SCOTTISH PUBLIC SERVICES OMBUDSMAN

People Centred | Improvement Focused

The Scottish Public Services Ombudsman Act 2002

Investigation Report

UNDER SECTION 15(1)(a)

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Scottish Parliament Region: Lothian

Case ref: 201901758, Lothian NHS Board - Acute Division

Sector: Health

Subject: Hospitals / Clinical treatment / diagnosis

Summary

Mr and Mrs C complained about the standard of care and treatment that Lothian NHS Board (the Board) provided to their child (Child A) in relation to their hearing from June 2012 until January 2018. Mr and Mrs C believed that Child A had a significant hearing impairment from two and a half to three years of age. They complained that this went undiagnosed, despite Child A undergoing multiple tests over a number of years with the Board's Audiology Service. Mr and Mrs C said that the Board's failure to diagnose Child A's hearing impairment within a reasonable timescale affected Child A's communication skills and, potentially, their ability to learn.

Mr and Mrs C explained that Child A had complex needs, including cerebral palsy and learning difficulties, and was also non-verbal. Child A failed the initial hearing screening test and was referred to the Board's Audiology Service, who found that Child A may have some mild hearing loss in both ears. Child A was then seen by clinicians at the Board's Audiology Service several times over the following years, and the audiologists told Mr and Mrs C that they frequently found it difficult to obtain reliable test results due to Child A's communication difficulties. However, Child A was discharged from the Audiology Service twice as a result of staff being satisfied that they did not have any significant hearing loss.

Mr and Mrs C did not accept the test results, saying that the audiologists were not taking into account Child A's symptoms and additional needs during testing. Following continued concerns being raised by Mr and Mrs C and Child A's school, Child A was eventually referred to audiologists at another health board for a second opinion. A number of tests were carried out and Child A was diagnosed with severe to profound hearing loss in both ears. Child A was eight years old at that point. Child A was subsequently fitted with hearing aids which Mr and Mrs C observed appeared to have helped their hearing.

We took independent advice from a specialised audiologist. We found that there was a significant and unreasonable delay in the diagnosis of Child A's hearing impairment resulting from unreasonable, sustained and significant failures in the diagnostic and testing process. We also found significant failings in the Board's investigation of Mr and Mrs C's complaint. The Board failed to identify even the most basic errors in the service they provided, as they should have done as part of their duty of candour, and the standard of their response to Mr and Mrs C was very poor.

We upheld Mr and Mrs C's complaint.

Redress and Recommendations

The Ombudsman's recommendations are set out below.

What we are asking the Board to do for Mr and Mrs C:

Recommendation number	What we found	What the organisation should do	What we need to see
1	We found there was a significant and unreasonable delay in the diagnosis of Child A's hearing impairment resulting from unreasonable, sustained and significant failures in the diagnostic and testing process. We also found significant failings in the Board's investigation of Mr and Mrs C's complaint in that they failed to identify even the most basic errors in the service they provided as they should have done as part of their duty of candour and that the standard of their response to Mr and Mrs C was very poor	Apologise to Mr and Mrs C for the failings identified in this investigation and inform Mr and Mrs C of what and how actions will be taken to prevent a reoccurrence. The apology should meet the standards set out in the SPSO guidelines on apology available at www.spso.org.uk/information-leaflets	A copy or record of the apology. By: 30 June 2021

We are asking the Board to improve the way they do things:

Recommendation number	What we found	Outcome needed	What we need to see
2	We found there was a significant and unreasonable delay in the diagnosis of Child A's hearing impairment resulting from unreasonable, sustained and significant failures in the diagnostic and testing process	Review the failures in the diagnostic and testing process identified in this investigation to ascertain: how and why the failures occurred; any training needs; and what actions will be taken to prevent a future reoccurrence	Evidence that the diagnostic and testing failings have been reviewed and learning taken from them to improve future service. By: 19 November 2021
3	We found there was a significant and unreasonable delay in the diagnosis of Child A's hearing impairment resulting from unreasonable, sustained and significant failures in the diagnostic and testing process	Arrange for an external audit of the testing of patients from 2009 until 2018 to be carried out to ensure there is no systemic or individual issue which may have affected other patients, and inform this office of the results	Evidence of the audit and its results. By: 19 November 2021

Recommendation number	What we found	Outcome needed	What we need to see
4	We found there was a significant and unreasonable delay in the diagnosis of Child A's hearing impairment resulting from unreasonable, sustained and significant failures in the diagnostic and testing process	Feedback the findings of our investigation in relation to the failures in the diagnostic and testing process to relevant staff for them to reflect on	Evidence the findings of our investigation have been fed back to relevant staff in a supportive manner. By: 30 June 2021

We are asking the Board to improve their complaints handling:

