Summary: Hearing Screening

Sweden (Stockholm Region)

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1. Glossary of Terms: Hearing Screening

Abnormal test result	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."
Attendance rate	The proportion of all those invited for screening that are tested and receive a result, • Invited for screening includes all those that are offered the screening test. • Tested and receive a result could be a "pass" or "fail". Attendance rate provides information on the willingness of families to participate in screening.
Attendance rate in first year of life	See definition of **Attendance rate.** The calculation cut-off is after one year of life.
Compliance with referral (percentage)	The percentage of those who are referred from screening to a diagnostic assessment that actually attend the first diagnostic assessment. Percentage of compliance provides information on the willingness of families to attend the diagnostic assessment after referral from screening.
Coverage	The proportion of those eligible for screening that are tested and receive a result within a specific time. • Eligible for screening includes those within the population that are covered under the screening or health care program. • Tested and receive a result could be a "pass" or "refer to diagnostic assessment". • Specific time can be defined, such as 1 month after birth, 3 months after birth, etc. Coverage provides information on the overall effectiveness and timeliness of a complete screening programme. 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.
Coverage in first year of life	See definition of **Coverage.** The specific time is pre-defined as within the first year of life. 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.
False negatives	The percentage of infants/children with a hearing loss (defined by the target condition) that receive a result of "pass" during screening.

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

Prevalence	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.
Programme	An organized system for screening, which could be based nationally, regionally or locally.
Protocol	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.
Quality assurance	A method for checking and ensuring that screening is functioning adequately and meeting set goals and benchmarks.
Referral criteria	A pre-determined cut-off boundary for when an infant/child should be re-tested or seen for a diagnostic assessment. For example, referral criteria may be "no response" at 35 dB nHL.
Risk babies / Babies at-risk	All infants that are considered to be at-risk or have risk-factors for hearing loss according to the screening programme. 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.
Sensitivity	The percentage of infants/children with hearing loss that are identified via the screening program. 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%.
Specificity	The percentage of infants/children with normal hearing that pass the screening. 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%.
Target condition	The hearing loss condition you are aiming to detect via your screening programme. This includes: • The laterality of the condition, whether the program aims to detect both unilateral and bilateral hearing loss or just bilateral hearing loss. • The severity of the condition, whether the program aims to detect hearing loss ≥ 30 dB HL, ≥ 35 dB HL, ≥ 40 dB HL or ≥ 45 dB HL
Well, healthy babies	Infants who are *not* admitted into the NICU or born prematurely. Well, healthy babies may or may not have additional risk factors for hearing loss, according to the procedures indicated in the specific screening programme.

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 Sweden, neonatal hearing screening and preschool hearing screening are organized regionally, though both screening programmes are nationally implemented. There are 27 regions of Sweden and each is responsible for organizing components of its own health care, including hearing screening.

The following report contains information with regards to hearing screening in the region of Stockholm. While all regions provide hearing screening and hearing screening programmes are quite similar, results are not reported nationally and protocols may differ slightly between regions.

3.1. General

Stockholm region, including the capital city of Stockholm and surround area, has a total area of 6524 km^2 with a population count of 2 303 417 in 2017. In the Stockholm region and in Sweden, each birth is registered. The number of births is 28 805 per year in Stockholm region and 115 416 per year in Sweden, acquired from 2017 national statistical data (Statistics Sweden, 2018)

The World Bank income classification categorizes Sweden as a high-income country (The World Bank, 2018). The gross domestic product (GDP) in 2015 was 627 000 SEK or approximately €60 000 per capita for Stockholm region and 444 000 SEK or €42 000 per capita for all of Sweden in 2016 (Statistics Sweden, 2018).

From the World Health Organization (WHO) Global Health Expenditure Database, health expenditure for all of Sweden in 2015 was 5 600 USD or €4 839 per capita (World Health Organization (WHO), 2018).

Data acquired from the 2016 United Nations Demographic Yearbook indicates an infant mortality rate of 2.5 per 1000 for the country of Sweden in 2015 (United Nations Statistical Division, 2016), and data from Statistics Sweden indicates an infant mortality rate of 2.4 per 1000 for 2017 (Statistics Sweden, 2018).

