Summary: Hearing Screening

Bulgaria

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Table of Contents

List of Tables

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 Bulgaria, hearing screening is performed nationally and organized nationally. The following report contains information with regards to childhood hearing screening in the entire country of Bulgaria.

3.1. General

Bulgaria has a total area of 110 994 km^2 with a population of 7 101 859 at the end of 2016 (National Statistical Institute, 2018).

In Bulgaria, all births are registered into public information. Birth information is regulated by a medical standard in Obstetrics and Gynecology. There were 63 955 births registered in 2017 (National Statistical Institute, 2018).

The World Bank income classification categorizes Bulgaria as an upper-middle-income country (The World Bank, 2018). The gross domestic product (GDP) in 2017 was €7,099 per capita in Bulgaria (National Statistical Institute, 2018).

From the World Health Organization (WHO) Global Health Expenditure Database, health expenditure for Bulgaria in 2015 was 572 USD or €502 per capita (World Health Organization (WHO), 2018).

An infant mortality rate of 6.4 per 1000 is reported for Bulgaria in 2017 (National Statistical Institute, 2018). The United Nations Statistics Division also shows a higher mortality rate in Bulgaria in rural areas compared to urban areas. Infant mortality rates in 2015 were 10.9 and 5.2 for rural and urban areas, respectively (United Nations Statistics Division, 2016).

3.2. Neonatal hearing screening

In Bulgaria, neonatal hearing screening is conducted universally. All babies in the country should have access to hearing screening, though participation is not obligatory for parents.

Hearing screening for both well and at-risk babies started and was fully implemented in Bulgaria in 2015. Screening for well babies is funded through the council (Ministry of Health) and it is roughly estimated that funding for at-risk infants is funded through the province/region. Screening is not embedded in the Preventive Child Health Care screening system. Neonatal hearing screening is organized by the Ministry of Health in Bulgaria.

National guidelines are available as is a screening protocol used across the country. Although a national universal programme is in place in Bulgaria and all hospitals should follow the same protocol, there are some inconsistences regarding how accurately the hearing screening protocol is followed in some hospitals.

3.3. Preschool hearing screening

Preschool hearing screening is conducted universally in Bulgaria. Before school start, children's hearing should be tested. Screening is not embedded in the Preventive Child Health Care screening system and is funded by parents or health insurance. It is unknown when preschool hearing screening started or was implemented across the country. It is typically organized by the child's physician and is performed in the clinic. Referrals are made to the ENT clinic when necessary.

4. Guidelines & Quality Control

There are national guidelines for hearing screening in Bulgaria.

The content of the general hearing screening programme was decided on by the Ministry of Health and has not been changed since implementation in 2015.

Quality assurance of hearing screening programmes is not imposed by the government; however, information is collected directly by the Ministry of Health. Each hospital provides screening information to the regional office of the Ministry. Data are unavailable on whether annual reports are produced.

It is unknown whether research has been done on hearing screening programmes in Bulgaria, but there has not been research performed on the effectiveness of screening in Bulgaria.

5. Process: Screening, Diagnosis, Intervention

5.1. Neonatal hearing screening

Well-babies and at-risk babies are screened in the hospital, NICU or private clinic. The percentage of infants born in a maternity hospital in Bulgaria is unknown though roughly estimated to be close to 100%, while home births are roughly estimated to be below 2-3%. The average length of stay in the maternity hospital after delivery is roughly estimated to be 3-5 days. Parents/caregivers of well and at-risk babies are invited to participate in neonatal hearing screening directly in person in the hospital.

Neonatal hearing screening for well babies should be completed before 3 months of age. For at-risk babies, screening should be completed before 3 months of gestational (corrected) age.

The definition of at-risk infants is listed according to the Joint Committee on Infant Hearing (2007).

Data on the prevalence of CMV and meningitis is not available in Bulgaria, but are roughly estimated to be very low (less than 0.5% and 1%, respectively).

The target condition for screening for both well at at-risk babies is a bilateral hearing loss of 40 dB HL or worse.