Recommendation number	What we found	Outcome needed	What we need to see
5	We also found significant failings in the Board's investigation of Mr and Mrs C's complaint in that they failed to identify even the most basic errors in the service they provided as they should have done as part of their duty of candour and that the standard of their response to Mr and Mrs C was very poor	Review the complaint handling failures to ascertain: how and why the failures occurred; any training needs; and what actions will be taken (or since then have been taken) to prevent a future reoccurrence	Evidence that the complaint handling failings have been reviewed and action taken to prevent a future reoccurrence. By: 30 June 2021
6	We also found significant failings in the Board's investigation of Mr and Mrs C's complaint in that they failed to identify even the most basic errors in the service they provided as they should have done as part of their duty of candour and that the standard of their response to Mr and Mrs C was very poor	Ensure Board investigations identify and address incidents covered by the duty of candour with the relevant Scottish Government guidance	Evidence that the failure to comply with the duty of candour has been reviewed and action taken to stop a future reoccurrence. By: 30 June 2021

Who we are

The Scottish Public Services Ombudsman (SPSO) investigates complaints about organisations providing public services in Scotland. We are the final stage for handling complaints about the National Health Service, councils, housing associations, prisons, the Scottish Government and its agencies and departments, the Scottish Parliamentary Corporate Body, water and sewerage providers, colleges and universities and most Scottish public authorities. We normally consider complaints only after they have been through the complaints procedure of the organisation concerned. Our service is independent, impartial and free. We aim not only to provide justice for the individual, but also to share the learning from our work in order to improve the delivery of public services in Scotland.

The role of the SPSO is set out in the Scottish Public Services Ombudsman Act 2002, and this report is published in terms of section 15(1) of the Act. The Act says that, generally, reports of investigations should not name or identify individuals, so in the report the complainants are referred to as Mr and Mrs C. The terms used to describe other people in the report are explained as they arise and in Annex 1.

Introduction

1. Mr and Mrs C believed their child (Child A) had a significant hearing impairment from two and a half to three years of age. They complained that this went undiagnosed, despite Child A undergoing multiple tests over a number of years with the Audiology Service at Lothian NHS Board (the Board). Mr and Mrs C said that the Board's failure to diagnose Child A's hearing impairment within a reasonable timescale affected Child A's communication skills and, potentially, their ability to learn.

2. The complaint from Mr and Mrs C I have investigated is that the Board failed to ensure clinicians provided a reasonable standard of care and treatment to Child A in relation to their hearing in light of their symptoms and additional needs from June 2012 until January 2018 *(upheld)*.

Investigation

3. In order to investigate Mr and Mrs C's complaint, my complaints reviewer carefully reviewed the documentation provided by Mr and Mrs C in support of their complaint and by the Board in response to enquiries they made of them. My complaints reviewer also sought independent advice from an appropriately qualified adviser (the Adviser, an experienced audiologist).

4. I appreciate that at this time, the whole of the NHS is under considerable pressure due to the impact of COVID-19. Like others I recognise, appreciate and respect the huge contribution everyone in the NHS (and public services) is making. However, much as I recognise this, I also recognise that patient safety, personal redress, and learning from complaints are as relevant as ever and it is important that we do not miss opportunities to learn for the future.

5. I have decided to issue a public report on Mr and Mrs C's complaint. This reflects my concern about the serious failings identified in Child A's care and treatment; the significant personal injustice Child A suffered; and the potential for wider learning from the complaint.

6. This report includes the information that is required for me to explain the reasons for my decision on this case. I have not included every detail of the

information considered but I am satisfied that no matter of significance has been overlooked. Mr and Mrs C and the Board were given an opportunity to comment on a draft of this report.

7. My complaints reviewer was asked to review the Board's actions between June 2012 and January 2018. However, the original complaint to the Board went back to Child A's birth in 2009 and I found that events from that time were directly relevant to the issues raised from 2012 onwards. As such, I have included events dating back to 2009 in this report.

Complaint: The Board failed to ensure clinicians provided a reasonable standard of care and treatment to Child A in relation to their hearing in light of their symptoms and additional needs from June 2012 until January 2018

Concerns raised by Mr and Mrs C

8. Child A was born in 2009. Mr and Mrs C explained that they had complex needs, including cerebral palsy and learning difficulties. Child A was also non-verbal; failed the initial hearing screening test and was referred to the Board's Audiology Service. A click auditory brainstem response (ABR test, a test to check the response of the brain and hearing nerves to sound) was carried out and suggested that Child A may have some mild hearing loss in both ears. A review of their hearing was scheduled for eight months' time.

9. Mr and Mrs C told us that Child A was seen by clinicians at the Board's Audiology Service several times over the following years. The audiologists told them that they frequently found it difficult to obtain reliable test results due to Child A's communication difficulties. However, Child A was discharged from the Audiology Service twice as a result of staff being satisfied that they did not have any significant hearing loss.

10. Mr and Mrs C did not accept the test results, as the audiologists' conclusions were based on perceived facial reactions by Child A to the noises being played during the tests. Mr and Mrs C explained that, as a child with cerebral palsy, Child A would consistently make facial gestures and movements, therefore, making these an unreliable basis for assessing their response to the sound test. Mr and Mrs C said

that, although Child A would not give the same responses during repeat tests, and despite raising their concerns with the audiologists, their requests for different tests to be carried out were repeatedly declined.

