



Summary: Hearing Screening Macedonia (Skopje 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	<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"> • <u>Invited for screening</u> includes all those that are offered the screening test. • <u>Tested and receive a result</u> could be a “pass” or “fail”. <p>Attendance rate provides information on the willingness of families to participate in screening.</p>
Attendance rate in first year of life	<p>See definition of Attendance rate.</p> <p>The calculation cut-off is after <u>one year of life</u>.</p>
Compliance with referral (percentage)	<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>
Coverage	<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"> • <u>Eligible for screening</u> includes those within the population that are covered under the screening or health care program. • <u>Tested and receive a result</u> could be a “pass” or “refer to diagnostic assessment”. • <u>Specific time</u> can be defined, such as 1 month after birth, 3 months after birth, etc. <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>
Coverage in first year of life	<p>See definition of Coverage.</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>
False negatives	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%.
False positives	<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>
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	<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>
Positive predictive value	<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 Target Condition (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>
Preschool or (pre)school children	All children between 3-6 years of age.
Preschool or (pre)school screening	<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>



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: <ul style="list-style-type: none"> • The <u>laterality of the condition</u>, whether the program aims to detect both unilateral and bilateral hearing loss or just bilateral hearing loss. • The <u>severity of the condition</u>, 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 <i>not</i> 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 Macedonia, hearing screening is implemented and organized regionally. The following report contains information with regards to status of hearing screening in the region of Skopje in Macedonia.

3.1. General

Macedonia has a total area of 25 713 km² with an estimated population of 2 073 703 in 2016. Skopje region has an area of 1818 km² with an estimated population of 624 585 in 2016 (State Statistical Office, 2018).

In Macedonia, all births are registered through the Ministry of Justice on a national and regional level. In 2016, there were 23 002 births registered for all of Macedonia and 8466 births registered for Skopje region (State Statistical Office, 2018).

The World Bank income classification categorizes Macedonia as an upper-middle-income country (The World Bank, 2018). The gross domestic product (GDP) in 2015 was €4377 per capita in Macedonia and €6290 per capita for Skopje region (State Statistical Office, 2018).

From the World Health Organization (WHO) Global Health Expenditure Database, health expenditure for Macedonia in 2015 was 328 USD or €289 per capita (World Health Organization (WHO), 2018).

An infant mortality rate of 8.6 and 11.9 per 1000 is reported across all of Macedonia in 2016 and 2017, respectively. An infant mortality rate of 8.3 and 12.0 per 1000 is reported for Skopje region in 2016 and 2017, respectively (State Statistical Office, 2018). The United Nations Statistics Division also shows a similar mortality rate in Macedonia in rural areas compared to urban areas. Infant mortality rates in 2015 were 8.7 and 8.4 for rural and urban areas, respectively (United Nations Statistics Division, 2016).

3.2. Neonatal hearing screening

In Macedonia, the universal neonatal hearing screening programme is under development. Neonatal hearing screening is selective, with only NICU babies having access to hearing screening. Neonatal NICU screening is funded through health insurance, but participation is not obligatory for parents. Screening started approximately 10 years ago, but is not yet fully implemented. It is not embedded in the Preventive Child Health Care screening system.

In the last 3 months, a project has started by the medical faculty in Skopje whereby all groups of infants are offered screening, including well infants, infants with risk factors, and infants in the NICU. This project is in preparation for the development of universal hearing screening across Macedonia.

3.3. Preschool hearing screening

Preschool hearing screening in Skopje Macedonia is provided at the ENT clinic at the University Hospital and at the Center for Hearing and Speech. All children in Skopje are offered to come in to have their hearing screened. Screening at this age started approximately 20 years ago and is funded through health insurance. It is incorporated in the Preventive Child Health Care screening system.

4. Guidelines & Quality Control

There are no national hearing screening guidelines for Macedonia. However, there is a protocol used for neonatal hearing screening for Skopje region.

Neonatal screening and revisions to the programme is decided on by the Macedonian Society of ENT doctors. The hearing screening protocol follows the standard European protocols and makes updates accordingly.

Quality assurance or data collection on hearing screening is not performed and there have been no annual reports or studies performed on hearing screening in Macedonia.



