Guest Editorial

Translating standards into practice: Experiences and lessons learned in biomedicine and health care

1. Introduction

The value of standards for the representation, integration, and exchange of data, information, and knowledge across the spectrum of biomedicine and health care has been widely recognized for years [1–7]. Recent initiatives further underscore the importance of standards (e.g., for certification and meaningful use of electronic health records [8]) and establishment of systematic approaches for achieving semantic interoperability. There is accordingly a need for detailed, experience-based discussions pertaining to the adoption and implementation of the breadth of standards in biomedicine and health care.

The goal of this special issue has been to provide a forum for describing advanced research and development in translating standards into practice. Each paper in this issue provides a comprehensive description of methodologies employed and challenges encountered during the process of implementing a specific standard or set of standards in a practical setting. The 22 papers (including one methodological review) represent a broad array of experiences with standards and are categorized into the following sections: (1) Terminology Standards, (2) Document Standards, (3) Decision Support Standards, (4) Standards-Based Infrastructure, and (5) Standards Adoption Processes.

2. Terminology Standards

The standardized coding of data within electronic health records and clinical databases is essential for sharing and exchange across heterogeneous systems [9,10]. Challenges to adoption of terminology standards include the use of local coding systems and effort needed to map from disparate systems to a given standard as well as identifying the appropriate standards to implement. The three sets of papers within this section aim to address such challenges by describing approaches for standardization of different types of data found in electronic health record (EHR) systems: medications, laboratory and other diagnostic tests, and diagnoses and problems.

This section begins with a set of papers focused on medications. Saitwal et al. [11] first provide a methodological review of twelve terminological systems highlighting how medication information is distributed across these systems and how they are linked through common codes. The authors then describe a case study demonstrating the ability to leverage cross-terminology linkages for mapping medications from an EHR system at the University of Texas Health Science Center at Houston. In particular, this study involved the use of a combination of approaches (automated, semi-automated, and manual) and terminology systems (Master Drug Data Base [MDDB], RxNorm, Systematized Nomenclature of Medicine–Clinical Terms [SNOMED CT], and the Unified Medical Language System [UMLS] Metathesaurus) for identifying SNOMED CT concepts and hierarchies as well as UMLS Concept Unique Identifiers (CUIs) for medications. The paper concludes with a discussion of general challenges for mapping across terminological systems.

The other two papers pertaining to medications portray two scenarios for local institutional use of RxNorm. Zhou et al. [12] discuss the use and evaluation of a natural language processing (NLP) system called MTERMS (Medical Text Extraction, Reasoning and Mapping System) for performing concept- and term-level mapping between RxNorm and the enterprise-wide Master Drug Dictionary (MDD) at Partners HealthCare. The authors discuss several challenges and gaps that may benefit other institutions seeking to map local medication terminologies to RxNorm. As an alternative to retrospective standardization of data, Bennett [13] describes the development and evaluation of a tool for direct capture of medication history in an RxNorm-compatible format at the point of care. The emphasis of this paper is on the restructuring of RxNorm to support practical use in production EHR systems.

The next set of papers is concerned with the use of LOINC (Logical Observation Identifiers, Names, and Codes) for standardizing laboratory and other diagnostic tests. With the goal of facilitating use by researchers, Abhyankar et al. [14] describe an effort to normalize clinical variables in the MIMIC-II (Multiparameter Intelligent Monitoring in Intensive Care) database that was developed at the Massachusetts Institute of Technology and contains data from the intensive care unit at Beth Israel Deaconess Medical Center. Initially focusing on laboratory tests, the authors found that the majority of tests could be mapped to LOINC and for those that could not be mapped, the main reason was ambiguous names. To address the challenge of test names with incomplete or ambiguous information, Kim et al. [15] describe the development of a process for enhancing local test names to improve LOINC mapping. This strategy was applied to laboratory and diagnostic test names in the EHR system at the University of California San Diego Medical Center and found to lead to more effective mapping. For assessing LOINC use across institutions, Lin et al. [16] developed a method for evaluating the consistency, usefulness, and degree of interoperability when using LOINC codes for laboratory data exchange. Comparison of coded laboratory data from three institutions (Associated Regional and University Pathologists [ARUP] Laboratories, Intermountain Healthcare, and Regenstrief Institute) revealed sources of contradictory knowledge to be addressed for improving semantic interoperability.

