Summary: Hearing Screening

Denmark

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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 Denmark, neonatal hearing screening is implemented nationally. Individual regions are responsible for constructing their own protocols, but most regions follow the national guidelines with only some exceptions.

The following report contains information with regards to hearing screening in the entire country of Denmark.

3.1. General

The country of Denmark has an area of 42 933 km^2 with a population of 5 806 081 as of January 2019. (Statistics Denmark, 2019). In Denmark, each birth be registered. The number of live births in Denmark was 61 476 in 2018 (Statistics Denmark, 2019).

The World Bank income classification categorizes Denmark as a high-income country (The World Bank, 2018). The gross domestic product (GDP) per capita in 2017 was €50 655 (Statistics Denmark, 2019).

From the World Health Organization (WHO) Global Health Expenditure Database, health expenditure in Denmark in 2015 was 5469 USD or €4839 per capita (World Health Organization, 2018).

Data acquired from the 2016 United Nations Demographic Yearbook indicates an infant mortality rate of 3.7 per 1000 for the country of Denmark in 2015 (United Nations Statistics Division, 2016).

3.2. Neonatal hearing screening

In Denmark, neonatal hearing screening is conducted universally, with all babies in the country having access to hearing screening, though participation is not obligatory for parents. Neonatal hearing screening started in Denmark in 2005 and was also fully implemented across the country for both well babies and at-risk babies in 2005. Neonatal hearing screening is funded through municipalities or the individual province/region in Denmark and is embedded in the Preventive Child Health Care screening system.

Neonatal hearing screening is organized by the Danish Health Authority. Though national guidelines are available, regional protocols may vary slightly. For example, OAE is used as a screening tool in Denmark, except in the Central Region of where aABR is used. The staff that perform the screening may vary across regions, as may the time between each screening step and between screening referral and diagnostic assessment.

3.3. Preschool hearing screening

There is no preschool hearing screening programme in Denmark.

4. Guidelines & Quality Control

National guidelines for child health care exist in Denmark, including the national hearing screening guidelines (Sundhedsstyrelsen, 2004).

The content of the general hearing screening programme was decided on by the Danish Health Authority, and has not been revised since implementation in 2005. However, the Danish Health Authority would be responsible for making revisions in the future.

Quality assurance of hearing screening programs is not imposed by the government, though information is collected about hearing screening outcomes by the Danish Health Authority via the Danish National Patient Register.

Annual reports are not available for Denmark, though the Danish Health Authority have conducted two quality assurance evaluations since implementation in 2005. One was published in 2007 (Sundhedsstyrelsen, 2007) and follow-up evaluation in 2010 (Sundhedsstyrelsen, 2010).

Studies have been performed on hearing screening in Denmark, including its effectiveness (Konrádsson, Kjaerboel, & Boerch, 2007; Pedersen, Moller, Wetke, & Ovesen, 2008).

5. Process: Screening, Diagnosis, Intervention

5.1. Neonatal hearing screening

In Denmark, screening protocols are defined for well infants and at-risk infants. Well babies and at-risk babies are screened in the hospital. According to Statens Serum Institut, 98% of infants are born in the hospital where the average length of stay after delivery is 1 day. Families are invited to participate in screening by nurses, midwives, or doctors via oral information provided directly at the hospital or through an electronic letter.

At-risk infants are defined as those taking medications with ototoxic effects, low birthweight under 1500g, hereditary predisposition, syndromes where hearing loss can occur, and perinatal infections that can cause hearing loss. Aside from those with risk factors, infants admitted to the neonatal intensive care unit for more than 48 hours are also considered at-risk and screened using the at-risk protocol.

The prevalence of the CMV antibody is 20-30% among 1-year-olds (Statens Serum Institut, 2015). The prevalence of meningitis 0.002 to 0.004% per year (Statens Serum Institut, 2013).

Neonatal hearing screening for well babies should be completed before 30 days after birth. For infants at-risk, there is no age limit, but babies should be screened before discharge from the hospital.

The target condition for screening for both well babies and at-risk babies is a unilateral or bilateral hearing loss greater than 30 dB HL.

5.2. Neonatal diagnostic assessment

The diagnostic assessment test performed after neonatal hearing screening referral is first, an aABR at 35 dB nHL, TEOAE and DPOAE. If no response is still detected, higher intensities on the aABR or a clinical ABR is performed.