11. Following continued concerns being raised by Mr and Mrs C and Child A's school, they were eventually referred to audiologists at another health board for a second opinion. A number of tests were carried out and Child A was diagnosed with severe to profound hearing loss in both ears. Child A was eight years old at the time. It was also established that Child A had had a congenital cytomegalovirus infection (CMV, a virus that can cause problems including late-onset progressive hearing loss in children). Child A was subsequently fitted with hearing aids which Mr and Mrs C observed appeared to have helped their hearing.

12. Mr and Mrs C said that they appreciated the difficulties involved in testing Child A's hearing. However, they did not feel that their concerns regarding the accuracy of test results, or their observations as parents, were properly listened to by the Board's staff. They considered that Child A's history suggested that hearing loss had developed at around two and a half to three years of age and went undiagnosed. Mr and Mrs C complained that this failure to diagnose Child A's hearing loss impacted on their communication abilities and, potentially, ability to learn.

13. Mr and Mrs C also said that Child A was meant to have a Magnetic Resonance Imaging (MRI) scan at the age of three months, following unclear results from an earlier scan. They noted that this was not carried out and felt that CMV may have been identified sooner had the MRI been done. They considered that, if the audiologists were aware of Child A's CMV, this may have led them to investigate their possible hearing loss more closely.

The Board's response

14. The Board noted that Child A underwent an MRI scan in November 2009. This identified features consistent with tissue injury due to hypoxic-ischaemic encephalopathy (HIE, a lack of oxygen getting to a baby via the placenta). The MRI also suggested an underlying anomaly with the way that Child A's brain had developed. Due to movement during the MRI, and difficulties related to the signs of HIE, the multidisciplinary team (MDT) were unable to make clear conclusions from

the MRI results and recommended a further scan be carried out at the age of three months. The Board acknowledged that this scan was not carried out. However, they did not consider that a further MRI scan at three months would necessarily have led to a diagnosis of CMV at that stage, as the normal process of brain development is often insufficiently advanced to allow malformations to be seen. The Board also noted that there would have been risks associated with a further MRI and that any results obtained would have been unlikely to change Child A's management.

15. With regard to Child A's hearing tests, the Board noted that, following their birth, Mr and Mrs C reportedly had no concerns about their hearing. They said that Child A reacted to sounds. The ABR test was carried out and showed a mild hearing loss at worst.

16. The Board noted that Child A had attended audiology assessments in July 2010 and February 2011. On both occasions, it was noted that it had been difficult to test Child A accurately; however, the testing that had been carried out showed that any hearing loss in 2010 was mild and that their hearing was within the normal range in February 2011.

17. At a further assessment in September 2011, it was not possible for staff to complete one type of testing (Visual Reinforcement Audiology (VRA, a test whereby the child is 'conditioned' to associate visual cues with sounds)) as they were unable to condition Child A. The assessment was completed using distraction testing (where the child's ability to hear and turn towards sound is observed). The Board said that the combined results of the tests indicated that Child A's hearing was within the normal range. However, a review was scheduled for six months' time due to Mr and Mrs C's concerns that it could be difficult to tell how well Child A was hearing at times.

18. On 25 May 2012, Child A attended an MDT assessment. Again, it was reportedly difficult to complete the assessment and results were based on a combination of VRA and distraction testing. It was noted that Child A was able to understand and follow instructions, but that their expressive language development was delayed. They were using a few single words and gestures to communicate. Follow-up with the specialist diagnostic audiology clinic was recommended.

19. Child A attended the diagnostic audiology clinic on 6 August 2012. Whilst Child A was observed to have responded to sounds in both ears, these results were not repeatable and a further review in six months' time was suggested.

20. Child A returned to the diagnostic audiology clinic on 13 May 2013. The Board noted that staff were able to obtain clear and repeatable results that indicated normal hearing in both ears. As a result, Child A was discharged from the Audiology Service.

21. Mr and Mrs C continued to have concerns regarding Child A's hearing and they were seen again at a community audiology clinic on 19 March 2015. It was noted that Child A had no speech and was using a sign-along (a form of sign language) to communicate. Staff were unable to obtain any clear test results on this occasion and a referral was made for follow-up at the diagnostic audiology clinic on 6 July 2015.

22. Testing with VRA and speech discrimination testing (a test to determine how well the individual understands words) found that Child A's hearing was normal. However, ear-specific tests were not possible and a further review in six months was scheduled. Child A's hearing was found to be within the normal range again at the review appointment on 18 January 2016. As such, they were discharged from Audiology again. The Board noted that Mr and Mrs C had requested hearing aids for Child A, but stated that, as their hearing had been found to be within normal levels, these would not have been appropriate.

23. Child A was referred back to the Audiology Service in May 2017. Testing demonstrated a mild hearing-loss. However, the tests could not be completed. As a result of Mr and Mrs C's continued concerns, it was agreed that Child A would undergo an ABR test under general anaesthetic.

