Summary: Hearing Screening

Serbia

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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 Serbia, hearing screening is performed regionally and organized by hospitals (locally). The following report contains information with regards to childhood hearing screening in the entire country of Serbia with information specific to the area of Belgrade.

3.1. General

Serbia has a total area of 88 361 km^2 with a population of 7 095 383 million in 2015 (Statistical Office of the Republic of Serbia, 2016).

In Serbia, all births are registered in the maternity ward by the community office, which then delivers data to the Statistical Office and the Institute of Public Health. The number of live births in Serbia in 2016 was 64587 (Statistical Office of the Republic of Serbia, 2018)

The World Bank income classification categorizes Serbia as an upper middle-income country (The World Bank, 2018). The gross domestic product (GDP) in 2016 was 640 558 RSD or €5412 per capita in Serbia (Statistical Office of the Republic of Serbia, 2018)

From the World Health Organization (WHO) Global Health Expenditure Database, health expenditure for Serbia in 2015 was 419 USD or €366 per capita (World Health Organization (WHO), 2018).

An infant mortality rate of 5.3 per 1000 is reported for Serbia (United Nations Statistics Division, 2016), with a higher mortality rate reported in urban areas (5.7 per 1000) compared to rural areas (4.4 per 1000; United Nations Statistics Division, 2016).

3.2. Neonatal hearing screening

In Serbia, the status of neonatal hearing screening is changing quickly. Currently, all maternity hospitals have the tools and capacity to implement a universal neonatal hearing screening programme, and organization is underway. However, screening may not yet be performed on all infants in the country. In Belgrade, all babies have access to hearing screening, though screening is not obligatory for parents. The year in which the universal program for well and at-risk babies was first implemented is not specified; however, an article was published in 2010 with the goal of establishing a neonatal hearing screening programme. It is roughly estimated that the screening for at-risk/ NICU infants began in 2012. Since 2017, all maternity hospitals in Serbia are equipped with screening devices, and national implementation is currently in progress.

Neonatal hearing screening is not embedded in the Preventive Child Health Care screening system. Screening for well and at-risk infants is funded by charity, company, council and the state.

National guidelines or a national screening protocol are not yet available in Serbia.

3.3. Preschool hearing screening

Preschool hearing screening is conducted universally in Serbia as part of the routine check-up prior to school entry. It is embedded in the Preventive Child Health Care screening system and is funded by the state. The exact date of when preschool hearing screening began is not known; however, it was prior to 1984.

4. Guidelines & Quality Control

National guidelines for hearing screening do not exist in Serbia.

A special board of ENT and speech-language pathologist professionals are selected by the Ministry of Health to develop the content of the hearing screening programme. In 2017, screening devices were provided to all maternity hospitals in Serbia, and staff education and training were organized. This organization for implementation was funded by the state/government.

Quality assurance of hearing screening programs is not imposed by the government. Information is collected locally by regional hospitals; however, the government does not yet collect screening data or publish annual reports.

5. Process: Screening, Diagnosis, Intervention

5.1. Neonatal hearing screening

Well-babies and at-risk babies are screened in the hospital or private clinic. In 2014, 98.3% of births took place in a maternity hospital (Statistical Office of the Republic of Serbia and UNICEF, 2014), where the average length of stay after delivery is estimated to be 3.98 days. It is roughly estimated that home deliveries account for 1.3% of births. Parents/caregivers of well and at-risk babies are invited to participate in neonatal hearing screening via a letter.

Neonatal hearing screening for well babies should be completed before 3 months of age. For at-risk babies, screening should be completed by 3 to 6 months of age (corrected), depending on the health and developmental status of the child.

At-risk infants are defined as those with a positive family history of hearing loss, admission to the NICU for more than 5 days, use of mechanical ventilation, prematurity, use of ototoxic medications, or with meningitis.

Data on the prevalence of CMV is not available in Serbia. The prevalence of meningitis was 137 cases (total) in 2015.

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

5.2. Neonatal diagnostic assessment

The diagnostic assessment after neonatal hearing screening referral is described in the article by Babac, Đerić, & Ivanković (2007) as including OAEs, tympanometry and click-ABR. The diagnostic assessment should be completed by 3-6 months of age for well infants, and after 6 months of age for at-risk infants, depending on the general health and developmental status of the child. The diagnostic assessment may be scheduled after 6 months of age if delayed neurological maturation may be suspected.

5.3. Preschool hearing screening

Preschool hearing screening is performed at primary or secondary health care centres, depending on the availability of pure-tone audiometers. Children and parents are invited to participate via a letter. Testing is performed by a trained audiologist.