The diagnostic assessment for well and at-risk infants should be completed before 3 months of age.

5.3. Preschool hearing screening

Not applicable.

5.4. Intervention approach

In Denmark, treatment options available include grommets, hearing aids, bone conductive devices, and cochlear implants. It is estimated that infants are fitted with hearing aids from less than 6 months of age or older, and that infants are fitted with cochlear implants from 6-12 months of age.

While there is no definite consensus on the fitting guidelines for hearing aids in Denmark, most audiologist tend to fit at least a 25 dB HL loss in one or both ears (congruent with the findings in Fitzpatrick, Roberts, Wittingham & Barreria-Nielsen, 2017).

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 neonatal hearing screening protocol for well babies is presented in Table 1. For all regions in Denmark except for the Central Region, OAE is performed at the first step. In Central Region Denmark, aABR is performed.

Table 1: Screening process for well babies in Denmark.

Test	Age	Referral criteria	Device	Unilateral Referrals?	Location
OAE1/aABR†	<24 hours to 10 days after birth‡	8x peaks of alternating-signs	Accuscreen	Yes	Maternity ward
OAE2 (+aABR*)	< 30 days after birth	*As above* 35 dB nHL	Accuscreen	Yes	Local hospital

† Central Region Denmark performs aABR at 35 dB nHL during the first step.

* aABR is recommended at step 2 if available, in combination with repeat OAE screening.

‡ Though guidelines stipulate screening after 48 hours, screening is performed earlier than 48 hours (and even < 24 hours after birth), if mothers are discharged early.

6.2. Neonatal hearing screening (at-risk)

The screening process for at-risk infants is presented in Table 2. It is recommended that both OAE and aABR are performed at the initial screening step. Infants that do not pass one or both tests are referred for diagnostic assessment.

Depending on the risk factors presented, infants that pass both screening tests may still be referred for follow-up assessment. These risk factors include, family history of hearing loss, syndromes associated with hearing loss, cranio-facial abnormalities, perinatal infections (CMV, rubella, or toxoplasmosis). Infants with other risk factors that pass both screening tests are discharged from the hearing screening programme.

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

Test	Age	Refferal criteria†	Device	Unilateral Referrals?	Location
OAE + aABR	< 30 days after birth	8x peaks of alternating-signs	Accuscreen	One or both	NICU / Audiology department

35 dB nHL

† Depending on the risk factors presented, infants may be referred for a diagnostic assessment, despite having passed both OAE and aABR.

6.3. Preschool hearing screening

There is no preschool hearing screening.

7. Professionals

7.1. Neonatal hearing screening (well)

Screening for well babies is performed by bioanalysts, social and healthcare assistants, midwives or any other staff who has completed the training in neonatal hearing screening. The training is performed by local experienced staff over 2-3 days. If an update to equipment or education is required, the local coordinator for the region will be contacted.

7.2. Neonatal hearing screening (at-risk)

Screening for at-risk infants is typically performed by local staff, as with well babies; however, regardless of the screening test result at-risk infants are referred and rescreened by staff in the audiology department.

7.3. Preschool hearing screening

There is no preschool hearing screening.

8. Results: Neonatal Hearing Screening

8.1. Coverage and attendance rates

In Denmark, the coverage rate for well babies within the first 30 days was 76.2% in 2016 (Danish National Patient Register, 2016 data), and 74% in 2009 according to the 2010 report (Sundhedsstyrelsen, 2010). Figures may be underestimated due to lack of reporting to the national register and changes to the electronic patient record platforms.

The number of infants that missed being *offered* screening is not specified, and therefore, attendance rate is not known.

The coverage rate for well babies across the calendar year (i.e., number of infants screened / births) was 85% in 2009 (Sundhedsstyrelsen, 2010).

8.2. Referral rates

Pass rates for neonatal hearing screening for well babies are derived from a controlled study comparing OAE to aABR screening during the first step. In total, 1656 infants participated and were screened with both techniques, first aABR and then TEOAE (Pedersen, Moller, Wetke, & Ovesen, 2008).

Table 3: Referral rates for neonatal hearing screening (well babies) in Denmark (Pedersen, Moller, Wetke & Ovesen, 2008)

Test	Referral Rate
OAE1	11%
/ aABR1	4%
OAE2 + aABR	N/A

Referral rates assume 100% attendance. Rates reflect the number of infants referred out of the number of infants screened at each step.