5.2. Neonatal diagnostic assessment

The diagnostic assessment after neonatal hearing screening referral should include an ABR assessment and be completed by 3 months of age for well infants, and 3 months corrected age for at-risk infants.

5.3. Preschool hearing screening

Hearing screening is performed on children before they start school. They are invited to participate by their general practitioner, and screening is performed there in the health care clinic by the GP. Follow-up may be made to the ENT clinic if necessary.

The target condition for preschool hearing screening is a unilateral or bilateral hearing loss of 40 dB HL or worse.

5.4. Intervention approach

In Bulgaria, treatment options available include grommets, hearing aids, bone conductive devices, and cochlear implants; however, not all children in Bulgaria are treated due to capacity problems and payment problems. Furthermore, children with deaf parents who refused cochlear implats for their children are not fitted with cochlear implants.

Infants are fitted with hearing aids from 6-12 months of age or older and with cochlear implants from 1-2 years of age or older. The fitting criteria in Bulgaria for a hearing aid is roughly estimated to be bilateral 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. If the infant fails the first test, rescreening occurs at 1 month of age. A subsequent fail at rescreening would warrant a referral to the ENT department for clinical/diagnostic ABR.

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

Test	Age	Referral criteria	Device	Unilateral Referrals?	Location
OAE1*	24-72 hours	4 of 6 freq: >5dB SNR (TE); 3 of 4 freq: >6dB SNR (DP).	Various	Yes	Maternity hospital
OAE2	1 month	4 of 6 freq: >5dB SNR (TE); 3 of 4 freq: >6dB SNR (DP).	Various	Yes	Maternity hospital

* OAE1 may be performed 1-3 times before discharge.

6.2. Neonatal hearing screening (at-risk)

The screening process for at-risk infants is described in Table 2. A combined TEOAE+aABR screening is in effect whereby both OAE and aABR is performed before the infant is discharged from the NICU. Both aABR and TEOAE are required for all at-risk infants. Additionally, follow-up is performed on all at-risk infants at 6 months of age.

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

Test	Age	Referral criteria	Unilateral Referrals?	Location
OAE+ aABR	24-72 hours	40 dB nHL	Yes	Maternity hospital / NICU

6.3. Preschool hearing screening

Hearing screening is performed in health care clinics at 7 years of age. The screening test is pure-tone audiometry.

Table 3: Process for preschool hearing screening in Bulgaria.

Test	Age	Referral criteria	Unilateral Referrals?	Location
Pure-tone audiometry	7 years	40 dB HL	Yes	Health Clinic

7. Professionals

7.1. Neonatal hearing screening (well)

Neonatal hearing screening is performed by a nurse, audiologist, midwife or paediatrician.

There is currently no specific training for hearing screening staff. The training currently provided is practical (on the job).

7.2. Neonatal hearing screening (at-risk)

Screening for at-risk infants is performed by paediatricians.

7.3. Preschool hearing screening

Screening for preschool-age children may be performed by general practitioners, ENT physicians or audiologists. This is not clearly defined in Bulgaria.

8. Results: Neonatal Hearing Screening

8.1. Coverage and attendance rates

In Bulgaria, the coverage and attendance rates of neonatal hearing screening are unknown.

8.2. Referral rates

The referral rates for neonatal hearing screening of well, healthy infants are roughly estimated. The referral rate for OAE1 is roughly estimated to be less than 20% and the referral rate for OAE2 is roughly estimated to be less than 50%.

The final referral rate to a diagnostic assessment for well, healthy babies is roughly estimated to be 0.5%, and the final referral rate for at-risk infants is roughly estimated to be 1-2%.

8.3. Diagnostic assessment attendance

The compliance rate of a referral to diagnostic assessment from neonatal hearing screening for well infants and for at-risk infants is roughly estimated that more than 80% and more than 95%, respectively.

