



## **Summary: Hearing Screening**

### **Germany**

### **Produced as part of Work Package 4**

**Date: 2019-06-25**

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This project has received funding from the European Union's Horizon 2020 research and innovation programme under Grant Agreement No 733352

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## 1. Glossary of Terms: Hearing Screening

<b>Abnormal test result</b>	A test result where a normal “pass” response could not be detected under good conditions. The result on screening equipment may indicate “no response,” “fail,” or “refer.”
<b>Attendance rate</b>	<p>The proportion of all those <u>invited for screening</u> that are <u>tested and receive a result</u>,</p> <ul style="list-style-type: none"> <li>• <u>Invited for screening</u> includes all those that are offered the screening test.</li> <li>• <u>Tested and receive a result</u> could be a “pass” or “fail”.</li> </ul> <p>Attendance rate provides information on the willingness of families to participate in screening.</p>
<b>Attendance rate in first year of life</b>	<p>See definition of <b>Attendance rate</b>.</p> <p>The calculation cut-off is after <u>one year of life</u>.</p>
<b>Compliance with referral (percentage)</b>	<p>The percentage of those who are <u>referred from screening</u> to a diagnostic assessment that actually <u>attend</u> the first diagnostic assessment.</p> <p>Percentage of compliance provides information on the willingness of families to attend the diagnostic assessment after referral from screening.</p>
<b>Coverage</b>	<p>The proportion of those <u>eligible for screening</u> that are <u>tested and receive a result</u> within a <u>specific time</u>.</p> <ul style="list-style-type: none"> <li>• <u>Eligible for screening</u> includes those within the population that are covered under the screening or health care program.</li> <li>• <u>Tested and receive a result</u> could be a “pass” or “refer to diagnostic assessment”.</li> <li>• <u>Specific time</u> can be defined, such as 1 month after birth, 3 months after birth, etc.</li> </ul> <p>Coverage provides information on the overall effectiveness and timeliness of a complete screening programme.</p> <p>Factors such as being offered screening, willingness to participate, missed screening, ability to complete the screen, and ability to document the screening results will influence the coverage.</p>
<b>Coverage in first year of life</b>	<p>See definition of <b>Coverage</b>.</p> <p>The <u>specific time</u> is pre-defined as within the first year of life.</p> <p>In other words, the coverage is the proportion of those eligible for screening that complete the screening sequence to a final result within the first year of life.</p>
<b>False negatives</b>	The percentage of <u>infants/children with a hearing loss</u> (defined by the target condition) that <u>receive a result of “pass”</u> during screening.



	Example: If 100 infants with hearing loss are screened, and 1 infant passes the screening, the percentage of false negatives is 1%.
<b>False positives</b>	<p>The percentage of <u>infants/children with normal hearing</u> that <u>receive a result of “fail”</u> from the final screening test.</p> <p>Example: If 100 infants with normal hearing are screened, and 3 infants fail the screening and are referred for diagnostic assessment, the percentage of false positives is 3%.</p>
<b>Guidelines</b>	Recommendations or instructions provided by an authoritative body on the practice of screening in the country or region.
<b>Hearing screening professional</b>	A person qualified to perform hearing screening, according to the practice in your country or region.
<b>Inconclusive test result</b>	A test result where a normal “pass” response could not be detected due to poor test conditions.
<b>Invited for screening</b>	Offered screening.
<b>Outcome of hearing screening</b>	An indication of the effectiveness or performance of screening, such as a measurement of coverage rate, referral rate, number of infants detected, etc.
<b>Permanent hearing loss</b>	<p>A hearing impairment that is <i>not</i> due to a temporary or transient condition such as middle ear fluid.</p> <p>Permanent hearing loss can be either sensorineural or permanent conductive.</p>
<b>Positive predictive value</b>	<p>The percentage of infants/children referred from screening who have a confirmed <u>hearing loss</u>, as described by your protocol or guideline and indicated in the <b>Target Condition</b> (see definition).</p> <p>For example, if 100 babies are referred from screening for diagnostic assessment and 90 have normal hearing while 10 have a confirmed hearing loss, the positive predictive value would be 10%.</p>
<b>Preschool or (pre)school children</b>	All children between 3-6 years of age.
<b>Preschool or (pre)school screening</b>	<p>Screening that takes place during the time children are between 3-6 years of age.</p> <p>This refers to <i>any</i> hearing screening during this age. The location of the screening is irrelevant to the definition.</p>