In total, the referral rate for well babies to a diagnostic assessment after the screening process is 2.21% with +/- 0.08% from 2011 to 2017 (Danish National Patient Register, 2011-2017 data).

The referral rate for at-risk babies to a diagnostic assessment after the screening process is unknown.

8.3. Diagnostic assessment attendance

The compliance rate for a diagnostic assessment after neonatal hearing screening is unknown; however, the representative indicates that compliance is not an issue in Denmark. The percentage of well or at-risk babies who actually received a diagnostic assessment in Denmark is unknown.

8.4. Prevalence / Diagnosis

The prevalence values of permanent hearing loss among neonates in Denmark is presented in

Table 4, based on a sample of 1637 infants screened (Pedersen, Moller, Wetke, & Ovesen, 2008). The sample was well infants with no known risk factors for hearing loss, with the exception of two infants admitted to the NICU; these two infants passed screening. Therefore, it can be assumed that prevalence values in Table 4 represents that for well infants with no known risk factors: however, the small sample size for determining prevalence should be noted.

Table 4: Prevalence of permanent hearing loss (well babies) in Denmark (Pedersen, Moller, Wetke, & Ovesen, 2008)

	Bilateral		Unilateral	
	≥ 35 dB HL	≥ 80 dB HL	≥ 35 dB HL	≥ 80 HL
Prevalence (per 1000) (Pedersen, Moller, Wetke, & Ovesen, 2008)	0.6		1.2	

The percentage of infants diagnosed with permanent hearing loss in Denmark after neonatal hearing screening is the same data as those used for prevalence in Table 4.

The prevalence of bilateral auditory neuropathy in well or at-risk-babies is unknown.

8.5. Treatment success

It is unknown how many children are fitted with hearing aids each year in Denmark. It is estimated that around 50 children with hearing impairment are fitted with cochlear implants per year in Denmark.

8.6. Screening evaluation

The false negative rate for neonatal hearing screening is unknown. False positive rates are also unknown, though assumptions can be made. If the total prevalence rate of bilateral and unilateral hearing loss ≥ 40 dB HL is 0.3% (Pedersen, Moller, Wetke, & Ovesen, 2008) and the referral rate is approximately 2.21% (Danish National Patient Register, 2011-2017 data), then assuming a 0% false negative rate, the false positive rate can be calculated to be approximately 2%.

Sensitivity, specificity, and positive predictive values are unknown.

9. Results: Preschool Hearing Screening

9.1. Coverage and attendance rates

Not applicable.

9.2. Referral rates

Not applicable.

9.3. Diagnostic assessment attendance

Not applicable.

9.4. Prevalence / Diagnosis

Not applicable.

9.5. Treatment success

Not applicable.

9.6. Screening evaluation

Not applicable.

10. Costs: Neonatal Hearing Screening

There has not been a cost effectiveness analysis completed in Denmark.

10.1. Screening costs

Recent data on neonatal hearing screening costs are unavailable; though data from the 2007 report indicates average national screening costs of 195 DKK (€26.13) per primary screen (Sundhedsstyrelsen, 2007).

10.2. Equipment costs

Costs for equipment, maintenance and replacement are unknown. The costs for aABR disposables are €1 per screen, and the costs for TEOAE disposables are negligible.

10.3. Staff costs

The number of screening professionals per one million people in Denmark is unknown. The salary costs per year for hearing screening professionals is €38 000 to €52 000 per year or €20-27 per hour. The training costs are unknown.

10.4. Diagnostic costs

The cost for a diagnostic assessment is not provided.

10.5. Amplification costs

In Denmark, all eligible children are treated for hearing impairment.

According to the Diagnosis-Related Group (DRG) tariffs for 2018, the running expenditure for unilateral cochlear implantation is 163 136 DKK (€21 862) and for bilateral cochlear implantation is 314 849 DKK (€42 193). Hearing aid intervention costs are unknown.

10.6. Social costs

There are 2 specialized schools in Denmark for deaf and hard-of hearing students. The number of children that attend these schools is unknown. Special support is also available in mainstream schools for deaf and hard of hearing students (hoerelse.info; Videnscenter for hørehandicap, 2007).

The costs for special schools or support are also unknown.

11. Costs: Preschool Hearing Screening

11.1. Screening costs

Not applicable.

11.2. Equipment costs

Not applicable.

11.3. Staff costs

Not applicable.

