 100 personnes. Le respect des procédures de réalisation des tests de dépistage rapide et de l'algorithme national s'est fortement amélioré dans les sites. Des acteurs qui avaient des formations avec d'autres supports ont déclaré avoir mieux assimilé la réalisation des dépistages par cette approche

Conclusion: Le succès d'une formation dépend de la qualité des supports et de la technique pédagogique utilisée.

POSTER 20

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Piloting Ogawa Kudoh for Solid TB Culture at District-level Laboratories in Mozambique

Background: The National TB Reference Laboratory in Maputo (NTRL) is the leading diagnostic center for testing in Mozambique. Since 2009, the American Society for Microbiology (ASM), with support from the US Centers for Disease Control and Prevention – Mozambique (CDC) has been supporting them to improve their diagnostic techniques, implement new methods such as liquid culture using the MGIT 960 and GeneXpert. Objective The objective for ASM was to provide a low grade, safe and effective method to expand culture capacity outside of the main TB laboratory, one of the country objectives described in the Mozambique NTP Strategic Plan within the infrastructural constraints of the national laboratory network.

Methods: To this end, an ASM consultant provided training to the NTRL on the Ogawa Kudoh method for sample processing, eliminating some of the biosafety necessities for sample processing prior to solid culture. She subsequently also provided a training of trainers to NTRL staff after assessing two preliminary pilot sites in Maputo for rollout. The NTRL was then tasked with providing this training to both sites. Sites are then expected to roll out the method but initially provide cultures to NTRL to incubate.

Results: In July 2013, the NTRL provided the first pilot training to the health assessment site. A subsequent analysis of needs and gaps has resulted in a request for additional supplies and support for a 'culture referral' system from the two sites back to the NTRL for incubation.

Conclusion: The NTRL laboratory staff is fully trained and competent to pilot Ogawa Kudoh method expansion for solid culture to the sites selected. They will however require additional resources to roll out the training and additional capacity within their laboratory to incubate the additional samples. Incubation at sites would be the long term goal and infrastructure at sites will need to be developed to accommodate this in future.

POSTER 21

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Country Ownership Approach to Scaling Up Biosafety Practices in Kenya

Background: Safety is a key component of the ISO 15189 standard for medical laboratories. Prior to 2010 a shallow comprehension of biosafety comprising only of “universal precautions” existed. When laboratories embarked on strengthening laboratory systems towards accreditation (SLIPTA), the full breadth of biosafety became evident as internal audits revealed both lapses and opportunities for improvement.

Methods: A national biosafety technical working group was constituted and tasked to develop a national biosafety training curriculum comprising of both theory and practical sessions. Key staff was supported to receive specialized biosafety training internationally at ACILT in South Africa, Eagleson Institute in USA and Sandia Laboratories in USA. These became national flag bearers of biosafety. A biosafety training faculty comprising of trainers of trainers (TOT) was established. Regional trainings were scheduled in liaison with MOH and PEPFAR implementing partners.

Results: A comprehensive curriculum covering all 14 areas of biosafety was developed. Up to 200 trainings based on the national curriculum have been conducted. Beneficiaries include 963 HCWs from all tiers of the health system ranging from National (level 6) to health centers (level 2) and dispensaries (level 1). Of these, 886 are from the ministry of health including 23 HCW from the blood banks, 29 from implementing partners, 26 from Faith Based Organizations, 15 from the County Council facilities in Nairobi and 7 from medical training institutions. Trainees also represent various cadres of HCW including 927 Laboratorians, 24 Morticians, 7 lecturers from training institutions and 3 Nurses. All trained facilities have identified biosafety officers. Biosafety is now a well-recognized section within MOH.

Conclusion: Building on the biosafety foundation laid by PEPFAR, Kenya has institutionalized biosafety practices nationally. Biosafety has been embraced by all sectors and cadres of health services. The wide acceptance and engagement of pre-service sector fosters country ownership and sustainability.

POSTER 22

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Seroprevalence of HIV and Syphilis among Pregnant Women in Gondar, Northwest Ethiopia: Awaking Message

Background: HIV and syphilis are major public health problem in sub-Saharan Africa. They complicate pregnancy seriously and result in spontaneous abortion, stillbirth, intrauterine growth retardation as well as serious negative outcomes in live born infected children like abnormalities of major organ systems. The study was aimed to assess seroprevalence of HIV and syphilis among pregnant women attending antenatal care service.

Methods: An institutional based cross-sectional study was conducted in Gondar university teaching hospital from March 01 to April 30, 2012. Participants were face-to-face interviewed. Serum and/or plasma samples were tested for HIV following current HIV1/2 testing algorithm. Syphilis reactivity was also tested using RPR test. The hemoglobin level was measured by Sysmex KX-21 haematology analyzer.

Results: Of the total 302 pregnant women, 31(10.3%), 11(3.7%) and 3(1%) were seroreactive for HIV, syphilis and HIV-syphilis co-infection respectively. High prevalence of HIV is found in urban dwellers (87%), having secondary school and above educational status (74.2%), occupationally housewives (64.5%), age of 25-29 years (58.1%) and low income group (58.1%). Syphilis is high in occupationally housewives (90.9%), low income group (81.8%), age of > 30 years (63.6%), urban residents (63.6%), having below secondary school education (63.6%). Low-level husband educational status was significantly associated with high prevalence of HIV (AOR [95% CI] = 5.75 [2.40, 13.69]) whereas low-level maternal educational status was associated with high seroprevalence of syphilis (AOR [95% CI] = 0.23 [0.08, 0.66]). Anemia was significantly higher in HIV seroreactive (AOR [95% CI] = 2.31[2.31, 14.93]) but not in syphilis seroreactive women.

Conclusion: Seroprevalence of HIV and syphilis was high. Low-level husband and maternal educational status were predictors for high seroprevalence of HIV and syphilis respectively. Substantial efforts have to be made to reinforce prevention strategies, and to screen as early as possible which offers an additional opportunity to prevent mother-to-child transmission and further horizontal transmission.

POSTER 23**Gapelba Aime**, Gapelba Aime, Errol Visser

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Challenging Experience of Blood Units Supply in a Remote Area: Case of Mogadishu, Somalia

Background: Blood needed in mass casualties in conflict area. Units lifetime limited. Importations highly regulated. Introduction: 97.7% Blood units supplied to a Remote medical facility in Mogadishu in 2013-14 come from an Amsterdam based company. With this come the challenges of timely and adequate delivery and rational use of this precious item. As a result a lot of units where discarded upon expiry. Therefore, we undertook to study retrospectively the whereabouts of all the units from previous supplies in order to improve the benefits.

Methods: Analysis of all batches of units supplied against the whereabouts of each units.

Results: 345 units out of 353 managed, were received in 13 batches during a period of 11 months; an average of 26.5 units per delivery or 31.4 units a month. on average every batch arrives with validity of 52.6% of its lifespan (15.7days/30). The best was in November 2013 with 27days valid (90%) and the least was in october when it arrived expired by 1 day (0%). A month length is covered by 56% (16days), 44% of the month (14days) not covered with blood available. By misfortune, on 19 June 2013 and 13 February 2013 attacks, we had no blood in our stock, although we could ask help from local sources should the need arise. During New year's attack there was no blood in supply. The best month covered was November (30days) and the least covered was September (8days). 53.6% of stock ended up discarded at expiry. An extra 8 units of whole blood from local sources in june and july 13. ** Out of 345units, 131 units (38%) were issued usefully from the stock, 1.7% used at our facility, 8.3% transferred to level1 field hospitals, 30% issued to a level 2 field hospital.

Conclusion: This results showing a lot of loss due essentially to the delay on transit has led to recommendations under implementation. And improvements are essential. Reduction on local blood collection, reduction in units incinerated and a full time availability of units as security backup. ** Ethical dilemmas – transfusion of locally procured blood supplies, collection from donors in malaria areas.

POSTER 24**Jeanine Nkakulu Luzolo**¹, Mah-Séré Keita Sow², Jean Willy Tshimpaka Tshiamala¹, Daniel Yavo², Jérémie Muwonga Masidi¹, Samuel Edidi Bazepeyo¹, Berthe Vantoto Mpova¹, Thérèse Mujanyi Kasonga¹, Antoinette Mayamba Tshindibu¹, Nadine Damaris Abiola³

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Evolution du Réseau de Contrôle de Qualité des Laboratoires VIH en RDC

Background: Le réseau de contrôle de qualité des laboratoires VIH en RDC est opérationnel depuis 2009, organisé par le LNRS-RDC grâce à l'appui technique de l'ASM financé par CDC/PEPFAR-RDC. A ce jour, plusieurs laboratoires appuyés par les partenaires d'implémentation CDC/PEPFAR-RDC y ont intégré, et le nombre des laboratoires participants au contrôle de qualité par échantillons séchés dans le tube (DTS) ne fait qu'accroître.

Methods: Un panel de 6 DTS est envoyé à chaque structure une fois par semestre. Un formulaire est utilisé pour collecter les données des sites. La saisie et l'analyse des données sont effectuées au LNRS-RDC sur un fichier Excel (CDC Templates), après collecte des résultats des sites via les points focaux de chaque province ou les partenaires d'implémentation (IPs).

Results: L'effectif des laboratoires ayant intégré le contrôle de qualité DTS est passé de 26 en 2009 à 254 en Décembre 2013. La décentralisation a été amorcée en 2013 pour les pools du Katanga et de la Province Orientale. Le pool de Kinshasa seul regorge un effectif de 179 sites parmi lesquels 143 sont appuyés par CDC/PEPFAR-RDC. Les erreurs constatées portent sur le respect des algorithmes, les résultats incorrects, la transcription des résultats, le délai de rendu des résultats, le remplissage du formulaire des résultats et le non envoi des résultats au LNRS par les sites autres que ceux appuyés par CDC/PEPFAR-RDC.

Conclusion: Le nombre des laboratoires participant au programme de contrôle de qualité DTS accroit chaque semestre malgré quelques difficultés rencontrées sur le terrain. Le renforcement des stratégies mises en place permettra d'y remédier notamment l'organisation des formations de recyclage des prestataires, l'appui régulier en réactifs, le renforcement de la logistique et les supervisions formatives.

POSTER 25

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Antituberculosis Activities of Crude Extract and Fractions of the Bulb of *Crinum jagus* against *Mycobacterium tuberculosis* Isolates

Tuberculosis (TB) is of great public health burden globally in developing countries. Current TB regimen involves multiple therapies and of long duration leading to poor patient adherence. Hence, there is a need for discovery of new anti-TB drugs. This study was designed to investigate the in vitro anti-TB activity of the crude methanol extract and chromatographic fractions of the bulb of *Crinum jagus* against *Mycobacterium tuberculosis* isolates. The extracts were screened for anti-TB activity against three different *M. tuberculosis* isolates and a drug susceptible reference strain H37Rv using Lowenstein Jensen (L-J) medium and Middle brook 7H10 agar (MB). The crude extract was prepared using soxhlet extraction method while its fractions (F1, F2 and F3) were obtained by column chromatography. The two media were inoculated with *M. tuberculosis* strains, after which the extract and its fractions were separately added. After 4-6 weeks incubation, colony forming units were counted and percentage inhibition was calculated. The percentage inhibition were plotted against the logarithm of the plant extract/fractions concentrations to determine the 50% inhibitory concentration (IC50). The extract and its fractions showed a concentration-dependent inhibition of all the isolates tested including the reference strain in both media (L-J and MB). Fraction 1 had the highest inhibitory activity (IC50 : 0.22mg/ml) comparable with rifampicin (IC50 : 0.19mg/ml) and isoniazid (0.23mg/ml). The order of inhibition was F1 > F2 > F3 > crude extract. Result showed that the crude methanol extract and fractions of the bulb of *Crinum jagus* exhibited antimycobacterial activity which indicated a promising potential of this plant for the development of antituberculosis agent.

POSTER 26

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Utilisation de l'Application Microsoft Excel® Comme Outil de Gestion des Données Qualité dans un Laboratoire de Biologie Clinique

La collecte et la gestion des données constituent la première étape de la démarche qui est l'instrument logique par excellence pour organiser les indicateurs et les suivre dans un processus d'assurance qualité. La prise des décisions dans un laboratoire de biologie clinique nécessite une collecte des données efficace et en temps réel. Les outils de collecte le plus souvent manuel rendent fastidieux leur traitement et ajouté au manque de personnel dans les Laboratoires de biologie clinique, l'opérationnalisation d'une démarche d'assurance qualité devient utopique. Il existe

néanmoins quelques outils électroniques du quotidien qui sont sous utilisés. Nous proposons un ensemble de 10 applications créées à partir de Microsoft Excel pour la gestion des indicateurs de la qualité dans les buts de la collecte des données. Les données sont saisies dans un ordinateur avec une application Microsoft Excel installée. Il s'agit d'un outil conçu pour gérer de façon semi-automatique les résultats de contrôle-qualité interne des tests quantitatifs, semi-quantitatifs et qualitatifs. Il est basé sur une série de feuilles de calcul qui permet la saisie des données, la compilation et la consolidation automatique des informations. Cet outil nous permet de gérer les données dans tout le processus d'analyse du laboratoire avec le choix préférentiel de quelques indicateurs à chacune des trois phases ; soient, à la phase pré-analytique ; la satisfaction des clients, pour la phase analytique, la validation et la vérification des équipements, le suivi des contrôles interne de la qualité des analyses quantitatifs et qualitatifs et la génération des courbes de Levy-Jenning et pour la phase post analytique l'archivage des documents. Toutes ces applications ont été construites sur un format dont la mise en forme est simple et personnalisable pour chaque structure. Mots clés : Microsoft Excel, indicateur qualité, donnée, gestion.

POSTER 27

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Hematological Abnormality and Associated Factors among Children in Anti-retroviral Therapy Naïve and on Highly Active Anti-retroviral Therapy at Felege Hiwot Referral Hospital, Bahir Dar, Northwest, Ethiopia

Background: Human Immunodeficiency virus infection is a multi system disease. Hematological abnormalities are among the most common complications of HIV/AIDS in children. Objective: To assess hematological abnormalities and associated factors among children who were in Pre- ART and on HAART at Felege Hiwot Referral Hospital, Bahir Dar, Northwest, Ethiopia.

Methods: A cross-sectional study was conducted among children living with human immunodeficiency virus attending at Felege Hiwot Referral Hospital. Systematic random sampling method was used to select the study participants. After full informed consent and assent was obtained, socio demographic data were collected using a pre tested structured questionnaires. Blood was drawn and hematological profile was obtained by performing hematological tests. The data were entered, cleaned and edited, using EPI info version 3.5.2 and was exported in to SPSS version 20 for analysis. Descriptive statistics, independent t-test and chi square were used for analysis. Both bivariate and multivariate logistic regression was employed to assess the association between outcome and independent variables on the basis of P value <0.05 at 95% confidence interval.

Results: The study enrolled 224 participants (112 antiretroviral therapy naïve and 112 on antiretroviral therapies. The mean (SD) age of the children were 8(+3.46) years and mean (SD) CD4 percentage was 26.73+14.22. The prevalence of anemia, leucopenia, and thrombocytopenia was 15.2%, 14.7% and 4.9%

in pre-ART, whereas it was, 14.3%, 12.9% and 3.1% on HAART respectively. CD4% and MCV had statistical significant mean difference in hematological parameters of ART naïve and on HAART. The prevalence of anemia in severe immune suppression was 47.5% and severity of immune suppression (AOR=3.97 (95% CI 1.33-11.85) and Gastroenteritis (AOR= 4.00, 95% CI 1.10-14.53) were found to be the independent predictors of anemia while age 12-14 years were preventive factor. Leucopenia was associated with oral esophageal thrush (AOR=5, 95% CI 1.6-16.9), being female (AOR=0.512 (95% CI 0.27-0.98), farmer (AOR=5.8 (95% CI 1.6-20.4) and governmental employed (AOR=4 (95% CI 1.14-14.37).

Conclusion: Hematologic abnormalities were common problems among the children in pre ART and On HAART. Therefore, especial emphasis should be given for investigation and management of hematological abnormalities among children living with HIV/AIDS, those who had low CD4%, with the presence of gastroenteritis and oral esophageal thrush.

POSTER 28

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Preliminary Investigation of Antimicrobial Potential of Giant African Land Snail (*Archachatina marginata*) Epiphram and Egg against Selected Pathogenic Isolates

Background: Snail products have been reported recently to be used for different medicinal purposes. Prominent among such usage include its use against some illness like inflammatory skin diseases, bronchitis, catarrh and asthma. Its usage in wound healing was also documented, which reveals the potential of this animal to contain antimicrobials.

Methods: Pathogenic isolates of *Klebsiella* spp, *Bacillus* spp, *Salmonella* spp, *Pasteurella* spp, *Listeria* spp, *Hemophilus* spp and control isolate of *Staphylococcus aureus* (ATCC 25698) and *E. coli* (ATCC 25699) were obtained from public health facilities in Abeokuta and were biotyped. MIC of both epiphram and egg of *Archachatina marginata* were determined by standard micro-broth dilution method. Ciprofloxacin was used as control.

Results: Results showed that there was significant susceptibility of *Bacillus* spp, *Salmonella* spp, *Pasteurella* spp, *Listeria* spp and *Hemophilus* spp to epiphram of *A. marginata* at MIC of 0.25 µg/ml while MIC value of 3.3 µg/ml was recorded for egg. The control (Ciprofloxacin) had MIC of 0.25 µg/ml for epiphram against *Staphylococcus aureus* (ATCC 25698) and *E. coli* (ATCC 25699) while egg showed MIC of 3.3 µg/ml and 6.25 µg/ml against *Staphylococcus aureus* and *E. coli* respectively.

Conclusion: The findings of this study showed that both epiphram and egg of giant African land snail (*Archachatina marginata*) contain substance(s) probably antimicrobial peptides that could help in the control of these pathogenic organisms.

POSTER 29 CANCELLED

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Uptake of Free Viral Load Services in Kenya

Background: The first Viral load test performed in KEMRI was in March 2012 and was introduced as a free service to monitor Kenyans on ARV treatment. The Ministry of Health Kenya has scaled up testing so that all 644,000 ART patients are able to receive one viral load test each year. The service has seen growth over the past two years where patients have been able to receive this test. Viral load (VL) testing was initiated in the country using the systems and platforms used for the Early Infant Diagnosis (EID) program.

Methods: This is a cross sectional descriptive study of data collected from March 2012 to April 2014. The testing lab supports 678 facilities and has tested 37,885 samples so far. The service relies on ROCHE CAP-CTM and Abbott m2000 for testing. A Laboratory Information Management System is used to facilitate data entry which captures information given on the viral load request form on the patient which includes, CCC number, sex, date of birth, date of collection, sample type, current regimen, date of ART initiation and justification for the VL test. All data analysis was done using IBM SPSS Statistics version 19.

Results: Number of viral load tests done since March 2012 is 37,885, there has been a two fold increase between 2012 and 2013, the number of samples tested in the first quarter of 2014 is almost as high as those in the year 2013 alone where thirty one (66%) of the 47 counties are represented here. Patients whose ages ranged between 27-45 years were 49.8% of the patients tested while those above 45 years were 43.48% one patient was aged 94 years. The main reason this test is requested, according to the data given is immunological i.e. fall of CD4 count to baseline and 50% fall from baseline, clinical failure and routine switch, 43.6% of responses had no data.

Conclusion: The Viral load services provided by the testing lab has seen growth in numbers of patients in regions in Kenya. Patients on ARV's have benefited by the monitoring of their viral load count which allows for better management of these patients. There is a need for correct patient information to be emphasized to improve policy development on a national scale.

POSTER 30

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Quality Improvement Initiatives towards Provision of Safe and Sufficient Blood in Kenya

Background: A structured quality system is vital to a strong, efficient, and self-sustaining national blood transfusion service with the capacity to respond to the needs of safe and sufficient blood for the entire country. Global Communities Blood Safety program funded by the U.S. Centers for Disease Control and Prevention (CDC) under the President's Emergency Plan for AIDS Relief (PEPFAR) is supporting Kenya National Blood Transfusion Service (KNBTS) to undertake Stepwise Laboratory (Quality) Improvement Process Towards Accreditation (SLIPTA). A structured approach with Strengthening Laboratory Management Towards Accreditation (SLMTA) as a key tool is being used in SLIPTA to ensure a high-quality functional system of blood transfusion services.

Methods: In January 2013, a baseline audit was conducted at 6 regional blood transfusion centers (RBTCs) using the SLIPTA checklist. SLMTA 1 and 2 workshops were held and intervening mentorship visits were conducted. The program was customized to suit the scope of blood transfusion services and additional trainings provided.

Results: Six RBTCs and the national office were audited. The average score was 97 out of the possible 258 points (range 61 to 120). Facility and safety and information management section had the highest scores. Notable areas that need major improvement to ensure effective blood services include: taking corrective actions, management of occurrences and conducting internal audits to improve the quality management system. Thirty-four technical and management staff members attended SLMTA 1 and 2 workshops. Participants were drawn from key cadres in blood services including laboratory, donor clinic, management and quality departments. Hands-on activities covering vein-to-vein blood transfusion services have been adopted during the training. Mentors with blood transfusion services were used to during the site visits.

Conclusion: Lack of quality practices was widespread supporting the need to implement SLIPTA. An action plan endorsed by the top management of KNBTS has been put in place to respond to deficiencies identified. Internal and external mentors with experience in blood transfusion and quality management system are being utilized to aid in the implementation of SLMTA. Additional training and embedded mentorship on identified deficiencies is being performed to improve quality in KNBTS

POSTER 31

Barbara McKinney

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Designing a Curriculum to Promote Publication of Laboratory Quality Improvement Work in Vietnam

Background: The Vietnam pilot of the Strengthening Laboratory Management Toward Accreditation (SLMTA) quality improvement (QI) program was completed in June 2013. The in-country SLMTA team desired to share and publish their successes and lessons learned with the laboratory community.

Methods: A three-day publishing workshop was organized and conducted by an international trainer and U.S. Centers for Disease Control and Prevention, Vietnam laboratory leaders. The workshop participants identified the proposed topics, and worked as a group to determine the focus and outline of the papers. The curriculum combined short didactic sessions, activities, and group writing – all focused around the Standards for Quality Improvement Reporting Excellence (SQUIRE) Guidelines, which were developed specifically to increase the scholarly level and quality of QI reporting. The 19 items on the SQUIRE Checklist were presented and used to critique a published QI paper in the didactic sessions. Participants then used the SQUIRE framework to draft their papers.

Results: Three papers were conceptualized and outlined. To date, one has been accepted for publication, and one is in process of publication.

Conclusion: This publishing workshop format, which balances didactic sessions, activities, and group writing, does yield papers. It is hypothesized that the following changes will improve the workshop's yield of published papers: 1) Use SQUIRE to outline the entire QI project prior to the study, including an aim, metrics, and changes to be tested. 2) Lengthen the workshop or conduct multiple sessions. 3) Follow up timelines. 4) Provide research, editing, and submission assistance for scholarly writing. The SQUIRE Guidelines provide practical guidance for reporting QI work. Adding to the body of laboratory improvement knowledge, sharing best practices, and proffering lessons learned are key benefits of publishing improvement work. As healthcare funding diminishes, sharing quality improvement work through publishing will become even more valuable to the global community.

POSTER 32

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Viral and Bacterial Etiology of Severe Acute Respiratory Illness in Children <5 years of Age in Niger, 2009-2012

Background: Globally, pneumonia is the leading cause of morbidity and mortality in children, with the highest burden experienced in sub-Saharan Africa and Asia. However, there is a dearth of information on the etiology of severe acute respiratory illness (SARI) in Africa, including Niger.

Methods: We implemented a retrospective study from April 2009 to December 2012 as part of the national influenza sentinel surveillance in Niger. We randomly selected 10% of upper respiratory tract samples collected from children (<5 years of age) hospitalized with SARI as part of the national influenza sentinel surveillance system from April 2009 through December 2012 in Niger. The samples were selected from individuals that have been tested negative by realtime reverse transcription polymerase chain reaction (rRT-PCR) for influenza A and B virus and were analyzed using the Fast Track Diagnostic Respiratory Pathogens 21plus Kit (Biomérieux). This kit detects 23 respiratory pathogens including 18 viral and 5 bacterial agents.

Results: Among the 160 samples tested, we detected at least one respiratory virus in 125 samples (78%); at least one bacterium in 103 samples (64%) and 105 cases of viral and bacterial co-infections (65%). Respiratory syncytial virus (35%), rhinovirus (29%) and parainfluenza type 3 virus (19 %) were the most common viral pathogens detected. Among bacterial pathogens, *Streptococcus pneumoniae* (56%), *Haemophilus influenzae* (12%) and *Staphylococcus aureus* (11 %) predominated.

Conclusion: The high prevalence of certain viral and bacterial pathogens among children <5 years of age highlights the need for expanded surveillance in Niger so as to inform policies and interventions. Selected pathogens should be included in routine SARI surveillance in Niger.

POSTER 33

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Characterisation of Non-Polio Enteroviruses Circulating in the South African Population

Background: Human enteroviruses (family Picornaviridae) consist of 106 serotypes and are divided into four species: Human enterovirus (HEV)—A, B, C, and D. Enteroviruses cause a variety of clinical symptoms from severe (e.g. acute flaccid paralysis) to less severe (e.g. gastroenteritis). Whilst there is currently no antiviral treatment, viral genotyping allows for: identification of increased virulence, identification of new enteroviruses, correlation of virus types with immunity, epidemiological investigations and provides information on viral inter-relationships. A comprehensive study is underway to determine the prevalence and type of circulating non-polio enteroviruses in South Africa, specifically for those involved in recent outbreaks.

Methods: This study investigated the prevalence of non-polio enteroviruses circulating in South African between 2010 and 2012 using samples obtained from 2 national surveillance programs conducted at the National Institute for Communicable Diseases: Acute Flaccid Paralysis (AFP) and Rotavirus. Typing was performed using a Real-Time PCR (RT-PCR) assay, followed by Sanger sequencing.

Results: 831 samples were tested to date (560 from the Rotavirus and 271 from the AFP surveillance programs, respectively). 451 positive enterovirus samples were detected from which 230 samples were successfully sequenced. Specimens from the AFP program yielded mostly HEV-B serotypes (91.67%), whereas samples typed directly from stools yielded mostly HEV-C serotypes (51.82%). 91.72% of typed samples were from patients under 5 years. Despite most detections being HEV-B (64.35%), the most commonly detected virus was Enterovirus 99 (7.39%) from the HEV-C species.

Conclusion: RT-PCR and sequencing, whilst more expensive, have proven more efficient than cell culture and neutralization assays for typing enteroviruses. In South Africa, HEV-B viruses were predominant, and in comparison to studies from other countries, a larger proportion of HEV-Cs were detected. This study is to be expanded to include samples from the Respiratory Virus Surveillance program

POSTER 34

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Performance of an Early Infant Diagnostic (EID) Test, AmpliSens DNA-HIV-FRT (AmpliSens), in Comparisons with Abbott Real Time HIV-1 Qualitative (Abbott Qualitative) and Roche COBAS® Ampliprep/COBAS® Taqman HIV-1 Qual Test (Roche CAP/CTM Qual) Using Dried Blood Spots (DBS) Collected from Children Born to HIV-infected Mothers in Ukraine

Background: Accurate and accessible EID is critical for identifying HIV-infected infants and linking them to care and treatment. To potentially improve EID services in Ukraine by collecting infant DBS, AmpliSens was compared to Roche CAP/CTM Qual and Abbott Qualitative.

Methods: Whole blood and DBS were collected from 237 HIV-1-exposed children (<18 months) in Ukraine during 2012-2013. The blood samples were routinely collected and tested by the AmpliSens test at the regional EID Laboratories in Ukraine. The DBS were tested at the US CDC by AmpliSens, Roche CAP/CTM Qual, and Abbott Qualitative. The results were analyzed for sensitivity, specificity, positive and negative predictive values (PPV and NPV), and agreement between different tests using whole blood results generated from AmpliSens in Ukraine as a reference group.

Results: The sensitivity and NPV were 99% (95% CI: 95-100) and 99% (95% CI: 96-100) for the AmpliSens and Roche CAP/CTM Qual, and 96% (95% CI: 90-98) and 97% (95% CI: 93-99) for the Abbott Qualitative. The specificity and PPV were 100% (95% CI: 97-100) and 100% (95% CI: 96-100) for the AmpliSens and Abbott Qualitative, and 99% (95% CI: 96-100), and 99% (95%

CI: 95-100) for the Roche CAP/CTM Qual. McNemar's analysis indicated that the proportion of positive results for each test was not significantly different ($p > 0.05$) and all three tests were in agreement as the Cohen's Kappa values were, 0.97, 0.98, and 0.99, respectively.

Conclusion: The Amplisens test performs equally well with whole blood and DBS and matches the expected outcomes of two leading EID assays, which are used worldwide. Furthermore, Amplisens meets (or exceeds) WHO EID test qualification requirements and the use of DBS may improve EID services if implemented in Ukraine.

POSTER 35

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Surveillance des Méningites Bactériennes Pédiatriques à *Streptococcus pneumoniae* et à *Haemophilus influenzae* de 2011 à 2013 au Mali

Background: Les méningites à *Haemophilus influenzae* b (Hib) et à *Streptococcus pneumoniae* constituent un problème majeur de santé publique dans le monde avec une incidence annuelle de 250 / 100 000 chez les enfants de moins de 5 ans. Au Mali elles sont une des causes de morbidité et de mortalité avec une incidence de l'infection à pneumocoque (44 / 100 000) chez les enfants de 0 à 4 ans et une létalité de 10%. But : Evaluer la surveillance microbiologique des méningites bactériennes pédiatriques au Mali de 2011 à 2013

Methods: Les LCR sont collectés au niveau des districts sanitaires chez les cas suspect de méningite en respectant la définition de cas puis acheminés à L'INRSP pour confirmation. Le diagnostic étiologique a été fait par le Pastorex meningitis[®], suivi de la culture et de la PCR en temps réel.

Results: Sur 477 LCR 92 étaient positifs soit 19,28%. Les germes fréquemment identifiés étaient : NmW135 59,78%, *S. pneumoniae* 22,82% et Hi 7,61%. L'*Haemophilus influenzae* et le *Streptococcus pneumoniae* ont été majoritaire chez les moins d'1 an avec respectivement 79,4% et 43,6%. La majorité des *Haemophilus influenzae* et des *Streptococcus pneumoniae* ont été isolés chez les enfants avec statut vaccinal inconnu. Le statut vaccinal était inconnu dans 95% chez les moins de 5 ans et 2% statut vaccinal était renseigné. La PCR a détecté des *Haemophilus non b* 52,94%

Conclusion: Malgré les vaccins anti *Haemophilus influenzae* et anti *Streptococcus pneumoniae* ils continuent d'être isolés encore. Donc une étude va permettre d'évaluer l'impact du vaccin conjugué anti pneumocoque sur les sérotypes inclus dans le vaccin.

POSTER 36

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Sensitivity and Specificity of Diagnostic Assay Loop-mediated Isothermal Amplification for Identification of Influenza A Virus

Background: The method of nucleic acid loop-mediated isothermal amplification (LAMP) is a prospective assay for implementation into the veterinarian laboratory practice for high pathogen influenza virus detection due to its high sensitivity and ease of use. The aim of the present work is investigation of sensitivity and specificity of the diagnostic LAMP assay for high pathogen influenza virus identification. This assay had been developed in our laboratory before and was based on usage of Bsm DNA Polymerase.

Methods: Sensitivity of the LAMP methodology was determined by usage of cDNA of the H5N1 avian influenza reference strain obtained from the NSC IECVM (Kharkiv, Ukraine) in different concentrations, ng per investigated sample: 10,0; 5,0; 1,0; 0,1; 0,01. Specificity of the LAMP methodology was determined by usage of cDNA from reference samples of influenza virus different sub-types H1N1, H3N2, H5N1, H5N2, H7N1, H9N3; isolates of highly pathogenic avian influenza H5N1 that was extracted in 2008 in Ukraine – A/hen/SivashBay/02/05, A/hen/Primorsky/02/06, A/hen/Krasnohvardysky/58/08, A/hen/Krasnohvardysky/59/08, A/hen/Krasnohvardysky/60/08, and heterologous viruses – Newcastle disease virus, Infectious bronchitis virus, Infectious laryngotracheitis virus, Infectious bursal disease, Egg drop syndrome, Salmonella ser. Gallinarum, Pseudomonas Mycoplasma gallisepticum. For determination of repeatability, the procedure was carried out at least three times.

Results: The LAMP assay developed during our work, has specificity for detection of all investigated high pathogen influenza virus subtypes. Sensitivity of LAMP assay is equal to the concentration of influenza virus 0,1 ng per investigated sample.

Conclusion: Experimental study found that LAMP assay for identification of high pathogen influenza virus has high specificity, sensitivity and repeatability. Developed LAMP assay is recommended for registration with following introduction in the veterinarian medicine practice of Ukraine.

POSTER 37Veronique Akran Agbaya¹, EV Adjogoua¹, A Ouattara¹, M Kamagaté²¹ Pasteur Institute, Côte d'Ivoire, ² Service de Pharmacologie clinique, UFR Science médicale, Université Félix Houphouët Boigny, Côte d'Ivoire**Etude Prospective et Descriptive de la Prévalence de la Dengue dans des Episodes Fébriles à Abidjan, Côte d'Ivoire**

Background: La dengue est actuellement l'arbovirose la plus répandue dans le monde, touchant plus de 80 millions de personnes et provoquant environ 30 000 décès par an. En Côte d'Ivoire des études antérieures ont confirmé la circulation virale de la dengue. Récemment, deux cas de dengue 3 importés de Côte d'Ivoire au Japon et en France relançaient l'intérêt de cette arbovirose dans un pays d'endémie amarile. Objectif: Décrire la prévalence de la dengue associée à des épisodes fébriles à Abidjan

Methods: 812 patients de tout âge, consentant, vus en consultation pour une fièvre récente (température >38°C), avec ou sans signe hémorragique, à l'Hôpital Général de Koumassi à Abidjan et à la Polyclinique Internationale Sainte Anne-Marie, Abidjan ont été inclus dans cette étude. Le diagnostic biologique de la dengue a été effectué par l'utilisation des tests d'isolement viral, de la RT-PCR et la détection des IgM anti-virus de la dengue.

