



## **Summary: Hearing Screening Romania**

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## 1. Glossary of Terms: Hearing Screening

<b>Abnormal test result</b>	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.”
<b>Attendance rate</b>	<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"> <li>• <u>Invited for screening</u> includes all those that are offered the screening test.</li> <li>• <u>Tested and receive a result</u> could be a “pass” or “fail”.</li> </ul> <p>Attendance rate provides information on the willingness of families to participate in screening.</p>
<b>Attendance rate in first year of life</b>	<p>See definition of <b>Attendance rate</b>.</p> <p>The calculation cut-off is after <u>one year of life</u>.</p>
<b>Compliance with referral (percentage)</b>	<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>
<b>Coverage</b>	<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"> <li>• <u>Eligible for screening</u> includes those within the population that are covered under the screening or health care program.</li> <li>• <u>Tested and receive a result</u> could be a “pass” or “refer to diagnostic assessment”.</li> <li>• <u>Specific time</u> can be defined, such as 1 month after birth, 3 months after birth, etc.</li> </ul> <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>
<b>Coverage in first year of life</b>	<p>See definition of <b>Coverage</b>.</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>
<b>False negatives</b>	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%.
<b>False positives</b>	<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>
<b>Guidelines</b>	Recommendations or instructions provided by an authoritative body on the practice of screening in the country or region.
<b>Hearing screening professional</b>	A person qualified to perform hearing screening, according to the practice in your country or region.
<b>Inconclusive test result</b>	A test result where a normal “pass” response could not be detected due to poor test conditions.
<b>Invited for screening</b>	Offered screening.
<b>Outcome of hearing screening</b>	An indication of the effectiveness or performance of screening, such as a measurement of coverage rate, referral rate, number of infants detected, etc.
<b>Permanent hearing loss</b>	<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>
<b>Positive predictive value</b>	<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 <b>Target Condition</b> (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>
<b>Preschool or (pre)school children</b>	All children between 3-6 years of age.
<b>Preschool or (pre)school screening</b>	<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>



<b>Prevalence</b>	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.
<b>Programme</b>	An organized system for screening, which could be based nationally, regionally or locally.
<b>Protocol</b>	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.
<b>Quality assurance</b>	A method for checking and ensuring that screening is functioning adequately and meeting set goals and benchmarks.
<b>Referral criteria</b>	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.
<b>Risk babies / Babies at-risk</b>	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.
<b>Sensitivity</b>	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%.
<b>Specificity</b>	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%.
<b>Target condition</b>	The hearing loss condition you are aiming to detect via your screening programme. This includes: <ul style="list-style-type: none"> <li>• The <u>laterality of the condition</u>, whether the program aims to detect both unilateral and bilateral hearing loss or just bilateral hearing loss.</li> <li>• The <u>severity of the condition</u>, whether the program aims to detect hearing loss <math>\geq 30</math> dB HL, <math>\geq 35</math> dB HL, <math>\geq 40</math> dB HL or <math>\geq 45</math> dB HL</li> </ul>
<b>Well, healthy babies</b>	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 Romania, hearing screening is performed only locally but organized nationally. The following report contains information with regards to hearing screening across the entire country of Romania.

#### 3.1. General

The country of Romania has a total area of 238 391 km<sup>2</sup> and a population of 19 644 350 as of January 2017 (National Institute of Statistics, 2017). In Romania, each newborn is registered at birth. The number of live births in Romania in 2017 was 191 694 (National Institute of Statistics, 2017).

The World Bank income classification categorizes Romania as an upper-middle-income country (The World Bank, 2018). The annual gross domestic product (GDP) is 10 932 USD €9 459 per capita.

From the World Health Organization (WHO) Global Health Expenditure Database, health expenditure in Romania in 2015 was 442 USD or €382 per capita (World Health Organization, 2018).

Infant mortality rate in the country of Romania was 7.3 per live 1000 births in 2015. This rate was higher in rural areas (9.6 per 1000) compared to 6.0 per 1000 in urban areas (United Nations Statistics Division, 2016; National Institute of Statistics, 2017).

#### 3.2. Neonatal hearing screening

In the country of Romania, neonatal hearing screening has been conducted locally from 2006-2019, where babies in only some hospitals have access to hearing screening. Neonatal hearing screening was first performed in Romania in 2006 and in 2016, the Ministry of Health approved national neonatal hearing screening guidelines. In December 2018, equipment was provided to maternity hospitals. Screening is not yet implemented across the country, but the goal is that there will be national coverage by 2020.