5. Process: Screening, Diagnosis, Intervention

5.1. Neonatal hearing screening

In Skopje region, it is roughly estimated that around 6% of neonates are admitted to the NICU.

NICU babies are screened in the hospital. Families are invited to participate in screening via a letter provided to the parents.

In Macedonia, at-risk infants are defined as those with the following risk factors: prematurity, toxemia during pregnancy, lack of oxygen (anoxia), low APGAR scores, prolonged mechanical ventilation, low birth weight, viral infection, sepsis, hyperbilirubinemia, ototoxic exposure, family history of congenital hearing loss, or craniofacial anomalies. However, with regards to the current project, these infants with risk factors are not screened differently than NICU infants. Data are unavailable on the prevalence of CMV or meningitis in Macedonia.

At-risk babies should be screened before 5-6 months of age.

Hearing screening for well babies is currently being performed in the region of Skopje in Macedonia but not in other regions of Macedonia. In the past 3 months, well babies were added in the project for neonatal screening with support by the medical faculty in Skopje, Macedonia.

Macedonia is preparing screening in neonatal screening program to all groups of newborns; including healthy infants, infants at risk, and infant which are at the NICU.

The target condition for screening for at-risk babies is not quantified but is only according to the OAE results.

5.2. Neonatal diagnostic assessment

Infants referred from neonatal hearing screening to diagnostic assessment are tested with a combination of expanded audiological assessment including diagnostic ABR (testing from 70 to 40 dB nHL) and behavioral assessment, as well as tests of middle ear function using acoustical impedance /admittance.

The diagnostic assessment is completed around 3-4 months of age and should be completed by 6-7 months of age.

5.3. Preschool hearing screening

Preschool hearing screening takes place at the Department of Audiology, ENT University Hospital or at the Center for Hearing and Speech. The target condition is not indicated; however, the referral criterion is 30 dB HL.

5.4. Intervention approach

In Macedonia, treatment options available include grommets, hearing aids and cochlear implants. Infants are fitted with hearing aids from less than 6 months of age or older, and infants are fitted with cochlear implants from 1-2 years of age.

The hearing aid fitting criteria in Skopje, Macedonia is a hearing loss of at least 40-50 dB HL. Both bilateral and unilateral hearing loss are treated with hearing aids in Skopje, Macedonia.

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)

This screening process for well babies was recently implemented as a pilot project in the past few months. The pilot protocol for neonatal hearing screening for well babies is summarized in Table 1, whereby a 2-step OAE - OAE protocol is in effect. If the infant does not pass the OAE in one or both ears prior to discharge, a rescreening OAE is held at the age of 1 month.

Table 1: Screening process for well, healthy babies in Skopje, Macedonia.

Test	Age	Referral criteria	Device	Unilateral Referrals?	Location
OAE1	2-3 days / Before discharge	500-4000 Hz	OtoRead	Yes	Maternity
OAE2	1 month	500-4000 Hz	OtoRead	Yes	ENT Dept, University Hospital

6.2. Neonatal hearing screening (at-risk)

For at-risk infants, the same protocol is followed as for well babies. There are no differences in the protocols.

Prior to 3 months age, only selective at-risk babies were screened using this protocol indicated in Table 1. However, just in few the recent months have well babies been included in the screening in Skopje, Macedonia. This is in preparation of a universal newborn hearing screening programme.

6.3. Preschool hearing screening

Pure-tone audiometry is performed in the ENT department at the University Hospital and at the Center for Hearing and Speech in Skopje, Macedonia. Children age 5-6 years are invited for screening, which is performed by speech therapists.

Table 2: Screening process for preschool-age children in Skopje, Macedonia.

Test	Age	Referral criteria	Unilateral Referrals?	Location
Pure-tone audiometry	5-6 years	30 dB HL	Yes	Hearing Clinic



7. Professionals

7.1. Neonatal hearing screening (well)

In Skopje, Macedonia, screening for well babies only started 3 months ago. So far, well-baby newborn screening has been performed by audiologists, as have been the case previously for at-risk infants. Audiologists education is one year in length, and a training programme is included specifically for learning about how to perform hearing screening. The training program is about knowing how to use the screening devices and how to prepare newborns for testing.