Results: Trois cas de dengue confirmée ont été identifiés sur 796 cas fébriles inclus pour lesquels les résultats de la sérologie et de la RT-PCR étaient disponibles soit une prévalence de 0,38%. Deux cas ont été confirmés par sérologie et le troisième par RT-PCR. Pour ce dernier, le sérotype 3 a été mis en évidence. Les patients tous de sexe masculin de différent âge (05, 39 et 53 ans), ont été infectés respectivement en août, septembre et octobre 2012. Ces syndromes fébriles étaient sans signe hémorragique. L'isolement viral effectué sur les 3 cas confirmés s'est avéré négatif. Deux sujets résidaient dans l'agglomération d'Abidjan tandis que le troisième vivait sur une plateforme pétrolière.

Conclusion: Ces 3 cas confirmés ont encore mis en évidence la circulation de la dengue qui devient un diagnostic obligatoire dans les états fébriles en Côte d'Ivoire.

POSTER 38Scholastica Okui¹, George Pariyo², David Ndungutse²¹ Central Public Health Laboratory /Ministry of Health, Kampala, Uganda, ² School of Public Health, Makerere University, Kampala, Uganda**Comparison of Two Communities Affected by Cholera in Kasese District in Uganda**

Background: Some sub-counties in Kasese District, experienced frequent cholera out-breaks, while others did not. The reasons for this difference were not clear nor had they been explored. This study was therefore carried out to establish factors why cholera out-breaks were frequent in some areas and not others of the same district.

Methods: A cross-sectional study comparing the situations of residents of Karambi and Bugoye was carried out. Focus group discussions, Interviews and observations of the homesteads, latrines and markets for sanitation and hygiene were conducted; Water samples from sources and households were analysed for faecal contamination. Similarly stool samples obtained from victims who had recovered from cholera were cultured and isolated cholera organisms, tested for sensitivity to first line antibiotics.

Results: The main findings why cholera remains problematic in Karambi included: poor hygienic practices, (difference significant $p \leq 0.004$), significant $p \leq 0.001$). as well as eating communally from the same dish (difference significant $p \leq 0.008$) and unsafe water sources, contaminated with faeces (both E.coli and cholera organisms were isolated from R. Mbabaine of Karambi). In Karambi, 36% of the cholera victims who had recovered were found to be asymptomatic carriers of cholera organisms, resistant to first line antibiotics.

Conclusion: Factors therefore responsible for the difference in cholera outbreaks in the two communities were: Unsafe water sources, poor hygienic practices; and high carrier status among the Karambi community with cholera organisms resistant to first line antibiotics.

POSTER 39Isatta Wurie¹, Eric Sefoi², Doris Harding², Ralph Timperi¹¹ Association of Public Health Laboratory, Silverspring, USA, ² Central Public Health Reference Laboratory, Ministry of Health and Sanitation, Sierra Leone,**Adopting Traffic Light System To Monitor SLMTA Progress (Sierra Leone Experience)**

Background: In 2012 the Central Public Health Reference Laboratory (CPHRL) in Sierra Leone was activated with the initiation of four departments (Molecular, Serology, Bacteriology and Specimen Management). With technical support provided by international partners, CPHRL commenced work in the World Health Organisation stepwise accreditation process. The technical team introduced traffic light coding into the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) material to give a visual picture of the status of each element and also the progression of improvement on the quality indicators.

Methods: Two SLMTA trainers provided SLMTA workshop to staff of CPHRL and the TB Reference Laboratory. The SLIPTA scoring was aligned to three colours of the traffic light. The selected codes were: Green for completion and compliance to ISO 15189; Amber for commencement of progress in identifying standard item and Red for non-compliant (no star). Each member of staff was responsible to monitor an area and undertake improvement projects to ensure element progress to attain full marks or green.

Results: At baseline the average score for all departments was 104 (no star). Follow-up audit at three months showed TB lab remaining at no star and CPHRL at 141 (one star). The traffic light display, at baseline was 30% red, 35% amber and 15% green. This changed to 20% red 60% amber and 20% green at three months.

Discussion: Visual representation of status inspires efforts for continual quality improvement. The traffic light system will be used in the next assessment to represent scores by sections to aid setting priorities as well as and acknowledging progress in specific operational areas improve morale and commitment to the process.

Conclusion: For a sustained effort towards accreditation the pictorial adaptation of the SLIPTA tool improved motivation and fostered a healthy competition within the departments to move improve quality.

POSTER 40

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CD4 Count and Some Trace Elements in Seropositive HIV Undergoing Highly Active Antiretroviral Therapy in Osun State

Background: Low serum concentrations of trace elements have been associated with an increased risk of HIV disease progression and mortality in HIV infected individuals. This study is designed to evaluate the levels of serum copper, zinc and selenium in correlation with the CD4 count. In the current study, we investigated the effects of HAART on selected trace elements such as selenium, zinc and copper and on CD4+T-cell count in HIV-positive persons.

Methods: Fifty HIV-positive individuals with 25 on HAART and 25 who were not on HAART were recruited for the study. Twenty five apparently health persons who were HIV-negative serve as a control group. Serum concentrations of selenium, zinc and copper were estimated by atomic absorption spectrophotometric method while CD4+T-cell count was determined by flow cytometric method.

Results: Subjects on HAART showed significantly ($P < 0.05$) high Zn and CD4+Tcell count compared to PRE-HAART. There was no significant difference in the serum selenium and copper levels between HAART and PRE-HAART persons. The mean serum concentrations of CD4+, Se and Cu were significantly ($P < 0.05$) lower in PREHAART patients compared to control subject. Patients on HAART had higher ($P < 0.05$) levels of Zn compared to control subjects. On the other hand, the mean serum levels of Cu and Se were significantly ($P < 0.05$) decreased in HAART patients in comparison to control subjects.

Conclusion: In conclusion, the decrease in antioxidant micronutrient selenium that accompanies HIV infection suggests a potentially important role of nutritional supplementation and good nutrition in proper management of HIV/AIDS. HAART significantly improved the immunological status as evidenced by increased CD4+T-cell count and also significantly increased the zinc level in the same group. Thus, early evaluation of nutritional status of these subjects and providing appropriate nutritional support and mineral supplementation along with the specific anti-retroviral treatment are highly recommended.

POSTER 41

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Comparison of Malaria Rapid Diagnostic Tests with Microscopy for the Diagnosis of Malaria at Lubwe Mission Hospital, Samfya, Zambia

Background: High quality malaria diagnosis is the pillar to proper treatment and reduction in mortality and morbidity in a malaria endemic area like the community surrounding Lubwe Mission Hospital. Although microscopy is the golden standard method of malaria diagnosis, due to erratic power supply in the area, RDTs are often preferred to microscopy and due to short turnaround time. However, the results obtained are not of quality assured standards as compared to microscopy. Finding the contributing factors will help improve to provide quality assured accurate reliable laboratory results.

Methods: Malaria RDT tests results data were routinely captured in registers in all the 5 PoC sites. Comparison with microscopy data and repeated RDTs based on Hospital numbers for 11 months period (including OPD, Wards, Doctors room, MCH and CTC) were entered in a database and analyzed to identify which PoC sites are commonly affected.

Results: From May 2012 to March 2013, Lubwe Mission Hospital recorded a total of 4,595 with 93,116 false (positive and negative) results tested with a mean of 417 false (positive and negative) RDT results per month. False negative results recorded a higher percentage (4.0%) than false positive results (0.9%). Although false (both positive and negative) results were recorded from all the 5 PoC sites, OPD and wards accounted for 80.7% of all false malaria RDT results.

Conclusion: There is a high rate of false malaria RDT tests results in PoC sites at Lubwe Mission Hospital. Therefore the interventions required will be to sensitize and train personnel especially at OPD and nurses in the wards; also to establish a quality assurance system in all the sites performing RDTs.

POSTER 42

Phidelis Maruti¹, Ekesa A. Mulianga¹, Lorna N. wambani¹, Melda N. Wafula¹, Fidelis A. Mambo², Shadrack M. Mutisya³, Erick N. Wakaria⁴, Erick M. Mbatia⁵, Angela A. Amayo⁴, Jonathan M. Majani¹, Bryan Nyary⁶, Kilian A. Songwe³

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Creating a Sustainable Culture of Quality through the SLMTA Program in a District Hospital Laboratory in Kenya

Background: Bungoma District Hospital Laboratory (BDHL), which supports a 200-bed referral facility, began its Strengthening Laboratory Management Toward Accreditation (SLMTA) journey in 2011 together with- eight other laboratories in the second round of SLMTA rollout in Kenya.

Methods: SLMTA implementation followed the standard 3 workshop series, mentorship site visits and audits. In order to build sustainability of progress made BDHL integrated quality improvement processes into its daily operations. The lab undertook a process of changing its internal culture to align all hospital stakeholders—including upper management, clinicians, laboratory staff, and maintenance staff—to the mission of sustainable quality practices at BDHL.

Results: After 16 months in the SLMTA program, BDHL improved from zero stars (38%) to four stars (89%). External quality assurance results increased from 47% to 86%; staff punctuality increased from 49% to 82%; clinician complaints decreased from 78% to 27%; customer complaints decreased from 12% to 2%; sample rejection rates decreased from 12% to 3%; equipment down time decreased from 89% to 17% and costs for engineer repairs decreased from 80% to 30%. Twelve months later the laboratory scored three stars (81%) in an external surveillance audit conducted by Kenya Accreditation Service (KENAS)

Conclusion: Management buy-in, staff participation, use of progress- monitoring tools and feedback systems, and incorporation of improvement processes into routine daily activities are vital in developing and sustaining a culture of quality improvement.

POSTER 43

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Prevalence of Bacterial Vaginosis among Women of Reproductive Age Attending Thika District Hospital, Kenya

Background: Bacterial vaginosis (BV) is the most common cause of abnormal vaginal discharge among women of child bearing age and is associated with adverse obstetric and gynecologic outcomes. Objectives: The aim of the study was to determine the prevalence of BV by use of Amsel criteria and its correlates in women of reproductive age attending Thika district hospital.

Methods: The study was descriptive cross sectional where vaginal specimens from 150 women of child bearing age attending Thika district hospital were obtained. Bacterial morphotypes indicative of BV were identified at light microscopy. Precoded questionnaire were used to collect demographic and sexual behavioral characteristics of the study participants. Data analysis: In bivariate analyses, prevalence ratios (PR) and 95% confidence intervals (CI) for the association between BV and demographic or behavioral characteristics was calculated using Poisson regression.

Results: A prevalence of 26.0%, (95% CI 34.2- 48.6) was obtained from the study population. Classical BV cases were 16%, (95% CI 64.2-78.7) and non-classical 24%, (95% CI 12.0-28.3). Single sexual relationships, low socioeconomic status and hormonal contraceptive use were associated with BV. In terms of cervical lesions, 2% had HSIL, 4% LSIL, 2.6% Candidiasis, 3% Trichomoniasis and 1.3% Actinomyces.

Conclusion: The prevalence of BV was 26.0% in this population. BV correlates ought to be evaluated periodically for intervention strategies and further research is warranted to understand their role in BV and the socioeconomic context surrounding the condition in Kenya.

POSTER 44

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Epidemiology of Laboratory Confirmed Rubella Cases in Ethiopia, 2008-2012 from Measles/Rubella Case-Based Surveillance Data

Background: Rubella is a contagious rash illness. Trans-placental infection leads to serious fetal disorder called Congenital Rubella Syndrome (CRS). Worldwide, more than 110,000 infants are born with CRS each year; most of these occur in developing countries where information is limited on the epidemiology and vaccine not introduced. This study was conducted to see the regional distribution, yearly trend, seasonal variation and age distribution of rubella infection for 2008-2012.

Methods: Serum/plasma samples and demographic data were collected from measles/rubella suspected cases from all the 9 regional states and 2 city administration of Ethiopia, January 2008-December 2012. The samples were tested for rubella IgM by ELISA. The data was extracted from the national measles/rubella case-based surveillance data-base for the period 2008-2012 and analysed by Epi Info software version 3.5.4.

Results: A total of 11,205 patient samples were tested for rubella IgM. Out of which 1375 (12.3%) were found to be positive. The rate of rubella cases was higher in females 14% (743/5303) than males 10.8% (627/5830). 92.7% of the samples were collected from the five big regions, Oromiya, Amhara, SNNPR, Addis Ababa and Tigray. The positivity rate was highest in Addis Ababa 23.3% (282/1212) followed by Tigray 12.4% (59/474), SNNPR 11.8% (239/2018), Oromiya 10.8% (497/4610) and Amhara 8.7% (182/2085). The yearly positivity rate increases from 8.4% in 2008 to 24.3% in 2012. This study showed rubella is seasonal reaching peak level during April to June. Children 5-9 years were the most affected, with prevalence of 16.4% (577/3525).

Conclusion: Rubella become an endemic public health problem in all regions of Ethiopia and increased year to year. The infection is seasonal, highest in dry hot seasons affecting children 5-9 years age. The current prevalence of rubella cases calls for conducting CRS surveillance in infants, surveillance among pregnant women, reporting and necessitates vaccine introduction to the national routine immunization services.

POSTER 45

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Isolation and Antibiotic Susceptibility Patterns of Shigella and Salmonella among under 5 years Children with Acute Diarrhea, in Selected Health Facilities Addis Ababa, Ethiopia

Background: Diarrhoeal illness remains one of the leading causes of morbidity and mortality among children <5 years of age worldwide. Shigella and Salmonella are major causes of gastroenteritis in children and is associated with high resistance levels. Thus, the aims of this study was to isolate and determine susceptibility patterns of Shigella and Salmonella, at some selected health facilities in Addis Ababa, Ethiopia.

Methods: A cross sectional study was conducted from August – December 2012. A total of 253 children 115 males and 138 females with acute diarrhea were enrolled. Stool samples were cultured and isolated Shigella and Salmonella species were run for antimicrobial susceptibility testing using disk diffusion method. Besides, a total of 253 caretakers were interviewed using structured questionnaires.

Results: A total of 190 entropathogens were isolated. Sixty one (24.1%) was E. coli, (9.1%) was Shigella followed by (3.95%) Salmonella and Citrobacter species and 86 (34.0%) was parasites. The overall resistance rates of isolated Shigella and Salmonella spp were high for AMP (95.7%, 80.0%) and AUG(91.4%, 80) respectively. However, high sensitivity was observed among both isolates for CIP (91.3%, 100%) and CRO (91.4%, 100%). More than 87% of Shigella species were multiple resistances (resistance for two or more antibiotics). Whereas, 70.0% for Salmonella species. The prevalence of Shigella species was significantly isolated (P = 0.027, and 0.011) from patients whose parents are merchant and housewife respectively than government employers. Raw meat consumption was an independent predictor variable for exposures of Salmonella infection.

Conclusion: Isolation of high frequency of multidrug resistant Shigella and Salmonella spp. from children in the study area is an alarming for the present situation of emerging drug resistance. Therefore, based on our finding we recommend surveillance of diarrheal bacteria in hospitals and in the community are needed.

POSTER 46

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Access to CD4 Testing Improves Provision of H.I.V Quality Services (A Case Study of Two AHF-Kenya Supported Clinics)

Background: In resource limited setting such as Kenya, access to CD4 testing is limited though it remains to be the most relied immune progression marker used as a bench mark to monitor HIV clients and also defines the basis before ART initiation. Aids Healthcare Foundation (AHF) Kenya is currently providing HIV services in different counties within the country. This study was an effort to determine the role of improved access to CD4 testing in enhancing delivery of quality services in HIV clinics.

Methods: This was a cross sectional study which employed quantitative research method. Retrospective data was obtained from clients who were enrolled for the last one year in two AHF clinics which are 12km apart in a rural area. Enrollment cohort was categorized into three: clients transferred in, from V.C.T, and those from outpatient departments. A total of 999 clients were enrolled and this was used as the sample size for the study.

Results: 62% of the clients enrolled were transfers in from other facilities and 90% among these were due for CD4 testing, this enrollment rate was twice higher compared to that of three neighboring government clinics which don't have CD4 machines and refer samples to other facilities including AHF. 7% were from outpatient department and 10 % through V.C.T, loss to follow-up among all these enrolled clients for the last one year was reported to be only 13% and 98% of them had their CD4 test done within the same year in time. 86% indicated close relatives or spouse been their treatment supporter at household level none mentioned of community health worker.

Conclusion: Access to CD4 testing has shown to improve the quality of care to AHF clinics through increased enrollments and reduced number of clients lost to follow-up.

POSTER 47

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Diagnostic Outcome of GeneXpertsamboMTB-RIF versus Ziehl Neelsen Smear Microscopy

Background: Recent technological advancements in the diagnosis of tuberculosis (TB) are targeted at improving the limitations of laboratory conventional diagnostic methods and enhancing early diagnosis and prompt treatment of persons with the disease. The World Health Organization endorsed two molecular methods, GenoType[®] MTBDRplus and XpertMTB-RIF for rapid detection of Mycobacterium tuberculosis and (MTB) with simultaneous detection of susceptibility/resistance to specific anti TB drugs in sputum. We

tested sputum specimens by GeneXpertMTB-RIF and Ziehl Neelsen (ZN) smear microscopy to compare the detection rate for MTB and acid fast bacilli (AFB) respectively.

Methods: We performed parallel testing of 575 consecutive sputum specimens from TB suspect cases by GeneXpertMTB-RIF and ZN smear microscopy from February 2013 to February 2014.

Results: Of 575 total number of specimens examined, AFB was detected in 150 (26%) cases against 134 (23%) MTB with the patterns; ZN+,XpertMTB-RIF+; 123(21%), ZN-,XpertMTB-RIF+; 11(2%) and ZN+,XpertMTB-RIF-;27(4.7%). Resistance to rifampicin (RIF) occurred in 16/134 (12%) against 118/134 (88%) susceptible cases.

Conclusion: There was compatibility ($P=0.274$) in the detection of MTB and AFB respectively by XpertMTB-RIF and ZN smear microscopy. The discordant rate of 4.7% ZN+,XpertMTB-RIF- may be non tuberculous mycobacteria cases or other acid fast microorganisms. While the XpertMTB-RIF has the reserved advantage to simultaneously detect RIF susceptibility/resistance, parallel testing using both methods was very useful in our non-TB culture facility as the presence of other AFB may have been erroneously diagnosed as presumptive MTB resulting in inappropriate administration of treatment regimen.

POSTER 48 CANCELLED

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Assessment of Feto-maternal Hemorrhage among Rhesus D Negative Pregnant Mothers using the Kleihauer-Betke Test (KBT) and Flowcytometry (FCM) in Addis Ababa, Ethiopia

Background: This study aimed to assess fetomaternal hemorrhage (FMH) among RhD negative pregnant mothers. Assessing fetomaternal hemorrhage (FMH) would help us to adjust RhoGAM given to all affording RhD negative mothers. Because, in our country 300µg dose is given to all affording mothers assuming a 30mL fetal blood contamination, since no laboratory in the country to determine fetomaternal hemorrhage.

Methods: Hospital-based cross-sectional study was conducted among 75 RhD negative pregnant mothers using convenient sampling technique.

Results: FMH has been detected in 52% and 60% by Kleihauer-Betke (KBT) and Flowcytometry (FCM) methods, respectively. The volume of FMH quantified in the majority of the cases (92.5% and 87%) was <10mL fetal blood while >30mL in 1.3% (1/75) and 2.7% (2/75) as calculated by KBT and FCM, respectively. The FMH calculated by the two methods have good correlation; $r = 0.828$ ($p=0.000$) for categorized and $r = 0.897$ ($p = 0.000$) for continuous values and the agreement between the FCM and KBT was moderate with kappa (κ value of 0.53 ($p=0.000$)).

Conclusion: Most of FMH calculated (<10mL) could have been neutralized by lower doses which might have lower costs than administering 300µg dose which is currently in practice in our country for affording mothers. Besides, it also showed that the volume of FMH was >30 mL in 1.3% and 2.7% of the cases as calculated by KBT and FCM, respectively, which need more than 300µg dose RhIG for neutralization. Finally the correlation between two methods for calculating FMH was good.

POSTER 49

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Evaluation of a Malaria Rapid Diagnostic Test among Febrile Children in Nasarawa, North Central, Nigeria

Background: Malaria rapid diagnostic test (RDT) is an antigen capture assay that enables rapid diagnosis of malaria without the need for electricity or highly skilled technicians. Though potentially useful, its adoption needs to be guided by local test sensitivity. We evaluated the diagnostic performance of a commercially available RDT (Malaria Pf rapid device, Biotech Laboratories Limited, United Kingdom) among febrile children in Nasarawa State, Nigeria.

Methods: This was a prospective observational study involving 400 children (aged 6 months to 12years) who presented to the Pediatrics Outpatient Department (POPD) of Dalhatu Araf Specialist Hospital, Lafia, General Hospital Akwanga, and Federal Medical Center Keffi with fever between January to April, 2013. Finger prick blood samples were collected from each of the patient (day 0) and immediately tested for falciparum malaria by both Giemsa microscopy and rapid RDT. Patients with positive RDT and microscopy on day 0 were simultaneously retested on day 7 (after antimalarial therapy) by both diagnostic methods.

Results: The prevalence of malaria among the study cohort was 40.8% by microscopy and 39.5% by RDT. The RDT had a sensitivity of 90.2% and specificity of 95.4%; with positive and negative predictive values of 93.0% and 93.4% respectively. Test accuracy was 93.3%, whereas reliability was 85.3%. Test sensitivity is reduced by low parasite density (100% at > 1600/µl Vs. 69.2% at <800/µl). Of the 69 patients who were retested on day 7 after antimalarial treatment, 18 (26.1%) still had positive RDT test even though negative by microscopy and afebrile at the time of follow up.

Conclusion: The diagnostic performance of the RDT in this study is good. Hence, it is recommended as an alternative method for diagnosis of malaria, especially when microscopy is not feasible. Key words: Malaria, Rapid diagnostic test, Children, Nigeria.

POSTER 50**Thani Suleiman**¹, Samuel Lifumo², Hamadi Iddi Boga³, Joseph Oundo⁴

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Isolation, Antibiotic Susceptibility Profile of Escherichia Coli Pathotypes and Factors Associated with Well and Boreholes Water Contamination in Mombasa County

Background: Water is an important resource that is prone to bacterial contamination from a variety of hosts including mammals and avian species. The rapid expansion of this county has led to the residents relying on groundwater to supply them with portable water. However due to faulty sanitation leading to bacterial and chemical contamination in developing world makes the availability of safe water almost unattainable. Objective: To determine the frequency of Escherichia coli contamination, antibiotic susceptibility profile and risk factors associated with contaminated samples in Mombasa County.

Methods: This cross-sectional study was carried out on 157 water samples that were collected from all four divisions of the county. The samples were inoculated to Mac Conkey broth and incubated at 37°C for up to 48 hours. Positive results were compared to the 3 tube McCrady MPN table. The E. coli were confirmed by Eijkman's test and antibiotic susceptibility carried out on confirmed isolates.

Results: Of the 157 samples collected from around Mombasa County, 131 samples (83.4%) were contaminated by coliform bacteria. Of the contaminated samples, only 79 (60.3%) were confirmed to have Escherichia coli. Significant values (<0.05) were noted when coliforms were compared to variables including sampling site location, recent sampling site pump overhaul/repair and distance to pit latrine from water source. No significant values were noted when detection of E. Coli were compared to different variables. All (n = 77; 100%) E. Coli tested were sensitive to Gentamicin, while all (n = 77; 100%) isolates were resistant to Ampicillin.

Conclusion: These findings suggest that coliforms and E. coli are major contaminants of water in wells at Mombasa county. The E. coli showed a distribution of resistant and sensitivity patterns.

POSTER 51 CANCELLED**Justice Kumi**¹, Nicole J. Mitchell², Asare George³, Timothy D. Phillips⁴

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Aflatoxins and Fumonisin Contamination of Home-Made Food (Weanimix) from Cereal-Legume Blends for Children

Background: Weanimix is a nutritional supplement prepared from beans, groundnuts and maize for infants and children. Groundnuts and maize are susceptible to mycotoxin aflatoxin contamination while mycotoxin fumonisin contaminates maize. These mycotoxins are immune suppressant with aflatoxins associated with liver cancer and child growth disorders. Aflatoxins and fumonisins are produced by Aspergillus and Fusarium fungi respectively in tropical areas worldwide.

Objective: The study determined levels of aflatoxins and fumonisins in homemade weanimix in the Ejura-Sekyedumase district in the Ashanti Region, Ghana and the growth pattern of children fed the homemade weanimix.

Methods: Thirty six homemade weanimix samples (50g each) were collected from households that were actively feeding the weanimix to infants from three different communities in the district. Aflatoxin and fumonisin were measured using a fluorometric procedure described by the Association of Official Analytical Chemist (AOAC official method 993.31, V1 series 4).

Results: Aflatoxin and fumonisin were detected in all 36 samples. (Aflatoxin levels range: 7.9-500ppb. Fumonisin levels range: 0.74-11.0ppm). Thirty (83.3%) of the thirty six homemade weanimix samples were over the action limit of 20ppb for aflatoxin with an overall mean of 145.2 ppb. Fumonisin was detected in all 36 samples and 58.3% of the samples were above the action limit of 4 ppm with an overall mean of 4.7 ppm.

Conclusion: The results indicate that there were significant aflatoxin and fumonisin contamination of the homemade weanimix. This could negatively impact their immunity and primary health care. Therefore there is a critical need to educate mothers on the dangers of mycotoxin exposure.

POSTER 52**Olaniran Olarinde**, Saturday Jack Udoh

Obafemi Awolowo University, Ile-Ife, Osun State, Nigeria

Malaria Parasitaemia and CD4+ T Cell Count in HIV Patients Attending Tertiary Medical Center, Nigeria

CD4+ T Cell count is an important immunological marker of disease progression in HIV seropositive patients. This study was carried out to determine the effect of Malaria on the population of CD4+ T Lymphocytes, white blood cell, and pack cell volume of HIV sero positive patients attending active antiretroviral therapy clinic

of the federal medical centre Abeokuta. 122 subjects, 20 control subject were selected for this study. Clinical diagnosis was used as a case definition or malaria and malaria was confirmed from microscopic examination of thick film of blood sample obtained from the subject of study during presentation. The CD4+ count was evaluated during presentation by using flow cytometry. There was a significant decrease of CD4+ count of the subjects ($P < 0.05$). However of the 122 subjects, 73 (59.8%) and 49 (40.2%) were female and male respectively. Based on the presence of malaria Parasite, there is a significant decrease in CD4+ count in HIV and malaria co-infected subjects compared to the control subjects ($P < 0.05$), white blood cells was similar in both groups ($P > 0.1$). There was significant difference in age paired test between the two groups ($P < 0.05$), this result led to the conclusion that there is progressive depletion of CD4+ cells, PCV in HIV co-infection with malaria. A larger prospective study is needed.

POSTER 53

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Hematological Manifestation in HIV-Infected Children

Background: Hematological abnormalities are common in HIV infected children. Of these abnormalities, peripheral cytopenias and bone marrow abnormalities are common. Anemia is the most common hematologic manifestation. Other hematological findings include neutropenia, thrombocytopenia and coagulation abnormalities. Several mechanisms have been postulated in the pathophysiology of these abnormalities. Both impaired production of blood cells due to direct infection of the progenitor cell or through cytokine mediated and increased peripheral destruction may occur. The aim of this study was to determine the common hematological manifestations of HIV infected children.

Methods: This study involves 60 HIV infected children referred to the HIV Clinic of Korle Bu Teaching Hospital over a period of 6 months in 2013 underwent a baseline hematological analysis. All patients underwent a thorough clinical examination, CD4 count, opportunistic infections and their association with various hematological manifestations were studied. The data were analyzed by Chi square test and by Anova-1 test using ANALYSE-IT software.

Results: 48 patients (80%) had elevated ESR, 36 patients (60%) had anemia, 18 patients (30%) had leucocytosis, 15 patients (25%) had lymphopenia, 6 patients (10%) had thrombocytopenia and 3 patient (5%) had leukopenia with neutropenia. Patients with lymphopenia had a mean age of 5.7 ± 2.4 years Vs 3.6 ± 1.1 years which was statistically significant ($p = 0.01$) whereas patients with thrombocytopenia had a mean age of 5.4 ± 3.1 years Vs 4.0 ± 1.2 years ($p = 0.03$) and patients with elevated ESR had a mean age of 3.8 ± 1.2 years Vs 6.5 ± 3.0 years ($p = 0.03$). All patients with anemia had microcytic hypochromic anemia. There was no

correlation with lymphopenia and decrease in CD4 count ($p = 0.71$) or CD4% ($p = 0.34$).

Conclusion: Hematological problems in HIV infected children are common. Elevated ESR and anemia are the commonest features. Elevated ESR may be used as a marker to screen a child for HIV infection. Microcytic hypochromic anemia is the commonest type of anemia seen.

POSTER 54

Mikias Negash, Aster Tsegaye, Amha G/Medhin

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Diagnostic Predictive Value of Platelet indices for Discriminating Hypo-productive versus Hyper-destructive Thrombocytopenia in Patients Attending Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia

Background: Bone marrow examination may be required to discriminate causes of thrombocytopenia as hypoproduative or hyperdestructive. However, this procedure is invasive and time consuming. This study aimed to assess diagnostic value of MPV, PDW and P-LCR in discriminating causes of thrombocytopenia as hypoproduative or hyperdestructive.

Methods: A prospective cross-sectional study was conducted on 83 thrombocytopenic patients ($Plt < 150 \times 10^9/L$). From these, 50 patients have hypoproduative and 33 have hyperdestructive thrombocytopenia (ITP). Age and sex matched 42 healthy controls were used as a comparative group. Hematological analysis was performed using Sysmex XT 2000i 5 part diff analyzer.

Results: All Platelet indices were significantly higher in hyperdestructive patients (ITP) ($n=33$) than in hypoproduative thrombocytopenic patients ($n=50$) ($p < 0.0001$). In particular MPV and P-LCR have larger area under ROC curve (0.876 and 0.816 respectively), which have better predictive capacity, sensitivity and specificity in discriminating the two causes of thrombocytopenia. The indices were still significantly higher in hyperdestructive patients compared to 42 healthy controls ($p < 0.0001$). An MPV of $< 10.75fl$ can identify thrombocytopenic patients as hypoproduative with 74% sensitivity, 70% specificity, 79% PPV and 64% NPV (odds ratio 6.5, 95% CI 2.5–17.3). A significant and negative correlation was observed between the platelet count and platelet indices in hyperdestructive (ITP) patients, ($p < 0.001$).

Conclusion: MPV, PDW and P-LCR help in predicting thrombocytopenic patients as hypoproduative or hyperdestructive thrombocytopenia. If these indices are used in line with other laboratory and clinical information they may help in delaying/avoiding unnecessary bone marrow aspiration in hyperdestructive patients or supplement a request for bone marrow aspiration or biopsy in hypoproduative thrombocytopenic patients. Keywords: Bone marrow, platelet indices, hyperdestructive thrombocytopenia, hypoproduative thrombocytopenia.

POSTER 55

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Drug Resistant Pattern of *M. tuberculosis* Among TB Suspected Children at Tkur Anbessa Specialized Hospital, Ethiopia

Background: Drug resistant tuberculosis is a serious emerging problem in many recourse poor countries. Data on drug resistant TB in children are sparse and the actual magnitude of the problem is not known globally. Objective: To determine drug resistance pattern of *M. tuberculosis* from culture confirmed pediatric TB cases attending Tikur Anbessa Specialized Hospital.

Methods: Drug susceptibility testing was done on 41 culture isolates of *M. tuberculosis* which was collected from 385 TB suspected pediatric cases attending Tikur Anbessa Specialized Hospital department of pediatrics and child health. Drug susceptibility testing was done using GenoTYPE MTB DR plus and proportion methods for first line anti TB drugs.

Results: Out of 385 TB suspected children 41 were found culture positive. Drug susceptibility tests were done for all 41 culture isolates. Out of the 41 isolates 13(31%) were found resistant to any of the four anti TB drugs (Isoniazid, Rifampicin, Ethambutol, and Streptomycin). The prevalence of Isoniazid mono resistance was found 2 (4.9%) and 1(2.4 %) Streptomycin. Four isolates (9.8%) were found resistant to both Isoniazid and Rifampicin (MDR-TB). Two isolates were found resistant Isoniazid and Streptomycin. One isolate (2.4%) was found resistant to Isoniazid, Ethambutol and one (2.4%) additional isolate was found resistant to three drugs; Isoniazid, Ethambutol and Streptomycin.

Conclusion: In this study we found high prevalence of MDR-TB compared to similar study conducted 12 years ago in the same hospital and other studies conducted in pediatric TB suspects in the country.

POSTER 56

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Laboratory Systems and Quality Improvement: Accreditation: The Nyumbani Diagnostic Laboratory Experience

Background: Nyumbani Diagnostic Laboratory (NDL) started in 1998 as part of Nyumbani Children's Home in Nairobi. Nyumbani, which is Swahili for "home," was founded by a Catholic priest, Fr. Dr. Angelo D'Agostino, to care for abandoned orphans infected with HIV. The laboratory moved to a new building in 2011 and now supports more than 4,000 children under their care. As part of their growth the NDL wished to become internationally accredited and sought the support of FHI 360.

Methods: 360 employed a combination of methods to help the NDL: 1. Assessments: FHI 360 organized a baseline and subsequent ISO assessments. 2. Organizational culture: Mentors regularly updated the top management of the laboratory on the improvement process. The mentors worked with NDL staff to adapt to the requirements of the ISO standard. 3. Technical assistance: Mentors prepared and agreed an improvement plan with the laboratory. The work plan was executed by a combination of onsite and remote mentorship. 4. Training: FHI 360 provided training on the various aspects of laboratory technical and management quality management systems. 5. Leadership: FHI 360 supported NDL leadership in their commitment for success. 6. KENAS Involvement: FHI 360 encouraged the staff of Kenya Accreditation Service (KENAS) to visit the laboratory to help explain about accreditation. 7. Presentation for assessment: FHI 360 conducted a pre-accreditation inspection to confirm readiness for the actual accreditation assessment by KENAS.

Results: The mentorship model utilized by FHI 360 was shown to be highly successful. With the dedication of the NDL staff they were accredited to ISO 15189:2007 in 2013 by KENAS after nearly one-and-half years of a mentorship program implemented by the Laboratory Services Division of FHI 360. NDL is the first faith-based medical laboratory to be accredited in Kenya. It is recommended that other laboratories seek this important goal.

Conclusion: The mentorship model utilized by FHI 360 was shown to be highly successful. With the dedication of the NDL staff they were accredited to ISO 15189:2007 in 2013 by KENAS after nearly one-and-half years of a mentorship program implemented by the Laboratory Services Division of FHI 360. NDL is the first faith-based medical laboratory to be accredited in Kenya. It is recommended that other laboratories seek this important goal.