8.4. Prevalence / Diagnosis

Data are generally unavailable regarding the prevalence of neonatal hearing loss in Bulgaria. However, data from 2001 showed a prevalence rate of 1.63 per 1000 for neonatal permanent bilateral hearing loss ≥ 40 dB HL. From 1838 infants screened, 3 were diagnosed with bilateral hearing loss (Rouev, Mumdzhiev, Spiridonova, & Dimov, 2004). Data are unavailable regarding the prevalence of auditory neuropathy in Bulgaria.

8.5. Treatment success

As indicated, not all children in Bulgaria are treated due to capacity problems and payment problems. Furthermore, children with deaf parents who refused cochlear implants for their children are not fitted with cochlear implants. It is roughly estimated that 50-60 children are fitted with hearing aids and 30-40 children are fitted with cochlear implants each year in Bulgaria.

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.

However, estimations were provided. For well infants, sensitivity was estimated to be 100% and specificity was estimated to be 98%. For at-risk infants, sensitivity was estimated to be 99% and specificity was estimated to be 97%.

9. Results: Preschool Hearing Screening

9.1. Coverage and attendance rates

Data are unavailable regarding the coverage and attendance rates of preschool hearing screening in Bulgaria.

9.2. Referral rates

Data are unavailable regarding the referral rate for preschool hearing screening.

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 Bulgaria is organized by the Ministry of Health. Screening is free of charge for parents. There is no financial reward when parents attend hearing screening, nor a penalty for those who do not attend hearing screening.

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

10.1. Screening costs

The total screening costs for well babies per year is unknown; however, the cost of neonatal hearing screening provided by the Ministry of Health per child (all infants) is 10 BGN or €5.12 (Ministry of Health, 2016).

10.2. Equipment costs

(*Information extracted to protect commercially sensitive data*)

Maintenance costs are unknown. Devices are replaced every 10-20 years. The cost for disposables are unknown.

10.3. Staff costs

Data are unavailable regarding the number of professionals performing hearing screening in Bulgaria.

The annual salary for a screening professional (nurse) is roughly estimated to be 13 200 BGN or €6746. The educational fee per student is 1000-1500 BGN or €511-€767 per year.

10.4. Diagnostic costs

The total cost of diagnostic confirmation is not indicated.

10.5. Amplification costs

In the Bulgaria, not all children with hearing loss are treated due to capacity and payment problems. Children of deaf parents who refuse cochlear implant for their children would also not be treated.

The cost for a hearing aid is 1200 BGN or €613 and the cost for a cochlear implant is 33 600 BGN or €17 174. There are no treatment costs specifically for habilitation. The hearing aids and cochlear implant are covered by social and health system.

10.6. Social costs

There are 3 schools in Bulgaria for deaf and hard-of-hearing students that runs from preschool to primary school. It is unknown how many children attend this school. It is unknown whether extra support is not provided to children with hearing impairment in mainstream schools. All costs for mainstream or special education schools are unknown.

11. Costs: Preschool Hearing Screening

11.1. Screening costs

The total costs for preschool hearing screening are unknown. It is estimated that preschool hearing screening costs 20 BGN or €10.22 per child.

11.2. Equipment costs

The cost a pure-tone screening audiometer is not specified.

11.3. Staff costs

Salary costs are not indicated for preschool hearing screening.

12. References

Joint Committee on Infant Hearing. (2007). Year 2007 position statement: principles and guidelines for early hearing detection and intervention programs. *Pediatrics*, *120*(4), 898-921.

Ministry of Health. (2016, 09 02). *Response of the Minister of Health Dr. Petar Moskov to a question by the Minister of Health. Mr. Yavor Haytov*. Retrieved from Ministry of Health: http://www.mh.government.bg/bg/novini/parlamentaren-kontrol/otgovor-na-ministra-na-zdraveopazvaneto-02-09-16-7/

National Statistical Institute. (2018). *Statistical data*. Retrieved from Republic of Bulgaria National statistical institute : http://www.nsi.bg/en/content/11223/statistical-data

Rouev, P., Mumdzhiev, H., Spiridonova, J., & Dimov, P. (2004). Universal newborn hearing screening program in Bulgaria. *International Journal of Pediatric Otorhinolaryngology*, *68*, 805-810.

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)