3.2. Neonatal hearing screening

In Stockholm region, neonatal hearing screening is conducted universally, with all babies in the region having access to hearing screening. Screening is not obligatory for parents. The universal programme for well and at-risk babies was first implemented in 1998. By 2008, neonatal hearing screening was implemented across the country (Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU), 2004; Socialstyrelsen, 2014). Neonatal hearing screening is not embedded in the Preventive Child Health Care screening system. Regions in Sweden provide funding for well-baby screening, while hospitals provide the funding for screening infants at risk.

Regions may use different protocols for neonatal screening for both well babies at at-risk babies, and therefore tests performed and referral criteria may differ regionally. For example, regions may use aABR, OAE or both methods for screening.

3.3. Preschool hearing screening

In Sweden, preschool hearing screening exists regionally and is embedded in the general Preventive Child Health Care system. Similar to neonatal hearing screening, there are differences in preschool hearing screening across regions, as some regions may not screen hearing at age 4 years, though it is recommended in the guidelines for child health care.

4. Guidelines & Quality Control

National guidelines for child health care exist in Sweden, including guidelines for childhood hearing screening (Socialstyrelsen, 2014). While national guidelines exist for Sweden, protocols for hearing screening are decided regionally. A protocol exists for neonatal hearing screening in Stockholm region (Riktlinjer för screeningpersonal vid hörselscreening för nyfödda, 2008 or Gudielines for staff performing newborn hearing screening, 2008)

The content of hearing screening programme was decided on by the public health organization, paediatricians and ENT specialists. The content of the programme was revised in 1998-2005 when neonatal hearing screening was implemented in Stockholm region and behavioural observational audiometry screening at 7-8 months, previously provided by child health care centres, was abandoned. Furthermore, the neonatal hearing screening protocol in Stockholm region was revised in 2016 when aABR screening was added to the protocol.

It is unknown who decides on the revisions, how revisions take place or how revisions are funded.

Quality assurance is of hearing screening programmes is not imposed by the government, though information is collected about hearing screening outcomes in Stockholm region.

Annual reports are available for Stockholm region (e.g., Karolinska University Hospital, 2018).

Studies have been performed on hearing screening in Stockholm region, including its effectiveness (e.g., Berninger & Westling, 2011).

5. Process: Screening, Diagnosis, Intervention

5.1. Neonatal hearing screening

In Stockholm region, well-babies and at-risk babies are screened in the in the hospital where the average length of stay after deliver is 1.8 days. Approximately 99.8 % of infants in Stockholm region are born in maternity hospitals and 70-80 infants per year (0.25%) are born at home. Staff in the maternity ward invite well-baby families directly to participate in neonatal hearing screening as part of routine care after delivery. For at-risk babies, invitation is by staff in the NICU or from the ENT/Audiology unit. Information about hearing screening is also provided to families prior to delivery.

In Stockholm region, at risk infants are defined as those with congenital infections (CMR, toxoplasmosis), taking ototoxic medications, meningitis, craniofacial malformations, and syndromes, in addition to infants admitted to the NICU and who are extremely premature. Babies who meet these conditions are screened using a different protocol because of the increased risk of auditory neuropathy and other retrocochlear hearing impairment. It is estimated that approximately 5% of infants are screened with the at-risk protocol.

The prevalence of CMV infections and meningitis among neonates is not known.

Neonatal hearing screening for well babies should be completed before 4 weeks of age. For infants at-risk, screening should also be completed by 4 weeks of age or by discharge.

The target condition for screening for well and at-risk babies is a unilateral or bilateral hearing loss greater than 30 dB HL. For at-risk babies, the target condition also includes auditory neuropathy.

5.2. Neonatal diagnostic assessment

The diagnostic assessment tests performed after neonatal hearing screening referral are clinical ABR and ASSR.

The diagnostic assessment of well-babies should be performed before 3 months of age. For at-risk infants, there is no recommended maximum age, but the test should be performed as soon as possible depending on the child’s medical condition.

5.3. Preschool hearing screening

Preschool-age hearing screening takes place at child health care centres when children are 4 years old and at school when the children are 6 years old.

Children are invited to participate in hearing screening by the child health care centres through a letter.