POSTER 57

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Development and Validation of PCR-based Tools for Laboratory Diagnostics of Animal Brucellosis

Background: Brucellosis is a significant emergent disease of animals and humans, caused by the group of microorganisms from genus *Brucella*. Existing measures of disease control do not fit the modern tendencies of diagnostics. The PCR based techniques for *Brucella* spp. detection are described in OIE requirements. This work was aimed to implement the system for *Brucella* spp. detection and differentiation based on PCR in laboratory practice of Ukraine.

Methods: AMOS PCR primers were used for PCR protocol implementation. The *Brucella* spp. isolates of *B. ovis*, *B. abortus*, *B. melitensis* and *B. suis* from the collection of NSC IECVM were used. PCR-based protocol was evaluated in accordance with OIE requirements.

Results: The optimal DNA extraction method for cultures and contaminated animal products was the silica sorption method. The temperature of 56 C was determined as the optimal one, under 40 cycles of PCR. Primer amount was 5 pmol per reaction, and Mg ions amount – 2,5 mM/ml. The OIE prescribed products were amplified in the described conditions of the reaction. Elaborated protocol allowed the detection of specific products of amplification in the samples containing 102-107 PFU of *Brucella* spp. Also high specificity (99,9 %) and accuracy has been described for the technique.

Conclusion: The AMOS-PCR-based protocol has been developed and validated for *Brucella* spp. detection and differentiation of the main veterinary significant species. It would be implemented in veterinary medicine practice in Ukraine.

POSTER 58

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Prevalence of Vancomycin Resistant Enterococci and Associated Risk Factors among Clients with and without HIV in Northwest Ethiopia: A Cross-sectional Study

Background: Enterococci are the most important multidrug resistant organisms associated with immunocompromised patients. Data are lacking about the epidemiology of vancomycin resistant Enterococci (VRE) in Ethiopia. This study aimed to assess the prevalence of VRE, their susceptibility patterns to different antibiotics and associated risk factors in fecal samples of Human Immunodeficiency Virus (HIV) positive and HIV negative clients.

Methods: A cross sectional study was carried out in a total of 226 (113 HIV positive and 113 HIV negative) clients, from July 1/2013 to September 30/2013 at the University of Gondar Teaching Hospital. Data on socio-demographic characteristics and risk factors were collected with a short interview guided by pre-tested structured questionnaire. The enterococci were isolated and identified from stool sample using standard bacteriological procedures. Kary Bauer disk diffusion method was used to determine the susceptibility patterns of Enterococci isolates. Data were entered and analyzed using SPSS version 20 statistical package.

Results: The overall colonization of Enterococci was 88.9% (201/226) of which 11 (5.5%) were VRE. The prevalence of VRE among clients with and without HIV infections were 8(7.8%) and 3(3.1%), respectively. Ninety percent of the Enterococci isolates (181/201) were resistant to two or more antibiotics tested. Isolates of Enterococci recovered from stool samples of HIV infected patients were more resistant to amoxicillin and amoxicillin-calvulinic acid than HIV negative clients ($P < 0.05$). Antibiotic treatment for the last 2 weeks was found to be the risk factor that showed statistically significant association with the presence of high VRE colonization. However, the socio-demographic variables and factors

such as malnutrition, leucopenia, thrombocytopenia, anaemia, duration of Highly Active Antiretroviral Therapy, CD4 cell count, stage of WHO and drinking alcohol were not associated with VRE ($P > 0.05$).

Conclusion: The high prevalence of VRE in this study signals the emergence of VRE in the study area. Prior antibiotic treatment was associated with VRE colonization. Therefore, rational use of antibiotics and more detailed study using phenotypic and genotypic methods are needed.

POSTER 59

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Barriers, Facilitators, and Outcomes Related to the Introduction of a Point-of-Care (POC) CD4 Testing Program in Rural Tanzania: Perceptions of Health Service Providers and Recipients

Background: As a result of lack of access to CD4 testing, the majority of people living with HIV/AIDS (PLHA) in Tanzania who require ART are not receiving it. Point-of-Care (POC) CD4 testing is a promising strategy for reducing losses to follow-up between HIV testing and initiation of ART. This study explored barriers, facilitators and initial outcomes related to the introduction of a POC CD4 testing program in rural Tanzania, following the donation of a CyFlow[®] miniPOC to a local HIV/AIDS care and treatment center.

Methods: This study used a descriptive, qualitative design guided by Rogers' diffusion of innovations framework. In-depth interviews were conducted with 12 health service providers (HSP) and 6 health service recipients (HSR) following the inaugural trial of POC CD4 testing technology during a mobile HIV care and treatment clinic. Data were analyzed using qualitative content analysis.

Results: Key barriers to program implementation included relying on the capacity of existing parallel resources, including staff and transport, logistical issues such as procuring reagents, and lack of sustainable funding among other challenges. Key facilitators included the motivation, enthusiasm, and receptivity of both HSP and HSR, as well as the simplicity of training and ease of use of the POC technology. Immediate and/or anticipated benefits of POC CD4 testing included reduced travel time and cost burden for HSR in order to obtain their CD4 measurements, and reduced or eliminated waiting time for CD4 results and subsequent ART eligibility assessment. Anticipated outcomes mentioned included an increase in the number of PLHA testing for CD4, and a reduction of loss to follow-up for PLHA in this region.

Conclusion: Both health service providers and recipients welcomed POC CD4 testing. Increased POC CD4 testing in similar settings should anticipate challenges such as reagent supply, new technology training, shifting of health service provider roles, and transportation to remote locations.

POSTER 60**Erick Kamangu**

Service de Biochimie Moléculaire, Département des Sciences de Base, Faculté de Médecine, Université de Kinshasa, Kinshasa, RD Congo

Mise en Place d'une PCR Quantitative Temps Réel pour l'Evaluation de la Charge Virale à Kinshasa

Background: La mesure de la Charge Virale (CV) est le moyen virologique le plus fiable pour évaluation le suivi des patients infectés par le Virus de l'Immunodéficience Humaine (VIH). Il permet d'estimer la quantité de virus présent dans un volume déterminé. Du aux contraintes de couts, la CV n'est pas souvent demandé pour le suivi des patients dans les pays à ressources limités. D'où l'objectif de ce travail est d'implémenter une PCR Quantitative en Temps Réel pour évaluer la CV à Kinshasa.

Methods: 155 patients positifs pour le VIH type 1, naïfs de Traitement Antirétroviral (TARV) et éligibles pour le TARV ont été incluses pour l'étude. 5 ml de sang a été prélevé dans un tube avec anticoagulant. 1 ml de plasma a été acheminé au laboratoire pour analyse. Après extraction de l'ARN, une PCR Quantitative Temps Réel quantitative a été réalisé sur une partie de la région du Long Terminal Repeat (LTR).

Results: 155 échantillons ont été reçus pour détermination de la Charge Virale (CV) par PCR Quantitative Temps Réel. 153 échantillons ont été amplifiés avec succès selon le protocole. La valeur médiane de CV est de 301.052,97 copies/ml ou 5,48 log10.

Conclusion: Les résultats des Charges Virales ont permis d'évaluer la faisabilité de cette PCR Quantitative Temps Réel. Elle s'avère une alternative plus simple, fiable et moins couteuse pour le diagnostic et le suivi virologique des patients VIH.

POSTER 61**Chisenga Kalunga**, Sinkamba. E., Chomba Obbie, Zulu Kachaka, S.Phiri, Mbulo

Northern Biomedical Sciences College, Kasama, Zambia

Worm Infestation and Tuberculosis Diagnosis a Case Study

Background: In TB suspects and in HIV/AIDS infection there has been worm infestation that have not been attended to and no anti helminth drugs have ever been included in the treatment regimen, including those on antiretroviral drugs. The chest X-Ray graphs seem to and may not suggest anything concerning the Lung heart migration of the worms, if at all there is opacity it is usually ignored or misinterpreted. Hence worm infestation might mimic TB. leading to mortality. Aim To determine worm infestation in TB suspects and HIV/AIDS with haemoptysis sputum Specific objectives 1 To detect worms in sputum stained with blood in TB suspects and HIV/AIDS clients. 2 To make recommendations that treatment for worm infestation be included into the TB /HIV regimen.

Methods: 42 Blood stained sputum samples were collected from TB corner, in-patients and TB suspected sputum presented at the laboratory for investigations. Fluorochrome acid Fast Staining method was used using the Low Emission Diode Microscope. The fluorochrome dye, Auramine O, once raised to high energy level after absorbing the excitation light the dye molecules return to their normal lower energy state releasing excess energy in the form of fluorescent light. The dye binds non specifically to the worm larvae and mycobacteria making it to appear bright yellow or greenish against a black background.

Results: 12/42 had Larvae of *Strongyloides stercoralis*. 3/12 were HIV positive but smear negative and 8/12 were smear negative but were treated for Tuberculosis.

Conclusion: Worm infestation in HIV/AIDS /TB suspects have not been investigated for especially in clients coughing blood.

Recommendation: Blood stained sputum should be subjected to Auramine O stain in order to exclude worm infestation whenever a blood stained sputum is presented.

POSTER 62**Horace Gumba**, Brett Lowe, Moses Mosobo, Tuda Otieno

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Evaluating a STAT Laboratory Performance with Quality Indicators

Background: Quality indicators are very vital when determining quality improvements in a laboratory. The objective of this study was to review quality indicators in a STAT laboratory with the aim of improving its performance.

Methods: The study evaluated sample rejection as a quality indicator and find reasons for rejection in KEMRI-Wellcome Trust Research STAT laboratory for the year 2013. A total of 15261 samples were processed, and sample rejections for all sample-types were monitored and their reasons for rejections determined to initiate training to phlebotomists to reduce sample rejection rates.

Results: A total of 104 samples (0.68%) out of 15261 samples were rejected. Most samples rejected were EDTA for full blood count (52.88%), followed by blood gas (14.42%), heparin tubes (10.58%), EDTA pink for PCR (7.69%), malaria slide (5.77%), induced sputum (1.92%), plain tubes (5.77%) and stool (0.96%). Analysis of the reasons for rejection indicated that clotted samples (65.38%) accounted for the major reason for rejection. This was followed by haemolysed samples (15.38%), insufficient samples and delayed samples were 4.81% each, poorly stained slides stood at 3.85% while sample mismatched, samples not collected and those without request forms were each 1.92%.

Conclusion: The concept of quality indicators has made evaluating laboratory performance simple with the aim of improving its quality. Training of the fieldworkers who draw blood and transport it to the laboratory was initiated as a corrective action to further reduce the sample rejection rate. This will help improve the quality of laboratory services and proper patient management.

POSTER 63

Andrea Cossarizza¹, Milena Nasi¹, Sara De Biasi¹, Elena Bianchini¹, Lara Gibellini¹, Marcello Pinti¹, Alda Tiziana Scacchetti², Vanni Borghi³, Tommaso Trenti³, Cristina Mussini^{1,3}, Andrea Cossarizza¹

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Reliable and Accurate CD4 T Cell Count and Percent of the New Portable Flow Cytometer CyFlow MiniPOC

Background: Flow cytometry is the “gold standard” for CD4+ T cell count, but its use is limited in resource-constrained countries because of its cost, equipment complexity and need of trained personnel. We have tested a new portable flow cytometer for CD4+ T cell count and percentage, named CyFlow MiniPOC (Partec-Sysmex, Germany), for its accuracy, sensitivity, carry-over contamination and repeatability.

Methods: Venous blood from 59 adult HIV-1+ patients (age: 25-58 years; 43 males; CD4+ T cell count: 34-1,115 cells/ul; CD4%: 3.1-48.0) was collected in EDTA and stained with the Partec MiniPOC CD4% count dry kit. CD4+ T cell count and percentage were determined in triplicate by the CyFlow MiniPOC flow cytometer, that detects side scatter and 2 fluorescences. CD4+ T cell count and percentages were measured in parallel either by a CyFlow Counter (Partec) or by a dual platform system based upon Cytomic FC500, Cytostat tetrachrome kit, and Coulter HMX for absolute cell count.

Results: The accuracy of CyFlow MiniPOC against Cytomic FC 500 showed a correlation coefficient of 0.98 and 0.97 for CD4+ T cell count and percentage, respectively, as shown by linear regression analysis. The correlation coefficient between measures performed by CyFlow MiniPOC and CyFlow Counter was 0.99 for both CD4+ T cell count and percentage. CyFlow MiniPoc showed an excellent repeatability with an intra-assay precision below +/- 10% deviation. The sensitivity was linear in the range 0-5,000 CD4 T cells/ul. There was no effect of carry-over contamination for samples at different CD4 values.

Conclusion: The cost-effective and portable instrument CyFlow MiniPOC produces reliable and accurate results that are fully comparable with those obtained by using highly expensive dual platform systems. Finally, this instrument permits to perform a very high number of CD4+ T cells counts per day in a fast and precise manner.

POSTER 64

Michel Kengne¹

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Etude Microbiologique de l'Environnement du Service de Chirurgie de l'Hôpital de la Mère et de l'Enfant et de l'Hôpital de l'Amitié Tchad-Chine de N'Djamena

Background: Ces dernières années, de nombreuses études ont établi une corrélation entre la contamination de l'environnement hospitalier et les infections nosocomiales. L'environnement du service de chirurgie de l'hôpital de la mère et de l'enfant (HME) et de l'hôpital de l'amitié Tchad-Chine de Ndjamen (HATC) constitue-t-il un réservoir potentiel à l'origine d'infections nosocomiales du patient chirurgical?

Methods: Il s'agit d'une étude transversale qui a consisté à prélever les surfaces après nettoyage et désinfection, l'air et l'eau de robinet des services de chirurgie de ces hôpitaux et de quantifier d'une part les bactéries par numération des colonies sur milieu de culture et d'autre part d'identifier ces bactéries par les tests biochimiques de confirmation. Les résultats du dénombrement des colonies bactériennes étaient exprimés en UFC/25cm² pour les prélèvements de surfaces, UFC/boîte de pétri pour les prélèvements d'air et UFC/100ml d'eau pour les prélèvements d'eau; ces résultats étaient ensuite comparés aux valeurs de référence.

Results: Pour les surfaces, le nombre moyen de colonies bactériennes était de 99,70 colonies/25 cm² pour 77 prélèvements à HME et 97,10 colonies/ 25 cm² pour 49 prélèvements à HATC; le germe prédominant était *Staphylococcus aureus*. Pour l'air, le nombre moyen de colonies bactériennes était de 86,94 colonies/boîte pour 16 prélèvements à HME et 76,42 colonies/boîte pour 12 prélèvements à HATC; le germe prédominant était *Staphylococcus aureus*. Quant à l'eau de robinet, le nombre moyen de colonies bactériennes était de 99,12 colonies/100ml d'eau pour 8 prélèvements à HME et 55,37 colonies/100ml d'eau pour 8 prélèvements à HATC; l'espèce bactérienne prédominante était *Burkholderia cepacia*.

Conclusion: Les surfaces, l'air ainsi que l'eau de robinet du service de chirurgie à HME et HATC sont biocontaminés et nécessitent des mesures correctives afin de prévenir les infections nosocomiales.

POSTER 65

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Overcoming the Challenges of Implementing Quality Control in a Manual African Laboratory

Background: Quality control (QC) is an important part of the laboratory quality management system, which checks the analytical process to reduce errors. Materials employed are either precision or accuracy controls required for internal or external QC monitoring,

respectively. Most African laboratories employ manual processes with minimal semi-automation. This is mainly due to lack of funds and appropriate infrastructure. Implementing QC is seen as an extra expense, even though laboratory staff are aware of its usefulness. The fact that these laboratories are manual should stress the increased potential for errors, and so QC measures should be more stringent. This study aimed to determine the challenges faced by an African manual laboratory in implementing QC in a bid to describing strategies to overcome them.

Methods: This was a descriptive study carried out at the Chemical Pathology laboratory, where reagents are freshly prepared according to validated, published methods and takes readings with spectrophotometers. The quality system was reviewed to assess: the use of QC, type, cost, frequency of use, and preservation facilities.

Results: Lyophilized QC materials by RANDOX® were being used for the chemistry analytes. They were purchased as 20 vials per QC level, where each vial is reconstituted to 5mls and costs USD 5.63. QC is run once daily using test volumes ranging from 10µl (e.g glucose) to 1ml (e.g total protein), resulting in a total volume of 4.5mls of only one QC level for basic analytes of: electrolytes, glucose, urea, creatinine, bilirubin, total protein, albumin, lipid profile, liver enzymes, and calcium. Freezers (- 20°C) were available to store reconstituted QC materials.

Conclusion: Quality control is performed but its consistency is limited by the high sample volume required by the test procedures. It is recommended that alternative procedures with smaller sample volumes be utilized, which should reduce the cost spent on QC vials in these resource-limited laboratories.

POSTER 66

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Strengthening Mozambican Clinical Laboratory Technologists' Knowledge and Skills through an Intensive Technical In-service Training Program in Brazil

Background: One major and widely recognized weakness of the Mozambican clinical laboratory system is the lack of trained laboratory technologists (labtechs) From 2007 to 2013 UFRJ/ Laboratory Technical Assistance Project, funded by PEPFAR, delivered twelve, four months In-service Technical Training Programs, in Brazil, in microbiology, biochemistry, and hematology, for 72 labtechs from MISAU. An impact evaluation study carried out in 2011 investigated the extent that training efforts produced expected results in terms of applicability and usefulness of what has been taught, knowledge and skills learned, improvement of lab work quality, and changes in labtechs behavior.

Methods: Qualitative research methodology was utilized to collect data. An open ended questionnaire was designed to interview a sample of 23 labtechs and their respective laboratory supervisors

in 10 clinical laboratories of 6 Mozambican Provinces. Data obtained through interviews were analyzed and organized in three major categories: transfer of knowledge and skills learned; modifications/improvements in the quality of the lab routine; changes in labtechs behaviors in the work environment.

Results: Labtechs recognized opportunities to apply in the work environment what has been learned, through the training program, even though, these opportunities were limited due to lack of support from the laboratory supervisor and "indifference" from lab co-workers to learn from them new skills and techniques. A significant change on the pre-analytical phase that impacted the quality of lab routine was related to the acceptance or rejection of adequate specimens for testing using criteria learned in the Program workbench practice was reported by many labtechs. However lack of maintenance in lab equipment and disruption of reagents were also pointed out as a major limiting factor on skills application. For many labtechs the Program reinforce self-confidence to "do things right" and contributed positively to changes in personal behavior inside and outside the lab.:

POSTER 67

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Effects of Co-administration of Red Palm Oil and Rooibos on Glycaemic and Liver Function Parameters in Streptozotocin-Induced Diabetic Rats

Background: Diabetes mellitus is an endocrine disorder characterised by hyperglycaemia and results from defects in insulin secretion, insulin action, or both. The study was designed to investigate the effects two antioxidant-rich plant products (red palm oil and rooibos) and their combined treatment on the levels of glucose, insulin, glycosylated haemoglobin, fructosamine, and liver function in streptozotocin-induced diabetic male Wistar rats.

Methods: Diabetes was induced by a single administration of streptozotocin (50 mg/kg) and the rats were treated for 7 weeks. The effects of these plant products on glucose, insulin, glycosylated haemoglobin, fructosamine and liver function were performed using established techniques.

Results: Administration of red palm oil and rooibos alone to diabetic rats did not reduce glucose and glycosylated haemoglobin levels while the combined treatment of red palm oil and rooibos significantly ($P < 0.05$) decreased the levels of glucose, glycosylated haemoglobin, fructosamine and increased insulin levels in the diabetic rats. Liver function enzymes such as aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase, and gamma glutamyl transpeptidase markedly increased in the diabetic rats. However, the combination of red palm oil and rooibos extract significantly ($P < 0.05$) reduced alanine aminotransferase in the diabetic rats. The activity of pyruvate kinase was significantly ($P < 0.05$) reduced in all diabetic groups. The combined treatment with red palm and rooibos significantly ($P < 0.05$) increased the

activity of pyruvate kinase. There was no significant ($P>0.05$) effect on the activity of glucokinase in both the untreated and treated diabetic rats.

Conclusion: From these findings, it can be concluded that red palm oil and rooibos when co-administered could help in the improvement of blood glucose control and liver functions in diabetic conditions.

POSTER 68

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Cost-Effectiveness of Pima™ Point-of-Care CD4+ Lymphocyte Cell Count Testing in Antenatal Centers, Tanzania 2013

Background: Limited access to HIV-related clinical laboratory monitoring technology is a frequent barrier to the timely initiation of guideline-appropriate care and treatment for many patients in rural, resource limited settings. Compared with standard laboratory-based testing (FACScount™), point-of-care CD4+ cell count testing may improve linkages to HIV care, reduce time to initiation of antiretroviral therapy, and increase patient retention. Cost-effectiveness comparisons with standard lab-based CD4 testing have not been previously reported.

Methods: In this cost-effectiveness analysis, outcome data from a cluster semi-randomized evaluation of Pima™ point-of-care CD4 testing in rural Tanzania antenatal clinics on guideline-appropriate treatment and care linkages were combined with cost data from the health sector perspective. Cost data were collected from 8 clinics and 8 regional laboratories and the national reference laboratory. Incremental cost-effectiveness ratios (ICER) illustrating the cost per patient linked to guideline appropriate treatment for Pima and FACScount tests were modeled using the TreeAge decision tree analytic package. Uncertainty was assessed by a multi-variable sensitivity analysis, varying the total average costs and measures of effectiveness for both the Pima and FACScount tests.

Results: The estimated cost per patient initiated on guideline appropriate treatment and care was higher for the Pima (\$49.93) test relative to the FACScount (\$30.70) test. The Pima strategy was more effective in retaining patients through the treatment continuum, with approximately 65% of the Pima group receiving guideline-appropriate care and treatment relative to 8% of the FACScount group. The ICER for the Pima testing strategy is \$33.76 per patient initiated on guideline-appropriate treatment.

Conclusion: Pima point of care CD4 count testing offers a cost-effective tool for improving uptake of guideline appropriate HIV care and treatment within rural, resource limited settings. Pima CD4+ cell count technology may be a cost-effective option for reducing time to ART initiation and increasing retention of HIV-positive patients.

POSTER 69

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Improving Laboratory and Staff Testing Proficiency through Inter-laboratory Comparison, in the Absence of Proficiency Testing Scheme: a Pilot Study of Inter-lab Comparison in Kuje Area Council, Abuja, Nigeria

Background: Achieving ISO 15189 accreditation may not be an easy task for most laboratories in settings where there is lack of resources and capacity development or mentorship program. However, it is possible to gradually initiate programs like Inter-laboratory comparison, that could improve the testing of patient's samples, with a positive impact on lab reports. Inter-laboratory comparison is one of the indicators required for an effective Quality Assurance program, especially for medical laboratories. Kuje Area Council has twelve laboratories that are opened to the populace within the Area. As a pilot, we sent letter of invite to five laboratories for the purpose of Inter-Laboratory comparison. We aim to determine how comparable are the laboratory reports within Kuje Area Council and how we could support laboratories toward improving lab practices through corrective and preventive measures.

Methods: The laboratories received letter of invitation, guidelines for handling Inter-lab samples and samples, generated by one of the participating laboratories. The Inter-lab samples – urine for biochemical analysis, microscopy (wet preparation), culture and antibiotic susceptibility; unstained thin blood smear for manual full blood count (2 slides); unstained thick blood smears (positive and negative) for malaria examination; stained thin blood smears (positive and negative) for malaria examination (from UKNEQAS). All the samples were coded with alphabets and numbers. The submitted lab results were analysed based on total agreement% and performance cut off%. Feedback was provided to the labs (names of the other labs were coded with alphabets and numbers) and recommendations suggested for corrective and preventive actions. Unstained thin smears results were excluded from analysis.

Results: 3 out of the 5 laboratories, participated in the inter-lab pilot program. The 3 labs reported the same results for 9 biochemical analytes except for protein and ascorbic acid. Urine microscopy and culture – 2 labs had the same results. Unstained thick smears – 1 lab failed to identify the two slides. Stained thin smears – 1 lab failed to identify one of the control slides.

Conclusion: Participated labs accepted the suggested recommendations. All the laboratories indicated interest in the program and want it to continue and be extended to other laboratories.

POSTER 70

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Implementing Laboratory Quality Systems in Preparations for Accreditation, Experience of the National External Quality Assessment Centre, Zaria, Nigeria

Background: The Center for Diseases Control (CDC) engaged Axios to establish an External Quality Assurance (EQA) centre in Zaria, Kaduna State, Nigeria. We showcase and discuss the experiences, challenges and lessons learnt accrued by the centre during the process of implementing laboratory quality systems (QMS) in preparation for accreditation with the purpose of sharing lessons learnt with other Laboratories.

Methods: Axios employed a series of implementation activities using the World Health Organization's six building blocks for health systems as a guide to establishing the centre and series of strategies to implement QMS and prepare for accreditation. These included establishment of centre with accreditation in mind, providing good leadership and advocating for strong management commitment for sustainability, use of long term mentorship to implement QMS and build capacity of laboratory staff, use of Strengthening Laboratory Quality Improvement Process towards Accreditation (SLIPTA) checklist to conduct routine internal audits cycles, participating in country SLIPTA audits and mentoring programs, and capacity building exchanges with accredited Thistle QA.

Results: Five internal audits using the SLIPTA checklist noted improvements performance with 70.5%, 73.6%, 84.1%, 98.4% and 98% scores noted across a two year period. After the necessary improvements to QMS, the centre then participated in two external preparatory SLIPTA preparation audits. The first audit in Sept, 2012, awarded the centre three out of five stars (81.7%). Corrective actions were taken and a second held in Jan, 2013, awarded the centre five out of five stars (96.2%)

Conclusion: The approach of establishing the centre, use of long term mentor to implement QMS, exchange visits to accredited lab, use of SLIPTA tool for internal audits, participating in external SLIPTA audits amongst others are invaluable in the road towards accreditation. The use of the SLIPTA checklist internally at regular intervals helped laboratories prepare for external official SLIPTA audits, while external audits gave an unbiased view of the level of compliance and provide a sense of recognition of achievements.

POSTER 71

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Breaking Down Barriers to Quality Improvement

Background: Working with 5 Zonal hospital laboratories and the National Health Laboratory and Quality Assurance Centre (NHLQATC) to improve the quality of services, the Clinical Laboratory Standards Institute (CLSI) team recognized that significant problems existed with supply chain and equipment management. The solutions lay beyond the scope of authority of the hospitals and the CLSI team was challenged to find solutions.

Methods: Using ISO15189 – 2007 and the CLSI Quality System Essentials tools, a planned systematic approach to improving quality was applied over a period of 6 years. Each year began with an assessment against a standard checklist and development of an annual plan. MOHSW was tasked with improving the supply and distribution of reagents, a challenge familiar to many African countries. The solution eventually lay in enlisting the support of the local development partners assigned to each Zonal hospital and instructing laboratories in inventory management principles. To address the equipment maintenance problem, the MOHSW hired and trained bioengineers, who went out each of the 6 laboratories to provide service.

Results: Training of local bioengineers resulted in improved equipment maintenance which ultimately resulted in uninterrupted testing across the laboratories that were under assistance. Equipment downtime was reduced as a result of regular preventive maintenance. Efficient supply chain management of reagents and consumables improved,

Conclusion: Tanzania has demonstrated that training in-country bioengineers not only strengthens the equipment management of laboratories, it is also more cost effective and sustainable in resource limited settings. Enlisting local development partners in managing supply of reagents and consumables is a means to ensure continuous supply of laboratory reagents and consumables. However, sustainability of such a program needs to be looked at and addressed.

POSTER 72

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Application of Quality Management System Principles Results in Laboratory Accreditation: A Tanzanian Success Story

Background: A baseline assessment in 2007 of 5 of Tanzania's largest hospital laboratories and the National Health Laboratory

Quality Assurance and Training Centre (NHLQATC), demonstrated a need for significant improvement in the quality of services. PEPFAR funding was awarded to support the activities required to improve efficiency and accuracy of results.

Methods: Using ISO15189 – 2007 and the CLSI Quality System Essentials tools, a planned systematic approach was applied over a period of 6 years. Each year began with an assessment against a standard quality checklist, conducted by the CLSI assessor team and development of an action plan. The strategy included a series of quality management system workshops and volunteer mentors assigned to each lab for 6 to 12 weeks a year. With a view to sustainability, in-country hand picked laboratory staff were trained to be assessors and to mentor other laboratories. A project management team from the Tanzania Ministry of Health and Social Welfare, CDC and CLSI closely monitored the entire process.

Results: Planned and persistent application of quality management system principles has resulted in measureable improvement in work environment, operational efficiency and quality of test results. 3 of the hospital laboratories and the NHLQATC have been successfully accredited to ISO15189 by SADCAS. The remaining two laboratories continue to work towards the same goal. Challenges included shortages of staff, reagents and equipment, as well as equipment maintenance; all of which were addressed successfully.

Conclusion: A standardized approach to implementation of quality management systems has been successful in improving services in Tanzania hospital laboratories. The commitment of the project management team was essential and strong relationships between management, staff, the CLSI team and the volunteers played an important role. Accreditation by an external organization served as validation of the overall improvement. The ultimate beneficiaries are the doctors and their patients served by these laboratories.

POSTER 73

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The Prevalence, Distribution of Diarrheagenic E.coli Categories, and their Antimicrobial Susceptibility Patterns in Kenya

Background: Diarrhea is one of the main causes of morbidity and mortality among children in sub-Saharan Africa, and one of the main causes of hospital admissions in rural areas of Kenya. In Kenya, antimicrobial resistance surveillance has been conducted only at the institutional levels, with limited sharing of information and analysis of data. As a result, the actual scale of regional or national antimicrobial drug resistance is not well defined.

Methods: This was a cross-sectional hospital based study of which stool samples were collected between 1st February 2013 and 18th April 2014 from a total of 180 outpatients with diarrhea who were under five years of age from 5 cross border county hospitals in Kenya. Conventional, biochemical methods, multiplex PCR and antimicrobial susceptibility tests were conducted to identify the bacterial causes and virulence factors in the isolates, respectively.

Results: Of the 180 patients screened, we identified the causes of 110 cases (61%) as follows: Pathogenic E. coli 69 (62.7%) [enteroaggregative 11 (15.9%), enterotoxigenic 17 (24.6%), enteroinvasive 9 (13%), shigatoxigenic 7 (10%), enteropathogenic 25 (36.2%)], Salmonella 16 (14.5%), Shigella 23 (20.9%) and Vibrio cholera O1 2 (1.8%). The highest levels of resistance among the E. coli isolates were observed in ampicillin and trimethoprim/sulphamethoxazole each at 95% followed by tetracycline at 81%. Shigella isolate levels of resistance ranged from 80% to 100% for ampicillin, tetracycline and trimethoprim/sulphamethoxazole.

Conclusion: The highest prevalence of antimicrobial resistance was to ampicillin followed by trimethoprim/sulphamethoxazole and tetracycline. Though still at low levels, the major concern from our findings is the emerging resistance of enteric pathogens that was observed to quinolones (ciprofloxacin, nalidixic acid, norfloxacin) and gentamycin.

POSTER 74

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Determination and Compare the Tuberculosis Drug Activity and Minimum Inhibitory Concentration of Second Line Anti-Tuberculosis Drugs among Multi-Drug Resistant Tuberculosis (MDR-TB) Patient Admitted at Kibong'oto Infectious Diseases Hospital

Background: Plasma Bactericidal Assay is an assay that gives a quantitative estimates of effectiveness of the bactericidal effect in patients who are on anti-tuberculosis therapy. The assay involves the use of pre-isolated organisms and blood (plasma) from the same patient on treatment. Minimum Inhibitory Concentration (MIC), the minimum concentration of drug that will kill/inhibit the growth of micro-organism. This is the quantitative estimation of Drug Susceptibility of an organism to tested drugs. It involves the use of pre-isolated organisms from the patient before the start of treatment. Study aim: To determine and compare the Tuberculosis Drug Activity (Plasma Bactericidal Activity) and MIC of second line anti-Tuberculosis drugs among Multi-Drug Resistant Tuberculosis (MDR-TB) patient admitted at Kibong'oto Infectious Diseases Hospital.

Methods: The study was cross-sectional study. It involved participants who were diagnosed and confirmed to have MDR-TB, who agreed to sign the consent form. Prior to the start of MDR-TB treatment, sputum was collected from each participant, processed and cultured on solid and liquid media. Three weeks after the initiation of MDR-TB treatment, blood was collected from each participant and plasma separated. Plasma was used to test pre-isolated organisms in a liquid culture and Time to Positivity (TTP) was recorded. Drug Susceptibility Test (DST) using MIC was done on trek plates (Sensititre® MYCOTB MIC plates) using the pre-isolated organisms from solid media. Tuberculosis Drug Activity (TDA) calculated from TTP was correlated with MIC.

Results: The mean TDA among fourteen (14) participants was 2.19 ± 0.62 for those who were treated with Capreomycin, Ofloxacin, Ethionamide, and Pyrazinamide. Among 14 participants, seven (7) participants were treated with Kanamycin, Ethionamide, Levofloxacin, Pyrazinamide and Cycloserine later showed the mean

TDA of 2.19 ± 1.0 . MIC and TDA showed inverse relationship (i.e. the increased Drug Activity showed the lower concentration that inhibited/killed the organisms' growth).

Conclusion: Drug activity was found to correlate with Minimum Inhibitory Concentration during treatment of pulmonary TB. This indicates that, this marker (TDA) assay have a role and can be used in monitoring the treatment outcome which includes prediction of drug resistance in early stages of treatment.

POSTER 75

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The Clinic-Laboratory-Interface (CLI) – Assessment of Facilities' Post-analytic Systems and Processes to Receive Pathology Test Results, Manage Abnormal Results and Review Laboratory Use, in Five Districts in Eastern Cape and KZN Provinces, SA

Background: Laboratory testing is a key tool in clinical medicine. Studies have demonstrated areas of weakness in the post-analytic chain of activities. A key CLI element is the ability to receive results timeously, and systems to adequately respond.

Methods: Assessments were conducted at primary healthcare clinics and community health centers in 325 facilities in 2013 in Amathole, Harry Gwala, Buffalo City, Nelson Mandela Metropole and Cacadu districts. As part of a baseline situation analysis prior to an intervention, structured interviews with facility managers and healthcare professionals, and direct observation was used. Each category was scored as poor, partial or adequate. The questions asked were: i) How do you receive NHLS results; ii) manage laboratory test results; iii) review utilization of laboratory tests?