7.2. Neonatal hearing screening (at-risk)

Screening of at-risk infants is also performed by audiologists. See 7.1 for training details.

7.3. Preschool hearing screening

Preschool hearing screening is performed by speech therapists in Skopje, Macedonia.

8. Results: Neonatal Hearing Screening

8.1. Coverage and attendance rates

In Skopje, Macedonia, data are not collected on outcomes of hearing screening. Data are unavailable for coverage rates or attendance rates.

8.2. Referral rates

Data are unavailable on passing or referral rates in Skopje, Macedonia.

8.3. Diagnostic assessment attendance

Data are unavailable on the diagnostic assessment attendance rate in in Skopje, Macedonia.

8.4. Prevalence / Diagnosis

Prevalence rates of permanent hearing impairment among neonates and preschool-age children are provided based on the statistical data of the ENT department in the University Hospital in Skopje, Macedonia. These figures are presented in Tables 3 and 4.

Table 3: Prevalence rates (per 1000) of permanent neonatal hearing loss in Skopje, Macedonia (Internal data, ENT Dept., University Hospital).

	Bilateral		Unilateral	
	≥ 40 dB HL	≥ 80 dB HL	≥ 40 dB HL	≥ 80 dB HL
Prevalence per 1000 (ENT Dept. University Hospital)	5	15	1	10

Table 4: Prevalence rates (per 1000) of permanent childhood hearing loss in Skopje, Macedonia (Internal data, ENT Dept., University Hospital).

	Bilateral			Unilateral		
	≥ 25 dB HL	≥ 40 dB HL	≥ 80 dB HL	≥ 25 dB HL	≥ 40 dB HL	≥ 80 dB HL
	Prevalence per 1000 (ENT Dept. University Hospital)	30	8	3	15	2

Out of the children diagnosed with hearing impairment after neonatal hearing screening, 50% are diagnosed with a bilateral hearing loss and 50% are diagnosed with a unilateral.

Out of those diagnosed bilaterally, 80% are diagnosed with a hearing loss ≥ 80 dB HL, and out of those diagnosed unilaterally, 60% are diagnosed with a hearing loss ≥ 80 dB HL.

The source of these data is the statistical data from the ENT department at the University Hospital, and cannot be externally verified.

8.5. Treatment success

Not all eligible children are treated for hearing loss in Skopje, Macedonia. This is due to payment problems. Six children per year are fitted with cochlear implants in Skopje, Macedonia (ENT department, University Hospital).



8.6. Screening evaluation

Data are unavailable regarding the outcome measures for neonatal hearing screening in Skopje, Macedonia, though a sensitivity of 80% was indicated.



9. Results: Preschool Hearing Screening

9.1. Coverage and attendance rates

Data are unavailable.

9.2. Referral rates

Out of the preschool-age children that are screened, 20% are referred to a diagnostic audiological evaluation (ENT department, University Hospital).

9.3. Diagnostic assessment attendance

Data are not available.

9.4. Screening evaluation

Data are not available.



10. Costs: Neonatal Hearing Screening

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

10.1. Screening costs

Data on neonatal hearing screening costs are unavailable and covered by health insurance.

10.2. Equipment costs

The cost of a hand-held OAE screening device is not indicated. The cost of these devices is covered by Insurance Health Fund. The maintenance costs for these devices are about €7000 - 8000. The device is scheduled for replacement after 10 years. The costs of disposables for OAE screening and the costs of disposables for ABR are covered by Insurance Health Fund and not indicated.

10.3. Staff costs

In Skopje region, Macedonia, there are 4 hearing screening professionals in total. Costs for training hearing screening professionals from leaving secondary education to qualification is €30 000. The annual salary of a hearing screening professional is €600 or €20 per hour.

10.4. Diagnostic costs

The cost for a diagnostic assessment is not provided.

10.5. Amplification costs

The costs for hearing aid or cochlear implant intervention is not available.

10.6. Social costs

There are 2 special schools for the deaf and hard of hearing in Macedonia; however, data are unavailable on costs of specialized or mainstream schooling.



11. Costs: Preschool Hearing Screening

11.1. Screening costs

Data are not available.

11.2. Equipment costs

Data are not available.

11.3. Staff costs

Data are not available.

11.4. Diagnostic costs

Data are not available.

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