While the first three papers in this set highlight national implementations of LOINC, the fourth paper by Vreeman et al. [17] is...
concerned with global adoption of terminology standards and with methods for enabling interoperable health information exchange at the international level. The authors describe a process and set of tools for translating LOINC terms to different languages and discuss a specific case study for translation to Italian. The final paper in this set by Kroth et al. [18] describes a process for applying and extending existing terminology standards for unifying groups of existing standards in specialized domains. The specific goal of this study was to unify cephalometric measurements found within orthodontic records and ten existing cephalometric standards using LOINC.

The last set of papers in this section focuses on the standardization of diagnoses and problem lists. Matney et al. [19] aim to support interoperability of problem lists in the EHR by addressing the variability in representation of nursing diagnoses across nursing terminologies. In this study, an iterative process was used to query nursing diagnostic concepts in four nursing terminologies available in the UMLS Metathesaurus (Clinical Care Classification [CCC] System, International Classification of Nursing Practice [ICNP], NANDA International [NANDA-I], and Omah System) for developing a nursing problem list subset of SNOMED CT. Finally, Reich et al. [20] describe an effort by the Observational Medical Outcomes Partnership (OMOP) to develop a standardized environment for conducting drug safety surveillance across disparate observational databases. This study involved evaluating the suitability of ICD-9-CM (International Classification of Diseases, Ninth Revision, Clinical Modification), SNOMED CT, and MedDRA (Medical Dictionary for Regulatory Activities) for representing medical conditions and the effect of mapping to different terminologies on detecting associations between drugs and health outcomes of interest.

3. Document Standards

For the purpose of exchange, the HL7 Clinical Document Architecture (CDA) was developed as a document markup standard for specifying the structure and semantics of clinical documents (e.g., reports and notes in the EHR) [21], CDA allows for different levels of markup (document-, section-, and entry-level), thus supporting incremental semantic interoperability.

To facilitate the implementation of CDA, Scott and Worden [22] summarize a simplified approach involving the use of semantic mapping techniques. This CDA simplification is then described in the context of three use cases: two in the United Kingdom (the National Health Service [NHS] Interoperability Toolkit [ITK] project and Common Assessment Framework [CAF] project) and one in the United States (for patient summaries represented as Continuity of Care Documents [CCD]).

Given the wealth of free-text in EHRs, there will be an increasing need for NLP techniques to extract, structure, and encode information within narrative data [23,24]. Meystre et al. [25] describe the combination of two document standards, CDA and the ISO Graph Annotation Format (GrAF), for facilitating the comparison, integration, and use of annotations produced by different NLP tools. Validation of the resulting model called CDA+GrAF is then exemplified for two use cases: (1) clinical document sections and (2) medical problems, tests, and treatments and the relationships among them.

4. Decision Support Standards

Standards for representing and disseminating knowledge are fundamental to clinical decision support (CDS) systems [26]. The Arden Syntax has a long history dating back to the late 1980s as a CDS standard for representing clinical and scientific knowledge in an executable format, including ongoing use in some contemporary EHR systems. Samwald et al. [27] discuss implementation of the Arden Syntax for interpretation of hepatitis serology test results, prediction of metastatic events in melanoma patients, and monitoring of nosocomial infections in intensive care units. For each of these clinical problems, the authors describe their experiences as well as limitations and advantages of the Arden Syntax. Monsen et al. [28] aim to address the challenge of disseminating, implementing, and ensuring continued use of evidence-based clinical guidelines in practice settings. In this paper, the authors describe their approach and results from studying the feasibility of using the Omaha System to encode the Institute for Clinical Systems Improvement (ICSI) depression guideline.

To support clinical decision-making, infobuttons were introduced as computer-based information retrieval tools for providing access to contextually-relevant knowledge sources within clinical information systems. The paper by Del Fiol et al. [29] is focused on studying implementation of the HL7 Context-Aware Knowledge Retrieval standard (also referred to as the HL7 Infobutton Standard) that was developed to facilitate large-scale adoption of infobuttons. Here, the authors summarize findings from surveying and interviewing a combined total of 17 healthcare organizations, health IT vendors, and knowledge publishers about their experiences, challenges, and perceived benefits and adoption of the standard.

5. Standards-Based Infrastructure

The adoption and implementation of standards is key to large-scale interoperability across heterogeneous systems. The papers within this section describe the development of standards-based infrastructure to support the use and re-use of EHR data, quality reporting, and sharing of biological experimental results.