Results: 96% of facilities received laboratory paper-based results. Only 78% of facilities in the five districts had a working telephone line, 25% a fax line, and 13% email access. Results for each of these parameters varied significantly between districts and sub-districts. 57% of facilities had appropriate systems for responding to abnormal results, varying from 11% and 68% between districts. 42% of facilities checked that reports were received for all tests requested in the specimen tracking register. The minority of facilities (41%) had a mechanism for trouble shooting and identifying outstanding results. Review of laboratory usage and results was poor, with 15% reviewing reasons for sample rejection by the laboratory; 44% having overall review of results received; 11% reviewing turnaround times, 39% reviewing patterns of tests requested; and 4% reviewing expenditure patterns.

Conclusion: Systems for receiving and reviewing results; and external communication systems are inadequate for clinical, logistic and management issues. The only consistent means of receiving results is in paper form. Technical assistance will build capacity for improved results management systems, and more efficient laboratory utilization.

POSTER 76

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Prevalence of Intestinal Parasites and its Associated Risk Factors among Yadot Primary School Children of South-eastern Ethiopia: A Cross-sectional Study

Background: Intestinal parasitic infections are among the most common infections worldwide. In Ethiopia, particularly in the study area, due to poor socioeconomic status, inadequacy and lack of safe water supply intestinal parasitic infections are highly prevalent. The main aim of this study was to determine the prevalence of intestinal parasites and its associated risk factors among Yadot primary school children of the Delo Menna district, southeastern Ethiopia.

Methods: Institution based cross-sectional study was employed from March to April 2013. A total of 340 students was selected using simple random sampling. Data on socio-demographic and factors associated with the prevalence of intestinal parasites and stool samples were collected and processed accordingly. Direct stool examination and formol-ether concentration technique were employed for the laboratory diagnosis as per the standard procedure. Statistical analysis was done by SPSS version 16 and binary and multivariate logistic regression analysis was conducted to measure the strength of association between dependent and independent variables.

Results: The overall intestinal parasite prevalence of intestinal parasite in this study was 33.8%. Poly parasitism was detected in 8% of the students. Students who were infected with at least one, double, triple and quadruple infections were 26.5%, 6.5%, 1.2% and 0.3% respectively. The most prevalent parasites were *Schistosoma mansoni* 12.7% followed by *E. histolytica/dispar* 5%, *A. lumbricoides* 4.7%, and *Hymenolopes nana* 4.4%. Sex of the respondents [(AOR=2.51, 95% CI=1.23-3.95), $p=0.008$], mothers'™ educational status [(AOR=1.59, 95% CI=1.03-2.46), $p=0.037$], water contact activities [(AOR=2.28, 95% CI=1.19-4.34), $p=0.012$], reason of washing hands before meal [(AOR=0.20, 95% CI=0.10-0.40), $p<0.001$] not wearing protective shoe [(AOR=0.27, 95% CI=0.15-0.51), $p<0.001$] were among the factors significantly associated with intestinal parasitic infections.

Conclusion: Conclusion and recommendation: Intestinal parasitic infection is still found to be the highly prevalent among Delo Mena district school children. Hence, improving sanitation, provision of safe drinking water, increasing latrine use, snail control, health education, and de-worming to the students is crucial.

POSTER 77

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Presumptive Treatment of Malaria During a Peak Transmission Season in a Malaria Endemic Setting: a Cross-sectional Study

Background: Malaria, a febrile condition, is one of the leading causes of morbidity and mortality in sub-Saharan Africa, especially among children under five years of age. The current effective Artemisinin-based combination therapy for malaria is quite costly. Owing to the low sensitivity of routine microscopy, the primary diagnostic tool in sub-Saharan Africa, there is symptomatic treatment of malaria among febrile patients with negative blood smear (BS) results. This may be an irrational prescription practice. We investigated all malaria symptomatic (febrile) patients with negative routine BS during a peak malaria transmission season.

Methods: This cross-sectional study was conducted at Gulu regional referral hospital, Uganda, between October and November 2012. A routine BS was examined for all malaria symptomatic patients. A rapid diagnostic test (RDT) was performed on all patients with negative routine BS results. All smears were later double-read by expert microscopists.

Results: Of the 542 patients seen, 503 (92.8%) had negative routine BS results. Eighty nine (7.2%) were excluded due to history of treated fever in the previous two months. Of the 414 qualifying participants, 14 (3.4%) had positive RDT and 6 (1.4%) had positive expert BS. Nearly all participants (12/14) with routine BS-negative but RDT-positive results were children less than 5 years.

Conclusion: At a rate of 3.4% true malaria cases, administration of anti-malarial drugs to all malaria symptomatic cases offers a marginal benefit to children less than five years and is an uncalled-for expense among adults. Prescription practices consistent with these findings could greatly improve rational anti-malarial use and minimize costs, especially in sub-Saharan Africa.

POSTER 78

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Performance of LED Microscopy in the Diagnosis of Pulmonary Tuberculosis in HIV Positive Individuals in Addis Ababa, Ethiopia

Background: Ziehl-Neelsen (ZN) sputum microscopy remains the easiest and rapid diagnostic methods for Acid Fast Bacilli (AFB) in

sputum, which is used routinely in Ethiopia. Although the specificity of the method is high, the sensitivity varies. Löwenstein-Jensen (LJ) culture method is better performing compared to microscopic methods but their use for routine diagnostic purpose is limited due to the higher cost and prolonged time taken to get the result. Now a day, different advancements have been made to increase the sensitivity of sputum microscopy.

Methods: Performance of LED microscope was evaluated at Zewditu Memorial Hospital and Teklehaymanot Health Center ART clinics, in Addis Ababa from December 2011- June 2012. 178 HIV positive PTB suspected individuals were included to evaluate the performance of LED-FM against Löwenstein-Jensen culture. Three sputum samples were collected as per national guidelines, and transported to Ethiopian Public Health Laboratory, National TB reference laboratory. The specimens were examined by ZN microscopy and LED-FM in both direct and concentrated samples and the results were compared with LJ culture as a reference.

Results: From 178 study participants, 24 were positive for MTB with LJ culture; 7 were positive by direct ZN microscopy while 11 were positive by the concentrated ZN preparation. On the other hand, 15 were positive by LED microscopy in both direct and concentrated preparation. The sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of LED-FM microscopy in the direct and concentrated sputum sample was 62.5%, 100%, 100% and 94.5% respectively and for Direct ZN microscopy it was 29.2%, 100%, 100% and 90.1% respectively. And for concentrated ZN microscopy, it was 45.8%, 100%, 100% and 92.2% respectively.

Conclusion: LED-FM microscopy has better sensitivity for the diagnosis of PTB in HIV positive individuals as compared to conventional ZN microscopy. As WHO recommended, in areas where the use of fluorescent microscope is impossible we can use LED-FM as an alternative to conventional ZN microscopy.

POSTER 79

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Determination of Hematological and Immunological Parameters among HIV Positive Patients Taking Highly Active Antiretroviral Treatment and Treatment Naïve in the Antiretroviral Therapy Clinic of Gondar University Hospital, Gondar, Northwest Ethiopia: A Comparative Cross-sectional Study

Background: Anemia, leucopenia and thrombocytopenia are the commonest hematological abnormalities resulting from human immunodeficiency virus infection. The use of antiretroviral drugs could positively or negatively affect these disorders. Thus a specific diagnosis and a determination of hematological and immunological parameters are required for initiating and monitoring early treatment to avert disease progression. Therefore, this study aimed to compare hematological and immunological parameters in HIV

positive patients taking antiretroviral therapy and those treatment naïve patients in Gondar University Hospital.

Methods: A comparative cross-sectional study was conducted on a total of 290 HIV patients from February to May 2012 in Gondar University Hospital. Study subjects were divided into two groups: 145 HIV positive treatment naïve and 145 on HAART. Data of socio-demographic characteristics and clinical conditions of the study subjects was collected using structured pretested questionnaire at their follow up date. Hematological and immunological parameters were collected and processed by cell Dye 1800 and BD FACS count respectively. The variables compared here were Hematological parameters (Total and differential WBC, RBC, Hgb, HCT, MCV, MCH, MCHC, RDW, PLT, and MPV) and CD4 count. In order to compare means independent sample T-test was conducted using SPSS version 20 statistical software. P- Value < 0.05 was considered as significant.

Results: Prevalence of anemia, leucopenia, thrombocytopenia, neutropenia and lymphopenia were 11.7%, 35.9%, 4.1%, 28.3% and 2.1% in patients on HAART and 29.7%, 16.6%, 9%, 14.5% and 2.1% in HAART naïve patients respectively. There was a significant difference in total WBC, RBC, Hgb, MCV, MCH, MCHC, MPV and CD4 counts between patients on HAART and HAART naïve patients.

Conclusion: Prevalence of anemia was high in HAART naïve patients while leucopenia and neutropenia prevalence was higher in patients on HAART and their prevalence increased as the CD4 count decreased. HIV Patients should be investigated for hematological and immunological changes following with appropriate therapeutic interventions.

POSTER 80

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Implementing Quality Control Program at the HIV Counselling Testing Units at the Primary Health Centers (PHCs) in Lagos State, Nigeria

Background: Internal quality control (IQC) is a set of procedures undertaken by laboratory staff for the continuous monitoring of operations and the results of measurement in order to decide whether results are reliable enough to be released. Quality control (QC) within routine laboratory analysis helps to monitor the accuracy and precision of analytical process and errors due to operator's performance. As QC samples are not routinely analyzed at the PHCs, the reliability of HIV screening results cannot be guaranteed. Therefore, the objective of this project is to introduce and implement quality control analysis as a routine analysis at the HIV counselling and testing (HCT) units at the PHCs in the Local Government Areas supported by AIDS prevention initiative in Nigeria (APIN) in Lagos State, Nigeria.

Methods: In house prepared control materials- dried plasma samples (positive and negative) in a 2ml micro centrifuge tube and phosphate buffer (pH 7.2) were supplied to 35 PHCs that conducts HCT and have no QC program in place. Personnel that perform HIV screening were trained on how to reconstitute the dried control samples, analyze the negative and positive control

using the appropriate HIV test kits, and document results correctly. Results from each site on the control performance were collated and analyzed for concordance for the period of July to December, 2013.

Results: A total of 245 positive and 245 negative control samples were analyzed. Comparing all result with initial testing showed 100% concordance for both negative and positive. Through this project, these PHCs now routinely analyze QCs; this process has improved the accuracy and reliability of HIV screening results generated from these PHCs.

Conclusion: Implementing quality control at the lowest cadre of our health systems is achievable and sustainable. This process has contributed in improving accuracy of HIV testing results from these resource limited facilities.

POSTER 81

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Molecular Detection of *Clostridium difficile*, Pathogenicity, Virulence and Moxifloxacin Resistance in Stool from Children with Diarrhea at Mulago Hospital

Background: Diarrhea remains a major cause of morbidity and mortality accounting for 1.5 million deaths of children under 5 years in the developing countries (UNICEF). Diarrhea caused by *Clostridium difficile* is due to production of toxins A and B encoded by *tcdA* and *tcdB* genes. Pathogenicity due to these genes is regulated by the *tcdC* gene. Mutations in the regulatory gene are responsible for what is termed as hypervirulent strains, which cause severe disease. Another factor underlying severe disease is presence of moxifloxacin drug resistance. The contribution of *Clostridium difficile* remains hardly known in Uganda. However, there is limited data on the prevalence of toxigenic, virulent/hypervirulent and moxifloxacin resistant *C. difficile* among Ugandan children. Therefore the aim of this study was to determine the prevalence of toxigenic, virulent/hypervirulent and moxifloxacin resistant strains of *C. difficile* among children with diarrhea at Mulago hospital.

Methods: This was a cross-sectional study where stool was collected from 100 children aged 2-36 months clinically diagnosed with diarrhea at the acute care unit Mulago Hospital. The stool was tested for *C. difficile* using, a molecular test GenoType CDiff test (Hain life Science, Nehren Germany) at MBN Clinical Laboratories.

Results: Valid results were obtained for 99 samples. Two of the 99 samples were positive for toxins A and B genes but negative for the binary toxin genes (*cdtA* and *cdtB*), hypervirulent and moxifloxacin resistance mutations.

Conclusion: Based on molecular testing, the prevalence of toxigenic *C. difficile* is very low (2%) among children aged 2-36 months admitted with diarrhea at Mulago hospital.

POSTER 82

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Five Years of Early Infant Diagnosis in Papua New Guinea, Making Early Initiation of ART Possible

Background: Early Infant Diagnosis (EID) using HIV DNA PCR from dried blood spots (DBS) has been used extensively in resource limited settings to diagnose HIV in infants either known to be HIV-exposed or suspected of having HIV. Prior to EID in PNG, HIV status of these infants was assessed indirectly and commencement of anti-retroviral therapy (ART) for those in need was often delayed. We present a five-year progressive report on the PNG EID testing program.

Methods: The EID program certifies health care workers to collect DBS. DBS collected throughout the country from infants 6 weeks to 18 months are transported to two regional laboratories where HIV DNA PCR test is done only on samples of good quality. Positive samples are recollected and tested for confirmation.

Results: From 2008 to 2013, EID testing coverage extended from 9% (2 provinces) to 82% (18 provinces) and expanded from one to two regional laboratories. The total number of DBS samples collected increased from 152 in 2008 to 3411 in 2013 with an overall rejection rate of 11% (384). The total number of infants tested increased from 151 in 2008 to 2432 in 2013 and the total number of infants tested positive increased from 46 in 2008 to 500 in 2013. Of the positive infants, 56% (280) were aged 6 months and below while 26% (131) were six to eight weeks old. Test accuracy was 100% with no false positive tests detected.

Conclusion: The EID testing program in PNG has been very successful in providing high quality testing that is accurate and reliable for infants as early as six week old. The number of tests per year has increased dramatically. Continued support is needed to maintain the standard of testing and increase capacity to allow all PNG infants access to early testing and treatment.

POSTER 83

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Post Market Vigilance for Diagnostic Tests in Africa: A Pilot Study

Regulation of medical products is undertaken by National Regulatory Authorities to protect public safety and to facilitate timely access to new products. An important component of regulation for in vitro diagnostic (IVD) medical devices is postmarket surveillance which ensures quality and safety standards are maintained following premarket approval. There are two forms of vigilance. Proactive surveillance requires systematic

collection of data from laboratory studies or through field testing. Reactive surveillance requires voluntary reporting of problems by manufacturers, or users of the test. Capacity for postmarket surveillance is limited in Africa and the region lacks mechanisms for cross-border sharing of adverse events or for alerting manufacturers when corrective actions are needed. The Pan African Harmonisation Working Party is examining strategies to strengthen vigilance for IVDs.

A multi-centre pilot study was initiated for proactive surveillance of rapid tests for HIV. Protocols were developed by a multi-national team. Accredited laboratories, or those with proven competency in HIV testing, were invited to take part on a voluntary basis. Results were reviewed by an expert committee. Protocols will be made available and lessons learnt will be shared. A communications portal was established to pilot a mechanism for reporting adverse events and share information on substandard diagnostic tests. The principle of cross border collaboration and convergence of post market surveillance activities was established with regulators from three regions (East, Southern and West Africa) taking part. Convergence of post-market surveillance activities and cross border collaboration could maximise efficient use of regulatory resources and expedite corrective action and the removal of tests considered a danger to public health from the market. The quality and safety of in vitro diagnostics marketed in Africa could be improved through this strategy. Expansion to other diseases shall require support for laboratories to reach satisfactory performance and accreditation levels.

POSTER 84

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Harmonizing Regulation of Medical Devices and In Vitro Diagnostics to Improve Quality and Access

There are thousands of commonly used in vitro diagnostic devices in other parts of the world that are not accessible to the majority of patients living in Africa. In addition, while some very good tests are being marketed, tests of unknown or dubious quality are also being sold in the region. National Regulatory Authorities have a crucial role in protecting public safety while facilitating access to beneficial new products. Weak regulation allows poor quality products to enter the market whereas inefficient or overzealous regulation results in unnecessary delays, increases costs and act as disincentive to innovation and market entry. Adopting international standards and streamlining the regulatory process could reduce these barriers and improve transparency. The Pan African Harmonization Working Party (PAHWP) on the regulation of medical devices and diagnostics is a voluntary body that has been established to investigate and recommend harmonization activities with the aim of increasing access to high quality, affordable products in Africa. PAHWP follows principles established by WHO and the International Medical Devices Regulatory Forum (formerly the Global Harmonization Task Force). We collaborate with other regional harmonization bodies, including the Asian Harmonisation Working Party (AHWP) and the Latin American IVD Association (ALADDIV) and priority has been

given to in vitro diagnostic medical devices. Three technical working groups have been established to look at pre-market registration, post-market vigilance and reducing the unnecessary duplication in clinical performance studies that currently delays market access and increases prices. Recommendations include adopting a common risk classification system where the stringency of regulation is moderated according to the risk of harm from a product. A second recommendation is adoption of a common format for pre-market submission dossiers. It is vital as we build regulatory capacity in Africa that efforts are harmonized and international standards are observed.

POSTER 85

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Standardised Monitoring and Evaluating Framework for Xpert MTB/RIF Test Implementation

Background: World Health Organisation (WHO) endorsed the Xpert MTB/RIF test in 2010 for the diagnosis of tuberculosis (TB) and detection of rifampicin resistance in low and middle-income countries. Since 2010, over 2.3 million Xpert MTB/RIF cartridges were procured in the public sector worldwide. As National TB Programs (NTPs) scale up the use of the Xpert MTB/RIF test for case detection, there is a need to monitor and evaluate (M&E) test implementation. We have developed a standardised M&E framework for monitoring the programmatic and laboratory aspects of Xpert MTB/RIF implementation. The framework was customised and piloted in Tanzania and Lesotho.

Methods: The M&E framework consists of six steps, and eight standardised forms for data collection at various stages: (1) Pre-installation, (2) Installation, (3) Xpert MTB/RIF test verification, (4) Partner handover, (5) Supervisory visits, and (6) Quality assurance implementation. New and revised documents have been piloted to ensure feasibility of data collection and user-friendliness of the data collection tools. All tools are being reviewed and piloted with other implementing partners. Standardised training materials for different cadres of staff involved in M&E are being developed, including national level focal person, regional and district TB programme and laboratory supervisors and users.

The comprehensive M&E framework is an important tool for national programmes to customise and implement as part of their programmatic M&E. It should be used as the basis for a working document which allows coordination of activities of various stakeholders and regular review and evaluation of progress towards programme objectives. A manual system is currently being used, but innovative approaches to simplify data collection and analysis are being developed. The use of a standardised M&E framework can contribute towards sustainable implementation of Xpert MTB/RIF testing from planning to handover.

POSTER 86

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Contrôle de Qualité Externe du Dépistage Sérologique du VIH par le Drieb Tube Specimen dans les Régions de Segou, Sikasso et dans le District de Bamako (Mali)

Background: L'Institut national de recherche en santé publique était la seule structure qui effectuait le contrôle de qualité externe pour le dépistage sérologique du VIH. Le niveau actuel de la couverture en laboratoires ne permet pas à l'INRSP seul d'assurer efficacement le contrôle de qualité de tous les laboratoires du pays. C'est dans ce cadre que le programme a été décentralisé dans deux régions et le district de Bamako. Le but de ce programme est d'améliorer la qualité du dépistage sérologique du VIH des laboratoires et des centres de conseil et dépistage volontaire au Mali.

Methods: Ce contrôle de qualité a été réalisé en 2013 dans 33 sites dont 14 à Ségou, 10 à Bamako et 09 à Sikasso. Le sérum a été caractérisé par l'INRSP avec les tests Murex, Vironostika, Determine, Clearview, OraQuick et Immunocomb. Des DTS ont été préparés et testés avec les tests ci-dessus. Des panels de cinq DTS ont été envoyés aux sites participants une fois par trimestre. Après analyse des échantillons par les tests de routine, les sites ont envoyé leurs résultats à l'INRSP et ils ont été évalué en leur attribuant un score selon les critères suivants : taux de concordance des résultats avec l'INRSP, transcription des résultats.

Results: Tous les 33 sites ont répondu dans le délai lors des 4 envois. Il y a eu 100% de concordance entre les résultats de l'INRSP et 25, 27, 29, 28 sites respectivement au 1er, 2ème, 3ème et 4ème envoi. Les taux de concordance moyen globaux étaient respectivement de 96,51%, 97,72%, 97,87% et 98,03% pour le 1er, 2ème, 3ème et 4ème envoi.

Conclusion: Au regard de ces résultats, nous avons constaté une amélioration de la qualité de dépistage du VIH dans les sites participants. Mot clé : Contrôle de qualité, VIH, DTS, panel.

POSTER 87

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Laboratory Information System Implementation in Ethiopia: Success and Challenge

Background: In many developing countries, including Ethiopia, many factors hinder access to quality and affordable laboratory service. These factors include poor data management, lack of efficient sample referral system, a shortage of qualified laboratory professionals, and long turnaround times (TAT) for completing and reporting laboratory results. To overcome these challenges, Ethiopian Public Health Institute had implemented

Electronic Laboratory Information System at Selected Health Facilities. Objectives- The aim of this study was to evaluate the success and challenges of laboratory information system (LIS) implementation.

Methods: A cross-sectional descriptive study was conducted at health facilities that start LIS implementation. Ten sites were selected, which were investigated through quantitative methods using structured questionnaires and Reviewing of LIS support Registry log book.

Results: Polytech LIS Software from Comp ProMed,CA, (Computer professionals in Medicine) brings dramatic positive improvement in the laboratory quality management implementation in Ethiopian laboratories. It reduces laboratory errors, enables the application of unique identifier for each patient, increased productivity of personnel, reduce turnaround time, enables easy capturing, storage and retrieval of data, eliminated data loss and redundancy problems, standardizes reporting system, improve internal quality control practices and contribute valuable tool for the generation of work load, quality and other statistical reports. Success- A significant capacity building is done in manpower training and providing supplies. More than 400 laboratory and information technology professionals are trained on LIS. Computers with full accessories are provided in addition to LIS license for 19 facilities. Challenges- As a new program so many facilities were not fully institutionalize the program and equipment interfacing problems due to lack of equipment standardization and interface protocols.

Conclusion: Laboratory information system brings substantial improvement in the Strengthening Laboratory Management towards Accreditation implementation. Standardized equipment protocols should be available to avoid interfacing problems.

POSTER 88

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Antibiotic Susceptibility Profile of Enterococcus spp. Isolated from Patients with Urinary Tract Infection and Health Care Environment in Two Reference Hospitals in Cameroon

Background: Enterococcus spp. accounts for 14, 1% of the most encountered micro-organisms in urinary tract infection. Therapeutic problems are usually due to their natural resistance to most of the β -lactamines, the high level of acquiring resistance to the aminoglycosides and the emergence of strains which are resistant to the glycopeptides.

Methods: Clinical and environmental specimens were collected and cultured in the appropriate culture media: CPS chromogenic medium for urine, bile esculin agar supplemented with vancomycin for stools and bile esculin agar for environmental specimens. The antibiotic susceptibility testing was done using the disk diffusion method as recommended by Antibiotic Committee of French Microbiology Society (CASFM 2013) and the resistance to vancomycin was determined by the agar screen method.

Results: Out of 250 clinical and environmental specimens collected, 50 strains of enterococci were isolated with the most prevalent in the following order: 26 E. faecium, 17 E. faecalis, 4 E. durans, 3 E. avium. Resistance observed in E. faecalis and E. faecium to erythromycin (84)%, ampicillin (60%), cotrimoxazol (42.4)%, tetracycline (41.6)%, vancomycin 28% and teicoplanin (19.2%). Out of the 50 isolates, 7 were resistant to vancomycin (with CMI greater or equal to 4 μ g/ml) from which 04 were isolated from urine, 02 from environment and one from faeces. Genes Van A, Van B and the phenotypes S and SKG were frequently observed with E. faecium.

Conclusion: Vancomycin enterococci resistance and high level of aminoglycoside resistance (HLAR) lead us to recommend that health policy planners need to reinforce the bacterial resistance committee activities in order to monitor enterococci infections.

POSTER 89

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Implementation of CDC Global HIV/AIDS HIV-1 Viral Load Proficiency Testing in Ethiopia

Background: Proficiency testing determines the performance of laboratories for specific tests. It compares results obtained by different laboratories on identical Proficiency Testing (PT) panels. Six Ethiopian laboratories have been participating in HIV-1 Viral Load PT Program launched by Centers for Diseases Control and Prevention (CDC) Division of Global HIV/AIDS in April 2012.

Methods: The Ethiopian Public Health Institute (EPHI) enrolled laboratories upon acceptance of its request to the CDC. Each PT package consisted of two identical sets of 5 dried tube specimens with 13 ml reconstitution buffer and sent to laboratories two times per year in 2012 and 2013. The PTs were accompanied by instruction checklist and results submission forms. The PT materials arrived the EPHI and redistributed to participating laboratories. Results were used to be collected by the EPHI and sent to CDC for evaluation. Performance reports from the CDC were sent back to the participant laboratories. All laboratories were issued Certificate of Participation at the end of each year.

Results: Five laboratories have scored an average of 96.67% correct (93.33-100%) throughout the two years. The average response rate for each round was 58.34% (50-66.67%). The overall non-response rate was 41.6% for the two years. Non-responding sites faced reagent shortages 8.33 % (1 of 12 participation) in 2012 and 16.7% (2 in 12 participation) in 2013. Power shortage 8.33 % (1 of 12 participation) and One laboratory didn't report at all over the two years due failure to submit results before the deadline.

Conclusion: The program was successful in that it has addressed the long time quest for Viral Load PT. The launch of the program was also a relief for laboratories striving for international accreditation. Reagent shortage was identified as the most important problem hindering laboratories from consistent participation. Laboratories were also observed to fail in adhering to provider deadlines.

POSTER 90

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The Second Cohort of SLMTA Implementation in Mozambique

Background: Mozambique has been implementing the SLMTA program since 2010 with the objective of improving laboratory services both in the clinical and Public Health laboratories across the country. The ultimate goal of this program is preparing quality laboratory services that are geared towards client satisfaction. In this article, we describe the second cohort of SLMTA implementation where we enrolled 21 laboratories. We draw on the same perspective of the first cohort to interpret the experiences and define strategies for the added labs. We used the experience and lessons learned from the first cohort laboratories to manage and address implementation challenges related to quality improvement.

Methods: A technical working group was defined to plan, assess and oversee the implementation process. SLMTA trainers, supervisors, and auditors were available and had been previously trained to support the enrolled labs. Our approach was to implement SLMTA using a model of 4 workshops in every 4 months and a total of 7 site supervision visits. The 4th workshop was designed to share results, present awards to best performing lab, advocacy to high level delegates, and also describe the next steps after a full round of SLMTA implementation. The 7th site supervision visit was designed to strengthen the implementation of IPs and prepare laboratories for their exit audit. The baseline and final audits were conducted using the SLIPTA checklist.

Results: The number of the activities increased during program implementation in 19 months. 21 laboratories were enrolled: 6 nationals reference, 2 Centrals, 5 Provincials, 2 Generals, 1 District, 1 health care center, 2 blood bank and 2 water and food lab. For baseline assessment of the second cohort, 1 lab had 3 stars, 2 with 2stars, 3 with 1 star and 15 with 0 stars. In the exit audit 1 one laboratory achieved 4 stars, 2 had 3 stars, 4 had 2 stars, 5 had 1 star and 9 had 0 stars. Quality managers working also as mentors, staff motivation, a committed SLMTA technical working group and partners support sustained these results.

Conclusion: The complexity of the implementation of SLMTA in laboratories that are starting implementing quality system provided evidence for learning and action on the acquired results. The challenges encountered during the implementation of mentoring through quality managers were somewhat predictable; however, the adoption of a systematic process in which the quality manager is only dedicated to implementing quality will allow SLMTA to be implemented in a consistent and flexible manner to fit the limitations of the “real world” of our laboratories, keeping the system strengthen in the next cohorts.

POSTER 91

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Phenotypic Characterization of *Klebsiella* spp. Producing Beta Lactamase and Carbapenemase in Three Referral Hospitals of Cameroon

Background: Antimicrobial resistance constitutes a major public health issue in the world. In fact, it increases morbidity and mortality due to communicable diseases. In Cameroon, *Klebsiella* are incriminated in many hospitalized cases and most strains are multidrug resistant. This study aims at ameliorating the epidemiological and bacteriological knowledge of *Klebsiella* spp. in Cameroon and improving the management of these infections.

Methods: A descriptive, cross sectional study was carried for a period of 6 months from May to November 2013. *Klebsiella* strains were collected from three referral hospitals and analysis was carried out in the bacteriology laboratory of the Yaoundé University Teaching Hospital. The susceptibility testing was done using the diffusion disk method on Mueller Hinton. The antibiotics which were tested were the β -lactamine, and the inhibitors like clavulanic acid, tazobactam, EDTA, cloxacillin and 3-aminophenyl boronic acid hydrochloride. The determination of MIC was also carried out to identify the different resistance phenotypes.

Results: Strains were isolated from urine (52.5%), blood (21.2%), pus (15.2%) and other specimen (11.1%). Out of 99 strains, *Klebsiella pneumoniae pneumoniae* was the most prevalent (78.7%), followed by *Klebsiella oxytoca* (12.12%), *Klebsiella pneumoniae ozaenae* (5.05%), and *Klebsiella pneumoniae rhinoscleromatis* (4.04%). The antimicrobial susceptibility testing confirmed the natural resistance of *Klebsiella* spp. to amoxicillin (100%), and revealed a global predominance of resistant to ticarcilline (100%), piperacilline (76%), and to Cefalotine (85%). The most active antibiotics were imipenem (99%) and ertapenem (77%). The main phenotypes observed were: extended spectrum β -lactamase (30.30%), wild phenotype (27.27%), penicillinase resistant to inhibitors (16.16%), carbapenemase (11.11%). Out of the 11 *Klebsiella* producing carbapenemases, 5 were of class C and 6 of class D.

Conclusion: The emergence of *Klebsiella* producing carbapenemase in our health facilities is a reality. Thus there's a real need for microbiologists and health policy maker to monitor health care associated infections.

POSTER 92

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Implementation of One world Accuracy Proficiency Testing Program: Ethiopian Experience

Background: The implementation of robust and comprehensive proficiency testing (PT) programs for all tests performed by any laboratory is an important component of the overall quality assurance system. Ethiopia developed its first National External Quality Assessment (EQA) Operational Plan in 2007. EQA Programs from One World Accuracy, a Canadian PT provider were introduced into Ethiopia in 2009 with the initial enrollment of 30 laboratories.

Methods: The laboratories were enrolled into the scheme by the Ethiopian Public Health Institute (EPHI). Test menus, methods and technologies used in all laboratories were assessed and each laboratory was registered for PT programs ranging from one to 29 types depending on the scope of its test menu. All PT panels from the provider were received by the EPHI 2-3 times per year and distributed to participant laboratories. The results were collected through the same mechanism and collated at the EPHI for web based online submission to the provider. Feedback reports were published online and printed by the EPHI for distribution to participant laboratories.

Results: The number of laboratories participating in the PT programs offered by the provider has increased from 30 to 156 over the years 2009-2013. The average response rate for the years participation was 81.6 % (63.2-100%). The most frequent reasons for non responses were machine failures, reagent shortages and failure to report within deadlines.

Conclusion: Implementation of One World Accuracy PT programs has enabled Ethiopia to enroll almost its entire regional and hospital laboratories into EQA programs for many tests. The program has helped laboratories striving for accreditation to fulfill the mandatory requirement of participating in EQA programs. The program is supported by advanced informatics system. Thus, the full benefits of the program could be effectively harvested if participant labs had reliable internet access for prompt online result submission and easy access to feedback reports.

POSTER 93

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Using Local Postal Courier to Facilitate External Quality Assessment Programs: Ethiopian Experience

Background: Robust system for efficient transportation and distribution of proficiency testing materials and prompt delivery of feedback reports to participant laboratories is fundamental for the success of External Quality Assessment (EQA) programs.

In Ethiopia, the Ethiopian Postal Services Enterprise (EPSE) was formally entrusted with the responsibility to execute these activities under a pertinent Contractual Agreement reached and signed with the Ethiopian Public Health Institute (EPHI) in 2009.

Methods: The EPHI signed a Memorandum of Understanding with the EPSE in 2009 for the transportation and distribution of EQA specimens to laboratories, collection of results from the sites for delivery to the EPHI and distribution of providers' final feedback reports. EPHI trained EPSE staff on specimen transportation and handling prior to full-fledged engagement of the Enterprise with activities stipulated in the agreement. Sufficient cold chain packaging and transportation containers were made available to ensure the stability and integrity of the PT panels during transportation. EPSE has been providing these services 2-3 times per year for all EQA programs of the country.

Results: The number of laboratories covered by the postal service of long term contractual agreement has increased from 100-156 since 2009. Distribution of PT materials and delivery of results has become very efficient as compared to the previous years. The availability of postal service network across the country has made it possible to reach laboratories located even in the remotest parts of the country.

Conclusion: Engagement of the postal service has proved to be an efficient and cost effective system for the expansion of EQA programs in Ethiopia. Encouraging results has also been scored in expanding PT coverage, laboratories accessibility and response rates. Establishment of courier transfer centers that are equipped with systems for cold storage are recommended to further improve the quality of service provided by the postal courier system.

POSTER 94

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Using Laboratory Information System Data to Assess Successes and Challenges of an HIV Early Infant Diagnosis (EID) Programme

Background: Health programme implementation can only be monitored through use of reliably generated data. In settings with appropriate laboratory infrastructure and efficient laboratory information management systems, detailed analyses of such data can be valuable in monitoring the performance of public health programmes.

Methods: We conducted a retrospective data query of the HIV PCR results performed for EID by the two National Health Laboratory Service (NHLS) virology laboratories serving the entire Western Cape Province, South Africa, between 2008 and 2013.

Results: We observed only a modest increase in the number of HIV PCR tests performed for early infant diagnosis during this period, likely due to the rapid scaling up of the provincial EID programme between 2006 and 2008. Community-based HIV PCR positivity rates in children aged 7 weeks or less decreased from 3.7% in 2008 to 1.3% in 2013. About 50% of all tests were requested on infants younger than 7 weeks of age and 29% of tests were performed on infants older than 3 months. Worryingly, 61% of tests requested on children older than 3 months were first tests.

Conclusion: Judicious analysis of laboratory data can provide valuable insight for stakeholders and identify successes and challenges of EID programmes. While the abovementioned 61% is an improvement from 2008 when 87% of tests on children older than 3 months were first tests, this figure suggests that gaps in EID coverage remain. In addition to retrieving data indicating overall programme status, such efforts can be used at higher resolution to identify clinics with selected characteristics, such as outlier facilities in terms of test usage and test results; for example, the 17% of clinics with high requesting volumes from which more than 50% of requests are from infants older than 3 months. Such information might assist in addressing problems.