In places where neonatal hearing screening exists, it is embedded in the Preventive Child Health Care screening system. Screening is funded through parents, health insurance, and the state. It is not obligatory for parents.

There have previously been differences in how hospitals perform well-baby screening, where some hospitals may use DPOAEs and others may use TEOAEs. For at-risk infants, TEOAEs and aABR were performed. Since the release of the guidelines by the Ministry of Health, all hospitals should adhere to the protocol stipulated in the document.

#### 3.3. Preschool hearing screening

In Romania, there is no regulated preschool hearing screening programme. School physicians perform a whisper test as part of school-entry testing.

Doctors began performing the whisper test as part of school control testing since the 1960s. The whisper test is performed at schools across the country and is funded by health insurance.



#### **4. Guidelines & Quality Control**

There are national guidelines for neonatal hearing screening in Romania. A national protocol was recently published by the Ministry of Health in 2016 (Ministerul Sănătății [Ministry of Health], 2016).

The content of the programme was decided on by the Ministry of Health, in collaboration with four ENT-Audiologist physicians invited by the Ministry of Health. The guideline was approved by the Romanian and Society of Audiology and Communication Pathology and the Romanian Society of Otorhinolaryngology, after which it became mandatory, enforced by the Ministry of Health.

The neonatal hearing screening protocols have not changed since screening started in 2006. In 2016, the hearing screening protocol was standardized across the country by the Ministry of Health (Ministerul Sănătății [Ministry of Health], 2016).

Quality assurance of hearing screening programmes is not yet imposed by the government (Ministerul Sănătății [Ministry of Health], 2016); however, outcome measures are collected. Since 2006, data have been sent to the Ministry of Health and monthly reports are generated; however, data on test performance is not monitored (Ministerul Sănătății [Ministry of Health], 2016). A National Electronic Registry for Hearing Screening (RENSA) has been developed; however, this database is not yet used. In the future, a National-level coordinator will analyse and evaluate the data collected into RENSAs for quality assurance. Data collection will hopefully become mandatory from 2019 onwards.

Annual reports are not yet available, due to the current lack of data. Furthermore, neonatal hearing screening does not have national coverage, and therefore reporting on national data would reflect incomplete performance.

There has been one PhD thesis written on neonatal hearing screening in Romania. Other than this, there have not been any other studies performed on the effectiveness of neonatal hearing screening in Romania.



## 5. Process: Screening, Diagnosis, Intervention

### 5.1. Neonatal hearing screening

Well and at-risk babies are screened in the maternity hospital or a private clinic. Well-baby families and families of infants at-risk are invited for screening either directly in person in the hospital or via phone. It is calculated that 97.94% of births take place in the maternity hospital, where the average length of stay after delivery is 5 days. Only around 0.284% of births take place at home.

Hearing screening for well babies should be completed by 1 month. Hearing screening with OAE for at-risk infants should be completed by 1-month of age, but at-risk infants are also referred for ABR screening, which takes place by 6-months of age.

The target condition for screening for well- and at-risk babies is not defined in protocol, but is determined by the OAE screening method (i.e., bilateral or unilateral hearing loss of 30 dB HL).

There is no data available on the percentage of infants considered to be at risk. At-risk infants are defined in protocol as those admitted to the NICU or with a risk factor according to the list published by the Joint Committee on Infant Hearing (2007). Specifically, infants that are born premature and with birth weight <1500 g, hyperbilirubinemia, administration of ototoxic drugs, hypoxia at birth, genetic syndromes associated with hearing loss, craniofacial abnormalities, severe neurological disorders, congenital infections (specifically, TORCH), bacterial infections causing severe sepsis or meningitis, > 2 days mechanical ventilation, or a family history of congenital hearing loss (Joint Committee on Infant Hearing, 2007; Ministerul Sănătății [Ministry of Health], 2016).

The prevalence of CMV or meningitis in Romania is unknown.

Infants considered at-risk have a different screening protocol and also follow a schedule for surveillance at age 6, 12, and 18 months.