<b>Prevalence</b>	The number or percentage of individuals with a specific disease or condition. Prevalence can either be expressed as a percentage, proportion, or as the value per 1000 individuals within the same demographic.
<b>Programme</b>	An organized system for screening, which could be based nationally, regionally or locally.
<b>Protocol</b>	Documented procedure or sequence for screening, which could include which tests are performed, when tests are performed, procedures for passing and referring, and so forth.
<b>Quality assurance</b>	A method for checking and ensuring that screening is functioning adequately and meeting set goals and benchmarks.
<b>Referral criteria</b>	<p>A pre-determined cut-off boundary for when an infant/child should be re-tested or seen for a diagnostic assessment.</p> <p>For example, referral criteria may be “no response” at 35 dB nHL.</p>
<b>Risk babies / Babies at-risk</b>	<p>All infants that are considered to be at-risk or have risk-factors for hearing loss according to the screening programme.</p> <p>Two common risk factors are admission to the neonatal-intensive care unit (NICU) or born prematurely. However, other risk factors for hearing loss may also be indicated in the screening programme.</p>
<b>Sensitivity</b>	<p>The percentage of infants/children with hearing loss that are identified via the screening program.</p> <p>For example, if 100 babies with hearing loss are tested, and 98 of these babies are referred for diagnostic assessment while 2 pass the screening, the sensitivity is 98%.</p>
<b>Specificity</b>	<p>The percentage of infants/children with normal hearing that pass the screening.</p> <p>For example, if 100 babies with normal hearing are tested, and 10 of these babies are referred for diagnostic assessment and 90 pass the screening, the specificity is 90%.</p>
<b>Target condition</b>	<p>The hearing loss condition you are aiming to detect via your screening programme. This includes:</p> <ul style="list-style-type: none"> <li>• The <u>laterality of the condition</u>, whether the program aims to detect both unilateral and bilateral hearing loss or just bilateral hearing loss.</li> <li>• The <u>severity of the condition</u>, whether the program aims to detect hearing loss <math>\geq 30</math> dB HL, <math>\geq 35</math> dB HL, <math>\geq 40</math> dB HL or <math>\geq 45</math> dB HL</li> </ul>
<b>Well, healthy babies</b>	<p>Infants who are <i>not</i> admitted into the NICU or born prematurely.</p> <p>Well, healthy babies may or may not have additional risk factors for hearing loss, according to the procedures indicated in the specific screening programme.</p>



## **2. Abbreviations**

ABR – auditory brainstem response

aABR – automatic auditory brainstem response

ANSD – auditory neuropathy spectrum disorder

ASSR – auditory steady-state response

CI – cochlear implant

CMV – cytomegalovirus

dB HL – decibel hearing level

dB nHL – decibel normalized hearing level

dB SNR – decibel signal-to-noise ratio

DPOAE – distortion product otoacoustic emissions

HA – hearing aid

NICU – neonatal intensive care unit

OAE – otoacoustic emissions

TEOAE – transient-evoked otoacoustic emissions



### 3. Background

In Germany, hearing screening is performed nationally and organized both regionally and nationally. Specifically, guidelines and protocols are followed nationally, but neonatal hearing screening data are collected, and outcomes are monitored via regional tracking centres. The following report contains information with regards to childhood hearing screening in the entire country of Germany with information also provided for the region of Westfalia-Lippe.

#### 3.1. General

Germany has a total area of 348 900 km<sup>2</sup> with a population of 82.7 million in 2016 (Statistisches Bundesamt, 2018). Westfalia-Lippe has a total area of 21 427 km<sup>2</sup> with a population of 8 257 634 in 2017 (Landschaftsverband Westfalen-Lippe (LWL), 2017).

In Germany, all births are registered and the number of births in Germany in 2016 was 792 131 (Statistisches Bundesamt, 2018).

The World Bank income classification categorizes Germany as a high-income country (The World Bank, 2018). The gross domestic product (GDP) in 2016 was €35 734 per capita in Germany (Statistisches Bundesamt, 2018) and €70 542 per capita in Westfalia-Lippe (Landschaftsverband Westfalen-Lippe (LWL), 2017).