POSTER 95

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Dosage des CD4 : Identification des Facteurs Associés à une Prise en Charge Tardive des Patients Infectés par le VIH en Guinée

Background: Le nombre de CD4 est un paramètre biologique clé pour déterminer l'éligibilité au traitement. Le Laboratoire National de Santé Publique réalise cette analyse depuis 2006 par la technique d'immunofluorescence. La présente étude propose d'identifier les facteurs associés à une prise en charge tardive chez les personnes vivant avec le VIH en Guinée sur la base des données de mesures de CD4 stockées au LNSP.

Methods: Il s'agit d'une étude rétrospective de 2009 à 2012 chez les patients ayant un âge ≥ 15 ans, VIH positif, sans traitement antirétroviral. La prise en charge tardive était définie par un taux de CD4 $\leq 200/\text{mm}^3$ avant la mise sous traitement antirétroviral. Les facteurs ont été analysés par la régression logistique. Les Odds-Ratio ont été présentés avec leur intervalle de confiance à 95%.

Results: Sur 2127 patients naïfs inclus, 776 (36,5%) avaient un taux de CD4 $\leq 200/\text{mm}^3$. Les hommes (OR = 1,39; [1,16 – 1,66]), les mariés (OR = 1,35; [1,08 – 1,69]). Les patients âgés de plus de 28 ans: 28 – 35 ans (OR = 1,42; [1,10 – 1,83]), 35 – 44 ans (OR = 1,55; [1,21 – 1,9]), ≥ 44 ans (OR = 1,74; [1,36 – 2,22]) étaient à risque d'une prise en charge tardive. Cependant, les élèves et étudiants (OR = 0,58; [0,37 – 0,92]), les coutrières et coiffeuses (OR = 0,59; [0,37 – 0,94]), les cultivateurs et éleveurs (OR = 0,39; [0,16 – 0,93]) étaient moins à risque d'être pris en charge tardivement par rapport aux fonctionnaires (administrateurs civils, ingénieurs, juristes). Les analyses multivariées ont montré que l'âge et la profession étaient les facteurs indépendamment associés à une prise en charge tardive.

Conclusion: En Guinée, plus d'un PVVIH sur trois avait un taux de CD4 $\leq 200/\text{mm}^3$ avant la mise sous traitement antirétroviral. Des campagnes d'informations sont nécessaires pour promouvoir le dépistage et la prise en charge précoce du VIH.

POSTER 96

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A Snapshot of the State of Adult ART Programmes – an Analysis of Aggregated Laboratory HIV Viral Load Testing Data

Background: Reliable data is the foundation for monitoring the implementation of large-scale health programmes. In countries where good laboratory infrastructure exists, data from the laboratory information system, in conjunction with sentinel surveillance systems and clinical data collection systems, can be useful in monitoring the state of a public health programme.

Methods: As part of a joint review of HIV, TB and PMTCT programmes in South Africa, we conducted a retrospective query of the National Health Laboratory Service (NHLS) virology laboratories database for HIV viral load assays performed in adults in the Western Cape Province between 2008 and 2013. Virological suppression was defined as a viral load less than 1000 copies/ml.

Results: The programme saw significant expansion in HIV viral load testing, increasing from 50,000 in 2008 to almost 200,000 in 2013. Despite this growth in viral load testing, new patients accounted for 37% of the viral load testing during this period, suggesting lost to follow up and recycling of cohorts entering the program from the previous calendar years. Overall, 82% of viral loads were considered virologically suppressed. This proportion remained relatively constant over the study period. Even though there were no pre-ART viral loads monitoring scheduled, 19% of the first-time viral loads were above 1000 copies/ml, suggesting a common adherence issue among new ART initiations. More alarmingly, more than 60% of samples with prior virological failure fail to suppress at the next measuring point, highlighting persistent ART failure as a growing issue.

Conclusion: Despite its clear limitations, a careful interrogation of laboratory HIV viral load data can provide unique insight for ART programme coordinators. Our review suggests that HIV viral load testing data can supplement other data collection systems in helping to ensure that important programmatic issues are detected and monitored in real time.

POSTER 97

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Strengthening Laboratory Management Toward Accreditation Significantly Improved the Quality of Laboratory Results in Uganda

Background: To address the poor laboratory quality performance, the Ministry of Health, adopted the WHO/SLIPTA strategy in 2010. A framework was developed for the implementation of the program. This strategy was to yield results in quality domains of: improved quality laboratory results and patient management, attainment of national accreditation targets of WHO/SLIPTA star 3 and star 5 for general hospital and national hospital laboratories respectively and build capacity for sustaining accreditation status in the accredited laboratories.

Methods: We enrolled a cohort of 21 laboratories into SLMTA in 2011. The cohort consisted of two national referral hospital, five regional referral hospital and fourteen general hospital laboratories. At month zero, a baseline quality audit was conducted focusing on the 12 quality elements. Thereafter, three serial SLMTA training workshops were conducted together with improvement projects. At 20th month, an exit audit was conducted. At two time points, data was collected. Quantitative data was analyzed using descriptive and chi-square tests, whereas qualitative was analyzed using content analysis.

Results: At baseline, out of the 21 laboratories, 3 (14 %) were at star 3, 1 (5%) at star 1 and 17 (81%) at star 0. At the 20th month, there was 1 (5%) laboratory at star 5, 3 (14%) at star 4, 3 (14%) at star 3, 4 (19%) star 2, 2 (10%) at star 1 and 8 (38%) at star 0. This increment was statistically significant [$p < 0.01$, CI- 95%]. "During the Ebola outbreak in Uganda in 1996, the outbreak experts rejected to use our hospital laboratory because they rated it very low on standards. Now the SLMTA has removed shame by changing the status" qualitative data extract.

Conclusion: SLMTA has rapidly improved laboratory quality status in the context of Uganda. We therefore recommend SLMTA program uptake and scale up in the remaining laboratories.

POSTER 98

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Multidrug Resistant Salmonella enterica serovars typhi and paratyphi B Isolated at the University Teaching Hospital in Lusaka, Zambia, from 2010-2012

Background: Typhoidal Salmonellae are invasive and life-threatening human pathogens that cause typhoid and paratyphoid

fever in many developing countries, and have been associated with resistance to many antibiotics. This complicates the management of typhoid cases. Since November 2010, Zambia has experienced a rise in the number of typhoid fever cases but the antimicrobial susceptibility patterns of Salmonellae isolates is unknown. Therefore, the main objective of this study was to determine the antibiotic susceptibility patterns of Salmonella typhi and Salmonella paratyphi B isolated at the University Teaching Hospital in Lusaka, Zambia, from 2010-2012.

Methods: This was a laboratory-based cross-sectional study. Isolates of Salmonellae were analysed using standard microbiological methods. Antibiotic susceptibility testing was performed by the microbroth dilution method and by PCR and DNA sequencing to detect and confirm the presence of integron class 1, respectively.

Results: Salmonella typhi was the most common organism, accounting for 41.5% of the cases, followed by Salmonella paratyphi B (25.5%) and non-typhoidal Salmonella (33.0%). Salmonella typhi was 100% resistant to sulfamethoxazole, ampicillin, trimethoprim and, cotrimoxazole; 84.1% to chloramphenicol, 27.3% to azithromycin, 2.3% to both ciprofloxacin and amoxicillin + clavulanic acid. Salmonella paratyphi B were 100% resistant to ampicillin, cotrimoxazole, chloramphenicol, sulfamethoxazole trimethoprim and streptomycin; 11.1% to amoxicillin + clavulanic acid and 7.4% to both ciprofloxacin and tetracycline. Multidrug resistance was observed with 84.1 % of Salmonella typhi and 100% of Salmonella paratyphi B isolates. Class 1 integron, harbouring a 750bp integron containing the *df7* gene, was detected in both Salmonella typhi (65.8%) and Salmonella paratyphi B (81.5%).

Conclusion: Cases of multidrug resistant Salmonella serovars are emerging in Zambia leaving little treatment options. Therefore, regular monitoring of antibiotic susceptibility patterns is vital in guiding appropriate therapy and prevention of further emergence of drug resistance strains.

POSTER 99

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Comparison of Manual and Automated Nucleic Acid Extraction for HIV-1 Drug Resistance Genotyping

Background: Extraction of viral nucleic acid from clinical specimens is a critical step in HIV-1 RNA amplification. Successful isolation of nucleic acids from a clinical specimen can improve the reproducible performance of PCR applications even with the samples containing very low amounts of nucleic acid. Manual nucleic acid isolation methods are labor intensive and a potential cause of run-to-run variability. Automated sample processing provides a labor reducing the number of failed tests while potentially limiting the occurrence of sample-to-sample contamination during processing. We compared manual versus automated extraction of RNA for purposes HIV-1 drug resistance genotyping.

Methods: A total of 50 plasma samples were analyzed and the performance of the Qiagen automated (EZ1 machine) RNA extraction and Qiagen manual extraction was compared. The quantity and quality of automated and manually extracted RNA was determined using spectrophotometer and One-step RT-PCR.

Results: The results showed that 35(70%) of the samples were PCR successful with manual extraction while 41(82%) of the samples were PCR successful with EZ1 extraction machine. The agreement between the two methods was 78 %. The median viral loads for unsuccessful PCR from manually and automated extracted RNA was 3524 copies/ml (Q1,Q3: 1773 – 8411) and 3495 copies/ml (Q1,Q3: 1456 – 5645), respectively.

Conclusion: Amplification was more successful on RNA isolated with Qiagen automated method compared to manual RNA extraction. Automated RNA extraction using EZ1 requires less hands-on time, and increases productivity and could reduce wastage PCR reagents, although it is currently more expensive.

POSTER 100

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Automatic Quantification Malaria Test of Thick Smear

Background: Malaria is a major cause of morbidity and mortality in Angola. Limited access to drugs and the emergence of strains resistant to existing therapies require the use of alternative sources and effective means of diagnosis. Moreover, the high number of false positives in the thick smear examinations (official examination in Angola) resulting from inexperience of technicians and the high number of samples to be evaluated, contribute to unnecessary medication use and increased parasite resistance. In order to improve the diagnosis of malaria studies the Research Centre of the ISPB developed a software application for the identification and quantification of malaria.

Methods: In this project, a bacteriological binocular microscope coupled with a digital camera, or a cell phone that allowed the capture of images to a computer was used. The software application was developed in Java allowing the quantitative and qualitative identification of malaria parasites.

Results: The Research Centre of ISPB identified that in Angola in public and private hospitals, as well as in the various providers of health services, the rate of false positives in the test of thick smear between 35% and 50%. After developing the Java application allowing the analysis of digital images captured by a cheap camera associated with the microscope, the false positive rate was reduced to residual values.

Conclusion: The application allows efficient identification and quantification of Plasmodium species with a residual error rate, allowing an improvement in the quality of health of the populations served by this service.

POSTER 101

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Evaluation of a Chlamydia Trachomatis Rapid Test in Rwanda: The BioChekSwab Rapid Test

Background: Given the asymptomatic nature of most Chlamydia trachomatis (CT) infections in women, the availability of a point-of-care (POC) rapid test could potentially improve CT case finding and reduce the risks of sequelae and onward transmission. POC testing could also provide a cheaper and faster alternative to nucleic acid amplification testing in developing countries. We evaluated the performance of an enzymatic POC test for CT (the BioChekSwab CT Rapid Test, EnZtek Diagnostics, USA), which detects CT's Peptidase 123CBV enzyme.

Methods: Two endocervical swabs, including one BioChekSwab, per person were obtained from 136 women who participated in an EDTCP funded reproductive health study (RING PLUS study) in Rwanda. The BioChekSwab was immediately processed according to the manufacturer's instructions. In short, after specimen collection, a substrate was immediately squirted over the swab by the clinician. The swab was further processed in the laboratory by releasing another reagent over the swab tip. Specimens containing CT were identified by the development of a blue color within two minutes. The other regular flocculated endocervical swab was processed at the Institute of Tropical Medicine (ITM) using an extended gold standard testing algorithm: Abbott Real Time CT/NG assay with confirmation of positive results by an in-house qPCR assay.

Results: Of the 136 women that were tested, nine were CT positive by gold standard. All nine positive results were missed by the BioChekSwab assay and three false positive results were obtained. The sensitivity was therefore 0.0% (95% CI: 0.0 – 33.8%) and the specificity 97.6% (95%CI: 93.2 – 99.5%). A total of 8 samples became positive after 2 minutes, but none of them were positive in the gold standard test.

Conclusion: These preliminary results show that the BioChekSwab Rapid Test, although ISO13485 certified and CE labeled, is not sensitive in our setting.

POSTER 102

Vincent Aliong'o

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Prevalence of HIV Transmission among Transfused Children with Sickled Cell Anaemia in Bungoma

Background: There are a number of routes for HIV transmission in children. Blood transfusion-related HIV is still common in developing countries like Kenya, especially among high risk children such as those who require repeated blood transfusions

Aim: The aim of this study was to find the prevalence of HIV among transfused children with sickle cell anemia in Bungoma.

Methods: This is a descriptive cross-sectional study conducted at the POPC and Laboratory section Bungoma County Referral Hospital, Bungoma County. One hundred and nine transfused children with SCA were enrolled after obtaining consent from their caregivers and assent from older children in the mid 2013 to January 2014. Non transfused children matched for age, sex, and social status with the subjects served as control. Voluntary counseling and testing were then provided. Relevant data were obtained using pretested questionnaire. Statistical Package for Social Science (SPSS) version 11 was used for data analysis. The chi-square was used to test for significant association of categorical variables.

Results: HIV antibodies were found in 2.9% (2/109) of the subjects and in 1.6% (1/104) of the control. All the infected individuals among the subjects were males, had only been transfused once and were from the lower socioeconomic class. The only infected child from the control group was a 5-year-old male and he probably acquired it through vertical transmission since the mother also tested positive to HIV antibody.

Conclusion: Blood transfusion is still a risk factor for HIV transmission among children with sickle cell anemia in Bungoma County. Strategies that will ensure improved blood transfusion safety at health facilities need to be strengthened, and also introduction of satellite blood transfusion center (blood bank).

POSTER 103

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Influenza Surveillance in Zambia in the Last 5 Years: Successes, Challenges & Limitations

Background: Limited information exists about influenza viruses in Africa. In 2008, the Zambian Ministry of Health signed a cooperative agreement with the US Centres for Disease Control and Prevention which enabled them to develop a well-defined surveillance system that provides timely and relevant information. In order to strengthen surveillance and build capacity for outbreak preparedness and response activities, this program received funds for a period of 5 years.

Methods: We established a prospective, sentinel surveillance system for influenza-like illness (ILI) and severe acute respiratory illness (SARI) at 8 health facilities in Zambia. Nasopharyngeal and oropharyngeal swabs and structured questionnaires were collected from eligible patients and samples were tested by real-time reverse-transcription polymerase chain reaction (RT PCR) for influenza virus types and subtypes. Viruses were isolated in influenza positive specimens using MDCK cells.

Results: The first five years of the program, resulted in the lab being strengthened as RT PCR technique & virus isolation for characterisation of influenza viruses were adopted. The adopted system provides updated weekly reports on influenza in acute respiratory infections collected from sentinel sites. Outbreak preparedness and response was strengthened. Limited funds posed a challenge to sustain the purchase of required lab reagents

and supplies. Sustainability of the program beyond the CDC funding period ought to be well planned. The outbreak response capacity of the country was overwhelmed during the H1N1 pandemic. Sentinel surveillance is not population based and multiple years of data are needed to understand the circulation and burden of influenza in Zambia.

Conclusion: In Zambia, the MOH with support from its many partners has successfully built up capacity to generate data and viruses that contribute important information to the WHO global flu community. MOH needs to sustain these gains by integrating the program into Integrated Disease Surveillance and Response.

POSTER 104

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Evaluation of Morphology Flags on the Advia 2120 Haematology Analyser at a Large Academic Hospital

Background: The Advia 2120 automated haematology analyser provides suspect flags and additional differential parameters with enhanced sensitivity in order to reduce the manual peripheral smear blood (PBS) review rate. At the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) Laboratory Complex, criteria for PBS review are based on the international consensus group criteria and have been optimised with regards to the analyser, laboratory information system specifications and the large pool of oncology patients. The aim of this study was to evaluate the efficiency, sensitivity and specificity of the Advia morphology flags.

Methods: This study was performed at the National Health Laboratory Services CMJAH Complex during 2013 and 2014. Samples were randomly selected from the daily workload, representative of the laboratories' patient population. Analysis was performed on the laboratory's Advia 2120 automated haematology analysers. The data set included: immature granulocytes, blasts, atypical lymphocytes, red cell fragments, nucleated red blood cells, platelet flags and 'Haematology/Oncology' department. A positive smear result was defined according to the International Consensus Group criteria. The study was approved by the Human Research Ethics Committee (M090688). The data were summarised in truth tables.

Results: 466 Advia morphology flags were reviewed: 33 platelet flags, 301 white cell flags and 132 red cell flags. The overall efficiency was 53.32%. The white cell flags namely; atypical lymphocytes and blasts were found to have a superior sensitivity (97.01% and 95.24% respectively) at the expense of high false positive rate and low efficiency. The false negative rate was >5% for platelet and fragment flags. 188 oncology cases were reviewed. With the added criteria of 'haematology/oncology' department, no cases of acute leukaemia were missed.

Conclusion: This study revealed the need for further optimization of the laboratories' criteria for PBS review in order to improve laboratory productivity and ensure patient safety.

POSTER 105Hilary Lumano¹, Mangani Zulu², Peter Mutale¹, Fales Zulu³¹ Management Sciences for Health, Lusaka, Zambia, ² Zambia Prevention Care and Treatment II, Lusaka, Zambia, ³ Ministry of Health, Zambia**Performance Analysis of Data Management and Quality Improvement at Arthur Davidson Children's Hospital PCR Laboratory in Ndola, Zambia**

Background: To maintain reduced turnaround time and assure reliability of HIV DNA PCR test results, Ministry of Health (MoH) in collaboration with cooperating partners are implementing the Mwana program, a short messaging system (SMS) for PCR results delivery linked to the Laboratory Database. Analysis of data for 2012/2013 revealed amendments to transmitted results. 12 out of 20,000 records were affected representing 0.06% error. A quality improvement plan to introduce double data entry and cross checking of positive and negative results was introduced. The objective was to reduce the errors associated with entry of dry blood spot HIV EID results into the database between October 2013 and October 2014.

Methods:

1. Review of result printout; validation and transcription of results onto requisition forms.
2. Double data entry system into the Database.
3. Verification of entered positive results.
4. Weekly and quarterly data reviews and verifications for accurate results.

Results: 5,771 samples were received from 379 facilities between October and December, 2013 from 42 districts. 4,236 were tested, 205 were positive. Out of 4,236 tested, 2,797 were transmitted and no amendments were made after validation representing 100% accuracy. 1660 results were retrieved from 108 facilities across 32 districts, 79 of these were positive.

Conclusion: Data entry errors have an appalling effect on quality requiring data validation to be supported by quality assurance procedures. Adequate documentation must be included for all data generated for the highest level of accuracy and reliability. Double data entry proved to be a tool that ensures integrity of a quality data management process.

POSTER 106Gora Lo^{1,2}, Madiouba I², Diop-Ndiaye H², Dia A², Mané M², Sow-Sall A², Diop F², Kébé-Fall K², Gueye SB², Diallo S², Gaye-Diallo A², Mboup S², Toure-Kane C²¹ Centre Medical Inter Armees, ² Laboratoire Bacteriologie Virologies HALD**Marqueurs Virologiques de l'Hépatite B Chez les Patients initiant la Thérapeutique Antirétrovirale au Sénégal**

Background: L'infection au VHB est un véritable problème majeur de santé publique en Afrique Subsaharienne et en particulier au Sénégal. Ce travail a pour objectif d'évaluer la prévalence des marqueurs du VHB dans une population de personnes vivant avec le VIH avant leur mise sous ARV au Sénégal.

Methods: Il s'agit d'une étude rétrospective à partir d'une plasmathèque de 2006 à 2010. La recherche de l'AgHBs a été réalisée par les tests Determine AgHBs (Abbott Diagnostics), MONOLISA AgHBs Ultra (Biorad) puis confirmée par Architect Qualitative AgHBs (Abbott Diagnostics). Les autres marqueurs (AgHBe, Anti HBe et Ac anti HBC) ont été recherchés par Architect. La charge virale du VHB a été déterminée avec une technique de PCR en temps réel utilisant le SYBR Green. L'analyse des données a été effectuée avec Epi info 3.5.1 et tous les calculs ont été effectués avec un niveau de confiance de 95%.

Results: Un total de 466 plasmas a été testé pour l'AgHBs avec une prévalence de 8,8% (41/466) (IC95% [6,5-11,9]). Parmi ces 41 positifs, 24,4% (IC95% [12,1-41,2]) et 69,2% (IC95% [52,4 – 83]) étaient porteurs de l'antigène HBe et de l'Ac anti HBe respectivement. La charge virale du VHB a été réalisée sur 27 échantillons avec une charge virale médiane de 5,18 log copies/ml avec des extrêmes allant de 2,94 à 6,47 log copies/ml. Les patients les plus âgés étaient les plus affectés par le VHB ($p=0.047$).

Conclusion: Ce travail confirme l'endémicité du VHB au Sénégal et montre une forte répllication virale du VHB parmi les PVIH. Cependant, l'efficacité des ARV anti VHB au sein de cette population de même que la prévalence des hépatites occultes méritent d'être évaluées.

POSTER 107Barbara Namagambo¹, J. T. Kayiwa¹, T. Byaruhanga¹, R. Chiza¹, N. Owor¹, N. Babi², I. Nabukenya¹, B. Bakamutumaho¹, J. J. Lutwama¹¹ Uganda Virus Research Institute – National Influenza Centre (UVRI-NIC), Uganda, ² Uganda Virus Research Institute – Zoonotics Department, Uganda**Preparing for Seasonal Flu Vaccination in Uganda: Flu Seasonality and the Most Vulnerable Population**

Background: Influenza is an infectious disease caused by RNA viruses of the family Orthomyxoviridae, it affects humans, birds and other mammals worldwide. In Uganda, the virus displays strong seasonal cycles during the rainy seasons and it has a less defined seasonality in the dry seasons.

Influenza being a serious public health problem that causes severe illnesses and death worldwide, the purpose of this study was to assess flu seasonality in Uganda and to examine the exposed groups of people to be taken account of in the flu vaccination plans.

Methods: We established a sentinel surveillance system for influenza in five hospitals and outpatient clinics respectively and other identified areas of outbreaks in four distinct geographical regions of Uganda (northern, eastern western and central), using standard case definitions for influenza like illness (ILI) and severe acute respiratory illness (SARI).

Nasopharyngeal and oropharyngeal specimens were collected from April 2007 through Mar 2014 from patients with ILI and SARI aged ≥ 2 months, tested for influenza A and B with real-time reverse-transcription polymerase chain reaction, and subtyped for seasonal A/H1, A/H3, A/H5, and 2009 pandemic influenza A (pH1N1).

Results: Out of 11,254 specimens tested for Influenza, 1054 (9.4%) were positive for Influenza A, 415 (4%) positive for B and 2 (0.01%) were co-infections of Influenza A and B. The median age of patients affected with influenza was 5 years; patients aged Less than 5 years had the highest influenza-positive percentage (45%), and patients aged 45 and above years had the lowest percentage (2%). Influenza circulated throughout the years and percentage of influenza-positives peaked during June-November.

Conclusion: Supply of seasonal flu vaccinations should be carried out prior to the flu season and special emphasis should be put on targeting the most vulnerable populations.

POSTER 108

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Implementation of POC CD4 Testing in Uganda: Lessons Learned

Background: The traditional approach to CD4 testing in Uganda was centered on conventional, sophisticated instruments. Access to and management of such instruments was challenging owing to poor infrastructure and human resource capacity resulting in fewer patients accessing CD4 testing and many results getting lost due to poor records management and system-related challenges. Uganda was one of the pioneer countries to adopt and implement Point-Of-Care (POC) CD4 testing using the Alere Pima™ platform.

Methods: Following a successful pilot project for PIMA implementation at 7 health centres between January-April 2011, the Ministry of Health through National Medical Stores procured 250 devices which were placed in 270 health facilities without access to CD4 testing. There was centralized training-of-trainers (TOTs) followed by facility-based end-user training using a curriculum that incorporated both technical and systems integration components targeting both laboratory and ART clinic staff. Subsequently, a Public-Private Partnership with Alere was established for continued technical assistance and mentorship to these facilities. A retrospective review was conducted at a select 23 of the 270 sites after one year of implementation.

Results: There was a reduction in request to test time from an average 23 to 1 day, test to result from 55 to 8 days and an associated reduction of time to ART initiation from 59 to 11 days. Overall testing volumes increased by 35% with good acceptability of the POC testing by facility staff and patients. Challenges of data management, availability of supplies and quality assurance issues were experienced.

Conclusion: Although the implementation of POC CD4 testing has been successful in improving service delivery, there is need to strengthen component of data management, logistics systems, and quality assurance. Partner support is critical to ensuring this success especially for continuous mentorship and supportive supervision.

POSTER 109

Aicha Marceline Sarr¹, Winny Koster², Roughyatou Ka¹, Rokhaya Diagne¹, Oulimata Diémé¹, Adja Khady Datt-Fall¹, Constance Schultsz², Robert Pool³, Ahmad Iyane Sow¹, Pascale Ondoa²

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Organization and Practice of Rapid Albuminuria and Glycosuria Testing in Senegal: A Barrier to the Optimal Utilization of Laboratory Test in Antenatal Care?

Background: The utilization of rapid assays during ANC consultation can facilitate access to important biological parameters related to pregnancy. We explored the organization and practice of rapid tests (RT) for Albuminuria/Glycosuria (ALB/G) in health facilities and their implications on laboratory test use during ANC.

Methods: Qualitative data on the organization and conditions of ALB/GL testing were collected in 3 government hospitals and 8 health centers.

Results: All structures had ALB/GL test strips available. Two testing circuits were identified: 1) 5 of 11 structures: tests were executed and validated by the midwives during the ANC consultation. Results were delivered upon an average of 10 min; 2) 6 of 11 structures: RT were performed in the laboratory with results delivered together with other standard assays upon 3 to 24 hours, resulting in additional client's travelling to the laboratory, with associated costs and possible delays for clinical management. ALB/GLU testing was not requested as recommended (for all ANC visit): in all structure, test requests were done only at the first ANC visit or was based on warning clinical symptoms (1 structure), thereby leading to the risk that conditions such pre-eclampsia and diabetes might go unrecognized. Serious violations of good testing principles were observed in 3 structures performing ALB/G during ANC consultation. Price/test was 0.80€ when performed during ANC and varied between 0.38 and 4.62€ when performed in the laboratory.

Conclusion: The accessibility benefits potentially associated with the use of RT may be compromised by inappropriate test requests and poor quality of testing at ANC sites. RT should be performed in the laboratory whenever possible, with efforts to reduce RT price and time to give results. In all other situations, quality assurance of RT during ANC visit should be ensured. In any case, knowledge and application of guidelines for ANC screening should be reinforced.

POSTER 110 CANCELLED**Esther Obiakor**

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Outcome of Adequate Adherence to Antiretroviral Drug in the Prevention of Mother to Child Transmission of HIV. A Study Conducted at Federal Medical Center Abeokuta, Nigeria

Mother-to-child transmission (MTCT) of HIV is one of the biggest challenges of the HIV/AIDS pandemic especially in resource constrained settings. A cross-sectional study was conducted to evaluate the Impact of Antiretroviral (ARV) drugs in the Prevention of Mother to Child Transmission (PMTCT) of HIV/AIDS in sero-positive pregnant mothers. Structured questionnaires were administered to consented mothers to evaluate adherence rate to ARV drugs. Blood sample was collected from both the mother and the HIV exposed infants while CD4+ count tests were conducted for the mothers and early infant diagnosis (EID) done for the HIV exposed infants using (DBS) dried blood spot paper. Data were analyzed using SPSS version 16. All the mothers (100%) were on ARV which consist of Zidovudine, Lamivudine and single dose Neviraprine while all the HIV exposed babies (100%) received 1.5ml daily dose neviraprine from birth to their first EID. Age, knowledge of MTCT, marital status and occupation were identified as factors associated with good adherence rate to ARV drug, however significant relationship (P<0.05) only existed with age of respondents. Most of the infants (92.5%) were HIV negative showing a high prevention rate. In conclusion, reduction of MTCT of HIV is possible with effective adherence and administration of ARV drugs.

POSTER 111**Teri Roberts**¹, Kimberly Bonner¹, Reed Siemieniuk², Andrew Boozary³, Nathan Ford³, Jennifer Cohn¹¹ Medecins Sans Frontieres, Access Campaign, Geneva, Switzerland, ² Department of Medicine, University of Toronto, Toronto, Ontario, Canada, Harvard School of Public Health, Boston, MA, USA, ³ HIV/AIDS Department, World Health Organisation, Geneva, Switzerland,**Expanding Access to HIV Viral Load Testing: a Systematic Review Re-examining RNA Stability in EDTA Whole Blood and Plasma Beyond Current Recommendations**

Background: HIV viral load testing is the gold standard for treatment monitoring and is strongly recommended by the WHO. However, many barriers exist to testing scale-up, one of which is the very short time currently recommended for the transport of EDTA blood.

Methods: We performed a systematic review to re-analyze the stability data for viral RNA in whole blood and plasma beyond current recommendations. These include: 1) EDTA whole blood >6h at 25°C; 2) EDTA whole blood >24h at 4°C; 3) EDTA plasma >24h at 25°C; 4) EDTA plasma >5d at 4°C; 5) PPT whole blood >6h at 25°C; or 6) PPT plasma (post centrifuge but retained in the tube) >5d at 25°C. Four databases (Pubmed, EMBASE, Cabs Abstracts, and Biosis) were searched according to pre-specified search terms outlined in a pre-existing study protocol.

Results: 10,716 titles were searched and 320 titles were identified for abstract review. 58 abstracts were selected for full text review, of which 11 full-text articles were selected for inclusion. A Cartesian plot of log RNA degradation by time and temperature shows that HIV RNA remains stable far longer than current parameters. Less than 0.5 log decline in HIV RNA was found in EDTA whole blood up to 168hrs at 30°C. In EDTA plasma, every degree of temperature increase beyond the established standards added 0.021 log RNA degradation while every additional hour added 0.0023 RNA log decline, culminating in less than 0.5 log decline up to 168hrs at 30°C or 336hrs at 4°C.

Conclusion: Preliminary evidence suggests that EDTA whole blood and plasma may be transported and stored under time and temperature conditions exceeding current manufacturer recommendations. These recommendations are highly restrictive and present an access barrier to sample transport in resource limited settings. Further evidence is required to facilitate a change in recommendations, particularly for samples with low-level viraemia.

POSTER 112**Kenneth Hammond-Aryee**¹, Kenneth Hammond-Aryee¹, Andre Roux², Monika Esser², Paul Van Helden¹DST/NRF Centre of Excellence for Biomedical Tuberculosis Research, MRC Centre for Molecular and Cellular Biology, Division of Molecular Biology and Human Genetics, Faculty of Medicine and Health Sciences, Stellenbosch University, P.O. Box 19063, Tygerberg 7505, South Africa, ² Immunology Unit, Division of Medical Microbiology, Department of Pathology, NHLS and Stellenbosch University, Cape Town, South Africa**Toxoplasma gondii IgG Antibody Avidity testing at National Health Laboratory Services, Tygerberg Academic Hospital Cape Town. A Case of Value Added**

Background: Toxoplasmosis is a disease caused by the protozoan parasite *Toxoplasma gondii*. Different serology tests are used for the initial diagnosis of toxoplasmosis, with PCR tests mainly employed in a confirmatory capacity. Serology and PCR based *T. gondii* diagnoses are fraught with problems including the inability to differentiate between acute or chronic infections. The IgG avidity tests have been introduced in a number of laboratories worldwide and these tests are able to discriminate between acute and chronic infections and are useful especially in the case of congenital and AIDS related toxoplasmosis.

Methods: We retrospectively reviewed the NHLS database for patient samples referred to NHLS Tygerberg for *T. gondii* serology determinations from July 2013 to April 2014, for IgG and IgM (+) and or (-) as well as IgG antibody avidity results.

Results: 1322 patient samples were tested over the period. 74.45% female and 25.02% male. Median age was 28.86 years. 13% of patients were from 0 to 2years old whilst 68% were between 18 to 40 years of age. 25.87% were IgG positive and 3.85% were IgM positive. Of the 295 that were tested for IgG avidity by default, 86.44% were high avidity, 7.8% were equivocal and 5.76 were low avidity mean IgG avidity was 77.73% (CI 95% 75.4-80.07).

Conclusion: The greatest value of IgG avidity testing is in HIV-AIDS patients and also antenatal cases where there is a suspicion of congenital infection and it is therefore vital to establish the time of the primary maternal infection. This becomes more relevant when we consider the fact that there is about a 30% seroprevalence of *T. gondii* infection in post parturient mothers in the Western Cape. Introduction of the IgG avidity test enables us to make quick and precise diagnosis especially where newborns and HIV-AIDS patients are concerned.

POSTER 113

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Plasmids and Antibiotic Resistant Profile of Extended Spectrum Beta Lactamase (ESBL) Producing *Escherichia coli* in Jos, Nigeria

Background: The prevalence and characteristics of Extended Spectrum Beta Lactamase (ESBL) producing *Escherichia coli*, a global cause of life threatening infections, remain unknown for many hospitals in Africa. We determined the presence of ESBL production in clinical isolates of *E. coli* from a North Central Nigerian hospital, their antibiotic susceptibility patterns and plasmid profiles.

Methods: Clinical isolates of *E. coli* from 220 patients seen at Jos University Teaching Hospital (JUTH) were evaluated by standard microbiologic and plasmid profiling methods. Antibiotic susceptibility testing was carried out by the modified Kirby-Bauer protocol while ESBL production was determined by the Double Disk Synergy Test (DDST). A structured questionnaire was used to collect clinical and demographic information, while data analysis was by EPI Info version 3.5.2.