The target condition for preschool-age screening is a bilateral or unilateral hearing loss of >25 dB HL from 500 to 4000 Hz. For school-age screening, the target condition is a bilateral or unilateral hearing loss of >20 dB HL from 500 to 6000 Hz.

5.4. Intervention approach

In Stockholm region, treatment options available include grommets, hearing aids, bone conductive devices, and cochlear implants. Infants are fitted with hearing aids from less than 6 months of age and infants are fitted with cochlear implants from 6-12 months of age or older.

The hearing aid fitting criteria in Stockholm region is a bilateral hearing loss of >25 dB HL or a unilateral hearing loss of >40 dB HL.

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 3-step OAE and aABR protocol is in effect. The first OAE is performed in the maternity hospital typically before discharge. Infants that do not pass the initial OAE are rescreened in the maternity hospital. If the infant fails the second OAE, a third rescreening of OAE takes place in the audiology department before the age of 4 weeks. Infants that do not pass the third OAE screen are directly screened with aABR in the same appointment.

Table 1: Screening protocol for well babies in Stockholm region, Sweden.

Test	Age	Referral criteria	Device	Unilateral Referrals?	Location
OAE1	24-72 hours	4 dB SNR, 3/4 freqs & 70% reproducibility	Otodynamics	Yes	Maternity ward
OAE2	2 weeks			Yes	Maternity ward
OAE3	< 4 weeks			Yes	Audiology dept
aABR	< 4 weeks	30 dB nHL	Accuscreen	Yes	Audiology dept

6.2. Neonatal hearing screening (at-risk)

The screening process for at-risk infants is described in Table 2. These infants are screened with both OAE and aABR. At-risk infants that fail aABR are referred directly for a diagnostic assessment. At-risk infants that fail OAE but pass aABR are called back at one year of age.

Table 2: Screening protocol for at-risk babies in Stockholm region, Sweden.

Test	Age	Referral criteria	Device	Unilateral Referrals?	Location
aABR + OAE	ASAP after 35 weeks gest.	30 dB nHL (aABR), 4 dB SNR at 3/4 freqs & 70% reproducibility (OAE)	Accuscreen, Otodynamics	Yes	NICU or Audiology dept

6.3. Preschool hearing screening

The screening procedure for preschool-age hearing screening is described in Table 3. If the child meets the referral criteria, they are rescreened before being referred for a diagnostic assessment.

Table 3: Screening process for preschool-age children in Stockholm region, Sweden.

Test	Age	Referral criteria	Location
Pure-tone audiometry1 Pure-tone audiometry2	4 years	30 dB HL or worse at 2 frequencies or 40 dB HL or worse at 1 frequency (0.5, 1, 2, and 4 kHz)	Child health care centers

7. Professionals

7.1. Neonatal hearing screening (well)

Screening for well babies is performed by nurses, midwives, assistant nurses or audiologists. When screening was first implemented, a training session was held including a full day of lectures, followed by practical training. Theoretical and clinical training of professional staff is also held when a new device is added to the protocol.

Today there is no specific training programme or certification requirement for new staff, but new screeners are trained on the job by experienced staff. On-the-job training takes approximately 4 weeks. Screening results (specifically referral rates) are assessed for each screener to monitor inexperienced staff. Furthermore, a yearly seminar is held where screeners are invited to attend to hear about updated methodology as well as yearly performance results and feedback.

7.2. Neonatal hearing screening (at-risk)

Screening for at-risk infants is also performed by nurses, midwives, assistant nurses or audiologists. Training is the same as for staff performing well-baby screening (see section 5.1, above).

7.3. Preschool hearing screening

Preschool hearing screening is performed by nurses with special training. Training on hearing screening for these nurses is not indicated.

8. Results: Neonatal Hearing Screening

8.1. Coverage and attendance rates

In Stockholm region, the birth registry is connected to the neonatal hearing screening database. This system allows for all infants to be offered hearing screening, even if they are missed in the maternity hospital before discharge. Infants registered in Stockholm region without a screening result are sent a letter offering hearing screening. If the family does not respond after two letters are sent, the infant's well-baby clinic is informed. Using this method and the data available in the screening registry it can be determined that 100% of families of infants born in Stockholm region are offered hearing screening. It was reported that only 1 infant was missed being offered screening in 2017 (Karolinska University Hospital, 2018).