Barbarito et al. [30] share their experiences in setting up the Regional Social and Healthcare Information System to connect healthcare providers in the Lombardy Region of Italy through use of HL7 and IHE (Integrating the Healthcare Enterprise) integration profiles. For facilitating the adoption of varying EHR architectures, Maldonado et al. [31] present the ResearchEHR platform that aims to develop and apply semantic technologies for managing existing EHR systems where archetypes play a crucial role in the overall approach. In collaboration with the Hospital of Fuenlabrada in Spain, an evaluation of this platform was conducted for medication reconciliation using the CEN/ISO 13606 standard.

In the United States, the Office of the National Coordinator for Health Information Technology (ONC) initiated the Strategic Health IT Advanced Research Projects (SHARP) program to improve the quality, safety, and efficiency of health care through use of information technology where the consortium for Research Area 4 of the program (referred to as SHARPn) is focused on enabling the use of EHR data for secondary purposes. Rea et al. [32] describe the open-source services and components of the SHARPn framework for normalizing structured and unstructured EHR data that involves a variety of standards including HL7 (2.x messages and CDA), NwHIN (Nationwide Health Information Network), CEM (Clinical Element Model), UIMA (Unstructured Information Management Architecture), ICD-9-CM, RxNorm, and LOINC. A demonstration of the framework is then presented using EHR data from the Mayo Clinic and Intermountain Healthcare for a diabetes mellitus phenotyping algorithm.

Another ONC initiative for NwHIN Health Information Exchange (HIE) demonstration projects focused on exploring the feasibility of using existing or emerging standards for automated quality reporting, guided by a specific Quality Use Case (QUC). Fu et al. [33] describe efforts at one of the demonstration HIEs, Long Beach Network for Health, to develop a quality measure conceptual framework and Quality Assessment Service that incorporate several standards including the QDM (Quality Data Model), HQMF
(Health Quality Measures Format), and QRDA (Quality Reporting Document Architecture). Quality measures from the Coordinated Diabetes Care Measure Set maintained by the Integrated Healthcare Association in California were used for demonstration of the QUC and service.

The last paper in this section by Deus et al. [34] addresses the challenge of integrating genomic experimental results for improving translational research and enabling pharmacogenomics. In this work, the authors discuss the use of Linked Data and Semantic Web technologies, particularly RDF (Resource Description Framework) and SPARQL (SPARQL Protocol and RDF Query Language), for a *posteriori* data integration. Use of this approach is then described for the representation of three microarray-based transcriptomic experiments: Gene Expression Atlas at the European Bioinformatics Institute, BioRDF provenance of microarray experiments, and HSCI (Harvard Stem Cell Institute) blood genomics project.

### 6. Standards Adoption Processes

The emphasis of this last section of the special issue is on systematic processes for the development of software and hardware solutions and adoption of standards as part of this process.

The paper by van der Peijl et al. [35] addresses the role of an iterative usability engineering process in the development of medical devices to potentially reduce use-related hazards. As part of a collaborative effort in the Netherlands, the authors describe implementation of IEC 62366 (medical device standard for “Application of usability engineering to medical devices”) and conclude with recommendations for improvement of IEC 62366 and ISO 14971 (standard for risk management).

Finally, Bouhadou et al. [36] describe experiences with standards adoption at the United States Department of Veterans Affairs (VA), including development of a six-phased *Standards Life Cycle* (SLC). The authors describe use of the SLC process for implementation of four categories of standards: security and privacy, terminology, health information exchange, and modeling tools. The paper ends with a discussion of a generalized framework for standards adoption (involving people, processes, and tools) and a *Likelihood of Adoption Scale* providing a three-level categorization of standards.

### 7. Conclusion

Collectively, the papers in this special issue on *Standards in Practice* provide both national and international perspectives on standards adoption in a variety of contexts to support applications ranging from patient care to decision support to biomedical research. While each paper addresses particular standards, it is anticipated that the approaches and lessons learned from each experience may provide generalized principles and an overall framework applicable across standards and settings (e.g., by offering methodologies and guidelines to facilitate the comprehensive standardization of data from disparate EHR systems, including problems, procedures, laboratory test results, medications, immunizations, and patient summaries). We thank the authors for sharing their experiences as well as the reviewers for contributing their expertise with respect to standards adoption and implementation. Our hope is that this issue will serve as a valuable resource to readers as they embark on the journey to implement standards in their own settings.

### References


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