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Setting up a paediatric vestibular testing laboratory

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Abstract
This paper describes the vision of networked balance testing centres as set out in the Balance Good Practice Guide published in 2009. It provides examples of room design and enabling works. A suggestion for hardware and software specifications for a supra-specialist balance centre is provided. How to design, evaluate and commission such a laboratory will be covered, including brief descriptions of the qualitative and quantitative balance tests used in assessing vestibular function in children, maintenance and training issues. The appendix provides guidance on making a business case, applying for capital bids, option appraisal, writing equipment specifications, bid evaluation, and procurement.

Key words: *balance assessment, specifications, vestibular laboratory*

Introduction

The function of a balance testing laboratory/centre is primarily to help diagnose patients referred with balance problems, dizziness and/or vertigo. There is a rehabilitation component to the activity of many balance centres, especially with some current objective techniques used to treat, e.g. visual-vertigo. The research component should not only standardize and improve the application of existing tests but also develop new ones with a higher sensitivity and specificity in differential diagnosis of dizziness than those currently available. The evidence base for the 'recommended' best practice is still not as good as it should be and therefore research and development will be important for many years to come. Several documents have been issued recently focusing on adult balance services (1–4). As part of the 18-week modernizing project, the Department of Health released several 'best practice guidelines' in 2009. One of these focused on patients with dizziness, namely the 'Provision of Adult Balance Service: A Good Practice Guide' (1). The main purpose of this guide is to provide 'practical evidence-based advice on how to improve people's access to, and experience of, balance services'. One of the chief recommendations is that services to patients with balance problems should be delivered in networks – with basic testing facilities available in general practice and 'poly-clinics' but also access to 'high quality specialist and supra-specialist centres'. It highlights the need for different facilities and equipment at balance centres depending on whether they are 'primary', 'specialist' or 'supra-specialist' and these are summarized in Table I.

This paper describes details of how to design, evaluate and commission a Paediatric Supra-specialist Balance Centre. It will also include brief descriptions of the qualitative and quantitative balance tests used in assessing vestibular function in children.

Room design and services

Heath Building Note (HBN) series is designed to 'give advice on the briefing and design implications of Department of Health Policy'. Although long due for a revision, HBN 12 Outpatient Department along with Supplement 3 ENT and Audiology clinics, hearing aid centre, 1994 Section 4.63 (5) is required reading especially if starting a new building project. There are a few required considerations, primarily around the amount of space and number of rooms required. Although it is possible to combine a significant amount of test equipment into one room, ideally certain functions should be separate. The suggestion for a basic design and purpose for each room may be found in Table II. The details of nominal room size, lighting levels, number of twin-socket electrical outlets, sink facilities and room air changes may be found in HBN 12. However, it is worth going through each testing area

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Table I. Facilities and equipment required for networked balance services (proposed by Good Practice Guide 2009).

Local Balance Service	Pure tone audiometry
	Videonystagmography/videonystagmoscope
	Microscope with microsuction
	Ophthalmoscope
	Office rotating chair
	Snellen chart
	Balance foam cushion
	Tuning fork
	Sphygmomanometer for lying and standing blood pressure
Specialist Balance Centre	Videonystagmography +/−electonystagmography
	Caloric testing
	Vestibular evoked myogenic potentials
	Auditory electrophysiology and auditory brainstem response test (ABR)
	Otoacoustic emissions and contralateral suppression
	Speech audiometry
	Foam pad/balance cushion
Supra-specialist Balance Centre	Rotating chair and computerized analysis
	Visual vertical and horizontal equipment
	Posturography
	Optokinetic stimulation
	Novel vestibular rehabilitation including, for example, virtual reality and strategies for visual vertigo
	Advanced auditory electrophysiology

in turn and highlighting some considerations particularly relevant to paediatric balance assessment.

Examination room

Basic equipment should consist of an office rotating chair and a reclining couch covered with child friendly 'fun' images. Frenzel glasses or portable video systems to observe and record eye movements should be readily available. It is appropriate to use child friendly targets (illuminated finger puppet) along with colourful house with windows for saccades and pursuit testing (Figure 1). This clinical examination room should have sufficient space to allow access to both sides of a reclining examination couch and sufficient floor space for any significant deviation that may occur during tandem walk and/or Unterberger/Fikuda tests. Child friendly Snellen/logmar chart (which use shapes rather than text) should be located on a wall easily viewed without distractions and at an appropriate distance. This equipment and room set-up is essentially the same as that which could be found in a local balance service.

Specialist balance centre

The next group of facilities and equipment if added to those above could also act as specialist balance centre. HBN 12, Supplement 3, only refers to a vestibular function test room, typically where objective eye movement assessments (smooth pursuit, saccades, gaze and optokinetic) and caloric testing is carried out. Particularly with small children (and only occasionally with adults) it is very difficult using video-oculography systems to record eye movements and therefore electro-oculography systems must also be available. HBN 12 states that the test room should have a temperature of 18°C with a notional six air changes per hour. Although lighting level luminance suggested is 100 lux, it would be more appropriate to have variable lighting levels, which reflect the anticipated multi-function use, e.g. 100–300 lux. It is easy to forget to install more than one light switch at convenient points around the room, e.g. near entrance door and caloric tank operating unit. There should be at least four electrical twin-socket outlets; one of these should have residual current device (RCD) option and be used for a water caloric irrigator if this version is installed. Drinking water supply with pressure regulators, de-calcifier and water filters should be available if using water caloric irrigators as well as a sink to allow drainage of wastewater. Worktops for equipment and desk area would be advantageous. It should be possible to screen any light generating equipment being used from the patient, i.e. a lightproof test area. Windows are not required. Room size suggested is 15 m^2. Other rooms required that will not be described are

Table II. Suggested Testing Rooms for Paediatric Vestibular Laboratory (with details of assessment and equipment required for each room).