Out of all infants offered screening in Stockholm region, 98% have an initial hearing screening result. The reasons that infants may not be screened vary, and include parental refusal, infant death, if the family moves from the region, or if the infant was born and screened in a maternity hospital outside of Stockholm region (Karolinska University Hospital, 2018).

Exact attendance rates for OAE2 and OAE3 are not available; however, high attendance rates are presumed due to the procedure of booking the follow-up directly at the screening appointment.

Data for at-risk infants are not available; however, given the data collected for all infants in Stockholm region, it can be determined that more than 99% of at-risk infants are invited for neonatal screening.

8.2. Referral rates

Referral rates for Stockholm region are calculated from 2017 data and presented in Table 4. Data are estimated calculations due to the fact that NICU infants are included in the percentages but do not follow the complete well baby protocol and are referred to the Audiology Department for screening.

Table 4: Referral rates for neonatal hearing screening among well, healthy infants in Stockholm region, Sweden.

Test	Referral Rate
OAE1	3.5%
OAE2	31%
OAE3	73%
aABR	60%

Referral rates assuming 100% attendance at each step.

In total, the referral rate for well-babies to a diagnostic assessment after the screening process was 0.32% in 2017.

Data for at-risk infants are not available.

In total 0.46% of all neonates received a diagnostic assessment in 2017

8.3. Diagnostic assessment attendance

The compliance rate for a diagnostic assessment after neonatal hearing screening was 97% in 2017 and is generally estimated to be >95% annually.

8.4. Prevalence / Diagnosis

The prevalence rate values of permanent hearing loss among neonates in Stockholm region is presented in Table 5 based on calculated estimates (AudioHab database, 2017). About 30-40 children are diagnosed with hearing impairment each year after neonatal hearing screening. Data are calculated from a database *AudioHab* within Karolinska University Hospital, where all children with a hearing loss diagnosis in Stockholm region are registered.

Table 5: Prevalence rates of permanent hearing loss among neonates in Stockholm region, Sweden (Karolinska University Hospital, 2017).

	Bilateral		Unilateral	
	≥ 40 dB HL	≥ 80 dB HL	≥ 40 dB HL	≥ 80 dB HL
Prevalence (per 1000 neonates)	0.7	0.2 - 0.3	0.3	0.1 - 0.2

The percentage of infants diagnosed with permanent hearing loss in Stockholm region after neonatal hearing screening is the same as for prevalence rates in Table 5.

8.5. Treatment success

Data are unavailable regarding how many children with neonatal hearing impairment are fitted with hearing aids per year in Stockholm region. It is estimated that around 25-40 infants with neonatal hearing impairment are fitted with cochlear implants per year in Stockholm region (Cochlear Implant Team, Karolinska University Hospital, 2017)

8.6. Screening evaluation

In a cohort of 440 children ages 2-9 years old with hearing impairment, 15% had passed neonatal hearing screening; however, this does not account for late-onset or acquired hearing loss (Persson, 2013).

The percentage of false positives after neonatal hearing screening for well babies is estimated to be 4% after 2xOAE and 2% after aABR. It is roughly estimated that the positive predictive value of a refer result is 80-90% after the multistep OAE and aABR protocol for well babies.

Sensitivity is estimated to be very high, but cannot be determined accurately due to existence of delayed-onset and acquired hearing losses. Specificity is estimated at around 95%, depending on clinical routines and test staff.

For at-risk infants, positive predictive value of a refer result is likely to be lower than for well babies due to feeding tubes, malformations, and smaller ears that may contribute to more false responses. The sensitivity is expected to be high, similar to well babies.

9. Results: Preschool Hearing Screening

9.1. Coverage and attendance rates

It is estimated that >99% of children age 4 are invited for preschool hearing screening, as this is part of the child health care system in Stockholm region. The coverage rate and attendance rates are roughly estimated to be >90% though data are not available.

9.2. Referral rates

These data are unavailable.

9.3. Diagnostic assessment attendance

These data are unavailable.