### 5.2. Neonatal diagnostic assessment

The diagnostic assessment tests performed after neonatal hearing screening referral is OAE, ABR and ASSR. Diagnostic testing should be performed at 3 months and no later than 6 months of age for well and at-risk infants. At-risk infants that pass screening are rescreened at 6, 12, and 18 months of age.

### 5.3. Preschool hearing screening

The whisper test is performed in schools by school physicians. Children are tested directly in schools; families are not invited separately. There is no target condition for the whisper test.

### 5.4. Intervention approach

In Romania, treatment options available include hearing aids, bone conductive devices and cochlear implants. Infants are fitted with hearing aids from 6 months of age and cochlear implants from 12 months of age.

The hearing aid fitting criteria in Romania is a bilateral hearing loss (mild to profound), sensorineural or permanent conductive.

## 6. Protocols

Hearing screening protocols are described for neonatal hearing screening (well-baby 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 in Romania is described below. From 2006 to 2019, the protocol involved a 3-step protocol OAE-OAE-aABR. The first OAE is performed in the maternity hospital and the second OAE is performed by the age of 1 month. If the second OAE fails, an aABR is performed directly after during the same session. Those that do not pass the aABR were referred for diagnostic assessment. The national guidelines indicated a 2 step OAE-OAE protocol. The Ministry of Health has recently distributed OAE equipment to hospitals. The third step (aABR) performed in the previous protocol is not part of the national protocol, due the lack of aABR equipment at maternity hospitals across the country.

Table 1: Screening process for well babies in Romania

Test	Age	Referral Criteria	Device	Unilateral Referrals?	Location
OAE1*	24-72 hours	3/4 freqs	Interacoustics	Yes	Maternity hospital / Private clinic
OAE2	1 month		Sera	Yes	Maternity hospital / Private clinic
aABR**	1 month (same session)	35 dB nHL		Yes	Maternity hospital / Private clinic

\*OAE1 may be performed once or twice before discharge. It is recommended that a failed OAE be repeated before discharge, if possible. This repeat-OAE would still be included under OAE1. \*\*From 2006-2019, the screening protocol included aABR for infants that did not pass the OAE at the 1-month rescreening. This is no longer the case according to the national protocol.

### 6.2. Neonatal hearing screening (at-risk)

From 2006 to 2019, OAE and aABR were performed before discharge from the maternity hospital. The protocol is described in Table 2.

Since the 2016 guidelines, the protocol has changed. Because maternity hospitals are only equipped with OAE devices, at-risk infants are screened with one OAE before discharge (Table 3); however, infants at-risk that pass neonatal hearing screening are monitored, including an ABR screening at 6-months of age. Follow-up screening is performed at age 6, 12, and 18 months.

Table 2: Screening process for at-risk babies in Romania (2006-2019)

<b>Test</b>	<b>Age</b>	<b>Referral Criteria</b>	<b>Device</b>	<b>Unilateral Referrals?</b>	<b>Location</b>
OAE+aABR1	24-72 hours	3/4 freqs / 35 dB nHL	EchoScreen	Yes	Maternity hospital / NICU / Private clinic
OAE+aABR2	1 month			Yes	Maternity hospital / Private clinic

Table 3: Screening process for at-risk babies in Romania (2019-present).

<b>Test</b>	<b>Age</b>	<b>Referral Criteria</b>	<b>Device</b>	<b>Unilateral Referrals?</b>	<b>Location</b>
OAE	24-72 hours / before discharge	3/4 freqs	Interacoustics Sera	Yes	Maternity hospital / NICU / Private clinic

### 6.3. Preschool hearing screening

Table 4: Screening process for school-age children in Romania.

<b>Test</b>	<b>Age</b>	<b>Referral Criteria</b>	<b>Location</b>
Whisper test	6 years	None (physician's discretion)	School

## **7. Professionals**

### **7.1. Neonatal hearing screening (well)**

Screening for well babies is performed by nurses, audiologists, and ENT physicians. Nurses performed screening in the maternity wards in public hospitals, and audiologists or ENT physicians perform screening private clinics in private hospitals.

Training is provided during implementation of screening within a hospital. It is typically 3-5 days, but depends on the number of nurses participating in the training session. Update to staff training is provided on request only. This training is not accredited or certified.

### **7.2. Neonatal hearing screening (at-risk)**

Screening for at-risk infants is performed by nurses, audiologists and ENT physicians, similar to well babies. See 7.1 for information on training.