From the World Health Organization (WHO) Global Health Expenditure Database, health expenditure for all of Germany in 2015 was 4 592 USD or €4 032 per capita (World Health Organization (WHO), 2018).

An infant mortality rate of 2.7 per 1000 is reported for all of Germany by Statistisches Bundesamt (2018), and data from the World Health Organization cites an infant mortality rate of 3.3 per 1000 for 2015 (World Health Organization (WHO), 2018). A mortality rate of 4.1 is reported for the federal state of North Rhine-Westphalia for 2015, which includes the region of Westfalen-Lippe (Landesbetrieb Information und Technik North Rhine-Westphalia (IT.NRW), 2018).

#### 3.2. Neonatal hearing screening

In Germany, neonatal hearing screening is conducted universally, with all babies in the country having access to hearing screening, though screening is not obligatory for parents. The universal program for well and at-risk babies was first implemented in 2002 in various regional projects (e.g., in Hessen) and became available across all of Germany in 2009 when written into national guidelines. Neonatal hearing screening was implemented in Westfalia-Lippe in 2007.

Neonatal hearing screening is embedded in the Preventive Child Health Care screening system (Die vom Gemeinsamen Bundesausschuss (G-BA), 2017). Screening performed in the maternity wards is funded by health insurance as part of the service coverage for birth, while screening performed externally (during the first outpatient check-up at 3-10 days) is funded through health insurance remuneration to the paediatrician for the routine exam.

National guidelines are available for the detection of childhood disease (Die vom Gemeinsamen Bundesausschuss (G-BA), 2017), and in 2009 this directive was updated to include neonatal hearing screening (Nennstiel-Ratzel & Brockow, 2013). A national protocol is stipulated in the directive for the detection of childhood diseases (Die vom Gemeinsamen Bundesausschuss (G-BA), 2017) as well as in the Guidelines for Peripheral Hearing Disorders in Children, published by the Germany Society



of Speech and Pediatric Audiology (Deutschen Gesellschaft für Phoniatrie und Pädaudiologie; Nennstiel-Ratzel & Brockow, 2013). These guidelines and protocol are followed across the entire country.

### **3.3. Preschool hearing screening**

Preschool hearing screening is conducted universally in Germany as part of the routine check-up (“U8”) at 4 years of age. Preschool hearing screening is embedded in the Preventive Child Health Care screening system and is funded by health insurance for remuneration to the paediatrician for the complete routine examination. The general screening program for childhood disease was first implemented in 1971. Childhood hearing screening was initially part of the U9 examination at 6 years of age, though it was recently moved to the U8 examination during the most recent (2017) revision of the national guideline (Lawrenz, 2017).<sup>1</sup>

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<sup>1</sup> It was indicated in the questionnaire responses that preschool hearing screening occurs during the U9 examination; however, an article (<https://www.allgemeinarzt-online.de/1588246/a/neue-richtlinie-1808810>) indicates that, as of the 2017 revision, the hearing screening test is now part of the U8 examination and removed from U9.



## 4. Guidelines & Quality Control

National guidelines for hearing screening exist in Germany, published by Die vom Gemeinsamen Bundesausschuss (GBA), in a document outlining all required childhood examinations. These guidelines describe the protocol for neonatal hearing screening. Preschool-age hearing screening is also stipulated in this guideline, included as one of the tests performed during U8 (or the 8<sup>th</sup> examination) at 46-48 months of age (Die vom Gemeinsamen Bundesausschuss (G-BA), 2017). Other childhood hearing guidelines are published by the Germany Society of Speech and Pediatric Audiology. These guidelines also describe the protocol for performing neonatal hearing screening, diagnostic assessments on children, in addition to intervention protocols for conductive and sensorineural hearing losses (Deutschen Gesellschaft für Phoniatrie und Pädaudiologie, 2013).

The G-BA guidelines/protocol are followed across all of Germany; however, a recent report on 2011-2012 data noted some deviations across regions and maternity centres (Nennstiel-Ratzel, et al., 2017). Furthermore, there are differences in how data tracking is performed across regions, with regards to the organization, financing, as well as the structural and technical aspects of the tracking service.