Results: A total of 41 (18.6%) of the 220 *E. coli* isolates studied were ESBL positive. Sixteen (13%) of the 123 isolates from outpatients (community acquired) and 25 (25.8%) of the 97 from inpatients (community and hospital acquired) were ESBL producing. Majority of the ESBL producing isolates were resistant to the antibiotics tested. However, the ESBL producing isolates were susceptible to Meropenem (97.6%), Chloramphenicol (58.5%) and Amikacin (53.7%) while the ESBL negative isolates were susceptible to Meropenem (100%), Cefepime (97.8%), Ceftriaxone (96.6%) and Cefotaxime (96.6%). The plasmid analysis showed that all the ESBL producing isolates harbored detectable plasmids with sizes ranging between 2,322 to 23,130 base pairs.

Conclusion: We have shown that multidrug resistant ESBL producing *E. coli* is prevalent in both the hospital and the community. The fact that all the tested ESBL positive isolates harbor plasmids on which resistant genes may be located and which are highly transferable is quite alarming. Strengthening surveillance and antibiotic stewardship is therefore necessary to curb emergence and transmission of further multidrug resistant isolates.

POSTER 114

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Implementation of the ISO15189 Quality Management System at Ndola Central Hospital Pathology Laboratory (NCH-PL) through Training and Mentorship

Background: NCH-PL is a government public health medical laboratory in Ndola, Zambia. In Zambia there are no accredited public health Laboratories, therefore through Ministry of health and partners NCH-PL was enrolled in a program towards accreditation through a step wise implementation since 2010.

Methods: The lab through the Ministry of Health / partners started the implementation through a 3 part Strengthen of laboratory Management Towards Accreditation (SLMTA) workshop training in March 2010, December 2010 and April 2010 which saw the lab implement a total of 13 improvement projects.

The lab was also engaged in a 6 weeks laboratory mentorship program with Clinical Laboratory Standards Institute mentors. The mentorship programs were divided into 3 visits for a period of 6 weeks each from April 2012 to September 2013. Both the SLMTA and mentorship program had supervisory visits from the ministry of health team and partners between consecutive visits.

Results: The following Improvement Projects were implemented; establishing the turnaround Time, documenting and reviewing of quality controls, laboratory safety and signage, monitoring of statistics, customer satisfaction surveys and meet the clinician meetings, establishing programs for equipment maintenance, reagent inventory, sample management and sample referral systems through development of a sample collection manual. The lab was named best implementer among other participating laboratories. The laboratory produced an ISO15189 Quality Management System with included a write up of a quality Policy manual, Standard operating Procedures and other supporting documents. Through the system, the lab was able to identify Non-Conforming events and implement corrective action, and training of staff. The lab measured improvement through internal audits using the WHO-SLMTA checklist with a baseline of 96 points in 2010, 152 points in 2011, 120 points in 2012 and 174 points during an external audit by WHO / African Society for Laboratory Medicine.

Conclusion: Training, mentorship and coordinated team work helped the laboratory to improve the Quality Management System, despite the slow progress due a resource constrained environment.

POSTER 115

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Mains Power Quality Monitoring and Analysis for Innovative Medical Equipment Power Management Development

Background: The World Health Organization encourages quantified electrical access profiles of health care facilities in resource-constrained locations (RCLs; Sub-Saharan Africa) for effective health care delivery. However, mains power quality is often overlooked in the design and commercialization of medical devices used in RCLs. Further, there is limited published literature on power quality across RCLs, although anecdotal information suggests that power quality incidents cause frequent medical equipment failure. These incidents may include frequency deviation, impulses, outages, surges, and sags. To prevent medical equipment failure, standard voltage protection devices (SVPD) are sometimes utilized, but frequently at the cost of down-time during critical medical procedures. By characterizing power quality across multiple countries in Sub-Saharan Africa, medical equipment may be designed to handle incidents without down-time or hardware failure.

Methods: 1,421 hours of power quality has been monitored across six countries (11 health facilities, 15 hotels, 1 university) – Ethiopia, Malawi, Nigeria, South Africa, Tanzania, and Zambia – using a commercially available PowerWatch recorder (ACR Systems, Surrey, Canada).

Results: Insignificant power frequency deviation was observed. Time of day had no impact on incidents, which allowed for analyses of all data to be representative of normal working hours. 20 hot-to-neutral (H-N) surges $\geq 380\text{Vrms}$ (1.8min average, 0.01s – 14.4min range) and 280 H-N sags $\leq 85\%$ of the nominal 230Vrms (16.7min average, 0.01s – 350min range) were recorded. Both incidents have the capacity to damage medical equipment and/or the hardware protecting it. On average, when using a SVPD, power was unavailable for nearly 4 min/hour (91.7 min/day; 6.4% of total monitored time), with contributions from H-N surges (20.5 min/day; 1.4%), H-N sags (7.9 min/day; 0.6%) and outages (63.4 min/day; 4.4%).

Conclusion: Preliminary results have led to an expansion of data collection efforts across Sub-Saharan Africa which will better direct future development of innovative power management solutions for medical equipment.

POSTER 116

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Factors Affecting Implementation of Chemistry Tests in Rural Areas in Zambia

Background: ART related tests mainly consist of Complete Blood Count (especially Hemoglobin), CD4 count and Chemistry test (especially ALT and Creatinine) in Zambia. With the expansion of ART service into the rural areas, CD4 count has been more available. The demand for chemistry test is high; however, chemistry test is confronted with difficulties on implementation. Supply chain and equipment maintenance are major adverse factors in conducting chemistry tests. This time the details for those factors were investigated.

Methods: Descriptive method was taken by checking tested numbers of CBC, CD4, ALT, Creatinine and the availability of equipment for CBC, CD4 Count and Chemistry tests in 4 laboratories in 4 districts in 2012 and 2013. Also the used order forms for laboratory commodities were reviewed.

Results: Tested total number of CBC, CD4, ALT, and Creatinine in all 4 laboratories for 2 years was 26901, 23244, 9904 and 12888 respectively. Total number of month in which equipment was available and used for testing CBC, CD4, ALT, and Creatinine in all 4 laboratories for 2 years was 96, 95, 64 and 65 respectively.

Conclusion: Erratic supplies of consumables, the requirement of many types of consumables for just one test (e.g., Creatinine), slow vendor's responses and inadequate preventive maintenance negatively affected the implementation of chemistry tests. One of solutions might be the usage of appropriate POCT devices which are durable, easy to use and maintain, have small battery function and don't require many consumables and water. Also there was need of improvement on the order form and computerized ordering system. On implementation of chemistry tests, supply chain and equipment maintenance were critical and improvement on these two factors may bring good impact.

POSTER 117

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Coagulation Factors Level in Fresh Frozen Plasma in Rwanda

Background: Fresh Frozen Plasma is used in transfusion medicine and is associated with many risks if used inappropriately. There are limited studies conducted in Sub-Saharan Africa including Rwanda

despite the limited known shelf life and storage condition of FFP that varies across many countries' transfusion guidelines. The aim of this study was to determine the level of coagulation factors in fresh frozen plasma in subsequent period of routine storage conditions.

Methods: A cross section study was designed to determine the level of coagulation factors and inhibitors over the time comparing baseline results and up to three months of storage based on both age, sex, weight and blood group of blood donors. A total of seventy two, fresh frozen plasma, have been collected from three blood transfusion sampling centers in Rwanda in three days after scientific review and ethical approval. The samples have then been analyzed using a full automated machine ACL 7000, using turbidimetric clot and chromogenic methods for factors assays and Prothrombin time and activated partial thrombin time tests.

Results: We found significant decrease of fibrinogen (-10%), FII (-8%), FV (-15%), FVII (-13%), FX (-15%), FXIII (-5%), PC (-7%), and ATIII (-5%), show a decrease from baseline up to three months, whereas FVIII (-8%), F IX (-4%), FXI (-6%), FXII (-3%), FPS (-3%), and VWF-Ag (-7%) have been constant without significant change (+/-0%) from baseline to one month then changed also significantly over time and decreased up to three months.

Conclusion: Our findings revealed that all coagulation factors and inhibitors in plasma could still be retained in fresh frozen plasma stored under -18 °C for three months. Such plasma would be acceptable product for most patients requiring fresh frozen plasma. However, the existence of labile factors including APTT and PT should be confirmed before transfusing.

POSTER 118

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Genotype Diversity of Mycobacterium Isolates from Children in Jimma, Ethiopia

Methods: Gastric lavage or sputum samples were collected from consecutively enrolled TB suspect children visiting Jimma University Hospital in 2011 and cultured on Middlebrook 7H11 and Löwenstein-Jensen media. Acid fast bacterial (AFB) isolates were subjected to molecular typing targeting regions of difference (RDs), 16S rDNA gene and the direct repeat (DR) region using multiplex polymerase chain reaction (mPCR), gene sequencing and spoligotyping, respectively. Molecular drug susceptibility testing of *M. tuberculosis* isolates was performed by Genotype[®]MTBDRplus line probe assay (LPA) (Hain Life Sciences, Germany).

Results: Gastric lavage (n = 43) or sputum (n = 58) samples were collected from 101 children and 31.7% (32/101) of the samples were positive for AFB by microscopy, culture and/or PCR. Out of 25 AFB isolates, 60% (15/25) were identified as *M. tuberculosis* by PCR, and 40% isolates (10/25) were confirmed to be non-tuberculous mycobacteria (NTM) by genus typing and

16S rDNA gene sequencing. Lineage classification assigned the *M. tuberculosis* strains into Euro-American (EUA, 66.7%; 10/15), East-African-Indian (EAI; 2/15), East-Asian (EA; 1/15) and Indo-Oceanic (IO; 1/15) lineages. Seven *M. tuberculosis* strains were new to the SpolDB4 database. All of the *M. tuberculosis* isolates were susceptible to isoniazid (INH) and rifampicin (RIF), except for one strain (of spoligotype SIT-149 or T3_ETH family) which had a mutation at the *inhA* locus which often confers resistance to INH (low level) and ethionamide.

Conclusion: Analysis of the genetic population structure of paediatric *M. tuberculosis* strains suggested similarity with that of adults, indicating an on-going and active transmission of *M. tuberculosis* from adults to children in Ethiopia. There were no multidrug-resistant TB (MDR-TB) strains among the isolates.

POSTER 119

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Drug Susceptibility Pattern and Genotypic Diversity of Mycobacterium tuberculosis Isolate Collected from Community-based Survey in Ethiopia

Background: The aim of this study was to characterize and describe drug susceptibility pattern of *M. tuberculosis* complex isolates collected from diverse geographical locations of Ethiopia.

Methods: The present study was conducted as a continuation of the Ethiopian National TB Prevalence Survey carried out during 2010/2011. The laboratory investigation was performed on all culture positive samples. The isolates were characterized using RD9-PCR deletion typing and spoligotyping. Drug resistance was tested using indirect proportion method on L-J media.

Results: Ninety two culture positive isolates of mycobacteria were analyzed using RD9-PCR deletion typing and all of them were identified as *M. tuberculosis* species. Spoligotyping revealed 41 spoligotype patterns with over all diversity of 45%. A total of 64 isolates were grouped into 14 clusters consisting of 2-15 isolates each. The dominant spoligotypes were SIT53 (15/91), SIT149 (11/91) and SIT37 (9/91). Cluster formation within the same kebele was observed in 26.4% of the isolate for registered spoligotypes whereas 81.8% for newly identified spoligotypes. Among 90 isolates mono-resistance was found in 27.7% and poly-resistance in 5.5% of cases. The highest level of mono-resistance was observed for streptomycin 26.6%. Majority (91.1%) streptomycin mono-resistant strain belongs to Euro-American lineage. MDR were detected in 4.4 % of the cases.

Conclusion: The dominant strains of *M. tuberculosis* were SIT53, SIT149 and SIT37. This study demonstrates the importance of considering other factors in strain clustering and recent transmission.

POSTER 120

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Same-day Diagnosis ('SPOT- SPOT') versus the Conventional Strategy ('SPOT-MORNING-SPOT') with Three Specimens, Direct Ziehl-Neelsen and Floursecet Microscopy on both HIV+ and HIV- Patients

Background: Diagnosis of spot-morning-spot (SMS) smear microscopy may be inconvenient for patients, who have to make multiple visits to health facilities to submit multiple sputum specimens over two days. An extra day to collect results. Optimization of smear microscopy will decrease the inconvenience of the patients so as to increase the case detection rate. **Objective:** To determine the sensitivity, specificity and predictive values of a "proposed same day" strategy for one day diagnosis of tuberculosis (TB) and compare it to the conventional method, as culture is the reference standard.

Methods: A cross-sectional study was conducted from June to August, 2013 from University of Gondar Hospital (UoGH) and Debrtabor Rural Hospital (DTH), North West Amhara. A total of 180 TB suspected patients were enrolled. Patients suspected for TB submitted SMS sample (the conventional method). One additional sample was collected \geq 1h after the first sputum (the proposed same-day method) and one sample selected and cultured. OpenEpi data & McNemar's tests were used to compare the test.

Results: The sensitivity of the conventional method (27/160) was 81.8%, 95%CI (65.6-91.4) & that of the proposed spot method (25/160), was 75.8%, 95%CI (58.9- 87.2) by Ziehl-Neelsen (ZN) but the difference was not statistically significant; P-value=0.298. Their specificity was similar 100 % (97.1-100); P-value=1.00. The light emitted diode (LED-FM) sensitivity was 84.9% (69.1- 93.4) Vs 81.8% (65.6- 91.4) in conventional and proposed methods respectively. The difference in sensitivity was not significant; P-value=0.568. The specificity was [84.9 % (69.1-93.4) Vs 81.8 % (65.6-91.4)] conventional Vs proposed same day respectively; P-value=0.155.

Conclusion: Since the sensitivity and specificity were statistically non-different in conventional (SMS) and proposed spot-next spot specimen of ZN and LED-FM method, but a 6% difference in sensitivity in ZN methods. This difference happens in two cases, this is due to poor sample preparation (especially first day next spot smear). But this study shows, it is possible to diagnose PTB in one day by giving extensive and comprehensive training for laboratory technicians and technologists and the practicability needs further research.

POSTER 121

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The Impact of Laboratory Infrastructure on the WHO AFRO Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) in the Bamenda Regional Hospital Laboratory (BRHL), Cameroon

Background: The infrastructure of a laboratory is one of the aspects that must be considered in order to succeed in a good quality management system. Once the testing environment is conducive, all the other aspects shall follow suit. Good infrastructure includes: a building that permits smooth work flow with safety majors, adequate ventilation, separate area for testing, storage, dressing, specimen collection, counselling and eating. SLIPTA was introduced to the BRHL by the Centre for Disease Control and Prevention, Global Health Systems Solutions and the Ministry of Public Health Cameroon, in order to improve the quality of laboratory infrastructures/services in 2010.

Methods: This was a retrospective observational study. Secondary data between June 2010 to August 2013 was extracted from assessment results of the WHO Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) checklist which is comprised of the 12 quality system essentials and photographs of pre and present SLIPTA implementation. Results were based on a series of questions, with a maximum total of 258 points. Assessments were conducted by certified laboratory auditors.

Results: The following assessment results in percentage of the maximum number of points on the checklist were observed: June 2010 (Baseline): 18.0%, February 2011: 33.7%, July 2011: 55.8%, December 2011: 76.8%, February, 2012: 85.3%, September 2012: 67.1%, May 2013: 79.1%, August 2013: 81.4%. The pre and present SLIPTA photographs indicated drastic improvements which included: renovation of the modest building, tiling of the floors and work stations, embedding all cables, construction of a new reception area with separate rooms for specimen collection, counselling and eating, and relocation of some departments.

Conclusion: The great improvements in infrastructure were due to inputs such as finance and technical assistance provided by the upper management and good mentoring from the laboratory management. In order for laboratories to succeed in accreditation they should embark on good infrastructure as a priority.

POSTER 122

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The Use of an Internal Quality Control Programme to Monitor Quality Assurance of HIV Rapid Testing in the Limpopo Province, South Africa

Background: There are 2.4 million individuals on antiretroviral therapy in South Africa. Substantial testing is still required to reach all estimated 6.4 million infected individuals. HIV rapid testing at a facility level ensures the greatest coverage for testing. Ensuring the accuracy of HIV rapid testing is a major challenge. Non-medical/non-laboratory personnel carry out testing at facilities. The NICD has rolled out limited quality management systems training for HIV rapid testing at the national, provincial and district levels. To further assist the provinces to ensure accurate HIV rapid testing the NICD initiated an internal quality control (IQC) programme to provide real time monitoring and opportunities for immediate interventions. The first province to implement an IQC programme was Limpopo Province in 2009 based on the QMS rollout training in that province.

Methods: Two serum IQC standards, a positive and negative control were produced. A standard operating procedure (SOP) was developed to accompany the materials. To assess the routine implementation of IQC use, a template with 14 key quality indicators was introduced. Following phased QC/IQC training starting in 2009 two site visits were performed viz., baseline visit and a follow-up visit 3-4 months later to assess compliance.

Results: The coverage of sites implementing IQC over a 4-year period was 340 sites (70% coverage). The compliance was variable by district and attainment of 80% compliance for all indicators was not achieved at the follow-up visits. Overall compliance was 78%. Key problem areas included, inappropriate storage of material, training of the right staff and lack of participation of all staff performing testing and/or supervision, limited recording of data and data analysis.

Conclusion: The implementation of the IQC programme in the Limpopo Province was not fully successful and provided several key lessons in terms of monitoring quality assurance implementation. The implementation is highly staff and time intensive and affected rates of coverage. The Provincial staff taking on greater responsibility for implementation is encouraging and critical for success.

POSTER 123

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Evaluation of the Performance of SD BIOLINE HIV/Syphilis Duo Kit as a Point-of-Care Assay at a Rural Health Center in Southwestern Uganda

Background: Both HIV and syphilis infections remain a major public health challenge worldwide, particularly among pregnant women and their newborns. A novel, point-of-care chromatographic test, the first of its kind, for dual diagnosis of both HIV and syphilis has recently been developed, but has not been evaluated in rural settings. Therefore, we evaluated the performance of the SD Bioline Syphilis/HIV Duo kit in rural Uganda.

Methods: This was a cross-sectional study conducted from March to May, 2013, among pregnant women attending a rural Uganda health care facility. We assessed the performance of SD BIOLINE HIV/Syphilis Duo kit and reported the sensitivity and specificity of the syphilis component of the SD Bioline assay compared to the *Treponema pallidum* hemagglutination test and the HIV component of the assay compared to the serial HIV algorithm (Determine HIV-1/2/0 (Abbott Laboratories, Abbott Park, IL), HIV 1/2 Stat-Pak Ultra Fast (Chembio Diagnostic Systems), Uni-Gold Recombinant HIV-1/2 (Trinity Biotech)).

Results: Of the 220 samples tested, antibodies against *T. pallidum*, HIV, and, both HIV and Syphilis were detected by the dual rapid test in 19(8.6%), 16 (7.3%), and, 3 (1.4%), respectively. The sensitivity and specificity of SD BIOLINE HIV/Syphilis Duo kit was 100% (79.0 – 100.0) and 100% (97.6 – 100.0) respectively, for syphilis, and, 100% (75.9 – 100.0) and 99.51% (96.8 – 99.9) respectively for HIV. The duo kit was found to be faster, cheaper and easier to use compared to the current HIV and syphilis testing techniques.

Conclusion: The high burden presented by HIV and/or syphilis calls for increased frequency of diagnosis using highly sensitive, specific and cost effective tools that are also adaptable to resource-limited settings. The SD BIOLINE HIV/Syphilis Duo kit should be further evaluated with larger sample size, but shows promise as a tool for improved HIV and syphilis surveillance, diagnosis, and treatment in similar settings.

POSTER 124

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Prevalence of Some Intestinal Parasitic Infections and Malaria Parasitaemia in Relation to Body Mass Index of Children Resident in Orphanages in Anambra State, Nigeria

Background: This study investigated the prevalence of some parasitic infections in relation to Body Mass Index (BMI) of children resident in orphanages situated in Anambra State. This is due to

paucity of information on the prevalence of infections in this study group

Methods: A total of 272 subjects consisting of 172 orphans and 100 children from community (control) were investigated for intestinal parasitic infections using formol-ether concentration method; and malaria parasitaemia using thick and thin blood film stained with Giemsa stain. Underweight, overweight and obesity in the study group were determined from BMI using the International Obesity Task Force cut-off points. Malaria parasite density was carried out according to the World Health Organization (WHO) recommendation.

Results: A prevalence of 23.3%, 5.8%, 4.7% and 1.2% were observed in malaria parasitaemia, *Ascaris lumbricoides*, *Necator americanus*/*Ancylostoma duodenale*, and *Entamoeba histolytica*/dispar infections respectively. Prevalence of 23.3% and 12.0% for malaria parasitaemia; and 12.7% and 6.1% for intestinal parasitic infections were observed for children in orphanage and community respectively ($P < 0.05$). The mean malaria parasite density (603.16 ± 373.04) calculated based on WHO assumed WBC mean was significantly higher than using the actual WBC (367.95 ± 228.91) count ($P < 0.05$). The prevalence of *Plasmodium* species observed were: *Plasmodium falciparum* 82.5%, *Plasmodium malariae* 12.5% and *Plasmodium vivax* 5.0%. No significant changes were recorded in the BMI of children who had parasitic infections ($P > 0.05$). Percentages of children in orphanage and community who were found to be underweight were 8.1 and 0 respectively. Orphans and children in community found to be overweight had percentages of 3.5 and 8.0 respectively. No cases of obesity were recorded.

Conclusion: Children in family setting seem to thrive better than those in orphanage homes. Reference range of total WBC to be used in a given locality in calculating malaria parasite density rather than an assumed value may be more appropriate.

POSTER 125

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Assessing the Performance of CareStart™ Malaria Pf/Pv Combo Test against Thick Blood Film in the Diagnosis of Malaria in Northwest Ethiopia

Background: Bivalent Rapid Diagnostic tests are promising diagnostic tools for *P.falciparum* and *P.vivax*. Their diagnostic performance was evaluated against thick blood smear to assist national malaria control programs.

Methods: A cross-sectional study was conducted to evaluate the performance of CareStart™ against thick blood smears among 398 acute febrile patients visiting the Felegeselam Health Center in December 2011. Thick blood smears were examined under $100\times$ objectives to diagnose *Plasmodium* species. Similarly, CareStart™ Malaria Pf/Pv Combo test was performed as per the manufacturers' instruction.

Results: The ability of CareStart™ Malaria Pf/Pv Combo test to diagnose *Plasmodium malariae* was very good with 99.8% (97.7–100%, 95% CI) sensitivity and 97.7% (94.6–99.1%, 95% CI) specificity.

Conclusion: The sensitivity and specificity of CareStart™ test is comparable with the thick blood smear in diagnosing malaria. Hence, it is preferable to use CareStart™ Malaria Pf/Pv Combo test instead of Microscopy in areas where microscopic diagnosis is limited. Key words: CareStart™, Sensitivity, Specificity, *Plasmodium*

POSTER 126

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Establishing an Occupational Safety and Health Program to Improve Laboratory Biosafety in Kenya

Background: An employee occupational safety and health (OSH) program is a key element for a successful biosafety program. During baseline assessments for WHO-AFRO Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA), OSH was identified as one of the major gaps. It was realized that although Kenya had an OSH Act (OSHA, 2007), it didn't address issues related to OSH among health care workers (HCWs). Implementing a successful work safety program in a healthcare setting requires: i) performing a work hazard assessment to identify the necessary safety precautions and ii) development of pre-exposure, emergency response and post-exposure protocols in advance to protect personnel and ensure readiness to respond to events. The US Centers for Disease Control and Prevention (CDC) supported the Ministry of Health (MOH) to set up an OSH program.

Methods: A technical working group was formed to coordinate assessment, policy development, advocacy and capacity building. Members included CDC, MOH, WHO, US President's Emergency Plan for AIDS Relief (PEPFAR) implementing partners, medical professional associations and training institutions.

Results: Three stakeholders' meetings were held between April and July 2013 to assimilate findings from an earlier work hazard assessment that the MOH had conducted countrywide to ensure buy-in on issues related to policy development and capacity building. A 3-day workshop was held in July 2013 to draft OSH policy guidelines. Participants were drawn from all 47 counties of Kenya. Thereafter, the technical committee reviewed and finalized the policy guidelines. An OSH specialist was recruited to set up model sites to showcase best practices and complement SLIPTA.

Conclusion: Kenya has embarked on the path to improve OSH among laboratory personnel and other HCWs. Preliminary outcomes include improved awareness on OSH, strengthening of infection prevention department at MOH headquarters, setting up needle-stick management and surveillance system and an improvement in Hepatitis B vaccination of HCWs.

POSTER 127**Neliswa Chigudu**, NHLS Trainers, Patience Dabula

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Piloting SLMTA in South Africa: Overview of Deviations and Operational Challenges in the Implementation of the Program

Background: The National Health Laboratory Service (NHLS) is committed to the provision of high-quality laboratory services to the South African public. As part of improving quality, the NHLS enrolled selected laboratories on the Strengthening Laboratory Management Towards Accreditation (SLMTA) programme. The successful implementation of SLMTA is highly dependent on the trainers and participants. The main objective of this study is to identify key deviations and challenges encountered during implementation.

Methods: Twelve NHLS laboratories were enrolled. Each laboratory selected representatives with the number of participants per laboratory varying depending on the size of the laboratory. The programme included a series of three workshops and six laboratory visits at three months interval. Following each workshop, Improvement Projects (IPs) and Activities were issued to participants for implementation in their laboratories. Trainers assisted the laboratories with implementation during their laboratory visits. Data was collected through reports and communications received.

Results: A total of 48 participants and 17 trainers were involved in the project. Two key program deviations were logged in the first cycle, four in the second and nine in the third. Some of the deviations logged were as a result of trainers being unavailable to conduct a scheduled laboratory visits, resignations from the NHLS and exclusion from the programme due to non-performance. Of the 48 participants that started, 39 completed all three workshops. Site visit reports indicated that although IPs were completed, it was not without challenges including staff shortages and participants not always implementing prior to the first visit.

Conclusion: Site visit reports showed that a customized approach to the implementation of the program resulted in improvements. The unavailability of trainers during scheduled laboratory visits as well as resignations of participants may have had a negative impact on the program, however this will be determined by the exit audits results.

POSTER 128**Olatilewa Amusu**¹, Godwin I. Ayuba², Johnbull Mbibi²¹ Military Hospital, Lagos, Nigeria, ² 44 Nigerian Army reference Hospital, Kaduna, Nigeria**From Zero to Five Star: The Improvement Process of 44 Nigerian Army Reference Hospital Laboratory**

Background: The Strengthening Laboratory Management Towards Accreditation (SLMTA) programme was introduced into Nigeria following the first SLMTA Training of Trainers conducted in 2009.

The implementation of the programme allowed for domestication of the process which was to expect considerable quality improvement over two years. Our laboratory supports a tertiary military hospital in Nigeria and committed to prepare for accreditation using the SLMTA/SLIPTA model.

Methods: A baseline assessment of the laboratory was conducted in 2010 and the laboratory scored 49% (Zero Star). There were deficiencies in all areas covered in the checklist, particularly Documents and Records and Internal Audit. The laboratory commenced an improvement plan with training, mentoring support and advocacy for the hospital management support for the process.

Results: Twelve months after the baseline, the laboratory improved to a One Star rating in August, 2011. Though staff were excited and committed, the process of improvement was slow. Twenty six months after the baseline assessment, the rating had improved to 3 –Star. Deficiencies were observed mainly in Occurrence /Incident management, Management Reviews as well as Internal Audit while the laboratory had made tremendous improvement in Purchase and Inventory, Documents and Records, Corrective Actions and Information management. An audit conducted 41 months after the baseline reported a 5 – Star rating. Staff were of the opinion that committed leadership, hard work, higher administrative support were some of the factors that contributed to the improvement in rating.

Conclusion: The goal of the SLMTA process is to strengthen laboratory management to achieve immediate laboratory improvement and also accelerate the process to achieve accreditation. Though many factors were important contributors to the improvement process, our staff were of the opinion that laboratory leadership commitment was the most significant contributor.

POSTER 129**Olatilewa Amusu**¹, Idemudia Otaigbe¹, Nkiru Nnadi², Augustine Akindoye², Yeibo Bibode², Jacinta Elemere², Barnabas Nzekwe²¹ Military Hospital, Lagos, Nigeria, ² 68 Nigerian Army Reference Hospital, Yaba Lagos, Nigeria**Performance of GeneXpert MTB/RIF in Diagnosis of Tuberculosis and Rifampicin Resistance in 68 Nigerian Army Reference Hospital, Yaba, Lagos, Nigeria**

Background: Tuberculosis (TB) is a major public health threat in Nigeria. Prior to introduction of the GeneXpert technology in our laboratory, Ziehl- Neelsen smears, Tuberculin Sensitivity and radiology were used to aid diagnosis in patients with a clinical suspicion of TB. The Xpert MTB/Rif assay is however a more laboratorian-friendly method of diagnosing TB as it frees more time for the technologist and reduces the risk of occupational exposure to the mycobacterium.

Methods: This prospective study was conducted on routine samples between October 2012 and December 2013. During the period, 492 patients had both GeneXpert testing and AFB smears. The ages of the patients ranged between 2 years and

72 years. Twenty-four of them were less than 18 years old. 90 of the study population were HIV positive. All patients were referred for laboratory testing following positive clinical screening for Tuberculosis.

Results: Of the study population, 72 patients (14.63%) were smear positive while 134 (27.23%) were positive on Xpert. In persons co-infected with HIV, the sensitivity of smears alone was 33.3% with a Negative Predictive Value (NPV) of 77.7%. Among the 24 paediatric cases, 6(25%) were positive on GeneXpert compared to 4 (16.67%) on AFB smear. 6 (1.22%) specimens showed resistance to Rifampicin. Four of these were from patients with HIV infection.

Conclusion: The GeneXpert technique increases Tuberculosis case detection significantly. Our observation is that this detection is even more pronounced in patients that are HIV co-infected. It has the advantage of reduced risk to laboratory staff and a quicker turn around time. It is recommended that the availability of this technology is scaled up as its continued use will contribute to improved diagnosis and management of tuberculosis.

POSTER 130

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Diagnosis and Phylogenetic Analysis of Orf Virus from Goats in Tanzania: A Case Report

Orf virus (OV) is a prototype of the genus Parapoxvirus (PPV) under the family poxviridae. The virus is the causative agent of contagious pustular dermatitis which is the zoonotic and neglected disease of humans and small ruminants. It causes a severe exanthematous dermatitis that afflicts domestic and wild small ruminants. Cases of orf virus infection in goat in Tanzania have been reported for many years. Bases of reporting OV cases were mainly clinical signs which were non confirmatory (Ministry of Livestock Development reports-Tanzania). In this study, a case of proliferative dermatitis in goats is reported. The investigation was carried out by physical examination of the animal and Laboratory examination of tissue scrapings collected. The presence of OV in tissue scrapings from the lips was tested by GIF / IL-2 gene polymerase chain reaction (PCR) amplification. The molecular characterization of the ORFV was performed using PCR amplification, DNA sequencing and phylogenetic analysis of the GIF/IL-2 gene. The results of this study indicated that clinical picture of the disease was caused by infection which is closely genetically related to several OV found in the data base as appreciated in the phylogenetic tree with bootstraps value of 100%. OV involved in this case report was closely related to other OV deposited in the NCBI. This is the first report to provide phylogenetic information about the OV in Tanzania which will be useful in prospective public health studies.

POSTER 131

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The Magnitude of Anemia among Geriatric Patients Attending at Gondar University Hospital, Gondar, Northwest Ethiopian: An Ignored Problem

Background: Anemia is a significant problem in elderly patients worldwide. Even though it has often been assumed as a normal consequence of aging, such age-related decline of erythrocyte production obscures the effect of other factors. In this population, anemia is multifaceted; has terribly magnified impact on health due malnutrition and inflammation of varying etiology. Hence, the objective of this study was to assess prevalence of anemia and its association with nutritional status and inflammation in geriatric patients.

Methods: An institutional based cross-sectional study was conducted among geriatric patients in Gondar town. A total of 200 study participants were selected using systematic random sampling technique. Data were collected after obtaining verbal consent from the respondents. The data were entered and analyzed SPSS version 20 for analysis. Summary statistics were computed. Chi-square and p-value were used to see association between anaemia, and nutritional status and inflammation.

Results: The mean age of the study participants was 67 \pm years, 51% of them belong to 62-70 years age group. Majority of them were males (54.5%, n=109) and resides in urban setting (55%, n=110). About 25.5% were underweighted and majority (70.5%) of them had an elevated erythrocyte sedimentation rate. The mean hemoglobin concentration was 12.2g/dl. The prevalence of anemia in the geriatric patients was 109(54.5%); of which 64 (58.7%) were males and 45 (41.3%) were females; mild type anemia is predominant (56.9%). Body mass index and erythrocyte sedimentation rate were found to be associated factors of anemia.

Conclusion: The prevalence of anemia in geriatrics was high; and it is a severe public health problem. Only erythrocyte sedimentation rate and body mass index were associated with geriatric anemia. Early diagnosis and management of anemia in geriatrics is valuable to prevent adverse outcomes of anemia. Large scale population based study need to be conducted.

POSTER 132

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Serological Evidence of Acute Dengue Virus Infection among Febrile Patients Attending Plateau State Specialist Hospital(PSSH) Jos, Nigeria

Background: Dengue is the most rapidly spreading mosquito-borne viral disease in the world. In just the past decade, the significance of dengue as a threat to health and a burden on health services and economies have increased substantially. The worldwide incidence of dengue has risen 30-fold compared with the situation 50 years ago. More countries are reporting their first outbreaks.

Methods: This is a cross-sectional study, involving patients of both sexes regardless of age who attended outpatient clinics or on admission at the PSSH and who met the WHO case definition for suspected dengue virus fever infection and gave either oral or written consent to participate in the study. The Panbio Dengue Early NS1 antigen capture ELISA test was used to test the sera for the serological evidence of acute dengue virus infection. The data generated was entered and analyzed using SPSS version 18.0 for windows software.

Results: Serological evidence of acute dengue virus infection was assessed in 182 sera of the subjects, made up of (78(42.9%) Males and 104 (57.1%) Females). The age range of the subjects were 2 to 70 years, with mean (\pm SD) age of 31.8 ± 14.3 years. A total of 4 subjects were aged 11-40s were positive for dengue NS1 antigen (DEN NS1), giving a seroprevalence rate of 2.2%. Three, 3 (2.9%) females and 1 (1.3%) male were positive for DEN NS1, there was no significant difference according to gender. Two of the 4 positive cases also had malaria on presentation, while the other two had typhoid. All the positive subjects had complaints of fever and headache. All the seropositive cases occurred in the months of May and August which corresponds to the breeding season of the Mosquito (*Aedes* species) vectors for dengue virus.