Room designation	Assessment	Equipment required
Clinical Examination Room (see figure 5)	Taking history and performing clinical tests of balance such as Romberg[1a], Unterberger[1b], Tandem walk[1c], Dix-Hallpike and positional tests[2], dynamic visual-acuity (for HVOR & VVOR)[3], horizontal VOR[4], basic eye movement tests[5] (cover, range of eye movement, smooth pursuit and saccades, gaze testing)	Foam cushion[1a] Marked area for estimating deviation from centre in subjective balance tests [1b&1c] Adjustable couch[2] Snellen/log mar wall chart[3] Office rotating chair[4] Frenzel glasses or video recoding goggles[5]
Functional Balance Testing Room	Static posturography[1] and dynamic posturography[2]	Fixed force platform[1] Moving force platform[2]
Audiometric room 1*	Pure tone audiometry[1], Speech audiometry[2] and middle ear[3]	Pure tone audiometer[1] with CD/DVD for delivery of speech material[2] Middle ear analyser[3]
Audiometric/ Electrophysiological Room 2*	Vestibular evoked myogenic potential as well as standard electrophysiological tests (ABR, cortical, etc.)[1]; galvanic stimulation[2]; otoacoustic emission with contralateral suppression of TOAE[3]	Two-channel AEP system with bio-feedback system for VEMP recording[1]. Comfortable reclining chair/couch[1&2&3] Electrical stimulator[2] Equipment to record otoacoustic emission[3]
Vestibular Assessment Room 1 - Specialist (see figure 5)	Basic eye movement assessment (smooth pursuit, saccades, optokinetic and fixed gaze position)[1] and evaluate horizontal vestibular-ocular reflex[2]	System capable of generating eye tracking stimuli) and recording and analysing resulting eye movement (video- and electro-nystagmography)[1&2] Caloric tank irrigators[2] Services – water supply if required[2] Reclining couch (adjustable to upright pos)[1&2] Target in horizontal position and also ceiling mounted[1&2]
Vestibular Assessment Room 2 - Supra-specialist (see figure 5)	Horizontal vestibular-ocular reflex (VOR)[1], Otolith function[2], Tests of vertical VOR[3], Machine based rehabilitation therapies[4]	Rotating chair and computerized analysis[1]; visual vertical and horizontal equipment[2]; off-vertical axis rotation (OVAR)[2]; vestibulo-auto-rotational test (VAT)[1&3]; novel vestibular rehabilitation including, for example, virtual reality and strategies for visual vertigo[4]

*Although not the main focus of this paper, the audiometric testing facilities cannot be ignored although it is again appreciated that most balance centres will not exist in isolation and will be adjoining audiology departments where these facilities will already exist. Audiometric booths and clinical examination room design criteria – see HBN 12, Supplement 3.
HVOR: horizontal vestibulo-ocular reflex; VVOR: vertical vestibulo-ocular reflex.

typical audiometric room for pure tone audiometry, speech testing, and middle ear analysis. A separate room is required for recording auditory evoked potentials (auditory brainstem response and vestibular evoked myogenic potentials).

Supra-specialist Balance Centre

Expanding the facilities previously described along the lines listed below would create the Supra-specialist Balance Centre. This would primarily involve

Figure 1. Child Appropriate Balance Testing Equipment and Information Leaflet.

installation of a motorized chair with computerized analysis; equipment to test subjective visual-horizontal and visual-vertical; posturography, optokinetic stimulation with sufficient space and adaptability to cope with emerging technologies such as virtual reality. There is no formal suggested room size, but 30 m^2 should provide sufficient space (or two rooms of 15 m^2).

Most equipment used within such a department would only require 240v power supply. However, it is worth noting that some of the high-torque motors on commercially available motorized chairs require more than 13A of current for short periods and therefore a three-phase power supply may also be required. The cost of this is not inconsiderable and should be a consideration in the option appraisal process.

The figures above are nominal and any final figures should be determined by a detailed examination of the proposed function of the room.

Vestibular laboratory for testing children – suggested specification

A supra-specialist vestibular laboratory has many components and to include the specifications for all the pieces of equipment required would generate a very large and cumbersome document. It is for this reason that the medical devices to record auditory evoked potentials, active head rotation test and posturography, will not be described in detail. The aim is to describe and specify the components of a comprehensive vestibular laboratory for testing children from birth to 18 years of age, mainly the specification for an instrument that may be used to record and analyse eye movement during and following a variety of predefined visual and vestibular stimuli. The device should be capable of generating appropriate smooth pursuit, saccadic, optokinetic, fixation and vestibular (including rotational and caloric) stimuli. Specifications are usually submitted as a table to potential suppliers, with space for the companies' responses. Each specification must also state whether it is an essential or desirable feature.