The target condition for preschool hearing screening is a unilateral or bilateral hearing loss of 25 dB or worse.

5.4. Intervention approach

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

The fitting criteria in Serbia for a hearing aid is bilateral hearing loss of at least 30 dB HL in the better ear or a unilateral hearing loss of at least 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 2-step OAE protocol is in effect, whereby the first OAE is performed in the maternity hospital before discharge. If the infant fails the first test, rescreening occurs at 1 month of age. A subsequent fail at age 1-month would warrant a follow-up assessment at 3-6 months of age at a secondary referral centre (audiology department).

Table 1: Process for neonatal hearing screening for well, healthy infants in Serbia.

Test	Age	Referral Criteria	Device	Unilateral Referrals?	Location
OAE1	24-72 hours	Various	Otometrics, Fisher-Zoth Echo Screen, Maico	Yes	Maternity hospital
OAE2	1 month	Various	Otometrics, Fisher-Zoth Echo Screen, Maico	Yes	Maternity hospital

6.2. Neonatal hearing screening (at-risk)

The screening process for at-risk infants is described in Table 2. Infants in the NICU are mainly screened with TEOAE. In some hospitals, aABR may also be performed before discharge from the hospital, regardless of whether the infant passed or failed the OAE screen. If the aABR is a fail, the infant will be referred for further assessment. Additionally, infants that present additional risk factors for hearing loss (excluding NICU admission), may be referred for ENT follow-up at a later time by their pediatrician.

Table 2: Process for neonatal hearing screening for at-risk infants in Serbia.

Test	Age	Referral Criteria	Device	Unilateral Referrals?	Location
OAE1 (+aABR, some hospitals)	24-72 hours	Various	Various	Yes	Maternity hospital
OAE2	1 month	Various	Various	Yes	Maternity hospital

6.3. Preschool hearing screening

Hearing screening is performed prior to school entry during a routine childhood check-up at 6-7 years of age. Pure-tone audiometry, in addition to otoscopy, tympanometry, and a tuning-fork test is performed at the primary or secondary health center, depending on equipment availability. Referrals are made to ENT or to the audiology department depending on the suspected nature of the hearing loss (conductive or sensorineural).

Table 3: Process for preschool hearing screening in Serbia.

Test	Age	Referral criteria	Unilateral Referrals?	Location
Pure-tone audiometry + otoscopy + tympanometry + tuning fork test	6-7 years	25 dB HL	One or both	Primary or secondary health care centre

7. Professionals

7.1. Neonatal hearing screening (well)

Screening is performed by trained nurses or otolaryngologists.

There is no specific training for hearing screening staff or certified education. Training of the nurses involved in hearing screening is either performed by the manufacturers or companies providing the screening equipment or by a senior audiologist.

7.2. Neonatal hearing screening (at-risk)

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

7.3. Preschool hearing screening

Screening for preschool-age children is performed by trained audiologists.

8. Results: Neonatal Hearing Screening

8.1. Coverage and attendance rates

Data on coverage and attendance rates are not available nationally. In Belgrade, all newborns are offered screening; however, exact coverage and attendance rates are not known.

8.2. Referral rates

Data are unavailable regarding the pass or referral rates of neonatal hearing screening across Serbia or for regional data.

In a study prior to implementation in Belgrade, Babac, Đerić, & Ivanković (2007) measured pass and refer rates for a 2-step protocol with 917 infants, of which 33 were considered "at-risk". From the study, the pass rate for the initial test was 86.3%. The pass rate for the rescreening test is not described, nor is the number of infants that dropped out between initial screening and 1-month rescreening.

After the 2-step protocol, 6 infants of the initial 907 infants screened were referred for diagnostic assessment, equating to a 0.7% referral rate (Babac, Đerić, & Ivanković, 2007). Note that this final referral rate may be influenced by any infants that may have dropped out of the study before rescreening.

8.3. Diagnostic assessment attendance

Data are unavailable regarding the compliance rate to a diagnostic assessment.

In the study by Babac, Đerić, & Ivanković (2007), 5 of the 6 infants referred attended the diagnostic assessment (83.3%).

8.4. Prevalence / Diagnosis

Data are unavailable regarding the prevalence of neonatal hearing loss in Serbia.

An unofficial source describes the prevalence rate of all forms of neonatal hearing loss as 4.6 per 1000. The prevalence rate for permanent hearing loss of neonatal hearing loss is roughly estimated to be 2 per 1000 newborns (i.e., 130 out of 65000 infants screened).

