HSE South Audiology Review 2009

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Section 1- Background

During 2008, concerns were raised about the practice of an Audiological Scientist who had worked, primarily, in Cork from 2001 to 2007.

Audiological scientists work to diagnose hearing problems in children and adults, and also to restore or habilitate hearing loss though providing and fitting hearing aids and other assistive technologies.

From September 2001 to December 2007, the Audiological Scientist of concern had responsibility for community-based audiology services in Cork City and County, worked for a short time in Limerick during 2002 and 2003 and very briefly worked in Tralee during 2005 and 2006. This Audiological Scientist has not practiced in the audiology services since December 2007.

In late 2008, the HSE in Cork commissioned an external expert to assess a sample of files of clients of this Audiological Scientist. The assessment was carried out by an Audiological Scientist based in the UK. Having assessed the files of the sample cases, the UK reviewer identified that there was not sufficient evidence in the charts to be satisfied that the clients concerned had received appropriate diagnosis, habilitation (including selection and fitting of hearing aids) or referral onwards for other specialist services.

Based on this, the HSE recommended on December 2, 2008 that a Serious Incident be declared and immediately set up a Steering Group to manage the incident. The Steering Group concluded that a review would be required to confirm that people seen by the clinician had received the correct clinical management. The review related to audiology services provided by the Audiological Scientist concerned at the following times only:

- Cork: September 2001 to December 2007
- Limerick: February 2002 to November 2003
- Tralee: Six clinics held in Feb/Mar 2005 and July 2006

The HSE identified 1,910 clients who were seen exclusively by this clinician during these periods. The cohort consisted of approximately 88% children and 12% adults.

A team of experienced audiologists from the UK was recruited to complete a desktop audit of the case files of the 1,910 clients.

The purpose of this audit was to identify any clients who should be recalled for a check-up appointment. Case files were anonymised when sent to the UK. An audit tool was designed and validated by relevant expert members of the steering group for this purpose. The audit tool allowed standardised risk assessment of each case and recommendations on the management and prioritisation of each case.

The audit commenced on January 30th 2009 and was completed on March 9th 2009. The results showed that 672 clients files did not show cause for concern and these clients did not require call back to the clinic. The remaining 1,238 were recalled for precautionary check-up appointments. Adverse outcomes were not anticipated for the vast majority of those called for an appointment.

Reasons for being called back included scarcity of documentation; clients may have been assessed or treated correctly but the recording of the treatment was incomplete and overdue review appointments.

Section 2 - Review Findings

Clinical work in this review, and the outcomes listed in this document, cover the period from March 2009 up to and including July 2010. The appointment outcomes are provided below, Table 1.

Table 1

Review Findings	N
Clients invited for review	1238
Clients who did not attend or were not concerned	295
Clients who attended	943
Clients assessed with satisfactory hearing	645
Clients with transient / resolving hearing difficulty	170
Clients with some degree of permanent hearing loss	128

In total, 1,238 clients were offered appointments for a hearing check-up, of whom 943 (76%) chose to attend. Satisfactory hearing was established in 645 at their review appointment, representing 68% of the 943 clients who attended.

At the time of the review assessment, transient or resolving temporary hearing problems were identified or suspected in 170 (18%) clients. In the context of this review, these were not considered adverse outcomes neither did they provide evidence of findings inconsistent with those found previously. The key adverse finding would be the identification of previously unsuspected permanent hearing loss likely to be of congenital onset, or likely to have been present when the client was seen by the audiological scientist whose clinical performance gave cause for concern.

128 clients (13.6% of the 943 seen at call-back) had some degree of permanent hearing loss at review. Table 2.

- 77 of these clients were children under 18 years of age when the review was initiated.
- 51 of these clients were adults over 18 years of age when the review was initiated.

Table 2

Status at Review Appointment	N
Adult	51
Paediatric	77

Paediatric Audit

The three external advisors to the Audiology Review examined the case notes of those 77 children from the review cohort who were identified with permanent hearing loss and who were below 18 years of age on the date the review was initiated (2.12.08). Each client's case notes were discussed by the advisors and a consensus judgement agreed on the following questions concerning the original (i.e. pre-review) procedures:

- Was the correct prioritisation applied, based upon the referral letter and any other available information?
- Were the correct diagnostic procedures used?

- Was the correct clinical interpretation made?
- Were the correct management decisions made (including was the hearing aid fitting and management satisfactory, if applicable)?
- Were the administrative systems adequate (e.g. timely review appointments sent)?

The following observations, summarised in Table 3, were made from this exercise:

- Systems for prioritising incoming referrals worked in all but 12 of the 77 cases.
- Incorrect or inappropriate diagnostic procedures were used in 21 of the 77 cases (for example, undue reliance on the non-frequency-specific 'speech awareness test', misinterpretation of otoacoustic emissions data, absence of and incorrect application of ABR (auditory brainstem response) testing); incorrect clinical interpretations were made in a further two cases.
- Incorrect management decisions were evident in 30 of the 77 cases (some of which were, by definition, the missed diagnoses); for all cases (n=23) wearing hearing aids (i.e. where a permanent hearing loss had previously been identified), there was no evidence that the appropriate clinical standards of hearing aid fitting and verification had been used.
- Poor administration was evident in all but 14 cases, largely a failure to call clients back for reviews or further appointments which had been asked for by the clinician.
- In the cases of 16 children, the results from the review appointments did not support the original findings. They are newly-found cases and represent adverse findings as the hearing loss was likely to have been present when the child was seen previously. The table below summarises the degree of hearing loss and age at (correct) diagnosis in these cases.