General features

The devices must operate from a standard 240v mains supply through isolation transfers and UPS as required and the current consumption under all conditions of operation must be stated. As mentioned, some systems still require three-phase power supply but if a system requires this option, it would certainly add to the project enabling cost. The medical devices used must conform to all appropriate UK standards for the manufacture of medical devices and be CE marked (copies of certificates issued by Notified Body that are applicable to the design and manufacture of this device should always be provided by the manufacturer). The equipment must meet the particular requirements for electrical safety set out in IEC 60601-1 and CE marking in accordance with EC Medical Devices Directive 93/42/EEC. The answers given in response to questions raised in a Pre-Purchase Questionnaire (PPQ) will need to satisfy

appropriate Trust staff prior to an order being placed. The device should have appropriate resistance to fluid ingress and access to solid foreign bodies to the IP34 code level (reference standard IEC 60529) or equivalent. The expected life in years of this equipment should always be provided and it must be easy to use by appropriately trained and qualified staff and be easy to maintain and keep clean. The cost of any training course and maintenance contracts available must be quoted. The room design has already been covered and nominally 15 m^2 is suggested for the caloric test area and the same for the motorized chair area. However, when submitting any tender, specific room size restrictions must be stated. Minimum 180° (but preferably 360°) projection screen for visual stimuli is required, but with either system it should be possible to create a lightproof area for each test modality as and when required. Infrared cameras should be provided – one chair mounted for view of the patient and one to visualize the rotating chair and patient in the test room. A close-up face camera is very useful especially with difficult-to-test patients. An operator for patient bi-directional communication is also required.

The devices must have the capacity to communicate operational data via a standard data link with provision or future plans in place to provide compatibility with future NHS IT systems such as IClip. Details of the data link provided must be included in the quotation/tender.

The costs for all consumables, indicating the pricing structure for different volumes of purchase, should be provided. All consumables used per patient, and estimated cost of a single patient procedure, should be derived. The consumable suppliers should be listed and be available from established NHS supply networks such as the Purchasing & Supply Agency, NHS Logistics etc.

A factor sometimes omitted but that should be high on the agenda, is cleaning and infection control. The device must be easy to clean using disinfectants and detergents commonly available within a hospital and laboratory environment. (The manufacturer should provide the list of approved disinfectants and detergents suitable for cleaning the casing of the device.)

The vestibular tests should be operated by user-friendly software, which would allow a range of tests to be carried out quickly, eye movements displayed in real time, and analysed immediately if required in the shortest possible time (less than 45 min for full test battery). Software specifications are covered in detail later. The next sections look at basic specification of the technology used to record eye movement followed by the types of stimuli that should be available.

Recording eye movements

The system should be able to record movements of the eyes during and after visual or vestibular stimulation as appropriate (bi-ocular, monocular and/or separate eye recordings, horizontal and vertical).

Option 1. Videonystagmography (VNG) – eye tracking goggles used to record horizontal, vertical and torsional eye movement. Resolution of eye movements at least 0.2° horizontally and vertically and a range of eye movement at least 30° horizontally and 20° vertically. Video sampling rate should be a minimum 100 Hz. There should be a facility to transmit video images via wireless transmission and/or optical slip ring if used with a rotating chair. The weight of the goggles should be as low as practicable to minimize discomfort and adjustable to allow the system to be used with adults as well as children. The design of the video goggles should allow the patient to view the visual stimuli while recording eye movements. A facility to turn the on/off fixation light remotely within goggle set would also be required. The pupil tracking mechanism should be robust and be able to operate with the majority of different eye shapes and even with partial eye closure. It should be possible to use contrast and brightness adjustments before and during any recordings (see Figure 2).

Option 2. Electronystagmography (ENG). Three-channel system biological DC amplifiers with changeable low pass filter (typical acceptable range 30–50 Hz), optically isolated to measure and record the corneo-retinal potential. It should be possible to adjust the DC offset, where it is larger than expected or if electrode drift has occurred prior to stabilization. The system should be able to record two eyes simultaneously, separately, or simply one eye at a time (horizontal and vertical). A comprehensive vestibular laboratory for use with children would include both VNG and ENG eye movement recording systems. Video goggles may be used with older children but not with babies or young children, as they tend to close their eyes. Therefore, an ENG system is recommended for testing babies and young patients.

Provision of stimuli

It should be possible to set up and use a variety of test battery protocols, but also with the facility to

Figure 2. The operator station of modern vestibular suite (controlling test, recording eye movement and viewing patient).

change these as required. The system should be able to provide the following: smooth pursuit and saccadic eye tracking stimuli including fixation points for gaze testing; full-field optokinetic stimuli; impulsive, sinusoidal with visual-vestibular interaction whole body rotation stimuli; off-vertical axis rotation and caloric stimuli. The system should be able to record and display eye movements during each test and analyse eye movements at the end of each test component. The stimulus generation is now described in more detail.