Quality assurance of hearing screening programs is imposed by the government. With the implementation of neonatal hearing screening in the national guideline in 2009, an evaluation was stipulated to be carried out after the protocol had been in effect for 5 years. Neonatal hearing screening was therefore evaluated in 2011-2012, and the results of this evaluation were recently published in 2017 (Nennstiel-Ratzel, et al., 2017). The content of the programme has not been changed since it was implemented in 2009; to-date there have not been any changes based on the results from the 2017 report.

Aside from this national 5-year evaluative report, data collection and monitoring is performed regionally. Regional-based hearing screening tracking centres record the performance of neonatal hearing screening in connection with relevant data about each birth, as well as monitor the effectiveness of hearing screening across maternity centres. In Westphalia-Lippe, data are collected, and key performance indicators are reported on to maternity centres on a monthly, quarterly and annual basis. Anonymous benchmarking is also available online for the clinics to access (Matulat, Stroe, & am Zehnhoff-Dinnesen, 2014). While all regions in Germany have neonatal hearing screening, not all regions provide this level of tracking services for monitoring outcomes and evaluating to benchmark indicators.

Annual reports are not available on a national level. As indicated, a recent report was published evaluating the neonatal hearing screening programme on a national level from 2011-2012 data. Regional evaluations are conducted on a monthly, quarterly or annual basis, or for the purpose of publication. Research has been performed in Germany on the neonatal hearing screening programme (e.g., Rissman, et al., 2018).



## 5. Process: Screening, Diagnosis, Intervention

### 5.1. Neonatal hearing screening

Well-babies and at-risk babies are usually screened in the maternity hospital or NICU. It is roughly estimated that approximately 91% of screening takes place in the maternity hospital. If hearing screening is not carried out at the birth centre, it can be carried out as part of the infant's standard medical check-up.

Approximately 97% of births take place in the maternity hospital, where the average length of stay after delivery is 4.2 days. Infants with illness stay an average of 9.2 days (Technikerkrankenkasse, 2016). Only around 0.6% of births take place at home.

It was not indicated how parents/caregivers of well and at-risk babies are invited to participate in neonatal hearing screening.

Neonatal hearing screening for well babies should be completed before 14 days of age. For at-risk infants, premature infants should be screened by their calculated day of birth, and infants who are sick or handicapped (where screening becomes delayed) should be screened by at least 3 months of age.

In Germany, at-risk infants are defined as those with a family history of hearing loss, admission into the intensive care unit for more than 48h, the use of ventilation, prematurity of less than 32 weeks, a birth weight <1500g, pre / post-natal infections (e.g., toxoplasmosis, CMV, rubella, herpes, or bacterial infections), the use of ototoxic drugs (e.g., aminoglycosides, loop diuretics), critical hyperbilirubinemia (with exchange transfusion), malformations of the head (e.g., cleft palate, ear tag), or syndromes associated with hearing impairment (e.g., trisomy 21, CHARGE, Waardenburg syndrome). The percentage of at-risk infants is unknown due to variability in regional documentation of risk factors (Nennstiel-Ratzel, et al., 2017).

Data on the prevalence of CMV is not available in Germany. The prevalence of meningitis is 0.4 per 100 000, with 35% of cases occurring in infants and children 0-4 years of age (Ständigen Impfkommision (STIKO) am Robert Koch-Institut (RKI), 2018).

According to guidelines, the target condition for screening for well- and at-risk babies is a bilateral hearing loss of 35 dB HL or worse (Matulat & Parfitt, 2018).

### 5.2. Neonatal diagnostic assessment

The diagnostic assessment after neonatal hearing screening referral, includes otoscopy, tympanometry, TEOAE and a clinical ABR. Higher level centres may also perform DPOAEs, frequency-specific ABR, and behavioural observation audiometry for confirmation. Diagnostic confirmation should be performed before 3 months of age; however, the average age according to current data is 4.3 months.