24. On 4 September 2017, Child A underwent the ABR test. The Board explained that conditions were far from ideal with significant interference within the room from electrical equipment. Clear test results could not be obtained and staff offered Mr and Mrs C three options as to how to proceed:

a. re-run the ABR test at the risk of experiencing the same problems;

b. have another review in the diagnostic clinic; or

c. ask another health board for a second opinion.

The Board said that Mr and Mrs C opted to have Child A undergo further testing at the diagnostic clinic.

25. Child A was seen at the diagnostic clinic on 16 October 2017. Testing concluded that they had, at worst, mild hearing loss. Although staff felt that this was consistent with previous test results, Mr and Mrs C were keen to seek a second opinion and Child A was referred for review by audiologists in another health board.

26. Child A was seen by a consultant audio-vestibular physician in another health board (the Physician) in January 2018. They noted that Child A had undergone insert performance audiometry and transient evoked optoacoustic emissions (TEOAE test, a test of the response by the outer hairs of the cochlea to noise). The results indicated that Child A required sounds to be raised considerably before they responded. The Board commented that a TEOAE response had been identified in Child A's right ear and that this would not have occurred in the presence of severe or profound hearing loss.

27. The Physician had recommended that Child A undergo another ABR under general anaesthetic. This was carried out in August 2018 and showed that Child A had severe to profound hearing loss. Child A's referral to another health board also led to the diagnosis of their CMV.

28. The Board considered that the test results indicated Child A's hearing was normal until July 2017 in the left ear, and February 2018 in the right ear. They were satisfied that developmentally age-appropriate and internationally accepted audiology assessments were carried out by their staff.

29. The Board noted that congenital CMV is known to increase a child's risk of late-onset and progressive hearing loss.

Relevant legislation

30. The legal duty of candour for all organisations that provide health services, care services or social work services in Scotland is set out in the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 and The Duty of Candour Procedure

(Scotland) Regulations 2018. This relates to where there has been an unintended or unexpected incident that results in, for example, harm (or where additional treatment is required to prevent injury). The focus of the duty of candour legislation is to ensure that organisations tell those affected that an unintended or unexpected incident has occurred; apologise; involve them in meetings about the incident; review what happened with a view to identifying areas for improvement; and learn (taking account of the views of relevant persons). Organisations must ensure that support is in place for their employees and for others who may also be affected by unintended or unexpected incidents.

Medical advice

31. My complaints reviewer asked the Adviser whether the Board had provided a reasonable standard of care and treatment to Child A in relation to their hearing. The Adviser reviewed Child A's clinical records from birth and their view was that clinicians failed to provide a reasonable standard of care and treatment for Child A from the offset.

32. The Adviser explained that TEOAE is an automated test for sensori-neural function. Tympanometry is a test of middle ear function and is widely used to detect middle ear congestion. The Adviser noted that, on many occasions in Child A's case, no TOAEs were obtained in the presence of normal tympanograms since the first test on 27 October 2009, which was a red flag, indicating probable hearing loss, and should always be investigated further.

33. With regard to the ABR test on 28 November 2009, the Adviser explained that ABR testing requires little or no cooperation from the patient, as information is extracted from ongoing electrical activity in the brain and recorded via electrodes placed on the head. At least two traces are usually run at each intensity and if the traces are closely matched (similar) to each other, it can be said that there is a clear response (CR) at that intensity. The Adviser noted that some of Child A's ABR traces on 28 November 2009 were incorrectly labelled as CR and that the two traces were not similar enough to be labelled CR and should have been labelled as inconclusive. The Adviser further noted that click stimuli was used, and explained that this is a broad band stimulus which could potentially fail to detect all hearing losses. For

example, if Child A had better hearing thresholds at some frequencies and very poor hearing at other frequencies, a click stimulus would pick up information from the better frequencies and Child A would appear to have better hearing than they actually had. The Adviser said that click stimuli was more widely used in 2009 than it is today but even so more information should have been sought at this stage, rather than requiring Child A to wait until the age of eight to nine months. This was the first example of many throughout Child A's treatment that they had seen poor quality response being accepted without being supported by objective tests, as well as long gaps between appointments.

34. The Adviser told me that VRA testing works by conditioning a child to turn to locate a visual reward in response to hearing a sound. The child is conditioned first using a loud sound and, once reliable responses are obtained repeatedly, the intensity of the sound can be reduced to measure the exact intensity at which the child begins to hear.

35. The Adviser noted that, on 16 July 2010, Child A could not be conditioned to VRA, so the testers used distraction testing instead. The Adviser explained that, in distraction testing, sounds are made behind the child to see if they will turn in response to the sound. However, there are many pitfalls associated with this form of testing; a child with a hearing impairment may use their other senses to pick up on cues. They may detect perfume, shadows or reflections on shiny surfaces, air movements or slight eye and body movements. The Adviser noted that distraction testing was used frequently with Child A; however, as it is very easy for a child with a hearing impairment to pass a distraction test, this should not be relied upon in isolation.