Pursuit tracking system

The suggested pursuit-tracking system would use a laser mechanics assembly to generate stimuli in the horizontal and vertical directions at angles up to 30°, but other systems based on LED technology work quite well. The projection system should be adjustable so that the centre position is directly in front of the patient and at the level of their eyes when they are facing forward. The range of adjustment should be sufficient so that a tall child seated on the parent's lap or a small child sitting on its own may be tested. This

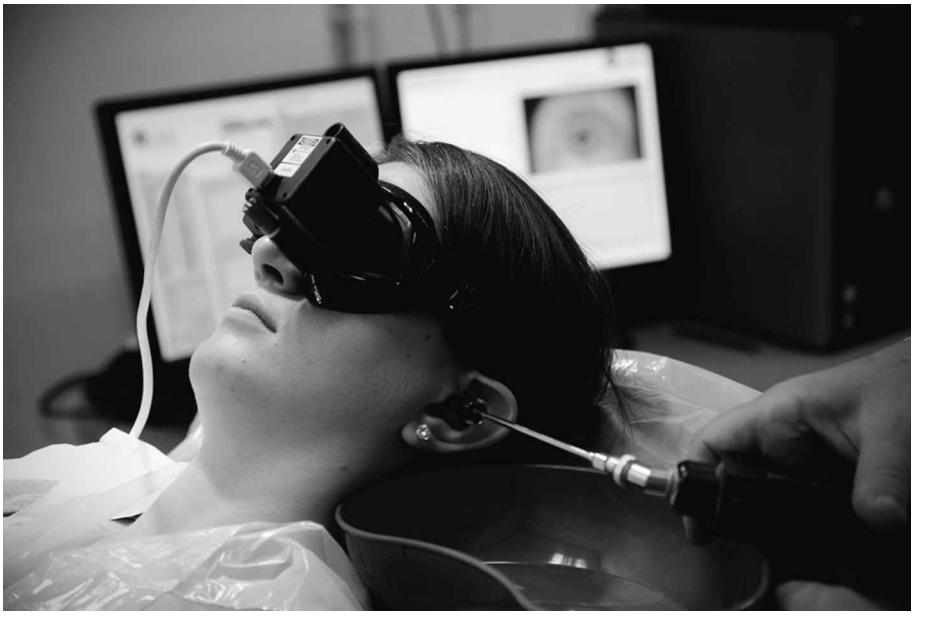

Figure 3. Caloric Test in adolescent.

Figure 4. Motorized rotating chair (off-axis) with colourful moving pattern to keep child entertained between tests.

system should be able to generate a slowly moving target (as in smooth pursuit or calibration test); rapidly moving target (saccadic or calibration test); a stable point at fixed user set angles (spontaneous or gaze tests or visual fixation test during rotation). The target should be a well focused red dot visible at a distance of 1 m to patients with severe myopia as well as not appearing too large to patients with normal vision (around 1 cm diameter). To make the target more interesting it should be possible to change the type of target, e.g. from a moving red dot to a moving spaceship.

Full-field optokinetic nystagmus (OKN) stimulus

This stimulus projection has full-field stimuli with velocities from $10\,s^{-1}$ to $60\,s^{-1}$ (clockwise and counter-clockwise). There is sufficient evidence to indicate that the most appropriate stimulus is one that comprises random unpredictable patterns rather than the usual black and white striped curtain or light bar. The latter is not recommended as it is obviously not a full-field stimulus and is more akin to a smooth pursuit test. It should be possible to project the OKN stimulus during chair rotation (either as a stationary image or at same speed as rotating chair up to 2 Hz maintaining peak amplitude).

Whole body rotary assembly

The key factor is the torque of the motor. More torque usually means more power and more speed (and usually more money). There is a reasonable argument for over- engineering the chair motor to cope with any future demands so that is does not have to work too hard to deal with the average patient tested being moved at a typical rotation speed of $90\,s^{-1}$. The motorized chair must cater for patients ranging from 100 cm to 1.9 m tall. It should also be able to accommodate a range of parent and child sizes with head rest adjustment, footrest adjustment, and retention strap for waist, chest, and legs with an easily adjustable mechanism such as those that may be found on rucksacks. The chair size should be at least 40–45 cm to accommodate parent and child. There should be a facility to fix onto the frame a baby seat for testing children up to one year of age. A cushion should be available to put on the chair for an older child who is going to be sitting on the chair independently from the parent. There should be a special mother/child chair provision that allows the rotation chair to be positioned between the standard on-axis position and up to 20 cm back from this position to allow for testing in the mother's arms (baby in centre axis position). The slide mechanics should have a locking mechanism provision. The chair mechanism should be constructed so that the parent or child can step onto it easily and safely and without the use of steps.

It should be able to carry the total weight of a parent and child up to 150 kg and generate the following stimuli:

- Angular velocities up to $200\,s^{-1}$ and accelerations up to $400\,s^{-2}$ (impulsive rotation or head-thrust tests – bidirectional and for an operator defined period of time).
- Sinusoidal rotation with peak velocities from $15\,s^{-1}$ to $150\,s^{-1}$ and frequencies from 0.01 Hz to 3 Hz.
- Constant acceleration adjustable instantaneously from $2\,s^{-2}$ to $200\,s^{-2}$.

Off-vertical axis rotation systems (OVAR)

The OVAR should have an angle tilt from 0 to 30° with a linear acceleration stimulus.