### 5.3. Preschool hearing screening

Preschool hearing screening is performed at the pediatrician's office as part of routine examination at 4 years of age (examination 8 [U8]). Prior to the 2017 revision, this screening test was performed during the 9<sup>th</sup> examination (U9) at 6 years of age; however, this was removed in preference for an



earlier screening test at age 4. An earlier hearing exam is also performed at U6 when children are approximately 2 years of age.<sup>2</sup>

The target condition for preschool hearing screening is not specifically indicated in the guideline; however, referral criterion is a threshold of 30 dB HL or worse in at least 2 frequencies in one or both ears.

#### **5.4. Intervention approach**

In Germany, treatment options available include grommets, hearing aids, bone conductive devices and cochlear implants. Infants are fitted with hearing aids from <6 months of age or older, and cochlear implants from 6 months of age or older.

The fitting criteria in Germany for an immediate hearing aid is a bilateral or unilateral hearing loss of 35 dB HL or worse. Hearing aids for mild losses of 25 and 30 dB HL can be considered at 1 year of age or later.

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<sup>2</sup> It was indicated in the questionnaire responses that preschool hearing screening occurs during the U9 examination; however, an article (<https://www.allgemeinarzt-online.de/1588246/a/neue-richtlinie-1808810>) indicates that, as of the 2017 revision, the hearing screening test is now part of the U8 examination and removed from U9.



## 6. Protocols

Hearing screening protocols are described for neonatal hearing screening (well and at-risk) as well as for preschool hearing screening when applicable.

- The Test performed is the screening technique used
- The Age of the child is indicated in hours, days, months or years
- Referral criteria may be the lack of an OAE response at specified frequencies, a response-waveform repeatability constant, the absence of an aABR response at a specified intensity, or an absent behavioural response at a specified intensity. Referral criteria may be defined within a protocol or limited based on the device used.
- The Device is the screening device used.
- Unilateral Referrals indicates whether children are referred if only one ear fails screening.
- The Location is where the screening takes place

### 6.1. Neonatal hearing screening (well)

The process for neonatal hearing screening for well babies is described in Table 1. A 2-step protocol is in effect, whereby the first test may be either OAE or aABR, and is ideally performed in the maternity hospital before discharge. If the infant fails the first test, rescreening occurs with aABR ideally before discharge. If screening does not take place in the maternity hospital, it is performed during the initial post-discharge check-up (“U2”).

According to a report based on 2011-2012 data, TEOAE was performed for 80% of initial screens, while aABR was performed for the remaining 20%. Furthermore, only around 50% of rescreens were conducted using aABR, despite protocol stipulations. This may be due to lack of education about the protocol and pressure on screening staff and/or a shortage of devices able to perform aABR in maternity hospitals (Nennstiel-Ratzel, et al., 2017).

**Table 1:** Screening process for well babies in Germany.

<b>Test</b>	<b>Age</b>	<b>Referral criteria</b>	<b>Device</b>	<b>Unilateral Referrals?</b>	<b>Location</b>
OAE1 <i>or</i> aABR1	<24 hours - 5 days	Various <i>or</i> 35 dB nHL <sup>3</sup>	Various	Yes	Maternity hospital / Paediatric Clinic
aABR2	Before discharge (ideal) or < 14 days	35 dB nHL	Various	Yes	Maternity hospital / Paediatric Clinic

### 6.2. Neonatal hearing screening (at-risk)

The screening process for at-risk infants is described in Table 2. Whereby well babies are initially screened with either aABR or OAE, infants at-risk should be screened with a 2-step aABR protocol before discharge. The age of screening depends on whether the infant was born prematurely and the health of the infant. Premature infants should be screened by the calculated day of birth.

**Table 2:** Screening process for at-risk babies in Germany.

<sup>3</sup> aABR screening referral information acquired from newborn hearing screening guidelines (Matulat & Parfitt, The newborn hearing screening programme in Germany, 2018).



Test	Age	Referral criteria	Device	Unilateral Referrals?	Location
aABR1	Varies	35 dB nHL	Varies	Yes	Hospital / NICU / Paediatric Clinic
aABR2	Before discharge	35 dB nHL	Varies	Yes	Hospital / NICU / Paediatric Clinic

### 6.3. Preschool hearing screening

Preschool hearing screening is currently (as of 2017) performed during the routine childhood check-up at 4 years of age (“U8”). Pure-tone audiometry is performed in the pediatrician’s office, and referral criteria are hearing thresholds greater than 20 dB HL at two or more frequencies in at least one ear.