36. The relevant guidance[1] is clear that this test is only recommended for use within a test battery of previous test methods. At this appointment, despite having normal tympanometry traces in both ears, the responses obtained during distraction testing were at a raised level. There is a note that Child A was reluctant to turn to the left side and that testing indicated a mild – moderate hearing loss, but Child A was left for

[1]British Society of Audiology: Practice Guidance - Assessment Guidelines for the Distraction Test of Hearing.

four months before being retested. There is no evidence in the notes or on the test sheet to say whether Child A's parents were asked if they were concerned.

37. On 4 February 2011, it is noted in the clinical records that Child A was distressed by inserts (headphones that go inside the ear canals similar to ear buds), so responses were measured using speakers (referred to as soundfield testing), which is reasonable and takes into account Child A's needs. It is also noted that responses were slow, but repeatable. It is not clear from the test sheet if the responses obtained were repeatable as there is only one entry for each response (there should be two entries to indicate that two responses were obtained). Child A was left for six month before being retested. Again, the Adviser said that there is nothing in the notes or on the test sheet to say whether Child A's parents were asked if they were concerned.

38. On 23 September 2011, VRA testing was again abandoned in favour of distraction testing as Child A was recorded as being *'a* challenge *to assess'*. The Adviser noted that some test results were obtained for the right ear; responses were behavioural or very slight (for example 'stilling' or 'pausing' to the sound). However, responses such as head turns or full eye movement is preferred. All responses apart from one were unrepeatable, which makes them un-recordable.

39. The Adviser explained that acoustic reflexes are a measure of the neural pathway and if present, it can be reasonably assumed that some cranial nerves are functioning and that sounds are reaching part of the brain. It is a very useful objective test and can be used routinely as part of diagnostic audiometry. On this day, reflexes were only present at low frequencies in the right ear, but Child A would not tolerate testing of their left ear. Again, there is nothing in the clinical notes or on the test sheet to say whether Child A's parents were asked if they were concerned and Child A was left for a further six months (which turned out to be eight months).

40. The Adviser went on to say that, on 25 May 2012, it was recorded that Child A was *'extremely difficult to assess'*. Their recorded reactions were in response to *'prolonged presentation, when [they] swung round in* annoyance'. The Adviser told

me and my complaints reviewer that this went against protocols[2]; test sounds should be no longer than two to three seconds and responses (head turns) should be clearly in response to the stimuli. The Adviser was very concerned by the audiologists' comments at this examination, as even a child with a severe hearing impairment will turn their head eventually if they got a reward each time. Child A was recorded at this point as having *'delayed expressive language'* and the Adviser said that this, combined with their lack of engagement with testing, should have rung alarm bells for the audiologists as both these things point to hearing loss, and that the standard of testing at this appointment was very poor.

41. With regard to the examination on 6 August 2012, the Adviser noted that Child A was conditioned for VRA testing, but the responses they gave were not repeatable. As such, these could not be recorded. It was also recorded in the notes that Child A *'ignored sound stimuli'*. However, no action was taken and Child A was simply listed for retest in six months' time (which turned out to be eight months).

42. The Adviser noted that, in March 2013, Child A's speech therapist contacted the Audiology Service and requested to be kept up to date with their case.

43. With regard to the 13 May 2013 examination, Child A was again tested using VRA. The Adviser was concerned to note that although the audiologists had recorded that Child A was *'unable to associate sounds with visual reinforcers'*, they concluded that their hearing was within the normal range and discharged Child A from the Audiology Service.

44. In 2014, it was recorded that Child A's speech had regressed, resulting in them being referred back to the Audiology Service, and their speech therapist contacted the department again to ask for an update.

45. The Adviser told me that at the assessment on 19 March 2015, when no results recordable were obtained, there were further red flags in that Child A was noted to have difficulty hearing and locating sounds, which indicated that hearing may be poorer in one ear than the other.

[2] British Society of Audiology Recommended Procedure for Visual Reinforcement Audiometry test protocol.

46. Child A was seen again on 6 July 2015 where VRA was deemed to be borderline normal. Child A was again described *'as difficult to test'*. It is noted that during this year, Mrs C requested that Child A be fitted with hearing aids, but this was declined as the Audiology Service felt Child A's hearing was normal.

47. The following year, the Adviser said that the clinical records indicated VRA was obtained in both ears, normal tympanometry traces were obtained and Child A was discharged. In May 2017, however, Child A was referred back to the Audiology Service following Evoked Potential Responses testing (similar to ABR testing), which indicated no response to sound.

48. Child A was seen again by the Audiology Service on 3 July 2017 when play audiometry was attempted. Initially Child A was conditioned to perform the test (this involves showing Child A what to do while using a loud sound), but as the test progressed, the reliability reduced. At this point, the Adviser said it would have been advisable to recondition Child A using the loud sound again or switch to a vibrotactile stimuli (a small bone vibrator that can be felt). This is normal practice which allows audiologists to ascertain if a child can be conditioned to play audiometry or if they simply are not hearing the sounds that are being presented. There are no notes to say that reconditioning or using a bone vibrator was attempted. It is noted at this appointment that the family were very concerned. Child A was listed for ABR in theatre under general anaesthetic.