9.4. Prevalence / Diagnosis

The prevalence rates of permanent hearing loss among preschool-age children in Stockholm region is presented in Table 6 based on calculated estimates (Karolinska University Hospital, 2017). As indicated in section 6.4, data are calculated from a database *AudioHab* within Karolinska University Hospital, where all children with a hearing loss diagnosis in Stockholm region are registered.

Table 6: Prevalence of permanent hearing loss among preschool-age children in Stockholm region, Sweden (Karolinska University Hospital, 2017).

	Bilateral			Unilateral		
	≥ 25 dB HL	≥ 40 dB HL	≥ 80 dB HL	≥ 25 dB HL	≥ 40 dB HL	≥ 80 dB HL
Prevalence per 1000 children (Karolinska University Hospital, 2017)	2-3	1.5	0.5 - 0.7		0.5 - 1	0.3 - 0.5

9.5. Treatment success

Information on 3-4-year-old hearing screening is unknown.

9.6. Screening evaluation

The percentage of false negatives for preschool hearing screening is believed to be low and sensitivity is high, though these data are unavailable. The percentage of false positives is roughly estimated to be >25% given that children often perform better in a quite clinical environment or had temporary ear problems during screening.

10. Costs: Neonatal Hearing Screening

Neonatal hearing screening in Stockholm region is free of charge for parents. There is no financial reward when parents attend hearing screening, and there is no penalty for those who do not attend hearing screening.

There has not been a cost effectiveness analysis completed in Stockholm region.

10.1. Screening costs

It is estimated that neonatal hearing screening costs 50€ per well-baby (Karolinska University Hospital internal budget, *source unverified*). Screening costs for at-risk babies is unknown.

10.2. Equipment costs

(*Information extracted to protect commercially sensitive data*)

A screening device is expected to be replaced every 10 years. The maintenance costs or cost of disposables are unknown.

10.3. Staff costs

Most hearing screening professionals perform screening as part of their daily work; therefore, there are several in every maternity hospital, though exact numbers are unavailable.

It is estimated that the annual salary of a screening professional is 350 000 SEK (€33 000), plus an additional 50% of salary is paid to the government by employers for social security (HR Department, Karolinska University Hospital, 2017). The hourly salary is estimated at 350 SEK.

The cost for higher education for a doctor is 1 200 000 SEK or approximately €113 000 (as cited by SACO Swedish Confederation for Professional Associations). The cost for nursing education is unknown.

10.4. Diagnostic costs

The cost for a diagnostic assessment is a separate cost and not included in the cost of screening. This cost is not indicated.

10.5. Amplification costs

In Stockholm region, all children with hearing loss are treated. Children may not be fitted with cochlear implants if deaf parents refuse this type of intervention.

The total cost for hearing aids, including the device and associated services for the first year is estimated to be around 50 000 SEK. The costs associated with hearing aid treatment after the first year is on average 20 000 SEK per year and child, based on the total cost for the intervention program including speech therapy, family support etc. (Karolinska University Hospital, 2018).

For cochlear implants, the cost of the first year of treatment is 350 000 SEK including the device and associated services (surgery, programming, rehabilitation, etc.) (Karolinska University Hospital, 2018). The cost of cochlear implant treatment after the first year is estimated to 20 000 to 30 000 SEK per year and child.

10.6. Social costs

There are 5 specialized schools in Sweden with primary and secondary education. There is one upper-secondary (high-school) that teaches in sign language. Around 600 students attend one of these schools (Specialpedagogiska skolmyndigheten, 2018).

The cost per child to attend a specialized school is around 900 000 SEK per year. The cost for a normal hearing child to attend a mainstream primary school is around 100 000 SEK per year. The total cost of mainstream primary school in Sweden is 98 000 000 SEK (Skolverket, 2018).

In mainstream schools, technical support systems are available for children with hearing aids or cochlear implants. Assistant teachers spend part of their time working with hard of hearing children, depending on the need and their availability.

11. Costs: Preschool Hearing Screening

11.1. Screening costs

Screening costs for 4-year old hearing screening are unknown.

11.2. Equipment costs

Screening costs for 4-year old hearing screening are unknown.

11.3. Staff costs

Screening costs for 4-year old hearing screening are unknown.

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