12. References

(n.d.). *Danish National Patient Register, 2011-2017 data.*

(n.d.). *Danish National Patient Register, 2016 data.*

Fitzpatrick, E. M., Roberts, C., Whittingham, J., & Barreira-Nielsen, C. (2017). Amplification decisions for children with mild bilateral and unilateral hearing loss. *Canadian Journal of Speech-Langugage Pathology and Audiology, 41*(2), 203-226.

hoerelse.info. (n.d.). Retrieved from Skole og undervisning: https://hoerelse.info/skole-og-undervisning

Konrádsson, K. S., Kjaerboel, E., & Boerch, K. (2007). Introducing universal newborn hearing screening in Denmark: Preliminary results from the city of Copenhagen. *Audiological Medicine, 5*(3), 176-181.

Pedersen, L., Moller, T. R., Wetke, R., & Ovesen, T. (2008). [Neonatal hearing screening. A comparison of automatic auditory brainstem audiometry and otoacoustic emissions]. *Ugeskrift for Laeger, 170*(8), 642-646.

Statens Serum Institut. (2013). *Meningococcal disease 2012*. Retrieved from EPI-NEWS: Monitoring and prevention of communicable diseases: https://www.ssi.dk/Aktuelt/Nyhedsbreve/EPI-NYT/2013/Uge 37 - 2013.aspx

Statens Serum Institut. (2015). *Cytomegalovirus (CMV) antibody (total, IgM) (R No. 281)*. Retrieved from Statens Serum Institut, Diagnostics: https://www.ssi.dk/Diagnostik/DiagnostiskHaandbog/200-299/281.aspx

Statistics Denmark. (2019). *BIRTHS*. Retrieved from Statistics Denmark: http://www.dst.dk/en/Statistik/emner/priser-og-forbrug/forbrugerpriser

Statistics Denmark. (2019). *KEY FIGURES, REGIONAL ACCOUNTS*. Retrieved from Statistics Denmark: https://www.dst.dk/en/Statistik/emner/nationalregnskab-og-offentlige-finanser/regionale-regnskaber/noegletal-regionale-regnskaber

Statistics Denmark. (2019). *POPULATION AND POPULATION PROJECTIONS*. Retrieved from Statistics Denmark: https://www.dst.dk/en/Statistik/emner/befolkning-og-valg/befolkning-og-befolkningsfremskrivning

Sundhedsstyrelsen. (2004). *Sundhedsstyrelsens retningslinier af 12. august 2004 for neonatal hørescreening.* København: Sundhedsstyrelsen. Retrieved February 26, 2018, from http://www.sst.dk/~/media/D8101DC05B7A430BA14675A61495AB56.ashx.

Sundhedsstyrelsen. (2007). *Evaluering af den neonatale hørescreeningsindsats.* København: Sundhedsstyrelsen. Retrieved February 26, 2018, from http://sundhedsstyrelsen.dk/~/media/5E88A1B21A064CFE9FE1877A55700D8F.ashx

Sundhedsstyrelsen. (2010). *Opfølgende evaluering af den neonatale hørescreeningsindsats.* København: Sundhedsstyrelsen. Retrieved February 26, 2018, from http://sundhedsstyrelsen.dk/~/media/162ACFD8D7DE41F59E225B17F63AEA0F.ashx

Sundhedsstyrelsen. (2012). *Kliniske retningslinjer for pædiatrisk cochlear implantation i Danmark – udredning, operation, efterbehandling og monitorering.* København: Sundhedsstyrelsen. Retrieved February 26, 2018, from https://www.sst.dk/da/udgivelser/2012/kliniske-retningslinjer-for-paediatrisk-cochlear-i-danmark

The World Bank. (2018). *World Bank GNI per capita Operational Guidelines & Analytical Classifications.* The World Bank.

United Nations Statistics Division. (2016). *Demographic Yearbook – 2016.* Department of Economic and Social Affairs. New York: United Nations.

Videnscenter for hørehandicap. (2007). *Børn i medvind og modvind - Hvad kan skolen gøre for, at børn med høretab trives bedst muligt?* Virum: Videnscenter for hørehandicap.

World Health Organization. (2018). *Global Health Expenditure Database*. (W. H. Organization, Producer) Retrieved 08 01, 2018, from NHA Indicators: http://apps.who.int/nha/database/DataExplorerRegime.aspx)