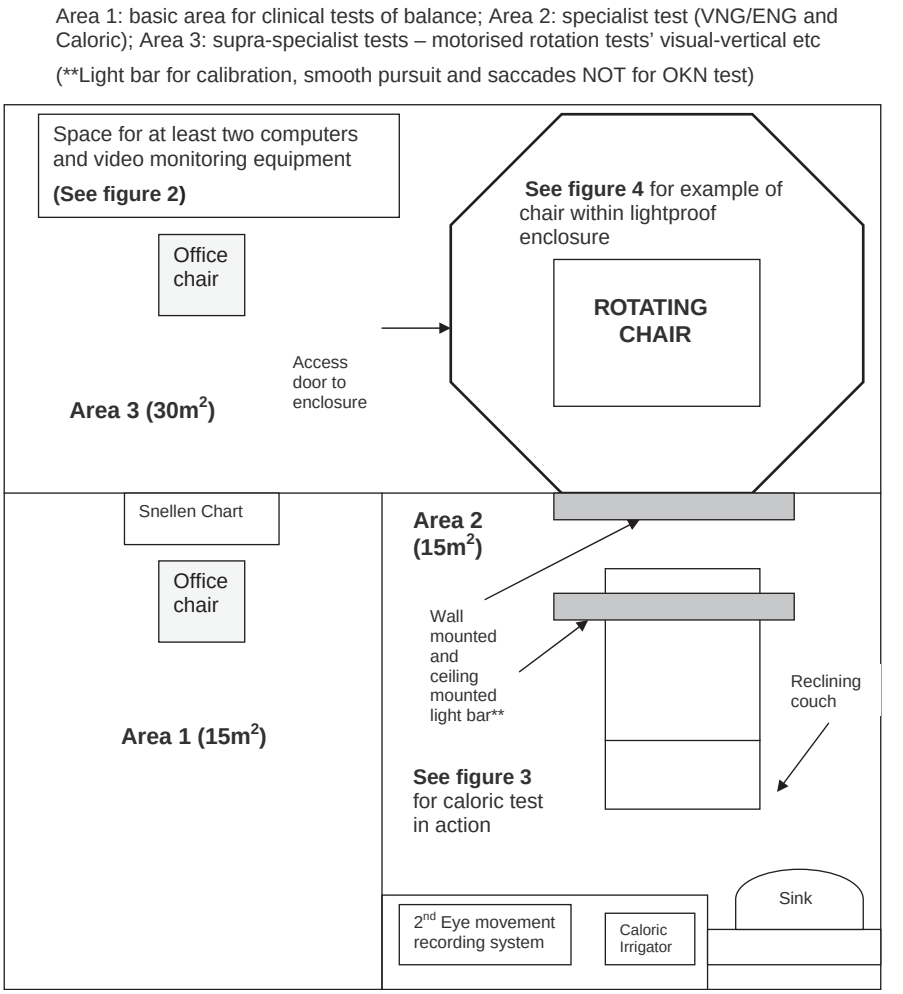

Figure 5. Exemplar Supra-specialist Balance Centre.

The velocity of the chair should be monitored continuously and have a stable velocity profile (0.1% DC tachometer). It should be constructed with at least 20 optical slip rings to allow video signals from goggles as well as signals from the EOG amplifier to be conveyed to the system computers, as well as communication (voice and video) signals from chair mounted video cameras and microphones. Automatic over-speed fail-safe systems should be in place for a motorized chair, which should operate independently of the controlling computer. The deceleration should not be excessive nor abrupt but comfortable and quick. It should also employ a safety stop facility if the operator should enter the chair enclosure or predefined area. If the enclosure is used this should be well ventilated and illuminated. The chair should have a fixed starting position, typically so that the chair is facing the exit door when either setting up the patient for testing or releasing the patient following completion of the test.

Subjective visual-vertical and visual horizontal systems

These comprise a mechanism attached to a chair, which allows the patient to adjust the position of a line (initial position offset from vertical) to their perception of vertical or horizontal. The final offset angle is measured. The length of the line should be adjustable (from 10 cm to 30 cm) as is the initial offset angle. It would be desirable for an image of a frame to be projected around the straight line when required ('Rod and Frame' test).

Caloric stimulus

This is provided by an open loop water irrigator (alternative, air caloric system). The caloric system should have paediatric nozzle(s).The system should be designed with infection control as a consideration. Patient applied parts should be either disposable or autoclavable. A foot pedal is needed to start data acquisition automatically and thereby allow one

operator to control the system delivery of the stimulus to the patient and run the system simultaneously. An added value specification would be to have auditory and visual cues on the computer to state how long the test has been proceeding, especially important for setting irrigation time (although it should be possible to turn off this facility). A ceiling mounted fixation and calibration lights should be provided. (Visual suppression and repeat calibrations are required if using electrodes to record eye movement.) It must be possible to set the temperature and flow rate to those described in the British Society of Audiology Recommended Procedure for the Caloric Test (6).