**Table 3:** Process for preschool hearing screening in Germany.

Test	Age	Referral criteria	Device	Unilateral Referrals?	Location
Pure-tone audiometry	4 years	20 dB HL at 2 or more freqs	50-40-30-20 dB HL at 5 freqs (0.5, 1, 2, 4, and 6 kHz)	Yes	Paediatric Clinic



## **7. Professionals**

### **7.1. Neonatal hearing screening (well)**

Screening for well babies is typically performed by pediatric nurses or midwives. Approximately 85% of the screening staff are nurses, 5% are midwives, 5% are pediatricians, and 5% are pediatric audiologists.

Training involves approximately 4 hours of education, including the medical background of neonatal hearing screening, performing screening on newborns, informing the parents, acquiring consent, data handling, and mediation of screening results. It is assumed that all screening performed is done so by a trained professional. It is the responsibility of the hearing screening centre to train each of its screening staff.

Quality of the screeners is monitored through data received from maternity hospitals. Data includes the number of attempts, electrode impedances and response curves, in addition to actual pass/fail results. The screening centre evaluates results on a monthly, quarterly and annual basis and provides feedback to the maternity hospitals on the quality of their results and whether benchmark indicators (14 in total) have been achieved. Individual feedback on staff is provided if necessary, and updated training may be offered.

### **7.2. Neonatal hearing screening (at-risk)**

Screening for at-risk infants is also performed by pediatric nurses or doctors (see 7.1 for training requirements).

### **7.3. Preschool hearing screening**

Screening for preschool-age children is performed by the staff at the paediatrician's office or by the doctor him/herself.



## 8. Results: Neonatal Hearing Screening

### 8.1. Coverage and attendance rates

The most recent report of national coverage was documented in 2017 report on data collected in 2011-2012 (Nennstiel-Ratzel, et al., 2017). Coverage rate in this report was determined by the number of neonatal hearing screening tests performed (on infants < 210 days of age), out of the calculated (target) number of live births in each maternity hospital plus the number of children born outside a hospital, and excluding the number of children deceased before age 7 days. The coverage across all of Germany in 2012 was 82.4% and included all babies (well and at-risk). Out of the infants not considered covered, a result of “not screened” was reported in 2.3% while a screening result was missing completely in 15.4%. It is unknown if in some cases screening was performed, but not documented. Coverage rate also varied largely across regions, with rates varying from 53% to 99% (Nennstiel-Ratzel, et al., 2017).

The number of children missed being *offered* screening is not indicated, and therefore, the attendance rate cannot be calculated for the initial screen. However, the report based on 2011-2012 data indicates a documented refusal rate of 0.1%. It is important to note that not all refusals may be documented in cases where a screening result is not established (Nennstiel-Ratzel, et al., 2017).

Furthermore, this report indicates that 74.8% of infants that required rescreening had a rescreening result. This percentage, however, is also confounded by the differences in reporting practice across regions (Nennstiel-Ratzel, et al., 2017).

More recent data collected from within the region of Westfalia-Lippe indicate a coverage rate of 94.6% in 2016 (all babies, well and risk), based on reported coverage rates from maternity hospitals participating in the regional-based project. Because data collection is managed regionally, more recent national-level data are not available.

### 8.2. Referral rates

The referral rate across all of Germany in 2012 are described in Table 4 below (Nennstiel-Ratzel, et al., 2017).

**Table 4:** Referral rates for neonatal hearing screening (all babies) in Germany in 2012 (Nennstiel-Ratzel, et al., 2017).

Test	Referral Rate
OAE/aABR1	10.9%
OAE/aABR2	18.5%

Referral rates assume 100% attendance.

Referral rate was defined as the number of infants referred to diagnostic assessment at discharge (including those where a screening was attempted but result could not be achieved), out of the total number of infants screened. This includes both well and at-risk infants. In total, the referral rate to a diagnostic assessment after the screening process was 5.3% in 2012 across all of Germany (Nennstiel-Ratzel, et al., 2017).

Within the region of Westfalia-Lippe, referral rate ranges from 3.8 to 4.8% across years. There is also a large variability across birth centres, where some report referral rates of 1% and others report greater than 10%.