Table 3

Degree of hearing loss	Number of cases	Age at diagnosis (years)	
Profound bilateral		6	
Severe bilateral	1	5	
Moderate/severe bilateral	1	12	
Moderate bilateral	2	2, 4	
Mild/moderate bilateral	1	16	
Mild bilateral	2	5, 12	
Profound unilateral	5	4, 4, 5, 5,6	
Severe unilateral	2	6, 9	
Moderate unilateral	1	8	

It should be noted that the effect of a missed diagnosis on a child and family will depend not only on the severity of the hearing loss but also upon a raft of child, family and social variables that will determine over time the extent of the harm done to the patient's development and quality of life.

Notwithstanding this caveat, and bearing in mind that age of first identification of permanent congenital childhood hearing loss is one of the most widely-used performance measures in paediatric audiology in developed countries, the figures in the above table indicate serious cause for concern about service performance during the time periods in question. The review team commented that actions to minimise the chances of such events recurring in future were required as a matter of urgency.

Adult Audit

In 24 of the 51 adults found at review to have a permanent hearing loss, the hearing loss had been correctly identified initially, Table 4. Of the 20 adults with inconsistent findings the hearing loss could conceivably have been acquired (e.g. by aging processes) since the client had been previously seen in 16 cases.

Table 4

Adults	51	
Consistent results	24	
Insufficient information to establish conclusion	7	
Inconsistent results	20	
	Progressive/aging	16
	Incorrect diagnosis	3
	Missed	1

The review findings for the four adults who had inconsistent results are summarised in Table 5

Table 5

Review Finding	Number of cases	Age at Diagnosis
Newly-identified likely to have	1	18
been present when that client		
was seen previously		
Conductive hearing loss	1	Over 65
diagnosed as Sensory Neural		
previous incorrect	2	18,19
identification of a permanent		
hearing loss when hearing		
was within normal limits		

Remedial intervention

All children and adult clients who required further assessment, intervention or referral were referred to the relevant service (Paediatric Audiological Scientists and/or ENT and/or Speech & Language Therapy) for urgent and appropriate management. In the case of newly-identified cases of permanent hearing loss in children, habilitation was initiated immediately.

Clients who did not attend for review

943 out of 1238 clients attended for the precautionary review appointment offered. 295 clients did not attend (DNA) for their given appointment. Every effort was made to contact this entire group to ensure they were aware of the review and the importance of attending their appointment. Clients were called for review by letter, and where the first appointment was not kept, or the letter returned, a second letter was sent with an additional appointment, by registered post. If no response was recorded, the file of the client was examined to determine if a telephone contact was available, allowing an appointment to be made in some cases. If no telephone contact was possible, then the file was again examined to identify a referral contact, e.g. Doctor, Therapist or P.H.N. etc. Contact was made with the referral source, again allowing postal contacts to be updated and a new appointment offered to the client in some cases. If all these efforts failed, and the appointments were not kept, only then was the client categorised as Did Not Attend. Reasons for not DNA included; client no longer concerned, client had emigrated, client obtained service elsewhere, client had died.

Section 3 - Outcomes and Learnings

HSE South Audiology Services would like to thank the reviewing and staff audiologists for the professionalism, care and sensitivity with which they undertook these review appointments and the compilation of the results and recommendations.

Based on the results of this review and the incident investigation, the following outcomes and learning points have been identified for follow up within the service concerned.

1: Restructuring of Audiology Services

- Audiologists and audiological scientists in HSE South should not work in isolation, but should be part of a team able to provide appropriate diagnostic and (re) habilitative services to meet the needs of clients of all ages, including those with complex needs, presenting with hearing, balance and/or tinnitus problems.
- In order to ensure effective critical mass, good clinical governance, efficient skill mix, efficient use of facilities and equipment, and opportunities for staff support, peer review and continuing professional development, and to minimize duplication and service complexity detrimental to the patient journey, audiology services in HSE South should be reorganised into a single managerial and clinical structure with identified high quality clinical leadership.
- The clinical leadership to the integrated all-age department of audiology should be provided from a fulltime consultant-equivalent audiology post occupied by a suitably qualified and skilled person whose primary speciality is audiology.
- The integrated department of audiology should have a main base location with adequate accommodation and equipment commensurate with good quality evidence-based audiology practice; justifiable outreach arrangements should be made as and where appropriate. Investment in accommodation and equipment should be made in order to reflect advances in technology. The clinical lead for the new unified department, working with HSE management, should draw up a list of justified needs and priorities as soon as possible. The installation of soundproof clinical rooms meeting required International Standards Organisation (ISO) noise and reverberation standards should proceed at the earliest possible time.