Software specification

The following general features are required:

1. Access to software and the patient database should be by password only. An administrator password should enable the operator to either allocate passwords to new operators or to generate new test battery protocols.
2. Patient details and test results should be saved in a database, accessible via hospital number, date of test and/or name. The operator should be able to export a summary of test results to a spreadsheet, and export raw eye movement and velocity traces for selected patients (into Excel spreadsheet and hospital archive database).
3. The operator should be able to access particular data on a specific patient from the database.
4. There should be a requirement to interface to NHS Trust data back-up facilities.
5. There should be flexibility of test protocols, with respect to which the test may be carried out, the order of tests and use and alteration of the default test parameters. It should allow the tests to be run in any order, repeated and duplicated and re-run at any time during the test. Analysis could be carried out at the end of each test or later after full test battery has been completed, if desired.
6. For all protocols, the operator should be able to interrupt the test at any stage without loss of data. All test protocols should be software controlled (with an option for manual override). The facility to design own protocols within the limits of the instrumentation would be an advantage.
7. Although currently not available, it should be possible to estimate the most appropriate default calibration factors for the patient and this would certainly be a long-term goal. If it was impossible to carry out formal calibration the operator should be able to use a default or user selected calibration factor that would yield sensible results.
8. The software should allow the operator to select the quick phase parameters that would result in the highest spectral purity of the eye slow phase response profile.
9. The tester should be able to erase the non-representative cycles and provide an analysis based on the best cycles of the patient's response.
10. A wide range of stimulus parameters should be programmed and written into the protocol.
11. Means and standard deviation of the wide selection of normals should be used as reference for all the vestibular tests.
12. Raw eye data should be saved for all tests.
13. The raw data and their analysis should be presented in numbers and graphs in the final report. This should include information regarding a record of eye movements and stimulus with access to it, so that operators could manipulate it in different ways.
14. The operator should be able to scroll through raw data and obtain the slow component velocity for any beat. It should be possible to insert or delete nystagmus beats as required.
15. Software algorithms should be able to identify and calculate velocity (slow component velocity – SCV) of any nystagmus beats generated during these various tests (optokinetic, rotation, caloric, gaze tests and positional tests).
16. The computer should be able to generate SCV against time graphs and identify the maximum velocity (based on average of fastest 1, 3 or 5 beats or suitable alternative), and calculate time constant of any decay response.
17. The software should be stable, there should be no interference with the stimuli or data acquisition if the computer should crash or is turned on and off suddenly.
18. The final report should be printed on high quality paper and should be saved to the patient database with facility to write the report summary with departmental details. Automatic report generation from analysis results is required. Print sections of data can be collected as required.
19. Critical upgrades should be provided free of charge within the service agreement.
20. For non-critical software upgrades, details of upgrades should be provided on a regular basis as and when new tests are developed.
21. The hardware and operating system platform that the clinical software uses should have

financial provisions in place to enable upgrades to be installed as required.

Tests enabled by the program

These tests should include display of eye movement traces during data acquisition, updated at least once every second; display of eye movement position, velocity; analysis for each test as appropriate.

1. Calibration for horizontal and vertical eye movements – calibration with amplifier set to give an automatic gain. Test stimuli options should include saccadic ($+/-15^{\circ}$, 1 s duration predictive saccades) and/or smooth pursuit target ($\sim$0.2 Hz adjustable). There should be facility for the operator to confirm that calibration is acceptable and to adjust the calibration gain manually if appropriate to do so. There should be a facility to use a default calibration value, which might be suitable for the vast majority of patients.
2. Smooth pursuit sinusoidal – full range of frequencies (0.1 and in 0.1 increments to at least 1 Hz) with defined amplitudes (typically 15°), horizontal and vertical directions. Analyse eye recording to generate mean gain, phase and asymmetry for each test frequency.
3. Saccadic – random and predictive saccades – at least 60 over a period of 80 s in horizontal and vertical directions. Analyse eye recording to generate mean gain (accuracy), latency and peak velocity of the generated saccades.
4. Gaze tests – typical paradigm centre position 5 s with fixation and approximately 15 s without fixation. Repeat test with fixation light to right and left (10° or 15°). The software should have a marker to indicate removal of visual fixation. There should be a tag for direction of testing and to indicate whether eyes are open or closed. There should be a facility to repeat any part of the tests several times (without repeating the full gaze tests).
5. Optokinetic – typical paradigm $20\,s^{-1}$ and $40\,s^{-1}$ clockwise and counter-clockwise for 15 s in each direction. The software should establish velocity and gain (accuracy) for each direction (mean and standard deviation) and directional preponderance.
6. Rotating chair – impulsive rotation. Default paradigm of $30\,s^{-1}$, $60\,s^{-1}$, $90\,s^{-1}$ and $120\,s^{-1}$, times taken to reach maximum speed 0.5 s and rotated for 60 to 90 s in each direction for default or operator set time period. Analyse eye recordings to generate gain, phase, time constant, duration, and frequency of beats. Directional preponderance/asymmetry based on maximum slow component velocity and time constant of responses.
7. For sinusoidal rotation, basic test paradigm should allow operator to test 0.02 Hz, 0.04, 0.08, 0.16 and 0.32 Hz at a peak velocity of $60\,s^{-1}$ (or $30\,s^{-1}$, $90\,s^{-1}$ or $120\,s^{-1}$ if appropriate). Visual suppression and visual enhancement test should be available to evaluate vestibular-visual interaction and visual dependency.
8. Visual-vertical and visual-horizontal – a series of random offsets lines of 10 cm in length but default should have at least four offsets to the right and four to the left for subjective vertical test (similar number right-side up and down for horizontal). This should compensate for the fact that any final position determined by the patient is usually affected by the initial offset direction.
9. Caloric test – calculation of unilateral weakness (UW), directional preponderance (DP), asymmetry and visual-fixation index based on machine derived maximum slow component velocity. If tests are repeated it should be possible to prioritize the recording that needs to be used in any UW/DP calculation. It should also be possible to change the 'tag' for any recording made. This would be required if the operator inadvertently started recording eye movements under a right 44°C tag but actually was irrigating the left ear with warm water.