Conclusion: Currently, there are no records in our health institution and epidemiological units in Nigeria, regarding dengue virus infection. There is therefore, the urgent need to include dengue virus infection in the differential diagnosis of all febrile patients, as evidenced from the current study.

POSTER 133

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Maximizing Mentorship: Variations in Laboratory Mentorship Models Implemented in Zimbabwe

Background: The Zimbabwean Ministry of Health and Child Care implemented four mentorship models in 19 laboratories in conjunction with the Strengthening Laboratory Management Toward Accreditation (SLMTA) program.

Methods: Eleven of the 19 laboratories had been previously trained with the SLMTA three-workshop series (Cohort I). They were assigned to one of three mentorship models based on programmatic considerations: Laboratory Manager Mentorship (Model 1, four laboratories), One Week per Month Mentorship (Model 2, four laboratories), and Cyclical Embedded Mentorship (Model 3, three laboratories). The remaining eight laboratories (Cohort II) were enrolled in a Cyclical Embedded Mentorship incorporated with SLMTA training (Model 4). Progress was evaluated using a standard audit checklist.

Results: At SLMTA baseline, Model 1-3 laboratories had a median baseline score of 30% (range 17%-48%). After completing the SLMTA workshop series, at mentorship baseline, these 11 laboratories had reached a median score of 54% (35%-75%); at the post mentorship audit these laboratories reached a median score of 75% (65%-88%). Each of the three mentorship models for Cohort I had similar median improvements from pre to post-mentorship (17% for Model 1, 23% for Model 2, and 25% for Model 3; $p > 0.10$ for each comparison). The eight Model 4 laboratories had a median baseline score of 24% (16%-33%); after mentorship their median score increased to 63% (54%-79%). Median improvements from pre-SLMTA to post-mentorship were similar for all four models (53% for Model 1, 34% for Model 2, 40% for Model 3, and 39% for Model 4; $p > 0.10$ for each comparison).

Conclusion: Several successful mentorship models can be considered by countries depending on the available resources, technical and managerial capabilities of the laboratory managers, and the accreditation implementation plan of the country.

POSTER 134

Lemma Bogale, Lucy Boulanger

Field Epidemiology Training Program (FETP)-Ethiopia

Rubella Outbreak – Southern Nations and Nationalities Peoples Region, Ethiopia, 2012

Background: Congenital rubella syndrome (CRS) can lead to congenital defects and fetal death. Due to widespread immunization programs CRS is rare in developed countries, but in resource-constrained countries, rubella infections can be uncontrolled. In April 2012 we received reports of a possible rubella

outbreak in the Southern Nations and Nationalities Peoples Region (SNNPR) and investigated to confirm the outbreak and implement control measures.

Methods: We conducted a field investigation in SodoWoreda in SNNPR, Ethiopia from April 7 to May 17, 2012. We defined a suspect rubella case as a patient in whom a health worker suspected rubella and had symptoms of fever, Maculopapular rash and adenopathy or arthralgias. Case register log books, morbidity and mortality reports from the local Buee health center were reviewed. Blood samples on five suspect patients were tested for rubella specific IgM antibody.

Results: We identified 100 suspected cases, and all areas (kebeles) of the SodoWoreda were affected by the outbreak. The attack rate was 4.3/1000. All five blood samples confirmed rubella. The majority (53%) of rubella cases were in 5-9 year old children. Four of the cases were in pregnant women; three were in the last trimester and had no complications and one had a spontaneous abortion following the illness. There were no other deaths. The measles vaccination coverage for the area was above 85%, but rubella was not included in the vaccine.

Conclusion: This was the first documented outbreak of rubella in this region of Ethiopia. We identified one spontaneous abortion, which highlights the complications that can arise from rubella infection. We recommend further consideration of including rubella vaccine in a combined vaccine with measles for Ethiopia.

POSTER 135

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Conversion of the WHO AFRO Stepwise Laboratory Improvement Process towards Accreditation (SLIPTA) Checklist to a Dynamic Digital Tool Capable of Supporting Multiple Checklists and Audit Tools

Background: In accordance with WHO's core functions of setting standards and building institutional capacity, WHO-AFRO has established the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) to strengthen laboratory systems of its Member States. The Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) is a framework for improving the quality of public health laboratories in resource poor settings in order to eventually achieve accreditation. A manual checklist (PDF Format) was developed that specifies requirements for quality and competency aimed to develop and improve laboratory services to raise quality to established standards. This project was focused on creating an electronic version of this checklist.

Methods: The project team used an Agile development methodology to gather and define requirements for the application. The system was developed in iterations called Sprints which included fragments of complete features that were presented to users to gather feedback and refine both the requirements and design of the system. The system design focused on flexibility and re-usability. A configurable tool was developed that allows administrators to change, add, delete checklist questions without any software development or updates to the user interface. The tool

supports multiple languages and is designed to be run on a laptop and then synchronized with a central database.

Results: The working application was delivered to the CDC on schedule and on budget and supports two additional checklists (Biosafety and Tuberculosis) in addition to the SLIPTA checklist.

Conclusion: The Agile methodology works well when stakeholders are available and engaged to provide iterative feedback on the system. The design of the application supports additional use with minimal (if any) technical or developer support. As it is completely configurable, a new checklist can be developed and deployed without any changes to the underlying application thereby reducing the costs of ongoing support and maintenance.

POSTER 136

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The Establishment of a Laboratory Information System Support Unit at Ministry of Health in Lesotho Assists in Assuring Quality Patient Results

Background: An effective Laboratory Information System (LIS) system is essential for the provision of quality laboratory services, use of data for planning, surveillance and accreditation. Laboratory Services, Ministry of Health (MOH), has implemented a comprehensive LIS. Prior to 2011 the laboratories in Lesotho employed a paper-based system only. The project was coordinated by the Association of Public Health Laboratories (APHL) and funded by PEPFAR (through CDC). As part of LIS implementation, it was critical to build local capacity to support and sustain the LIS. This was achieved through the establishment of an LIS Support Unit (Help Desk) within the Laboratory Services.

Methods: LIS "Super-Users" were trained at all laboratories, to provide first line support. Two LIS Officer positions were created (filled by laboratory professionals) within MOH, and the Help Desk was established. The Help Desk has provided effective second-line LIS support to laboratories. LIS Officers received training in conducting on-site preventative maintenance of hardware; logs were completed to track the number and time length of calls, problem type, number of on-site visits required, turnaround time for resolution, and the number and type of problems that required either the hardware or software vendor support.

Results: Problems resolved April 2013 to March 2014 are as follows: Total calls were 243. A total of 112 (46.1%) calls were resolved by phone, 69 (28.4%) were site visits and 62 (25.5%) were resolved by vendors. Average response times were 32 min, 56 min and 13 days respectively.

Conclusion: The majority of problems (74.5%) were resolved without the need of additional support from vendors. Since LIS is still relatively new, the number of calls is expected to decrease over time. The Help Desk has been highly successful in supporting quality laboratory services by providing timely and effective response to LIS problems.

POSTER 137Terence Asong¹, M.Rioja²

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The Use Telecommunication Networks to Remotely Monitor Data quality of POC CD4 Testing Data Amongst HIV Infected Clients in Cameroon

Background: As Cameroon transitions towards decentralization of laboratory and clinical services, point-of-care (POC) CD4 diagnosis of HIV infected clients provides an opportunity for on the spot assessment of ART eligibility and timely provision of treatment. However, remote monitoring of the test quality remains challenging. In order to address this problem, CD4 POC machines connected to a mobile modem linked to a central data base were implemented to enable real-time monitoring of testing volume, reagent consumption, and quality control runs for device performance and error rate documentation.

Methods: From September 2013 – February 2014, a field performance evaluation of the device was conducted in Northwest (NW) and Southwest (SW) regions in Cameroon. Following training of end-users, POC CD4 machines with the mobile devices were deployed to 81 facilities. Each machine was configured to prompt the end-user to send CD4 results from the machine to the server before shut down. Data captured at the central data base were used to monitor performance, testing volume, reagent consumption and quality.

Results: After 6 months, 76%(28/37) and 64%(28/44) of CD4 devices in NW and SW regions respectively, transmitted data to the central data base. The remaining failed, due to a lack of network connectivity, signal strength or internet access. In total, 7,064 CD4 tests were successfully performed with an average of 3.04% and 4.08% error rate recorded in the NW and SW regions respectively.

Conclusion: Remote monitoring via telecommunication network proved to be very effective in monitoring the quality of CD4 testing. However, validating connectivity uptime and signal strength needs to be assessed before deployment. We recommend the use of telecommunications network systems to monitor the quality of POC CD4 devices in order to improve the quality of testing services, which ensures appropriate treatment and care interventions are provided.

POSTER 138George Ademowo¹, Olawunmi Rabi¹, Ayokulehin Kosoko¹, Hannah Dada-Adegbola², Ganiyu Arinola³, Catherine Falade¹

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Assessment of Anaemia and Iron Status in Pregnant Women with Co-infections of Malaria, Intestinal Helminthes and HIV in Southwest Nigeria

Background: Malaria, HIV and helminth infections are diseases of public health menace in Africa. Pregnant women are a major group at risk of these infections. Iron deficiency and anaemia have been reported among these women. This study was therefore aimed at evaluating the prevalence of malaria, HIV and helminth infections and their effect on haemoglobin concentration and iron status in pregnant women.

Methods: Pregnant women (320) were recruited from the antenatal and HIV clinics of a secondary healthcare facility. Personal details of each participant was documented. Blood samples were obtained for haematocrit and, thick smears for malaria microscopy. Serum samples were used for ferritin and iron level estimation using ELISA and Atomic Absorption Spectrophotometry respectively. Stool was collected and used for identification and quantification of helminth ova by Direct and Kato-Katz methods.

Results: Twenty-three (7.1%) of the women were positive for malaria only, 11 (3.4%) for helminthes only, 65 (20.1%) for HIV only while 175 (54.2%) had no infection. There were 2 (0.6%), 46 (14.2%) and 1 (0.3%) cases of malaria/helminth, malaria/HIV and helminth/HIV co-infections respectively. 190 (60.9%) were not anaemic while 64 (20.5%), 57 (18.3%) and 1 (0.3%) had mild, moderate and severe anaemia respectively. A significantly lower haematocrit value was observed among those positive for HIV, malaria and malaria/HIV ($p=0.000$) infections relative to those without infections. Women positive for malaria only or coinfection of malaria/helminth had higher ferritin levels compared to those with no infections. There was no significant difference in serum iron levels among the groups.

Conclusion: The burden of malaria and HIV infections are high among the pregnant women. Pregnant women infected with malaria and/or HIV are more prone to anaemia relative to those infected with helminthes only. Effect of helminth coinfection with malaria and/or HIV are discussed.

POSTER 139

Victor Bigira

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Integration of HIV Point-of-Care Diagnostics into Existing Centralized Laboratory Networks: Uganda's Experience

Background: The last decade has seen a rapid increase in the development and uptake of Point-of-Care (POC) technologies for HIV diagnosis, staging, and treatment monitoring, including

technologies for CD4, Early Infant Diagnosis (EID), and Viral Load (VL). Simultaneously, a number of governments have invested in strengthening centralized laboratory networks. Uganda implemented the Alere Pima CD4 device at 270 health facilities in 2012 while also strengthening its sample transport network by creating a hub-and-spoke model connecting lower level facilities to hubs and central labs in Kampala. The centralized EID testing model has performed well with exponential growth in testing numbers, but still reaches only ~60% of infants in need of a 1st DNA-PCR test. Integration of POC into existing networks is crucial to bridge such unmet gaps.

Methods: Funded by UNITAID, Clinton Health Access Initiative (CHAI) is supporting 7 high-HIV-burden countries in Sub-Saharan Africa, including Uganda, to ensure well-coordinated introduction and scale-up of POC technologies through strong product and site selection, facility mapping and market segmentation, streamlining regulatory pathways for market entry, training facilities on POC testing and systems integration. CHAI is conducting a review of progress to date in Uganda.

Results: Integration of POC CD4 into the existing hub-and-spoke system improved CD4 access from <50% to ~70%, increased testing volume by 25%, and reduced turn-around-time and time to ART initiation. Ongoing activities will identify the 'sweet-spots' for POC EID/VL placement to ensure complementarity with existing systems and improved patient impact by increasing access, lowering result turn-around-time, time to ART initiation and regimen switching. These results will be available in Q3 2014.

Conclusion: Introduction and scale-up of POC HIV diagnostics requires holistic strategies to ensure sustained patient impact and positive returns on current and future investments. Uganda has achieved good POC CD4 integration and looks forward to similar POC EID/VL scale-up.

POSTER 140

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African Center for Integrated Laboratory Training: Improving Patient Outcomes in Africa through Stronger Laboratories

Background: A recent evaluation report on all countries supported by the US President's Emergency Plan for AIDS Relief (PEPFAR) documented the challenges faced by laboratories to scale up HIV/AIDS services; and brought to the fore the importance of building of a stronger laboratory workforce in Africa. The World Health Organization recommends a minimum of 2.3 healthcare workers per 1,000 country residents, but 36 African countries do not meet these criteria.

Methods: In 2008, to address the rapidly growing demand for a well-trained, competent, and motivated laboratory workforce in HIV, TB and Malaria clinical staff, the US Centers for Disease Control

and Prevention, PEPFAR, South African National Health Laboratory Service collaborated to launch the African Centre for Integrated Laboratory Training (ACILT) in Johannesburg, South Africa.

Results: As of 2013, ACILT had 107 course offerings, to 1435 participants from 41 countries in Africa, Asia and Caribbean regions. All ACILT courses are free of charge and serve to enhance technical skills of laboratory scientists, policy makers, strategic planners, bio-safety professionals and quality managers. Preparations are underway to assess and evaluate the transfer of knowledge and skills when participants return to their home countries.

Conclusion: Since 2011, African Society for Laboratory Medicine (ASLM) emerged as the new player to influence and strengthen laboratory network development in Africa. Today ACILT and ASLM strive together to promote a stronger laboratory workforce. ACILT will continue building a competent workforce who can manage laboratories efficiently and thus improve patient outcomes to combat major infectious diseases in Africa.

POSTER 141

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First Achievements of Strengthening Laboratory Management towards Accreditation (SLMTA) in Angola

Background: The quality improvement and accreditation of public health laboratories is a major concern of Ministry of Health in Angola. To address this issue and to promote immediate and measurable results SLMTA program was implemented, a program developed by CDC, WHO-AFRO and their partners to build laboratory capacity through mentorship. In 2012 the Institute of Public Health of Angola (INSP) was the pioneer to embrace SLMTA, and the present communication intends to resume the preliminary results of the four laboratories that enrolled the program.

Methods: The SLMTA program was implemented following the traditional model of three workshops together with 3 site visits. A mentorship program was provided to support participant labs by qualified mentors working alongside with laboratory teams to develop assigned improvement projects. The program was monitored by audit assessments based in the WHO-AFRO'S Stepwise Laboratory Quality Improvement Toward Accreditation (SLIPTA) checklist.

Results: Following SLMTA implementation, the comparative analysis between the baseline and the latest internal audit assessment revealed a considerable overall improvement in the four INSP laboratories. The major differences were observed in the following sections of SLIPTA checklist: Organisation & Personnel (54 ± 11%), Documents & Records (45 ± 3%), Facilities & Safety (33 ± 8%) and Corrective Action (31 ± 12%). Additionally, important positive achievements were observed in laboratory routine, data collection, turnaround time, sample rejection and sample management.

Conclusion: Gradually SLMTA program led to considerable improvement of laboratory quality management and validates its adoption in public health laboratories in Angola. Nevertheless, to maintain the gains, ensure sustainability and continuous improvement, the program faces several challenges; particularly it requires staff motivation, behavioural changes and continuous support from institutions.

POSTER 142

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Clinical Characteristics of Patients Tested for *Pneumocystis jirovecii* As Part Of Severe Acute Respiratory Infection (SARI) Surveillance at Three Sites in South Africa

Background: *Pneumocystis jirovecii* is a fungal pathogen that causes *Pneumocystis pneumonia* (PCP) in immunocompromised individuals, most notably in those infected with HIV. We describe the clinical characteristics of hospitalised patients with a positive *Pneumocystis* PCR test, recruited during surveillance for severe acute respiratory infections.

Methods: This study forms part of a prospective, hospital-based sentinel surveillance program for patients hospitalised for severe acute respiratory infections (SARI) at three hospital sites in South Africa. Surveillance officers collected clinical patient data, and oral washes, nasopharyngeal swabs and induced sputum samples for etiological testing. Samples were tested by quantitative real-time PCR for *Pneumocystis*. Chi-squared and one-way ANOVA tests were used to compare categorical and continuous variables.

Results: From May 2012 to March 2014, 6385 samples from 3245 cases were tested. Fourteen percent (453/3245) of cases tested positive for *Pneumocystis*. Compared with PCP-negative cases, these patients were more likely to be HIV infected (OR: 1.85; CI95%: 1.47-2.31; $p < 0.0000$), but less likely to be on current treatment for HIV ($p < 0.0013$); were less likely to report a history of fever before hospitalisation ($p < 0.0001$); had lower oxygen saturation levels ($p < 0.0001$), and were more likely to receive oxygen ($p < 0.0005$); be admitted to ICU ($p < 0.0016$), and require mechanical ventilation ($p < 0.0013$). In children < 5 years, a positive PCR result was significantly associated with prematurity ($p < 0.0025$) and a higher respiratory rate ($p = 0.0032$). The case fatality ratio of PCP-positive patients was significantly higher than in those that tested negative ($p < 0.0017$).

Conclusion: The presence of *Pneumocystis* organisms in the respiratory tract of patients has a significant effect on morbidity and mortality of patients, regardless of whether infection with *Pneumocystis* is the primary cause of severe acute respiratory infection, a secondary concurrent infection or merely colonisation.

POSTER 143

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The Role of the Laboratory in Nutrition Surveillance in Zimbabwe

Background: Micronutrient deficiencies are a problem of public health significance globally and they are a significant contributing factor to stunting, poor health and impaired development. According to WHO, deficiencies in iron, vitamin A and zinc each rank among the top 10 leading causes of death in developing countries. Most people affected by micronutrient deficiencies do not show overt clinical symptoms presenting a threat particularly to the health of children under 5 years and pregnant women. Micronutrients are important for immunity, growth, and psychomotor development because they catalyse many processes in the body and are essential components of specific tissues.

Methods: The ZNMS was a cross-sectional survey with a nationally representative sample done through situation description and biochemical analysis. Data was collected on household socio-economic characteristics, anthropometry, and food consumption information. Blood (DBS), urine and household salt samples were collected to ascertain levels of Iodine, C-Reactive Protein, Retinol binding protein, Haemoglobin and Serum Transferrin Receptors.

Results: The laboratory's involvement from survey planning, training, sample collection, handling, Haemoglobin and Iodine field testing, transportation, storage, actual laboratory analysis ensured that overall more than 90% of all the samples collected were of good quality. Through this collaboration the country was able to get reliable population estimates of anaemia and vitamin A, iodine and iron deficiency levels.

Conclusion: The ZNMS was a highly successful example of a collaboration between a specialist health science and the laboratory in Zimbabwe at a National level (beyond disease diagnosis and monitoring). The laboratory was central to the success of the micronutrient survey without which the biochemical results could not have been obtained. To this end, there is need to invest in capacitating laboratories while they should do a needs assessment across the health sector.

POSTER 144

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Working Towards International Certification/ Accreditation: The NEQAL Experience

Background: Located in Saye village, Zaria, Nigeria, the National External Quality Assessment Laboratory (NEQAL) which is the first internationally recognized and Presidential Emergency Plan for AIDS

Relief (PEPFAR) – funded External Quality Assessment (EQA) project in Nigeria currently provides – under the National Proficiency Testing Scheme (N.P.T.S) – HIV serology, CD4, Chemistry, Haematology, GenXpert MTB/RIF panels for proficiency testing for PEPFAR-supported and non- PEPFAR supported laboratories. In addition to constituting a national EQA corrective action team within Nigeria, NEQAL also oversees routine and scheduled post market validation (PMV) exercises for all rapid test kits (RTKs) used in the national algorithm for HIV/AIDS testing and management. Presented in a SWOT Analysis format, this paper examines NEQAL's journey so far and its implications for laboratory services and public health in Nigeria.

Methods: Prior to initial implementation of a functional quality management system (QMS), two staff of NEQAL participated in a 10-day SLMTA training. Improvement projects, training and retraining, involvement of management and all staff were deployed to drive and sustain implementation.

Results: From a base line score of 81.7% (3 Star rating) in July 2012 to a follow up/exit score of 96.2% (5 Star rating) in January 2013, NEQAL has achieved a 3 Star ranking on the SLIPTA Tier of Recognition of Laboratory Quality Management as at January 2014 after being audited with the WHO AFRO SLIPTA Checklist.

Conclusion: NEQAL has recorded significant strides in its journey to international certification/accreditation. As the first national reference centre of excellence for EQA in Nigeria, an international certification for NEQAL will no doubt enhance laboratory management and clinical laboratory interface with a view to further improving patients' outcome.

POSTER 145

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Tuberculosis Infection among Health Care Workers in Two District Hospitals – Kenya, August 2013

Background: Health care workers (HCWs) have an increased risk of *M. tuberculosis* infection and Tuberculosis (TB) disease compared to the general population. In 2011 there were 102,403 TB cases and 9,200 deaths in Kenya. Objectives of our study were to determine the magnitude of TB disease among HCWs in two Kenyan district hospitals.

Methods: Retrospective review of TB laboratory registers was conducted at each facility. Cases were; HCWs with confirmed TB diagnosis working at the two hospitals from 2010 to 2013. HCWs who met case definition were interviewed using structured questionnaire to collect clinical and epidemiologic information. Infection prevention practices were observed and recorded.

Results: Makindu and Kiambu have 91 and 450 HCWs respectively. A total of 6,275 sputum smears were examined and 1122 (18%) were AAFB smear positive. Kiambu and Makindu reported 11 and 5 cases of TB among HCWs respectively. Of

these, 57% were females; mean age was 45 years (range: 42–57 years). HCWs affected were; laboratory technician 4 (16%), nurses 4 (1.4%), occupation therapist 2 (15%), clinical officers 2 (2.5%), and one pharmacist, telephone operator, driver and casual worker. Mean working time lost recuperating was 14 weeks (range: 0-28 weeks). Use of coats and gloves were evident at both facilities whereas high-efficiency particulate air filters were lacking; Kiambu hospital lacked biosafety cabinet; Windows at both facilities were often closed and suspected TB patients shared common crowded outpatient waiting area where sputum was also collected. No standard reporting tool for TB disease among HCWs was in place.

Conclusion: TB disease was distributed across professional cadres, majority were females, with long period of work time lost. Inadequate infection prevention measures expose HCWs to occupational risk of acquiring TB disease. A standard reporting tool for TB disease among HCWs should be put in place.

POSTER 146

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Mentoring Laboratory Personnel in Viral Load and CD4 Testing in Botswana: Successes and Challenges

Background: CD4 and viral load testing is paramount to the success of any antiretroviral therapy program. When the Botswana government launched the National program to enroll HIV positive patients on HAART, CD4 and viral load were only done at the Botswana-Harvard HIV Referral laboratory (BHHRL). The BHP Laboratory Master Trainer mentorship program was therefore set-up to support the government goal of increasing the number of laboratories capable of performing ART related tests so as to relieve the burden and time delays at BHHRL.

Methods: A team of experienced laboratory scientists was formed under the guidance of a coordinator. Centralized and on site trainings were conducted for labs earmarked for decentralization of testing. The centralized trainings were 2 weeks long and included lectures, practical demonstrations and a quiz. On site trainings and 1-2 week mentoring visits were done to provide labs with hands-on assistance. The mentoring visits also served to strengthen the quality systems of the labs.

Results: The number of labs performing CD4 and viral load testing increased from 1 in 2002 to 32 in 2013. Over 300 lab staff have been trained since 2004.

Conclusion: We highlight the success of the program in terms of the increase in the number of CD4 and viral load testing laboratories, number of people trained to do the tests, participation in EQA and performance in the same. The challenges of the LMT program in the achievement of the goal of building capacity in government facilities and other operation related problems are also highlighted.

POSTER 147

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Phased Approach for Laboratory Information System Implementation and Expansion in Ethiopia

Background: The laboratory information system (LIS) is a class of software that receives processes, and stores information generated by medical laboratory processes. LIS is a highly configurable application which is customized to facilitate a wide variety of laboratory workflow models. **OBJECTIVES-** To establish and strengthen electronic laboratory information system in phased approach in different regions of Ethiopia.

Methods: Ethiopian Public Health Institute conducts base line assessment by structured comprehensive questioner to pilot the first LIS implementation. Sites were selected based on their patient load, availability of functional information technology unit, Good infrastructure, and availability of enough laboratory analyzers to interface with the LIS and Management and staff commitment to implement LIS. A plan was developed to implement an expansion until 2014 in four phases. First phase (2007/2008): piloting LIS expansion at four facilities including EPHI laboratories, Second phase (2010/2011): Implementation deployed at six facilities, third phase (2012) implementation at five facilities and fourth phase (2013) implementation is deployed at four facilities.

Results: Laboratory information system is implemented at nineteen facilities till September 2013 in Ethiopia. Among these facilities 17 are working successfully with the soft ware, the remaining two facilities implement the system but stop due to renovation. LIS brings dramatic change to data management, turnaround time reduction, better sample management, quick and easy access of patient data, reduce occurrence of errors anywhere in the process flow.

Conclusion: Polytech LIS is a complete full-featured Laboratory Information System which can interface to all of the analyzers commonly found in a modern clinical laboratory. LIS enhances the quality and efficiency of health care professionals, allowing them to deliver high quality, cost-effective service in all facilities. Therefore, expansion of LIS at regional and sub-regional levels will be important to improve laboratory data quality.

POSTER 148

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Détermination du Taux Normal des Lymphocytes TCD4+ chez le Sujet Sain Séronégatif au VIH par une Méthode de Cytométrie en Flux à Cotonou, République du Bénin

Background: Contribuer à une meilleure prise en charge médicale des personnes vivant avec le VIH par la détermination d'un intervalle de référence des taux de lymphocytes T CD4 chez l'adulte sain séronégatif au VIH à Cotonou.

Methods: Etude transversale sur un échantillon volontaire de donneurs de sang du 11 mai au 03 juillet 2009 au Service Départemental de Transfusion Sanguine de Cotonou. En plus des taux de TCD4, nous avons recueilli les caractéristiques sociodémographiques, les résultats de sérologies VIH, hépatites B et C, syphilis et hémogramme. Les numérations des TCD4 ont été faites à l'aide d'un cytomètre en flux CYFLOW SL_3 (PARTEC). Un test de comparaison a été fait selon l'âge et le sexe. L'autorisation du comité national d'éthique a été accordée.

Results: L'intervalle du taux de CD4 est de [299-1586] cellules/μL de sang. Le taux médian est de 699 cellules/μL de sang. Il est significativement plus élevé chez les femmes que chez les hommes : 772 contre 658 cellules/μL (P=0,004). 16 % des sujets ont un taux de TCD4 inférieur à 500 cellules/μL de sang. Il n'y a pas de variation selon l'âge. Il y a par ailleurs une corrélation positive entre le taux de CD4 et le nombre de globules blancs et le taux d'hémoglobine.

Conclusion: Le taux normal de lymphocytes T CD4 est abaissé chez environ 2 donneurs de sang sur 10 séronégatifs au VIH à Cotonou. Ces résultats devront être renforcés par une étude multicentrique au Bénin.

POSTER 149

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The Prevalence of HIV-Associated Nephropathy in pre HAART patients at The University Teaching Hospital (UTH) Lusaka, Zambia

Background: HIV-Associated Nephropathy (HIVAN) also known as HIV related renal disease is the most common classical form of kidney disease found in some HIV infected patients at all stages of the infection in different age groups. HIVAN is associated with a higher mortality rate especially in adults where it tends to progress rapidly to end stage renal disease (ESRD). The Dialysis Unit at

the University Teaching Hospital (UTH) in Zambia has also been increasingly managing HIV patients on dialysis machines with HIV as the underlying cause of the nephropathy. The present study aimed at determining the prevalence of Human immunodeficiency Virus Associated Nephropathy in HIV pre HAART patients at the UTH, Zambia.

Methods: Pre HAART HIV patients seen at the UTH were recruited for the study. Urine and blood samples were collected to determine the levels of albumin and serum creatinine using Combina 13 microalbumin sensitive strips and ABX Pentra 400 automated Chemistry analyzer respectively.

Results: Out of 200 patients included in the study, 104 (52%) females and 96 (48%) males. The mean age of this population was 36.6 (range, 18-64) years. A total of 50 (25%) patients had renal abnormalities. Of these, 36 (18%) presented with microalbuminuria only, 2 (1%) had elevated serum creatinine levels only and 12 (6%) had both. While there was no significant sex difference among patients with microalbuminuria, males were 4 times more likely to have elevated serum creatinine than their female counterparts (Odds ratio= 4.35, 95% CI: 1.17-16.12).

Conclusion: The prevalence of HIVAN based on hypercreatininaemia and microalbuminuria was high at the University Teaching Hospital in Zambia. Early screening for kidney diseases in HIV- positive patients followed by early initiation of antiretroviral therapy and other drugs when immune function is still preserved may possibly prevent progression of renal disease.

POSTER 150

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Rubella Disease Trends in Kenya, January–November, 2012

Background: WHO estimated that 1.4 million deaths among children <5 years were due to diseases that could have been prevented by routine vaccination. Rubella is usually a mild illness but when it occurs in a pregnant woman it can lead to congenital rubella syndrome (CRS) causing anomalies in the developing fetus. The birth defects associated with CRS include heart disease, blindness, deafness and mental retardation. The Global Measles and Rubella Strategic Plan (2012–2020) includes milestones to eliminate rubella and CRS in two WHO regions by 2015, and eliminate rubella in five WHO regions by 2020. In Kenya, the Rubella containing vaccine (RCV) has not been introduced into the immunization schedule hence outbreaks of rubella continue to occur. We analyzed case based data from the integrated disease surveillance and response system with the aim of describing trends of Rubella in Kenya.

Methods: We conducted a retrospective records review of nationwide case- based surveillance data from January to November 2012. Information on clinically diagnosed and subsequent laboratory-confirmed rubella cases was analyzed to determine rubella disease trends.

Results: From January to November, 2012, a total of 1996 suspected cases of rubella were reported nationally through the

rubella surveillance system in Kenya. Of these cases, 296 (14.8%) were laboratory confirmed. Slightly over half (52.6%) of the rubella cases reported, occurred among males. During the surveillance period analyzed there were two peaks of rubella cases, in July (18%) and October (22%). Geographically, twenty percent of the cases were reported in the central province with only 3% of cases from the north eastern province. All the cases had no history of vaccination with RCV.

Conclusion: Rubella cases in Kenya are many and thus the country would benefit from the introduction of the RCVs into the national immunization schedule. Additional effort is required to strengthen the rubella surveillance system to capture information on pregnancy status of reported cases and to detect cases of congenital rubella syndrome.

POSTER 151

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New Paradigms in Building Framework to Ensure Sustainable Implementation of Laboratory Technologies and Programs in Resource-Limited Countries: The Mozambique Experience

Background: Limited resource countries are heavily dependent on external funding to implement public health and medical care programs. Most of these external investments have a limited period of implementation, after which the recipient country struggles to ensure continuity. Building sustainability has become the state of the art in these settings. However, there is a need for a well-structured model to ensure sustainable delivery of health services after its implementation. This abstract describes a model developed and implemented in Mozambique to ensure continuity of service delivery after the external funding ends.

Methods: The foundation of this model is to utilize externally-funded projects as an opportunity to build program frameworks within the MoH by through experimental “sustainability projects”. The framework was developed by MoH-Mozambique based on the principles of i) country ownership, ii) country leadership and iii) country accountability in the implementation of any externally funded laboratory program. Program frameworks were piloted in the implementation of the Strengthening Laboratory Management Towards Accreditation (SLMTA) and Rollout of the PIMATM Point of Care CD4 testing (PIMA) in Mozambique.

Results: Provincial teams for PIMA and regional teams for SLMTA rollout were established and trained based on existing structure for the management of laboratory systems at provincial and regional level. The program frameworks were replicated in all provinces or regions. Although funding was provided through international partners, we observed strong provincial and regional ownership, leadership and accountability in all provinces or regions rolling out PIMA and SMLTA respectively. This has resulted in reduced need of national central government support, and increased regional and provincial commitment and ownership.

Conclusion: Our findings suggest that the frameworks in use for rollout of PIMA and SLMTA in Mozambique might represent successful models for sustainable implementation of new laboratory technologies and programs in resource-limited settings by increasing local ownership and accountability.

POSTER 152

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The WANETAM-TB Network Impact in the Surveillance of Tuberculosis Infection in Senegal

Background: The great challenge of tuberculosis control through the world remains the availability of a rapid, reliable, sensitive and specific diagnostic tools for developing countries – especially for patients living with HIV.

Methods: This study aimed to evaluate the impact of the WANETAM-TB Network on the surveillance of tuberculosis cases in Dakar and to assess the performance of GeneXpert versus the standard methods in diagnosing TB. During this study sputum, gastric lavage, body fluids, pus and urine were collected from external and hospitalized patients in various clinical services of Aristide Le Dantec University Teaching Hospital. The major part of patients were new cases with some who were in treatment or relapse. Microscopy, liquid culture and solid medium were conducted on all collected samples. A systematic susceptibility testing was performed on all isolates using the MGIT method and GeneXpert test were performed on request.

Results: Data suggested an increase of the number of patients recruited since 2010 and the availability of the sensitivity test of TB strains compared to 2009 which provided data on resistant strains. MDR cases increased over the year from 6.1% to 8.3%, respectively, in 2010 and 2012. The GeneXpert detected six additional TB cases among patients infected with HIV who were not detected by standard methods.

Conclusion: Laboratory Capacity building provided by WANETAM Network have significantly improved the performance of TB diagnosis and detection of MDR cases in Senegal. The HIV infection reduces the sensitivity of smear and increases the need for early diagnosis and treatment, while the new method, innovative and easy to use, allows to increase the detection rate of Mycobacterium tuberculosis.

POSTER 153

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From Grass to Grace: How SLMTA Revolutionized the Bamenda Regional Hospital Laboratory in Cameroon

Background: Public health laboratories form the foundation on which today's clinical laboratory practice in Cameroon is built. With greater focus on clinical laboratories in Cameroon and increased

competition between public and private laboratories, the delivery of high-quality healthcare services is both necessary and attainable. The advent of the Strengthening Laboratory Management Toward Accreditation (SLMTA) programme in 2009 empowered the Bamenda Regional Hospital Laboratory (BRHL) to improve its working culture, practices and management. This laboratory transformed its services while evolving from grass to grace.