2: Clinical Pathways & Processes

- Care pathways (CPs) for audiology with clear referral criteria that are understood at all levels of activity, by all staff, and that are clear to referral sources as well as to the general public should be developed for HSE South - underway
- Action should be taken by HSE South to improve administrative procedures such that cases due for review or referral are not unduly delayed or lost to the system.
- In order to avoid unnecessary duplication and complexity in the patient journey, the CPs should make explicit those conditions for which joint clinics involving audiology (ie clinics at which multiple procedures, investigations or consultations can be provided to clients) would be helpful and efficient. Examples would include children with Down's Syndrome, children with complex needs and/or developmental problems, children with cleft palate, and children with otis media likely to require surgical intervention.
- In implementing the CPs, urgent action should be taken by the audiology team clinical leadership to ensure that all audiological assessments and procedures conform to the most up-to-date evidence-based protocols (specifically those developed by the Newborn Hearing Screening Programme in England and the Modernisation of Children's and Adult's Hearing Aid Services initiatives, also in England).
- The audiological procedures for selection, fitting, verification and validation of hearing aid amplification should be improved for all ages. Digital Signal Processing (DSP)

hearing aids should be provided as standard and published prescription procedures utilised, managed via suitable real ear measurement systems.

3: Patient Management IT System

 To enable performance monitoring and to support clinical governance, a single unified audiology Patient Management System (PMS) should be piloted and introduced to cover the activity of the HSE South audiology department with the necessary training as a matter of urgency. The effective use of these systems will require additional IT support from the HSE.

4: Minimal Staffing for Paediatric Procedures

 Some paediatric audiological procedures, such as Visual Reinforcement Audiometry (VRA) and hearing aid and earmould procedures with infants and young children, require the direct involvement of two appropriately clinically qualified staff in order to reduce the possibility of clinical error. Efficient systems should be put in place by management to ensure that sufficient suitably-qualified audiological staff are available for clinics where these procedures are likely to be required.

Section 4 - HSE Actions

The HSE Community Audiology Department has during the review process engaged proactively to improve the standards of facilities, resources, procedures and skill mix to enable good practice to be implemented throughout the service. Listed below is an itinerary of developments that have arisen through the review:

- Investment in a new premise at Unit 4, South Ring Business Park thereby integrating the Department onto a main base and providing adequate accommodation commensurate with good quality evidence-based audiology practice.
- Further investment in equipment including additional Visual Reinforcement Audiometry (VRA), Noah software and networking of the ICT equipment.
- All audiological assessments and procedures now conform to the most up-to date UK evidence-based protocols. These include
 - o British Society of Audiology
 - o Neonatal Hearing Screening Protocols (NHSP)
 - o Modernisation of Children's Hearing Aid Service (MCHAS) guidelines for hearing aid review cases.
- Improvements to the audiological procedures for selection, fitting, verification and validation of hearing aid amplification for all ages.
- Digital Signal Processing (DSP) hearing aids are now provided as standard and published prescription procedures utilised, managed via suitable real ear measurement systems.
- For certain procedures, such as Visual Reinforcement Audiometry (VRA), the direct involvement of two appropriately clinically qualified staff, is now standard practice.
- The clinicians numbers in our paediatric service have increased from 2.4 (1 Senior and 1 Basic Audiological Scientist plus 0.4 PHN) to 4 (1 Senior Audiological Scientist plus 3 Audiologists); and from 2 to 3 Audiologists (1 Senior and 2 Basic Grade) in our adult service.
- Two sound booths have been purchased.
- Cork has been identified as the first site for the implementation of universal newborn hearing screening programme (UNHSP). This new screening service is due to commence in April 2011 in Cork University Maternity Hospital.

Section 5 - Conclusion

As part of the review, where adverse outcomes were identified the HSE apologised to the clients concerned.

The HSE has offered, and continues to make available, habilitation, treatment, information, counselling and support to the families of these clients, and is committed to working to ensure such events do not recur in the future.

The findings of this review will inform the work of the national audiology review group.

Appendix

Membership of the HSE South PCCC Audiology Review Group

Mr. Pat Healy, Regional Director of Operations, Chairperson

Ms. Deirdre Scully, HSE Local Health Manager, North Cork & North Lee

Dr Orla Healy, HSE Specialist in Public Health Medicine

Ms. Teresa O'Donovan, General Manager, HSE PCCC West Cork

Ms. Theresa Bulfin, General Manager, HSE PCCC Limerick

Ms. Fidelma Browne, Head of Public Communications

Mr. Peter O'Sullivan, E.N.T. Consultant

Mr. Michael Butler, HSE Care Group Coordinator and Secretariat

Mr. Ger Crowley, HSE, Assistant National Director

Professor John Bamford, Honorary Professor, School of Psychological Sciences,

University of Manchester.

Dr Cecily O'Donovan, HSE Senior Audiological Scientist - retired

Dr Gary Norman, AuD, M. Sc, B. Sc, Consultant Clinical Scientist

Ms. Angie O'Brien, HSE South Media Relations Manager

Mr. Raymond Daly, HSE I.T. Projects Manager