49. With regard to the ABR test on 4 September 2017, the Adviser explained that Wave 5 (or Wave V) is the main landmark looked for on an ABR trace. The audiologist noted in the Auditbase Journal: *'Wave V visible at initial presentation of sound both at 40 and 80 but no stability'*. The Adviser said that this was a clear contradiction to the information on the results sheet for that day. It was noted that there was too much interference to sufficiently record a stable Wave V. The Adviser commented that if there were no results obtained then it would be incorrect and misleading to record information that contradicted this. Any audiologist who carries out ABR testing regularly will be familiar with the fact that the initial trace observed at a few hundred repetitions often bears no resemblance to the final trace once a satisfactory 2000 to 3000 repetitions have been obtained. When using tone pip, traces can only be accepted once they reach 2000 to 3000 repetitions.

50. The Adviser considered that the information in the journal may have aimed to indicate normal traces at initial presentation of sound, but there was no evidence to support this. The Adviser questioned whether the tester had even considered that the lack of Wave V may have been due to a hearing impairment, particularly as there were no TOAEs present.

51. Child A next attended the Audiology Service on 16 October 2017 where behavioural responses indicated a mild hearing loss at worst. The Adviser noted that the audiologist recorded that Child A was '*inhibiting their responses'*. The Adviser said this was very concerning to read as it suggested the audiologist was not open to considering that Child A may not have been hearing the sounds.

52. The Adviser noted that, following Mr and Mrs C's request for a second opinion, Child A was seen in another health board four months later. Child A was successfully conditioned to play audiometry and it was ascertained that they had a bilateral profound hearing loss. The Adviser did not believe a child could go from a long history of being *'difficult to assess'* to performing a full play audiometry within the space of four months and said that this indicated poor testing, rather than a difficult to test child.

53. The Adviser was critical of a number of aspects of the Board's investigations into Child A's hearing:

- First, Child A was left for too long between appointments, with between four and eight months passing following assessments that were inconclusive or unusable results were obtained.

- Second, the statement that Child A was *'ignoring stimuli'* is particularly worrying because it reflects an attitude of trying to prove the child can hear without even considering that the child could have a hearing impairment.

- Third, Child A was repeatedly branded as being *'difficult to test'*; it is a failing of the audiologist if good quality results are not obtained, not the fault of the child.

54. The Adviser further considered that the concerns raised by the speech therapist, teachers and Child A's parents should have raised the alarm for the

audiologists. Moreover, while the evidence indicated clinicians took into account Child A's additional complex needs by tailoring the test to Child A's ability rather than age, there was no indication clinicians even considered that Child A was a hearing-impaired child. The Adviser concluded that there were many missed opportunities to diagnose Child A's hearing loss; the many red flags should not have been ignored (no TOAEs in the presence of normal tympanograms, parental concern, concern at school regarding lack of ability to localise sound, speech therapist chasing appointments). It was reasonable to expect a paediatric audiologist to notice these red flags and any audiologist with the basic level of knowledge and experience in paediatric audiology would be expected to pick up on parental concern and lack of hearing information from objective tests.

55. My complaints reviewer asked the Adviser whether they considered the Board's view, that Child A's hearing loss developed around the age of seven to eight, was reasonable. In response, the Adviser said that this was not a reasonable conclusion. Hearing loss at that age would have elicited a sudden change in behaviour, which was not reported. It was their professional opinion that Child A probably had at least a mild hearing loss since birth. This progressed and at age two and a half to three, the hearing loss reached such a level that Child A's speech regressed.

56. The Adviser said that a child with congenital CMV infection may be born with or develop a progressive permanent hearing impairment. It is recommended in many local audiology department protocols that they are screened very regularly (approximately every six months) until the age of five or six (the hearing loss usually stabilises by age six or seven). The Adviser referred to a selection of clinical guidelines (from different organisations) stating that children with CMV should have hearing tests regularly in early childhood to detect deafness.[3]

[3] NHS Greater Glasgow and Clyde Board at www.clinicalguidelines.scot.nhs.uk/ggc-paediatric-guidelines/ggc-guidelines/neonatology/cytomegalovirus-cmv-congenital-infection/; ENT and Audiology News at www.entandaudiologynews.com/features/audiology-features/post/targeted-cmv-screening-and-hearing-management-of-children-with-congenital-cytomegalovirus-infection; The National Deaf Children's Society at www.ndcs.org.uk/documents-and-resources/congenital-cytomegalovirus-cmv-and-deafness/.

57. In relation to the injustice these failings led to, the Adviser was very clear in their view that the Audiology Service's failure to diagnose Child A's hearing impairment in a timely manner denied Child A access to speech information and environmental sounds or cues, which in turn prevented Child A from developing speech and interacting normally with Child A's peers. Child A had some words before their speech regressed, so it is reasonable to assume Child A is physically capable of speech. It was also reported that since being fitted with hearing aids, Child A has been vocalising, responding to sound and interacting more with Child A's peers. This has been noticed both at home and school. Not being fitted with hearing aids has potentially caused delays in speech and general development and social interactions that need not have been the case. Denying the brain access to sound will also have caused degeneration of the auditory pathways meaning that hearing aids will be less useful than they could have been, had they been fitted within four to six months of either birth or onset of hearing impairment. The Adviser went on to say that Child A is unlikely to be a successful candidate for cochlear implantation (a small electronic device that electrically stimulates the nerve for hearing) due to the period of auditory deprivation. There may be other reasons why Child A would be an unsuitable candidate, but a period of auditory deprivation for this long, causing the neural pathways to degenerate as they will have, would undoubtedly make Child A less suitable for that reason alone.