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

8.5. Treatment success

In Serbia, it is unknown how many children per year are fitted with hearing aids or cochlear implants. The number of children fitted with cochlear implants varies across the regions in Serbia. At the Clinical Center of Serbia (Belgrade), 200 CIs have been implanted from 2002 to 2009. At the Clinical Center of Vojvodina (Novi Sad), 100 CIs were implanted from 2002 to 2013. There is one more center in Serbia that provide CIs; however, the number of children implanted is not available from this center.

8.6. Screening evaluation

Actual data on the sensitivity or specificity of neonatal hearing screening are not available, and neither are data on false positives, false negatives, or the positive predictive value.

A positive predictive value of 43% was roughly estimated for all infants (130 out of 300 referrals). False positives were estimated to be around 0.26% (170 out of 65000 infants screened).

9. Results: Preschool Hearing Screening

9.1. Coverage and attendance rates

All children in Serbia are offered preschool screening at age 6-7, before school entry. Data were published by the Institute of Public Health of Serbia. In 2016, 45% of preschool-age children in Serbia had their hearing screened. In Belgrade, 92% of children were screened (Institute of Public Health of Serbia, 2017).

9.2. Referral rates

Data are unavailable.

9.3. Diagnostic assessment attendance

Data are unavailable.

9.4. Screening evaluation

Data are unavailable.

10. Costs: Neonatal Hearing Screening

Financing of neonatal hearing screening in Serbia is organized by the hospitals and is free of charge for parents. There is no financial reward when parents attend hearing screening, nor is there a penalty for those who do not attend hearing screening.

A cost analysis of neonatal hearing screening in Serbia has not been completed.

10.1. Screening costs

The total screening costs cannot be calculated.

10.2. Equipment costs

The cost of an OAE screening device is unknown.

Maintenance costs are unknown. It is unknown how often devices should be replaced, though this would likely depend on the number of infants that are screened with each device.

The cost for disposables are unknown.

10.3. Staff costs

The number of screening staff across all of Serbia is unknown.

The average monthly salary for a screening professional is 30 000 to 40 000 RSD or €253 to €338. This equates to approximately €3000 to €4000 annually.

The cost for training hearing screening professionals is approximately 30 000 to 60 000 RSD or €253 to €507.

10.4. Diagnostic costs

The total cost of diagnostic confirmation is not indicated.

10.5. Amplification costs

In the Serbia, all children with hearing loss are treated, except for children of parents who refuse cochlear implant for their children.

The costs for a hearing aid is covered by the government, and costs approximately 100 000 RSD or €845, and the cost for intervention is approximately €845 per month. These costs are also covered by the government, though the costs associated with parental absence from work is not covered.

The costs associated with cochlear implantation and habilitation are not known.

10.6. Social costs

It is roughly estimated that there are 6 schools with special programs for hearing impaired students in Serbia. It is unknown how many children attend one of these special schools. The tendency is for children with hearing loss to attend mainstream schools.

In mainstream schools, extra support is not provided to children with hearing impairment.

All costs for mainstream or special education schools are unknown. All costs for education are covered by the government.

11. Costs: Preschool Hearing Screening

11.1. Screening costs

Data on screening costs are unknown.

11.2. Equipment costs

Data are unknown.

11.3. Staff costs

Data are unknown.

12. References

Babac, S., Đerić, D., & Ivanković, Z. (2007). [Newborn Hearing Screening]. *Serbian Archives of Medicine, 135*(5-6), 264-268.

Institute of Public Health of Serbia. (2017). *Analysis of the planned and realized extent and content of the rights of insured persons to primary health care in 2016.* Belgrade: Institute of Public Health of Serbia.

Statistical Office of the Republic of Serbia. (2016). *Statistical Yearbook of Serbia.* Belgrade: Statistical Office of the Republic of Serbia.

Statistical Office of the Republic of Serbia. (2018). *Gross domestic product, total and per capita*. Retrieved from Dissemination Database: http://data.stat.gov.rs

Statistical Office of the Republic of Serbia. (2018). *Vital events - data from 2011* . Retrieved from Statistical Office of the Republic of Serbia (SORS): http://www.stat.gov.rs/en-US/

Statistical Office of the Republic of Serbia and UNICEF. (2014, July). *2014 Serbia Multiple Indicators Cluster Survey, Key Findings.* Belgrade: Statistical Office of the Republic of Serbia and UNICEF. Retrieved from Unicef: https://www.unicef.org/serbia/sites/unicef.org.serbia/files/2018-08/MICS5_2014_SERBIA_Key_Findings_and_Roma_Settlements.pdf

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.

World Health Organization (WHO). (2018). *Global Health Expenditure Database*. Retrieved from NHA Indicators: http://apps.who.int/nha/database/DataExplorerRegime.aspx)