The referral rate specifically for well or at-risk infants is unknown.

### 8.3. Diagnostic assessment attendance

It is indicated that the compliance rate to a diagnostic assessment after neonatal hearing screening referral is difficult to estimate due to the continuous tracking method used in Westfalia-Lippe, whereby several attempts are made at contacting and inviting families for screening. Compliance rate in Westfalia-Lippe can be roughly estimated to be 90%.

In the report for all of Germany, a confirmatory hearing evaluation result was documented in 59.9% of infants referred for diagnostic assessment, with large variability across regions. However, it is important to note that this value is confounded, first by the fact that infants considered “lost-to-follow-up” at the time of this evaluation may have later had a confirmatory hearing test, and second because of variability in reporting results across diagnostic centres.

### 8.4. Prevalence / Diagnosis

The prevalence rate of permanent hearing loss among neonates was reported from two sources: from 2009-2012 data across four German regions (Matulat, et al., 2014) and from the evaluative report based on data collected across Germany in 2011-2012 (Nennstiel-Ratzel, et al., 2017). Values are presented in Table 5.

The prevalence rate of permanent hearing loss is defined by Matulat et al. (2014) as a hearing threshold above 25 dB HL for children greater than 3 months of age. While screening devices are sensitive to hearing loss > 35 dB nHL, a milder hearing loss may still be ascertained. Therefore, mild hearing loss was not excluded in the number of confirmed cases; however, due to screening limitations not all mild hearing loss would be detected.

In Nennstiel-Ratzel (2017), prevalence rate was determined via a survey returned by diagnostic audiology centres across Germany. The documented hearing loss for each case should be congenital in nature (not acquired) and over 3 months of age.

**Table 5:** Prevalence (per 1000) of permanent hearing loss among children > 3 months of age (Nennstiel-Ratzel, et al., 2017; Matulat, et al., 2014)

	Bilateral			Unilateral	
	≥ 25 dB HL	≥ 40 dB HL	≥ 80 dB HL	≥ 25 dB HL	≥ 80 dB HL
Matulat et al. (2014)	2.1			0.6	(0.15) <sup>†</sup>
Nennstiel-Ratzel, et al. (2017)	1.3	1.0 <sup>4</sup>	0.325*		

\* Estimated from the response that 25% were considered deaf or with residual hearing (≥ 80 dB HL).

<sup>†</sup> Data are unavailable. Value is roughly estimated.

Data are unavailable regarding the prevalence of auditory neuropathy in Germany.

### 8.5. Treatment success

<sup>4</sup> Estimated by the authors from the cited report that 77% of children with permanent bilateral hearing loss had a hearing loss of moderate or greater (Nennstiel-Ratzel, o.a., 2017).



The number of children with neonatal hearing loss that are fitted with hearing aids or cochlear implants each year in Germany is not known.

### **8.6. Screening evaluation**

In the report based on 2012 data, sensitivity was determined to be 95.1% and specificity was determined to be 97.1%, including both well babies and at-risk babies (Nennstiel-Ratzel, et al., 2017).

Sensitivity was determined from answers returned by pediatric audiology centres. Sensitivity was calculated as the number of children diagnosed with a hearing loss and with a result “refer” at discharge out of the total number of children diagnosed with a hearing loss (who were screened). For the remaining infants, it cannot be determined whether a hearing loss was present at the time of screening or whether these infants presented with a progressive or delayed-onset loss (Nennstiel-Ratzel, et al., 2017).

Specificity was calculated to be 97.1% and the positive predictive value of a refer result was 6.2%. Positive predictive value was calculated as the number of children referred who were diagnosed with hearing loss out of the total number of children referred (Nennstiel-Ratzel, et al., 2017).



## **9. Results: Preschool Hearing Screening**

### **9.1. Coverage and attendance rates**

Data are unavailable; however, in some regions, laws have come into effect mandating the participation in routine childhood check-ups. The Central Office of the State Institute for Health and Labour informs the public youth welfare institution if they do not receive a notice of participation for an examination 3 weeks after a reminder was sent.

### **9.2. Referral rates**

Data are unavailable.

### **9.3. Diagnostic assessment attendance**

Data are unavailable.