Maintenance

In order to ensure that the equipment is maintained in proper working order the basic maintenance requirements are as follows:

- Details of the service support options that are offered. All such service support must be within a BS EN ISO 9001:2000 compliant quality system.
- Clear instructions on the regular maintenance that should be carried out by the user including details of software upgrades. Details of the routine service needs of the system including frequency, parts requiring change and costs and details of the calibration schedule for the system.
- Engineer call-out response time of 48 h following initial assessment/advice from the Trust's medical physics team. Maintenance staff should be aware of how many trained engineers are

available to maintain the equipment in their region.
- In the event of a mechanical failure of the machine a service engineer should be contactable by telephone during normal working hours or by e-mail within 24 h. If the devices are supported by a maintenance contract, the engineer call-out response time should be known. Details of training courses that in-house engineers can attend to be trained for maintenance and repair, with issue of certificates of competence with details of costs and frequency, should be provided.
- Spare parts must be readily available over the lifetime of the systems. There should be a guaranteed duration of the availability of spare parts. A parts list and parts cost list with details of any discount available should be provided.
- Options available if the equipment is out of action for an extended period. Suppliers are required to specify the services they will provide and their cost.

The maintenance schedule is crucial to the successful operation of any laboratory. There should be facilities to check flow rate and temperature of caloric irrigator stimuli; there should be facility to independently check chair velocity, acceleration; ocular-motor test paradigms, e.g. frequency and amplitude of deviation. There should also be systems to independently check the software analysis routines (using 'phantom' patient data and technology with known values).

Training

In line with clinical governance issues around use of equipment it is essential that all staff using and supporting the use of the system be appropriately trained. The requirements are as follows:

- Suitable comprehensive initial training for all staff using the machine including basic troubleshooting.
- Technical support and training of the Trust's medical physics team representative.
- Further support and advice throughout the life of the machine as required.
- Supply of comprehensive technical documentation such as user manual and system schematics. Details of fail-safe limits, maximum ratings of mechanical system and electronic hardware and origin of all calculated values presented in data analysis. This should be available in an electronic format such as a PDF file. (This would allow the manual to be available on the departmental intranet site.)
- Suppliers should specify the training they will provide and any additional training opportunities.

General notes

The device supplied must be of sound construction, fit for purpose, comply with all relevant safety and construction standards for medical equipment, and be CE marked. A PPQ form will need to be completed and presented by the supplier prior to an order being confirmed. Preference should be given to devices that are reliable, easy to use, have the appropriate degree of flexibility and versatility, and are easy to keep clean and maintain. The final choice of device will depend not only on meeting this specification but also on user preference. Trials of suitable equipment may be necessary before a final decision is made. Users will assess the various features of any equipment on trial. The cost of all disposable parts should be included. All instructions for use, cleaning and maintenance must be included with the quotation. The costs of any repair and maintenance contracts that are available should also be stated, together with the typical costs of major repairs if these are not included in standard maintenance contracts. Any training provided, including any courses recommended/offered by the manufacturer/supplier should be stated together with any costs that may be incurred. In presenting a quotation, the supplier must fully specify the device that will be provided, and clearly identify where this does not meet the requirements cited in this document. As much information as possible should be requested: the terms of the warranty must be stated; when will equipment be delivered and installed (if this needs to be by a certain date, state it explicitly). Quotations should be supplied for vestibular testing suite – the supplier should provide details of any points of non-compliance. It is important that there is a nominated contact for suppliers in case there are enquiries concerning the medical use of this machine. However, any issues relating to cost and the tender need to go through an independent department responsible for purchasing the item, for example Procurement.

Conclusions

The essential components of a vestibular testing suite for use with children have been presented along with the key specification of such a system. Although this is a developing field and there are emerging technologies, it is likely that the vestibular

laboratory of the future may have similarities with today's systems. After all, the caloric test is still in existence after 60 years. However, technology will reduce the space required for evaluating vestibular function in patients presenting with dizziness, reduce test time, and increase efficacy of differential diagnosis. New tests will appear and almost certainly some will disappear. It is for this reason that the recommendations set out in this paper may not be applicable for very long, but hopefully it provides useful guidance on how to set up a vestibular testing laboratory, which may be used with children. More details on the procurement process from making the business case to final purchase can be found in the Appendix.

It is important to adapt test instructions as well as the test environment to make the entire process child friendly. Part of this is by providing clear child friendly instructions and a child friendly environment that is welcoming to both the parent and the child. It is also important to understand that most of the normal limits provided by equipment are based on adults and therefore there is a need to develop age appropriate normal limits. A significant amount of work has been carried out with ENG and caloric test, as exemplified by the work of Levens et al. (7). More recently, the 'Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology' (8) provided guidance on the assessment of vestibular testing techniques in adults and children. However, there is still very little published work on the results obtained from normal children to whole body rotation, off-vertical axis rotation and VEMPS. This gap in knowledge is gradually being filled, but it may take several years to collect good quality normative studies. Once these data are available, the paediatric vestibular laboratory may be used with the backing of a strong evidence base to support its role in the assessment and rehabilitation of children with balance problems.