Methods: The US Centers for Disease Control and Prevention (CDC), in collaboration with Global Health Systems Solutions (GHSS), implemented the SLMTA programme to improve laboratory quality management systems in 5 laboratories, including BRHL. Three workshops were conducted (the first centralized, the remaining two on-site at BRHL), and improvement projects were implemented after each workshop with the assistance of mentors. The World Health Organization Regional Office for Africa (WHO/AFRO) Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) checklist was used to evaluate their performance and identify areas for improvement.

Results: BRHL had the lowest score among the cohort at baseline audit, and the highest at exit audit. Its score increased from 18% in 2009 to 85% in 2012, and 81% at the official African Society for Laboratory Medicine SLIPTA audit in 2013. Staff investment and pride in the quality of laboratory services drastically improved.

Conclusion: BRHL's substantial improvement over the 18-month implementation period was achieved with a combination of SLMTA training activities, intensive on-site mentorship, and collective focus of all laboratory staff. The experience at Bamenda Hospital illustrates what can be achieved when a laboratory successfully harnesses the energy of its staff and implements changes to improve the quality of services in a transformation taking them from grass to grace.

POSTER 154

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Laboratory Based Surveillance for Bacterial Meningitis in Selected Health Facilities of Nairobi County, Kenya, March 2014

Background: Acute bacterial meningitis is an important cause of morbidity and mortality in many sub-Saharan African countries. Microscopic examination of cerebrospinal fluid using Gram stain and subsequent culture form the gold standard of diagnosis. We set out to assess the practice of laboratory confirmation for bacterial meningitis in selected health facilities of Nairobi County, Kenya.

Methods: We conducted a retrospective review of inpatient registers and patient files for cases with a confirmed or suspected diagnosis of bacterial meningitis seen in 6 major health facilities of Nairobi County, Kenya between 1st December 2013 and 5th March 2014. Socio-demographic, clinical and laboratory data were extracted from the case file using a standard extraction tool. We performed descriptive data analysis using Epi-info version 3.5.1 and Microsoft Excel.

Results: We retrieved 154(59%) files out of the 262 suspected meningitis cases seen in the 6 health facilities. Eighty two (53%) had bacterial meningitis as the final diagnosis. Majority were male 44(54%) with a median age of 6 years (range 1 month-61 years). Seventeen (21%) cases had HIV co-infection. Forty nine (60%) had a lumbar puncture done with 23 (47%) and 14(29%) having had a Gram stain and culture done respectively. Only two specimens demonstrated presence of bacteria on Gram stain while none of the cultures showed any growth. Eleven (22%) of the lumbar punctures were done on the day of admission while 15/34 were done >24 hours after treatment initiation.

Conclusion: Though laboratory confirmation is an important aspect of infectious disease management and surveillance, its application in the diagnosis and treatment of bacterial meningitis is still weak in the surveyed health facilities. There is need to strengthen the health system to enhance prompt specimen collection and processing of laboratory results to improve the clinical management of bacterial meningitis.

POSTER 155

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Improving the Quality of Laboratory Systems Through Strengthening Laboratory Management towards Accreditation (SLMTA) in Rwanda

Background: Efficient and reliable laboratory services and networks are essential for well-functioning health systems. In 2009, to improve the performance of laboratories and strengthen health care systems, the World Health Organization Regional Office for Africa (WHO-AFRO) and partners launched two initiatives: a laboratory quality improvement programme called Strengthening Laboratory Management Toward Accreditation (SLMTA), and what is now called the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) to help laboratories achieve ISO 15189 standards. This study describes the achievements of Rwandan laboratories in the implementation of the SLMTA programme four years following its introduction, using the SLIPTA scoring system to measure laboratory progress.

Methods: Three cohorts of five laboratories each were enrolled in the SLMTA programme in 2010, 2011, and 2013. The cohorts used SLMTA workshops, mentorship and quarterly performance-based financing incentives to accelerate laboratory quality improvement efforts. Baseline, exit and follow-up audits were conducted over a two-year period from the time of enrolment. Audit scores were used to categorize laboratory quality on a scale of 0 (<55%) to 5 (95 %+) stars.

Results: At baseline audit, 14 of the 15 laboratories received zero stars with the remaining laboratory receiving a two-star rating. At exit audit, after three SLMTA workshops and improvement projects,

five laboratories received a one-star rating, six received two stars and four received three stars. At the follow-up audit conducted in the first two cohorts, approximately two years after baseline, one laboratory scored two stars, five laboratories earned three stars and four laboratories, including the National Reference Laboratory, achieved four stars.

Conclusion: Rwandan laboratories enrolled in SLMTA showed improvement in performance. Sustaining the gains and further expansion of the SLMTA program to meet country targets will require further program strengthening.

POSTER 156

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Invalid Assessment Cases in the PCR Results Quality of the Virology – Bacteriology Laboratory of the National Institute of Public Health Research (INRSP) in Mali from 2009 to 2013: Challenges and Prospects

Background: Sectoral Cell of Fight against AIDS of National Health and Public Hygiene (CSLS/MSHG-Mali) in collaboration with INRSP through the financial support of several partners helped organize periodic supervisory training to improve the quality of early infant diagnosis. Despite efforts, we find a large number of invalid cases affecting the quality of PCR results. The Dried Blood Spot (DBS) should be evaluated through the quality of results. Our goal is to evaluate the rate of invalid results on the quality of qualitative PCR.

Methods: We conducted from January 2009 to December 2013 a cross-sectional study of 6067 PCR evaluative referred from health centers in references for 4 regions (Kayes, Koulikoro, Sikasso, Segou) and the District of Bamako. The majority of these were technical DBS from kits AMPLICOR HIV- 1 DNA test version 1.5 at the national reference laboratory in Bamako according to the extraction protocol. Molecular diagnosis was performed with the same algorithm as kits three identical PCR. Almost all cases have been disabled by a second test in order to improve the quality of PCR results.

Results: Totally 6067 PCR was performed with 554 HIV-1 positive of 9.13% of positive cases and 153 invalid or 2.52% degree of disability. According to the protocol used, 71.90% of disabilities were due to a problem of amplification and 28.10% were due to the proximity of positive wells. These disabilities can be explained by the quality of DBS crafted, the ELISA technique and conservation of DBS.

Conclusion: PCR remains a safe way in the Early Infant Diagnosis of HIV -1 infection in children born to HIV positive mothers. However, regular monitoring of monitoring sampling sites, the use of new, more efficient platforms can improve the quality of the results of Early Infant Diagnosis.

POSTER 157**Chinonyelum Okolo**, Anselem Akabueze, Joy Nzei

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Late Presentation of Pediatric Patients to Clinics: A Major Barrier to Uptake of Laboratory Services in Nigeria

Background: In Nigeria, pediatric patients present to health clinics at critical states that leave clinicians with no other choice but to blindly prescribe drugs without proper diagnostic investigations. This study aims at determining effect of late-presentation of pediatric malaria cases on uptake of laboratory services in an urban clinic.

Methods: We reviewed medical record content of 56 pediatric patients presenting at University of Nigeria Medical Clinic from January to March, 2014. Patient records were taken during clinic days at the outpatient department of the clinic. Malaria parasite test showing 3+++ and Packed Cell Volume (PCV) below 39% for pediatric patients were used as a basis for sampling. The following inclusion criteria were used: age bracket of 1-12years, late presentation, very weak with severe fever, malaria test result of 3+++ and PCV below 39% while exclusion criteria included adults, early presenters and patients presenting symptoms not related to malaria. The following were the main instruments used: structured questionnaires, medical records and Micro-haematocrit centrifuge.

Results: All pediatric patients admitted to the clinic during the period under review did not use laboratory services until they had completed their first line of anti-malaria treatment. 55% of these patients had a PCV reading of 39% while 45% had a PCV reading of 38%. In addition, 45% of these patients presented to the clinic on a weekend when the only available laboratory scientist was off duty.

Conclusion: Late presentation of pediatric patients with severe malaria symptoms to clinics often results in commencement of anti-malaria treatment without prior diagnostic investigations. There is an urgent need to remove barriers to uptake of laboratory services and enlighten care givers on the need to promptly bring their children to the clinic for laboratory investigation and malaria treatment in order to reduce mortality due to malaria.

POSTER 158**NNkiru Nwokoye**¹, Catherine Onubogu¹, Peter Nwadike², Abigail Abiodun¹, Toyosi Raheem¹, Uche Igbaesi¹, Oni Idigbe¹¹ National TB Reference Laboratory, Microbiology Division, Nigerian Institute of Medical Research, Lagos, Nigeria, ² KNCV/TB CARE1 Project, Abuja, Nigeria**Performance of GeneXpert MTB/RIF Assay Over Smear Microscopy in the Diagnosis of Tuberculosis in Both HIV-Positive and Negative Patients**

Background: A recently endorsed GeneXpert (Xpert) MTB/RIF assay has the capacity to simultaneously detect Mycobacterium tuberculosis (MTB) as well as rifampicin resistance directly from

sputum and provide result within 2 hours. With the successful implementation of Xpert technology in some of the health institutions in Nigeria, it is important to assess the performance of the new diagnostic tool over the existing smear microscopy which is the cornerstone for TB diagnosis in Nigeria. Objective: To evaluate the performance of Xpert over smear microscopy in the diagnosis of tuberculosis in both HIV-positive and negative patients.

Methods: Sputum samples were collected from patients presenting with signs and symptoms of tuberculosis. Smears were made directly from the specimens and stained using Ziehl Neelson (ZN) staining technique. The remaining portion of the sputum sample was processed as per protocol for Xpert assay.

Results: A total of 391 tests with valid Xpert results were used for analysis. Seventy-two (18.4%) samples were positive by smear microscopy while 91 (23.3%) were positive by Xpert. Xpert positive-smear negative were 26 (28.6%) while smear positive-Xpert negative were 7 (2.3%). Xpert positive-smear negative cases among the HIV negative and positive cases were 11 (22.5%) and 15 (37.5%) respectively. While smear positive-Xpert negative cases among HIV negative and positive patients were 3 (3.1%) and 4 (2.1%) respectively.

Conclusion: From our findings, Xpert demonstrated higher sensitivity over smear microscopy especially in HIV- positive patients. Employing xpert for the diagnosis of tuberculosis in HIV co-infected patients may lead to early detection of tuberculosis among this group. Thus, we strongly recommend the use of Xpert as a screening tool for tuberculosis in high HIV prevalent settings.

POSTER 159**Esther de Gourville**¹, Fales Z. Mwamba, Kunda G. Musonda², Katoba K. Musukwa², Mutinta Shisholeka-Yumbe³, Mwaka A. Monze², Clement B. Ndongmo¹¹ Centers for Disease Control and Prevention Country Office, Lusaka, Zambia, ² University Teaching Hospital, Lusaka, Zambia, ³ Ministry of Health, Lusaka, Zambia**The HIV Rapid Test Proficiency Test Programme in Zambia: Successes, Limitations and Challenges**

Background: There are 1,993 Human Immunodeficiency Virus Counseling and Testing (HCT) sites in Zambia and only HIV rapid tests (RTs) are used in the recommended test algorithm. A Proficiency Test (PT) Programme was launched in 2009 to document sites' performance.

Methods: The PT programme is coordinated by the University Teaching Hospital (UTH). Dry Tube Specimens are prepared by adding blue dye to diluted commercially procured samples which are aliquoted and dried overnight at room temperature. PT panels plus sample reconstitution instructions and a reporting form are distributed to sites and recipients are given one month to respond. Data are entered and analyzed in an electronic data base. PT scores (expressed as percentage of total samples with results agreeing with the PT provider's) are sent to sites and summary reports shared with stakeholders. Follow up is made with poorly performing sites.

Results: PT panels were distributed in years 2009, 2010, 2011 and 2013 to 550, 600, 600 and 641 sites, respectively. Response rates were 53%, 72% and 85% and 67%, consecutively from 2009 to 2013. A 100% score was achieved by 79%, 82%, 87% and 87% of respondents consecutively between 2009 and 2013. Sites scoring less than 100% generally failed to provide or interpret results for all samples. Summary reports were usually available more than six months after PT distribution. For follow up, phone calls and/or site visits were used in 2009, but only phone calls from 2010 onwards.

Conclusion: A high PT response rate and accuracy of testing were demonstrated. Limitations were: reaching only 30% of all HCT sites; possibility that results were not representative of routine site performance; introduction of a sample reconstitution step that is not normally required; and insufficient follow-up with low scoring sites. Challenges were complicated panel delivery logistics and inadequacies in resources and data management.

POSTER 160

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Development of the 1st Kenya Essential Medical Laboratory Commodities List (KEMLCL)

Background: Access to health products and technologies, including test kits and laboratory supplies, remain a major challenge in health care delivery. An essential product list is a powerful benefits management tool in addressing it. Key considerations in product selection for the list are relevance for public health, evidence of cost effectiveness, efficacy and safety, quality of available products and stability in storage. It positively impacts all aspects and players in a supply chain. For policy makers, enhanced efficiencies in resources use, opportunities to assess the quality of care and focused training. For the supply system, streamlined functions, guided procurement and better managed storage and distribution. For providers, expert consensus during selection, stabilization of demand and a basis for monitoring and supervision. For receivers, there's consistent availability and use of the most reliable investigations/diagnostics

Methods: A Selection Committee was appointed by the MOH to develop the KEMLCL. It had representation from laboratory staff in clinical settings at all levels of care across the country. Representatives from national reference laboratories, teaching and research institutions provided critical technical expertise. This experience and expertise was invaluable given limitations in the regulatory function and quality assurance for laboratories in Kenya. The National Clinical Management and Referral Guidelines (Volumes I – III) was the bases for identifying the essentials tests. For Draft 1, the Committee extracted the tests, and identified the techniques and reagents required. In 3 subsequent workshops, a small team refined the List and included reagent specifications. Draft 2 was circulated to the laboratory fraternity for inputs. A final review workshop captured the feedback and completed the KEMLCL.

Results: The KEMLCL 2014 has 216 reagents plus some consumables and minor equipment. It has been used in forecasting and quantification in some counties.

Conclusion: When fully implemented, the KEMLCL may lead to improved management of commodities and enhanced access to laboratory services.

POSTER 161

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EQA Programme for AFB Slides Improves Laboratory Presumptive Diagnosis of TB in Regions of Zambia

Background: Manual preparation, staining and microscopic reading of sputum smears remains the primary diagnostic laboratory procedure for detecting Acid Fast Bacilli (AFB) and making a presumptive tuberculosis (TB) diagnosis in Zambia. Most facilities are not equipped to perform TB culture and Gen Xpert analyses are limited to patients who are Human Immunodeficiency Virus (HIV) positive. Since 2008, the Tropical Diseases Research Centre (TDRC) became one of three TB reference laboratories in Zambia, with oversight for one geographical region in a national External Quality Assurance programme for AFB detection.

Methods: Five hospital laboratories were enrolled in a regional EQA program administered through TDRC in collaboration with the US Centers for Disease Control and Prevention Country Office in Lusaka, Zambia. Laboratories stain sputum smears, perform routine microscopic examinations and record their results. Up to 25 slides per site are "blinded" and re-read by TDRC personnel during quarterly on-site visits. Slides are scored for smear size, thickness, stain quality, cleanliness and evenness. Detected AFBs on positive slides are scored as actual number, or 1+, 2+ or 3+. Discrepancies between site and TDRC results are adjudicated by a second reader from TDRC.

Results: In the first year of the program (2008) the total number of slide reading errors observed for all sites was 36. This number improved dramatically by 2009 and continued to decrease to 0 by 2012. Slide preparation errors were less responsive to the implementation of the EQA programme. The average percentage of slides with errors remained between 50% and 32% across the 5 sites during the first 4 years of the program.

Conclusion: Implementation of the EQA program for AFB detection resulted in an immediate and sustained improvement in slide reading at all sites, while slide preparation errors persisted at most sites. Slide preparation training should be prioritized, as needed, during on-site visits.

POSTER 162**Zelalem Teklemariam Kidanemariam**

Department of Medical Laboratory

Infectious Disease Diagnostic

Background: Intestinal parasitic infection affects the health and quality of life of people living with HIV. This study was aimed to determine the prevalence of intestinal parasites among HIV positive individuals who are naive and who are on antiretroviral treatment (ART) in Hiwot Fana Specialized University Hospital, Eastern Ethiopia.

Methods: A comparative cross-sectional study was conducted on 371 (112 ART-naive group and 259 on ART) HIV positive individuals. Stool specimens were collected and examined by direct wet mount, formol ether concentration technique, and modified ziehl-Neelsen methods.

Results: The overall prevalence of intestinal parasitic infections was 33.7%; it was significantly higher among the study participants who were ART naive group (45.5%) (AOR: 2.60(1.56, 4.34)) and diarrheic (53.3%) (AOR: 2.30(1.34, 3.96)) and with CD4 count ≤ 200 cells/

POSTER 163**Angela Amayo**¹, John Mwhia², Benard Muture³, Jedida Wachira¹, Matilu Mwau⁴, Judy Mwangi¹

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Laboratory-Clinical Interface: Safe Phlebotomy Training Program Promotes a Shared Customer Service Culture in Public Hospitals in Kenya

Background: Reports have shown that most laboratory errors occur in the pre-analytic and post-analytic phases of the laboratory testing process. These extra-analytic phases are also referred to as the clinical-laboratory-interphase (CLI). Inadequate training has been cited as an important cause of pre-analytical errors. Management Sciences for Health-SPHLS funded by the U.S. Centers for Disease Control and Prevention (CDC) under the President's Emergency Plan for AIDS Relief (PEPFAR) has been supporting health facilities to improve phlebotomy practices in Kenya.

Methods: A strategic training model was adopted in Kenya where two (2) laboratory technologists and one (1) clinician per facility form a team in the training of the trainer's (TOT's) course. The TOTs subsequently transferred the safe phlebotomy knowledge and skills to their colleagues at the facility level, and played critical roles in monitoring the implementation of the safer practices in both laboratory and the clinical areas. Measures to support specimen rejection were undertaken, including provision of specimen rejection stamps.

Results: Clinicians comprised of 29% (n=60) of the TOTs trained; and formed part of the team that has successfully provided safe phlebotomy training to over 6000 healthcare workers (HCWs) in Kenya. In the County Referral Hospitals visited, there was availability and proper use of the specimen rejection stamps. These facilities recorded on average a monthly rejection rate of 20 samples (range=1-80). Following the training, the average rate dropped to 8 (range=0-34) samples. Communication between the clinicians and the laboratory improved, with laboratory staff citing increased courtesy calls from clinicians.

Conclusion: Other than improving the quality of samples collected, the safe phlebotomy trainings have resulted in improved relationships between the clinicians and the laboratorians in order to accomplish the best of patient care. This relationship remains a critical element of achieving the ultimate goal of Quality Health Care for all.

POSTER 164**Rafael Joaquim**¹, Rau Vaz¹, Dinis Jaintital², Oscar Fraile², Susana Oguntoye², Tomás Zimba¹

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Identification of Candida spp, Cryptococcus spp and Susceptibility Pattern of Candida spp. Isolates from Patients Admitted at the Central Hospital of Maputo, Mozambique

Background: The Candida species have been implicated in superficial and systemic mycoses, and Cryptococcus species is involved in meningitis and meningoencephalitis, mostly in immunocompromised patients. Data on fungal infections in Mozambique in general are scarce, which limits define appropriate strategies for control and prevention. This study was conducted to give a snapshot view on Candida spp. and Cryptococcus spp. in urban hospital of Mozambique.

Methods: The isolates of Candida spp. and Cryptococcus spp. previously isolated from various clinical specimens in the Laboratory of Microbiology were identified and the susceptibility of Candida spp. to antifungal agents was determined using the VITEK2[®] system.

Results: All 35 isolates of Candida spp. analyzed, was identified Candida albicans (74%), C. lusitanae and C. glabrata isolates each with (6%), C. parapsilosis, C. tropicalis, C. magnoliae, C. norvegenesis and C. famata (3%). All C. albicans, C. parapsilosis and C. norvegenesis were susceptible to fluconazole and amphotericin B. The two C. lusitanae strains, one was susceptible to fluconazole and amphotericin B and another was moderately resistant to fluconazole and amphotericin B. One C. glabrata was susceptible to fluconazole and amphotericin B, another intermediate to fluconazole and susceptible to amphotericin B. C. tropicalis, and C. magnoliae C. famata were not tested to antifungal. All 21 Cryptococcus spp. was identified as C. neoformans (85.7%), C. laurentii (9.5%) and C. albidus (4.8%). All Cryptococcus spp. were not tested to antifungal.

Conclusion: This is a pioneering study, being the first time that identifies yeast to the species level in the hospital and determines their susceptibility. There was a great diversity of *Candida* spp and *Cryptococcus* spp., variety patterns of susceptibility to antifungal agents for *Candida* spp. There is a need to implement a routine basis to identify to species level and susceptibility testing for yeast in clinical laboratories of the National Health System in Mozambique, monitoring and prevention of the emergence of resistant strains.

POSTER 165

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HIV Rapid Testing Policies and Practices in the Caribbean Region: Interventions, Outcomes, Challenges and Recommendations

Background: As of 2008, HIV rapid testing (RT) was being used only minimally in the Caribbean region; as such, a small percentage of people knew their HIV status.

Methods: Since 2008, regional efforts by governments and international partners have helped countries strengthen laboratory services and systems. A key component of these interventions has been ensuring that appropriate policies and processes are implemented to scale up HIV rapid testing. A survey was conducted among 12 countries in the region to 1) provide a situational analysis of HIV rapid testing in selected Caribbean countries and 2) identify strategies and make recommendations for expanding access to and coverage of high quality HIV RT in community- and facility-based settings.

Results: Of the twelve countries surveyed, 75% (9/12) have policies in place on HIV RT. Policies in only 42% (5/12) of these countries allow non-laboratory health professionals and counselors to perform HIV RT. All of the countries currently have a national HIV testing algorithm and are using HIV RT at least at the central or national reference laboratory. Serial and parallel testing strategies are used by 17% (2/12) and 83% (10/12) of the countries, respectively. All 12 countries have standardized logbooks and in-country capacity for dried tube specimen (DTS) based proficiency testing (PT) programs, but only 67% (8/12) are using standardized logbooks and have rolled out a DTS-based-PT program. Twenty-five percent (3/12) of the countries are currently using oral fluid HIV RT during surveys, surveillance, and special studies among key populations

Conclusion: Since 2008, there have been improvements in access to HIV RT in some countries in the region. However, more effort is needed to address issues around implementation of existing policies, quality of testing and testing strategies, and integration of HIV RT into HTC service settings.

POSTER 166

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Comparison of Four Commercial HIV-1 Viral Load Detection Technologies

Background: HIV Viral load testing is an important tool used to monitor therapy success or failure. Multiple high throughput platforms that are automated/semi-automated are available for expanded treatment programmes in South Africa where monitoring of viral loads is a key component. Four technologies were compared to determine their efficiency and suitability in high throughput laboratories when determining HIV-1 viral loads: Roche CAP/CTM, Abbott m2000, Nuclisens HIV-1 QT and Siemens kPCR.

Methods: Four platforms that were compared viz., COBAS AmpliPrep/COBAS[®] TaqMan, Abbott m2000, Siemens kPCR HIV and Nuclisens HIV-1 QT HIV-1 QT. Five parameters were assessed namely reproducibility, accuracy, contamination, lower limit of detection and sensitivity.

Results: Reproducibility Abbott m2000 had on average the highest reproducibility followed by Roche CAP/CTM. Accuracy – as determined by the deviation from the expected concentration – would be in sequence of most to least accurate – Roche CAP/CTM, Nuclisens HIV-1 QT, Abbott m2000 and Siemens kPCR. Sensitivity – the lowest limit of detection was obtained by the Roche CAP/CTM at 120 copies/ml followed by Abbott m2000 at 300 copies/ml. The only contamination observed was for the Nuclisens HIV-1 QT with one negative sample showing a copy number of 310. There were though one and three failed samples for the Siemens kPCR and Abbott m2000 technologies respectively. Roche CAP/CTM was used as the Golden Standard to which the other three technologies were compared using Bland Altman Difference Plots.

Conclusion: All four technologies can be used in high throughput laboratories with minor adjustments to improve functionality. For the Nuclisens HIV-1 QT HIV-1 QT there should be extra procedures in place to ensure the prevention of contamination and for the Siemens kPCR and Abbott m2000 technologies failed sample rate need to be monitored to ensure that productivity is not affected.

POSTER 167

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Ensuring Continuous Access to HIV Laboratory Services by Routine Monitoring of Stock Status to Attain National Commodity Security

Background: The Ministry of Health (MoH) relies on strategic information for appropriate evidence based decisions for Commodity security. The MoH has been spearheading efforts to ensure quality and timely data collection for analysis that is later shared with key stakeholders for decision making. There have been challenges in data quality and timeliness of these reports for the upstream transmission and use. This also involves ensuring data is used for decision making.

Methods: The Ministry of Health, through National AIDS & STI Control Program in collaboration with Health Commodities and Services Management (MSH-HCSM) program and other partners collect and analyze consumption and stock data for generation of reports on the stock status of HIV laboratory commodities in the country. Commodities that are monitored routinely include Rapid HIV Test kits, and reagents for blood safety, CD4, viral load and early infant diagnosis. At facility level, data is collected using registers and submitted monthly to central level using the facility commodity data reporting and request (F-CDRR) form. Additional upstream data is collected, including stocks available at Kenya Medical Supplies Agency (KEMSA), stocks pending with suppliers and other donor agencies, among others, as may be applicable. All these data is analyzed using automated templates to provide summary figures that demonstrate stock-out risks within the pipeline. A summary report is generated on a monthly basis and shared with key stakeholders that cover the stock status of stocks at facility and national level and those pending with suppliers.

Results: Stock status for HIV laboratory commodities has been demonstrated in form of Months-of-stock. The stock levels are usually highlighted at the levels of facility, central and those pending with suppliers. This simplified way clearly summarizes the stock-out risks for the country and highlights key interventions required to mitigate national stock-outs. During the last one year, the stock status report revealed incidences of low stock status that led to procurement of some of the blood safety reagents, Determine test kits and paediatric CD4% reagents. The reports also indicated incidences of overstock of Unigold leading to deferral of procurement, and informed the redistribution of short expiry blood safety reagents. In general has addressed HIV commodities stock outs from approximately 30% in 2010 to the current 70% in highlighting actions required.

Conclusion: Close monitoring of the stock status helps to minimize interruptions in the supply of HIV laboratory commodities. Analysis and sharing of the results with key stakeholders enables critical input and informs decision making to address identified supply chain challenges. This is critical for ensuring uninterrupted delivery of quality laboratory services.

POSTER 168

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ASM's EQA Plan Improves AFB Microscopy Services in Namibia

Background: Since 2006, the American Society for Microbiology (ASM) has provided support to the Namibia Institute of Pathology (NIP) to develop and strengthen the national External Quality Assessment (EQA) program for Acid-Fast Bacilli (AFB) smear microscopy in Namibia. This program enables national, regional, and district laboratories to implement and assure a quality AFB smear microscopy service.

Methods: ASM's comprehensive EQA Improvement Plan for TB Laboratories covers all the main areas of AFB smear microscopy EQA (blinded rechecking, proficiency testing, and on-site supervisory visits). It begins with a series of training workshops on internationally recognized EQA for AFB smear microscopy practices and transitions to on-site, one-on-one, mentoring visits, involving the NIP Quality Assurance (QA) department, to ensure appropriate implementation of their EQA program. On-site quality supervisory visits and blinded rechecking methods are introduced to the Central TB Reference Laboratory (CTRL) and regional laboratories. Once the regional laboratories become proficient, step-down implementation will be implemented at the district level.

Results: We present here an analysis of both qualitative and quantitative data from ASM-mentored TB laboratories demonstrating: (1) 20 technologists benefited from 10 on-site mentoring visits; (2) Establishment of NIP's EQA for AFB smear microscopy Checklist and Guidelines; and (3) Enhancement of TB diagnostic capacity with significantly improved EQA scores. Additionally, 28 technologists from 31 national, regional, and district TB laboratories engaged in two consecutive "EQA for AFB smear microscopy" workshops. We will discuss lessons-learned and challenges encountered throughout the implementation of this plan.

Conclusion: ASM's EQA Improvement Plan has demonstrated notable results in enhancing capacity and quality-assured AFB smear microscopy service of TB laboratories across Namibia. As the CTRL and regional laboratories become proficient, they support the district laboratories and promote sustainability and monitoring efforts. This model for improving AFB smear microscopy service can be easily implemented in other similar settings.

POSTER 169

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Association between Phenylthiocarbamide (PTC) Taste Perception and Malaria

Taste is one of the five special senses in humans and other animals by which four gustatory qualities of a substance are distinguished. However, ability to taste the bitter compound phenylthiocarbamide and related chemicals is bimodal in any human populations and has long been believed to be a simple Mendelian trait, with tasters defined as having at least one dominant allele, (TT or Tt) and non-tasters displaying double recessive genotype (tt). The ability or inability to taste phenylthiocarbamide has been associated with a number of diseases. Nevertheless, there is paucity of information about phenylthiocarbamide taste perception and malaria infection. The study was a cross-sectional study and was aimed to determine the association between ability to taste phenylthiocarbamide and symptomatic malaria. 200 patients with age ranging from 11-60 years old presenting with fever suspected to be malaria were recruited for this study. 2ml of blood sample was withdrawn from each participant, thick and thin Giemsa stained blood smear were prepared for malaria parasite examination. Tasters and non tasters were determined among the participants using phenylthiocarbamide taste strips. 154 of the 200 patients were positive to malaria parasite test while 46 were negative. Overall frequencies of tasters and non tasters of phenylthiocarbamide were 152(76%) and 48(24%) respectively. 124(62%) tasters had malaria while 28(14%) had no malaria. Also, 30(15%) non tasters had malaria and 18(9%) had no malaria. There was a statistical significant difference between tasters who had malaria and those without malaria ($\chi^2 = 7.498, df=1, p\text{-value} = 0.006177$). This study shows that acute malaria is more associated with ability to taste phenylthiocarbamide and could be used to determine peoples susceptibility to malaria especially in areas where the infection is endemic

POSTER 170

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Protein Patterns in Serum and Urine of Prostate Cancer Subjects

Background: The increasing prevalence of prostate cancer is a challenge. Early detection and diagnosis of prostate cancer are vital in the management of this cancer especially in subjects who have little or no symptoms. Therefore the present study was designed to determine proteins that may be expressed in serum and urine of prostate cancer subjects but not present in control subjects.

Methods: A total of one hundred males [fifty prostate cancer subjects and fifty apparently healthy males without family history (control)] were investigated. Blood and urine specimen were collected from the subjects for qualitative analysis of serum and urinary proteins using sodium dodecylsulphate polyacrylamide gel electrophoresis (SDS-PAGE) while serum Prostate specific antigen (PSA), Free PSA and Percent PSA were analyzed using Enzyme linked immunoassay technique.

Results: The results showed that some proteins (kDa) were exclusively detected in the serum and urine of prostate cancer subjects but not in control subjects. Total PSA, Free PSA and Percent PSA were significantly higher in prostate cancer subjects compared with control subjects ($p < 0.05$). Total PSA show positive correlation with P9.18 and P32.36 ($p > 0.05$) but negative correlation with P14.26 ($p < 0.05$), P17.28 and P93.21 ($p < 0.01$).

Conclusion: The proteins that show positive correlation with Total PSA may provide a strong lead way for the early detection and diagnosis of prostate cancer.

POSTER 171

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Evaluation of Laboratory Information Management Systems: Matching Issues and Methods

Background: Having efficient and effective laboratory information management systems (LIMS) is necessary to maintain a high-functioning, high-capacity laboratory. The importance of information management in laboratories is emphasized in the World Health Organization Regional Office for Africa (WHO AFRO) Laboratory Improvement Process; the WHO AFRO Checklist includes a section on information management. Indeed, all the current established laboratory quality standards checklists include document and record control or information management criteria.

Methods: Assessing LIMS is essential to understanding their level of efficiency and effectiveness in information management. Assessments provide an understanding of what problems may be occurring, what workflow processes may need improving, or what is working well. There are multiple perspectives from which to approach an assessment. Two common perspectives are formative, which supports continuous quality improvement efforts, and summative, which supports system accountability and certification. Although the two perspectives are often blended into one evaluation, the best approach is to conduct formative assessments, implement recommendations, and then conduct summative evaluations. A recent electronic LIMS assessment reflected the need for this three-step approach.

Results: When designing an evaluation, multiple factors must be considered. One consideration is the phase that the information system is in – the design, implementation, scale-up and integration, or sustained operation stage. Other considerations are the information system domains to be studied – technology and infrastructure, organization and governance, human, economic, business process, and health domains. A practical evaluation usually considers all of these domains. A more focused evaluation may examine only one domain, when a specific problem needs to be addressed.

Conclusion: Developing standardized methods, measures, and metrics is critical to developing a reliable evaluation. Both qualitative and quantitative evaluation methods should be implemented to have a comprehensive view. This presentation will provide examples in the form of case studies based on information system evaluations.

POSTER 172

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Over Diagnosis of Malaria: The Role of Non-Adherence to Test Negative Results

Background: Presumptive treatment of fever with antimalarial drugs has a long history in Africa, but rapid diagnostic tests and falling incidence of the disease is leading policy makers to recommend a “test and treat” approach. Nevertheless, some research evidence suggest these new guidelines are not being adopted, and health workers are still prescribing antimalarial drugs for people who are test negative. Objective: To explore why providers prescribe despite a test negative result, and identify potential strategies to improve quality of care.

Methods: We first constructed a logic framework of drivers for over treatment of malaria, and identified potential interventions to tackle these. We then chose to focus on the drivers to health-worker non-adherence to negative test results. We are currently conducting a scoping review of studies published in MEDLINE, to identify and examine studies that evaluate the causes of non-adherence among health workers, and studies evaluating interventions to improve adherence.

Results: We present our logic framework of drivers and potential interventions for over treatment of Malaria. Our search and study selection has yielded 109 potentially eligible abstracts. We are currently screening the full texts of these abstracts to confirm their eligibility and we will have mapped out these strategies prior to the conference.

Conclusion: Our review will summarize the evidence for drivers of health-worker non-adherence to negative RDT results, and identify strategies that may help in increasing adherence. Whether these strategies need to be evaluated in research or are common sense to implement will be discussed.