58. Finally, my complaints reviewer asked the Adviser about the standard of the Board's response in light of the evidence from the clinical records. The Adviser pointed out a number of factual inaccuracies in the response saying it was in fact the case that:

- there are no clear objective tests confirming Child A's hearing ability until 2017-2018;
- congenital CMV is known to cause hearing loss either at birth or later onset or both; and
- the auto neurological auditory brainstem test carried out by neurology did not support the Audiology Service's findings of normal hearing.

59. In a final point, the Adviser disagreed with the Board's statement about the impact of learning of a congenital CMV diagnosis earlier, saying that the risk of hearing loss with congenital CMV is very high so any parental concern should have been taken seriously in a child with congenital CMV.

Decision

60. Mr and Mrs C complained that clinicians failed to provide a reasonable standard of care and treatment to Child A in relation to their hearing (in light of their symptoms and additional needs) from June 2012 until January 2018. In reaching my decision, I have taken into account the advice I have received about the standard of care and treatment provided to Child A since birth (in 2009) in light of the evidence from that point onwards indicating a pattern of failings. This is pertinent given the Board's position that congenital CMV causes hearing loss at late onset (i.e. not birth) and that Child A developed sudden progressive hearing loss at seven to eight years of age.

61. The advice I have accepted is that the Audiology Service failed to diagnose Child A with hearing loss within a reasonable time and that this caused, at the least, delayed speech with probable delayed development and social interactions. While Child A's additional medical conditions means that their case is complex, there is evidence that clinicians took into account Child A's additional complex needs by tailoring the test to Child A's ability rather than age. Having said that, there was no indication clinicians even considered that Child A was a hearing-impaired child, which is a fundamental failing. I am highly critical of this. Moreover, from the outset, there were multiple failings which meant numerous opportunities to identify Child A's hearing impairment were missed since 2009. The Adviser said:

- assessments were ended without any recordable results being obtained, or with conclusions being reached on partial or sub-optimal results;
- the standard of testing was poor including incomplete tests;
- inconclusive sessions were ended without a timely follow-up;

- test results and numerous red flags which pointed to hearing loss were missed or not acted upon;

- there was evidence clinicians were focused on trying to prove Child A could hear rather than considering that they had a hearing impairment (notably Child A being recorded as *'ignoring stimuli'* or *'inhibiting their responses'*); and

- Child A was repeatedly branded as being *'difficult to test'* to explain poor quality results rather than considering any failings on the part of the tester, the audiologists.

62. I accept this advice. I am extremely concerned about these failings and the impact they have had on Child A. I am clear the evidence indicates significant, sustained and at times basic failings both at an individual level and with the Audiology Service as a whole, which has led to a significant injustice to Child A whose hearing impairment was not diagnosed until they were nine years of age. The Adviser said Child A probably had at least a mild hearing loss since birth, which progressed and several years later, it reached such a level that Child A's speech regressed. I accept the advice I received.

63. While the focus up to now has been on the impact on Child A, I cannot ignore the impact it had on Mr and Mrs C. It is evident to me it caused worry, concern and distress that could have been alleviated. While I recognise that parents and loved ones can sometimes be overly-concerned, what concerns me in this case is the communication and lack of evidence that Mr and Mrs C's concerns were listened to as well as they might have been.

64. I am also critical of the Board's response to this significant complaint. While the Board acknowledged the lack of a follow-up MRI scan when Child A was three months old, they failed to identify even the most basic errors in the subsequent provision of service to Child A for years after as they should have done as part of their duty of candour. I am highly critical of this. At the least, this should have been reviewed when the Board learned of the results of the second opinion; the Board should take action to ensure the integrity of their complaint handling.

65. In light of the failings identified, I uphold this complaint. My recommendations for action by the Board are set out at the end of this report.

66. The Board have accepted the recommendations and will act on them accordingly. We will follow up on these recommendations. The Board are asked to inform us of the steps that have been taken to implement these recommendations by the date specified. We will expect evidence (including supporting documentation) that appropriate action has been taken before we can confirm that the recommendations have been implemented.

Recommendations

Learning from complaints

The Ombudsman expects all organisations to learn from complaints and the findings from this report should be shared throughout the organisation. The learning should be shared with those responsible for the operational delivery of the service as well as the relevant internal and external decision-makers who make up the governance arrangements for the organisation, for example elected members, audit or quality assurance committee or clinical governance team.