APPENDIX. Business case, capital bids, option appraisal, writing equipment specifications, bid evaluation, and procurement

It may seem as if the process for setting up or developing a service is going too be too onerous, challenging, difficult and long-winded. There are obstacles at every stage, but the cornerstone of the entire process is to have the belief and conviction that one is developing a service that is in the interests of one's patients. There are many models and guidelines on option appraisal but the authors have found useful guidelines in the European research report No. 2 – options appraisal criteria and matrix (9).

Business case

An entire paper could be written on how to prepare a business case and it is beyond the scope of this article. However, it can be simplified as summarizing the benefits to the patient (e.g. more effective assessment and/or treatment; quicker; less distressing or upsetting) or to the organization (increased capacity, more cost effective; utilization of staff more effectively and appropriately). It is not required if one is applying for replacement equipment, but only when one is developing a new service.

Application for medical equipment

Application for Minor Capital medical equipment usually involves bids for devices or facilities costing between £5000 and £200,000. Most balance testing centres might cost more than this in its entirety but it is unlikely that individual items would cost more than this at 2009 prices. This stage allows one to formulate what one is planning to do. For instance, does the proposed new equipment require any changes to services i.e. electricity, including connection to essential supplies, uninterruptible power supplies, medical gases, water, changes to the building fabric or fixture and fittings or other estates issues? If it does, what is the cost of these works? Which budget will this money come from? Reasons usually need to be provided for requesting replacement of existing equipment or new additional equipment to provide the same service. It is important to include details of equipment maintenance and cost of repairs. This is used to provide evidence of either the unsuitability or unreliability of the existing device or improvements that are possible with newer devices. What improvements/changes to the services will arise as a result of the proposed purchase? (e.g. safety, efficacy, efficiency).

It is important that no commitment is made to particular manufacturers. If a bid for money is successful, and there is more than one prospective supplier, then a formal tendering process will need to be entered and at this stage potential supply companies may be contacted for loan equipment where this is feasible. Any loan equipment would need to have electrical safety checks and indemnity cover.

All organizations will have strict rules regarding the procurement procedure. This will include writing the specifications, tendering and evaluation and the award of business. While these may appear to be disruptive and unduly onerous, it is all part of good governance allowing purchase to be made, which not only meets the needs of the service but also provides good value for money and protecting the hospital from commercial litigation.

Option appraisal

Decide the options – this should be as comprehensive and rigorous as possible. Note that not doing anything is also an option. Some of the points that should be evaluated are:

1) Is the new equipment necessary in order for your department to meet national guidelines?
2) Is it part of a modernizing service programme – replacement of obsolete, dangerous and/or broken equipment?
3) Is it needed to meet the requirements of Supra, or simply a specialist balance centre?
4) Will the new equipment increase the capacity, quality, speed, sensitivity, and specificity of tests in differential diagnosis?
5) Who will the new equipment benefit – what are the intended benefits and can these be increased?

Equipment specifications

Write one's equipment specifications. This requires careful thought. Emphasis should be on what the service needs and not what manufacturers are currently able to supply. It is useful to establish a dialogue with manufacturers to facilitate the development of new technologies, which should be mutually beneficial.

Once the tender is completed it is submitted to potential suppliers (for larger capital bids there need to be country-wide or European-wide advertisements). During the tender process, companies must not contact any member of Trust staff associated with the tender without the authorization of staff in the procurement department. Trials and demonstrations may only be set up with the formal approval of the procurement department. Failure to comply with this requirement may exclude suppliers during the assessment and evaluation stages.

Bid evaluation

It is important to devise the technical award criteria for any medical device to be purchased. This allows the user to have a clear assessment of all the options, how to evaluate these options and the weighting for any of the criteria. Price is not usually included in the criteria; it should be based purely on technical issues. This is obviously a consideration that needs to be made with any procurement department. The cost not only includes the cost of purchase but running costs and cost of spare parts and maintenance and calibration. These criteria should be devised before the formal tender is sent to potential suppliers, again as part of the good governance process.

Typical criteria may include:

- Features (what does it do?);
- Technical performance (how well does it do the things it is supposed to do? Is it fast, effective and accurate);
- Ease of use;
- Safety;
- Technical and service (how long has the company existed? Does it have a reliable history? This does not mean that new innovative companies should be dismissed).

A weighting needs to be awarded to reflect the importance of each criterion. When bids are returned a meeting of the potential users needs to complete the award criteria document; the relative merits of the bids should be discussed and a score agreed. The score will be used to select the most effective and suitable product.

Although not an exact science, it is important that an open mind is maintained.

The pre-purchase questionnaire needs to be provided by potential suppliers and should verify the projected life of the equipment (e.g. how long spare parts are guaranteed) as well as information on maintenance and calibration required.

Procurement and installation

This involves disposal of old equipment; cancelling appropriate clinics for pre-arranged installation date; installation; checking instrument and training.

It is important not to underestimate the amount of work involved in the installation of a vestibular testing laboratory. It is advisable to have regular meetings between all those who are involved in the installation – representatives from Audiology and ENT (likely to be Chair and leading the project); Medical Physics; Building Estates; Procurement; Finance; Business Manager; Information Technology and last but not least perhaps a representative from patient user groups.

It is always wise to ensure that a supplier specifies the time required between placing an order and delivery of the equipment, and for the installation date and period required to be agreed and planned well in advance.

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