### **9.4. Prevalence / Diagnosis**

Data are unavailable.

### **9.5. Treatment success**

Data are unavailable.

### **9.6. Screening evaluation**

Data are unavailable.



## 10. Costs: Neonatal Hearing Screening

Neonatal hearing screening in Germany is financed by health insurance either as part of remuneration for the birth (when screened in maternity hospitals) or for the U2 examination (when screened during the first routine check-up by the paediatrician). There is no financial reward when parents attend hearing screening, and there is no penalty for those who do not attend hearing screening.

A cost analysis of neonatal hearing screening in Germany (specifically in Hessen) was completed by Böttcher, Gramß, Euler & Neumann (2009).

### 10.1. Screening costs

The total screening costs per year is approximately €910 000 or €13 per child, which includes the costs of employees, equipment, and maintenance. An additional €3 per child (€200 000 per year) is spent toward the quality assurance contract with a tracking centre. This service covers tracking, training, telemedical infrastructure, and support to maternity hospitals.

### 10.2. Equipment costs

*(Information extracted to protect commercially sensitive data)*

The most common devices used in Germany are the Madsen Accuscreen, Maico MB11 BERAphone, Natus Echo-Screen (II and III) and Path Medical Sentiero Advanced. Devices are also equipped with bidirectional data transfer for technical support and telemedical screening.

Maintenance costs vary by manufacturer and age of the device. An annual maintenance cost was roughly estimated to be €250-300. It is estimated that devices are replaced around every 10 years; however, device replacement is at the discretion of each individual hospital.

The cost for disposables varies by device, as some aABR devices require the use of disposable surface electrodes and/or ear cups, while other devices do not. The cost of surface electrodes also varies based on whether or not they are sold specifically by the manufacturer. It is roughly estimated that the cost per child for disposables range from €1 to €7.

### 10.3. Staff costs

The number of screening staff across all of Germany is unknown; however, there are currently 409 trained screening staff in Westphalia-Lippe across 58 maternity hospitals.

The average annual salary of a nurse in Westphalia-Lippe is €35,000. Training costs are not indicated.

### 10.4. Diagnostic costs

The total cost of diagnostic confirmation is not indicated.

### 10.5. Amplification costs

In the Germany, all children with hearing loss are treated.

The costs for hearing aid fitting for the first year (including the device) is unknown. That children require hearing aids are followed-up for regular speech-language appointments, hearing aid adjustments, and hearing assessments. The cost for intervention in the second year can be roughly estimated to be €3500.



For cochlear implant surgery, costs are roughly €28,000 for unilateral implantation, though there is some variation in basic cost per region. For habilitation, costs vary across CI centres in Germany. At one local CI centre, the costs for the first year of intervention are roughly estimated to be €7500, which includes mapping technical settings and the hearing and speech (re)habilitation. After the first year, costs will depend on the hearing and speech development of the child and will vary across individuals. Speech-language appointments, CI mapping (adjustments), and hearing assessments are performed regularly.

#### **10.6. Social costs**

In the region of Westfalia-Lippe, there are 2 primary schools and 1 secondary schools for deaf and hard of hearing. Information is not available on the number of children attending special schools; however, this value is roughly estimated to be less than 20% of hearing-impaired students due to the implementation of integration into mainstream schools.

In mainstream schools, extra support is provided to children with hearing impairment including technical assistance. This support is funded by health insurance. Extra staff support is available when needed and is funded by the social welfare institution.

The cost for a normal hearing student in a mainstream school is €5300 per year in North Rhine-Westphalia (Statista, 2018); however, the cost for special support in mainstream schools or the cost for a hearing-impaired student in a specialized school is not known.



## **11. Costs: Preschool Hearing Screening**

### **11.1. Screening costs**

Screening is integrated into the 8<sup>th</sup> routine childhood check-up (U8). Each check-up (including screening) costs €44.79 per child (Kassenärztliche Vereinigung Nordrhein, 2017).

### **11.2. Equipment costs**

The cost of screening audiometers is unknown, but is likely less than the cost of OAE-aABR screeners. Recalibration of audiometers is recommended annually (Lawrenz, 2017).

### **11.3. Staff costs**

The salary and costs for staff performing screening in the pediatrician's office is unknown.



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