What we are asking the Board to do for Mr and Mrs C:

Recommendation number	What we found	What the organisation should do	What we need to see
1	We found there was a significant and unreasonable delay in the diagnosis of Child A's hearing impairment resulting from unreasonable, sustained and significant failures in the diagnostic and testing process. We also found significant failings in the Board's investigation of Mr and	Apologise to Mr and Mrs C for the failings identified in this investigation and inform them of what and how actions will be taken to prevent a reoccurrence. The apology should meet the standards set out in the SPSO guidelines on apology available at www.spso.org.uk/information-leaflets	A copy or record of the apology. By: 30 June 2021

Recommendation number	What we found	What the organisation should do	What we need to see
	Mrs C's complaint in that they failed to identify even the most basic errors in the service they provided as they should have done as part of their duty of candour and that the standard of their response to C was very poor		

We are asking the Board to improve the way they do things:

Recommendation number	What we found	Outcome needed	What we need to see
2	We found there was a significant and unreasonable delay in the diagnosis of Child A's hearing impairment resulting from unreasonable,	Review the failures in the diagnostic and testing process identified in this investigation to ascertain: how and why the failures occurred; any training needs;	Evidence that the diagnostic and testing failings have been reviewed and learning

Recommendation number	What we found	Outcome needed	What we need to see
	sustained and significant failures in the testing process	and what actions will be taken to prevent a future reoccurrence	taken from them to improve future service. By: 19 November 2021
3	We found there was a significant and unreasonable delay in the diagnosis of Child A's hearing impairment resulting from unreasonable, sustained and significant failures in the testing process.	Arrange for an external audit of the testing of patients from 2009 until 2018 to be carried out to ensure there is no systemic or individual issue which may have affected other patients, and inform this office of the results	Evidence of the audit and its results. By: 19 November 2021
4	We found there was a significant and unreasonable delay in the diagnosis of Child A's hearing impairment resulting from unreasonable, sustained and significant failures in the testing process	Feedback the findings of our investigation in relation to the failures in the diagnostic and testing process to relevant staff for them to reflect on	Evidence the findings of our investigation have been fed back to relevant staff in a supportive manner. By: 30 June 2021

We are asking the Board to improve their complaints handling:

Recommendation number	What we found	Outcome needed	What we need to see
5	We found significant failings in the Board's investigation of Mr and Mrs C's complaint in that they failed to identify even the most basic errors in the service they provided as they should have done as part of their duty of candour and that the standard of their response to Mr and Mrs C was very poor	Review the complaint handling failures to ascertain: how and why the failures occurred; any training needs; and what actions will be taken (or since then have been taken) to prevent a future reoccurrence	Evidence that the complaint handling failings have been reviewed and action taken to prevent a future reoccurrence. By: 30 June 2021

6	We found significant failings in the Board's investigation of Mr and Mrs C's complaint in that they failed to identify even the most basic errors in the service they provided as they should have done as part of their duty of candour and that the standard of their response to Mr and Mrs C was very poor	Ensure Board investigations identify and address incidents covered by the duty of candour with the relevant Scottish Government guidance	Evidence that the failure to comply with the duty of candour has been reviewed and action taken to stop a future reoccurrence. By: 30 June 2021

Terms used in the report **Annex 1**

acoustic reflexes	a measure of the neural pathway
auditorium brainstem response (ABR)	a test to check the response of the brain and hearing nerves to sound
congenital cytomegalovirus infection (CMV)	a virus that can cause problems including late onset progressive hearing loss in children
cerebral palsy	a group of disorders that affect a person's ability to move and maintain balance and posture
Child A	the aggrieved
distraction testing	a behavioural test of hearing used as a screening test of hearing for children
evoked potential responses	a test that measures the speed of nerve messages along sensory nerves to the brain
hypoxic-ischaemic encephalopathy (HIE)	a lack of oxygen getting to a baby via the placenta
Mr and Mrs C	the complainants and the parents of Child A
magnetic resonance imaging (MRI)	a scan that uses strong magnetic fields and radio waves to produce detailed images of the inside of the body
the Adviser	an audiologist (specialist in identifying and assessing hearing and balance functions)
the Board	Lothian NHS Board

the Physician	a medical doctor in another health board in Scotland
transient evoked optoacoustic emissions (TEOAE)	a test of the response by the outer hairs of the cochlea to noise
visual reinforcement audiology (VRA)	a test whereby the child is ‘conditioned’ to associate visual cues with sounds

List of legislation and policies considered **Annex 2**

Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 and The Duty of Candour Procedure (Scotland) Regulations 2018

British Society of Audiology: Practice Guidance - Assessment Guidelines for the Distraction Test of Hearing

British Society of Audiology Recommended Procedure for Visual Reinforcement Audiometry test protocol

NHS Greater Glasgow and Clyde Board at www.clinicalguidelines.scot.nhs.uk/ggc-paediatric-guidelines/ggc-guidelines/neonatology/cytomegalovirus-cmv-congenital-infection/

ENT and Audiology News at www.entandaudiologynews.com/features/audiology-features/post/targeted-cmv-screening-and-hearing-management-of-children-with-congenital-cytomegalovirus-infection

The National Deaf Children's Society at www.ndcs.org.uk/documents-and-resources/congenital-cytomegalovirus-cmv-and-deafness/