### **7.3. Preschool hearing screening**

The whisper test is performed by school physicians.

## 8. Results: Neonatal Hearing Screening

### 8.1. Coverage and attendance rates

Currently, neonatal hearing screening does not have national coverage in Romania.

A 2017 report was published by the Ministry of Health indicating that a total of 35 206 infants were screened (Guvernul României Ministerul Sănătății, 2017). According to the National Institute of Statistics, 191 694 infants were born in Romania in 2017, resulting in a calculated national coverage rate of 18.3%. According to the same report, the coverage rate in hospitals where neonatal hearing screening is established was 89.63% in 2017 (Guvernul României Ministerul Sănătății, 2017).

The number of infants that missed being *offered* screening is not specified, and therefore, attendance rate is not known. Attendance rate is not indicated for the 1-month rescreen.

### 8.2. Referral rates

The pass rate for the first screen for both well and at-risk infants is roughly estimated to be 94%. The final referral rate after for all infants is roughly estimated to be 4% based on collaborative feedback from a maternity ward in Bucharest. Estimations are not available for each group of infants separately.

### 8.3. Diagnostic assessment attendance

The compliance rate to diagnostic assessment is roughly estimated to be 70%.

### 8.4. Prevalence / Diagnosis

Data are unavailable for the prevalence rate of permanent childhood hearing loss in Romania. However, the prevalence of permanent bilateral hearing loss  $\geq 80$  dB HL among neonates is roughly estimated to be 1.3 per 1000.

Data on the prevalence of bilateral auditory neuropathy is unavailable in Romania.

### 8.5. Treatment success

In Romania, it is unknown how many infants with neonatal hearing impairment are fitted with hearing aids per year. Last year, 200 children in Romania were implanted with cochlear implants. This figure increases annually. There were 167 CIs available for implantation in 2018 according to the National Insurance House (2018).

### 8.6. Screening evaluation

Data are unavailable regarding screening evaluation in Romania. However, it is roughly estimated that approximately 1 per 1000 infants are missed due to auditory neuropathy and approximately 10% of infants with normal hearing fail screening due to middle ear fluid or problems.

## **9. Results: Preschool Hearing Screening**

### **9.1. Coverage and attendance rates**

It is roughly estimated that approximately 90% of children in Romania undergo screening via the whisper test in schools.

### **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

Neonatal hearing screening in Romania is free of charge for parents in public hospitals only. Parents pay for care in private institutions. There is no financial reward when parents attend hearing screening nor is there a penalty for non-attendance. Participation in screening is not obligatory.

The Romanian Ministry of Health performed a cost-effectiveness analysis of neonatal hearing screening; however, this analysis is not published or available.

### 10.1. Screening costs

The Ministry of Health 2017 report indicates a cost of 9.14 lei per screen in Romania.

### 10.2. Equipment costs

*(Information extracted to protect commercially sensitive data)*

Data are not available on maintenance, disposables or replacement.

### 10.3. Staff costs

The salary of a nurse, audiologist or ENT performing hearing screening is unknown. It is roughly estimated that there are currently approximately 0.5 hearing screening professionals per 1 million people in Romania. The cost of education for hearing screening professionals is not indicated. The training of screening staff was provided voluntarily.

### 10.4. Diagnostic costs

The cost for a diagnostic assessment is not provided.

### 10.5. Amplification costs

In Romania, not all children are treated for hearing loss. Children are not treated due to capacity problems, if deaf parents refuse cochlear implants for their children, or due to the fact that neonatal screening does not have national coverage.

The cost of each hearing aid starts at around €350; however, this is the cost of the device only. Fitting costs and batteries are additional costs.

The cost of cochlear implant itself is €21 000, according to the National Insurance House. The family is not responsible for covering this cost, nor the cost of the surgery. The cost of batteries and replacement parts are the responsibility of the family.

### 10.6. Social costs

In Romania, information on special schools for the deaf is unknown. There is usually no extra support in mainstream schools for deaf or hard of hearing students.

Education costs are unknown.



## **11. Costs: Preschool Hearing Screening**

### **11.1. Screening costs**

The cost of the whisper test is not indicated (Ministerul Sănătății [Ministry of Health], 2016).

### **11.2. Equipment costs**

Not applicable.

### **11.3. Staff costs**

Not indicated.

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