



Summary: Hearing Screening

Croatia

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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	<p>A pre-determined cut-off boundary for when an infant/child should be re-tested or seen for a diagnostic assessment.</p> <p>For example, referral criteria may be “no response” at 35 dB nHL.</p>
Risk babies / Babies at-risk	<p>All infants that are considered to be at-risk or have risk-factors for hearing loss according to the screening programme.</p> <p>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.</p>
Sensitivity	<p>The percentage of infants/children with hearing loss that are identified via the screening program.</p> <p>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%.</p>
Specificity	<p>The percentage of infants/children with normal hearing that pass the screening.</p> <p>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%.</p>
Target condition	<p>The hearing loss condition you are aiming to detect via your screening programme. This includes:</p> <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	<p>Infants who are <i>not</i> admitted into the NICU or born prematurely.</p> <p>Well, healthy babies may or may not have additional risk factors for hearing loss, according to the procedures indicated in the specific screening programme.</p>



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 Croatia, hearing screening is organized nationally.

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

3.1. General

Croatia has a total area of 56 594 km² and a population of 4 284 889 as of 2011. In Croatia, each birth is registered. The number of births in Croatia was 39 939 in 2013 and 37 503 in 2015 (Croatian Bureau of Statistics, 2015).

The World Bank income classification categorizes Croatia as a high-income country. It was briefly classified as an upper-middle-income country in 2016 (The World Bank, 2018). The gross domestic product (GDP) is €10 586 per capita as of 2015 (Croatian Bureau of Statistics, 2018)

From the World Health Organization (WHO) Global Health Expenditure Database, health expenditure in Croatia in 2015 was 852 USD or €737 per capita (World Health Organization, 2018).

Data acquired from the 2016 United Nations Demographic Yearbook indicate an infant mortality rate of 4.1 per 1000 for the country of Croatia in 2015, a rate of 4.2 per 1000 in urban areas and 4.0 per 1000 in rural areas (United Nations Statistics Division, 2016).

3.2. Neonatal hearing screening

In Croatia, neonatal hearing screening is conducted universally, with all babies in the country having access to hearing screening, though screening is not obligatory for parents. The universal programme for well and at-risk babies was first implemented in 2002, and by 2005, neonatal hearing screening was implemented across the country. Neonatal hearing screening is embedded in the Preventive Child Health Care screening system. Screening is funded through health insurance provided by the state and organized by the government.

Regions use the same protocol for screening well babies, with the exception that locations with aABR devices in the maternity hospitals will screen using aABR (step 3) directly after a step 2 referral, while other areas will screen with OAE at step 2 and then refer to another hospital with aABR technology for step 3 screening. For at-risk babies, there are also slight differences. Three maternity hospitals screen NICU patients with aABR only while the rest screen with OAE then aABR.

3.3. Preschool hearing screening

In Croatia, preschool hearing screening is not performed.



4. Guidelines & Quality Control

National guidelines and a protocol for hearing screening exists in Croatia, though there is no official publication of these guidelines or protocol. A government document is available stipulating that neonatal hearing screening is mandatory (Ministarstvo zdravstva i socijalne skrbi, 2006).

The content of hearing screening programme was decided on by a professional body of audiologists within the government. The content of the programme has not been revised since its start and data are unavailable on the revision process.

Quality assurance of hearing screening programmes is not imposed by the government; however, in the past, information was previously collected about hearing screening outcomes through the citizen association HURDOS, made up of a group of audiologists who started neonatal screening in Croatia. Currently, the status of future data collection through this organization is unknown. Data from maternity hospitals across Croatia are currently sent to the Children's Hospital in Zagreb for outcome monitoring.

Data are unavailable about annual reports. Apart from auditing, occasional studies have been performed on neonatal hearing screening and its effectiveness in Croatia (Marn, 2005; Marn & Kekić, 2016; Prpić, Mahulja-Stamenković, Bilić, & Haller, 2007).



5. Process: Screening, Diagnosis, Intervention

5.1. Neonatal hearing screening

Well-babies and at-risk babies are screened first in the hospital, where the average length of stay is estimated to be 3 days. It is roughly estimated that less than 10% of births take place at home. Families of well and at-risk infants are invited to participate in neonatal screening via a letter.

It is estimated that neonatal hearing screening for both well and at-risk babies should be completed before 3 months of age.

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

In Croatia, at-risk infants are defined as those admitted to the NICU. There is no set duration for how long infants must stay in the NICU to be considered at-risk; though other risk-criteria are considered, including premature birth less than 34 weeks, requiring the use of a respirator, and intracranial bleeding. Data are unavailable regarding how many infants are screened with the at-risk protocol.

The prevalence of CMV infections and meningitis among neonates is not known.

5.2. Neonatal diagnostic assessment

The diagnostic assessment tests performed after neonatal hearing screening referral are ABR, ASSR and tympanometry which should be also performed before 3 months of age.

5.3. Preschool hearing screening

Not applicable.

5.4. Intervention approach

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

The hearing aid fitting criteria in Croatia is a bilateral hearing loss of 30 dB HL for the better ear.

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)

There are 2 to 3 steps of screening for well-infants in Croatia before referral to a diagnostic assessment. Step 1 screen occurs on day 2 or later but before discharge. The majority of maternity hospitals refer the infant back to the same hospital for step 2 screening. After a fail/refer from step 2, an aABR may be performed directly if the maternity hospital has aABR equipment available. Otherwise, a referral is made to an Audiology Centre before the infant is 3 months of age. Some maternity hospitals refer to an Audiology Centre directly after step 1. In these instances, both step 2 and step 3 are performed in the Audiology Centre.

Table 1: Screening process for well babies in Croatia.

Test	Age	Referral criteria	Device	Unilateral Referrals?	Location
OAE1	24-72 hours	4 dB SNR for 3/6 freq (Maico, 2017)	Maico Ero-Scan [†]	Yes	Maternity hospital
OAE2 aABR	One month	40 dB nHL		Yes	Maternity hospital/ Audiology centre

[†] Used in Clinical Medical Center University of Rijeka. May not be used universally in Croatia.

6.2. Neonatal hearing screening (at-risk)

The sequence for screening infants at-risk is similar to that for well-infants, in that the infant progresses through three steps of screening before referral to diagnostic assessment. In most NICUs, aABR is used for the step 1 screen before discharge; however, in some NICUs OAE is performed as the initial screen prior to discharge.

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

Test	Age	Referral criteria	Device	Unilateral Referrals?	Location
aABR1/OAE	< 2 weeks (36-42 weeks gestation)	40 dB nHL or 4 dB SNR for 3/6 freq	-- Maico Ero-Scan [†]	Yes	NICU
aABR2	One month	40 dB nHL		Yes	Clinic with aABR tech

[†] Used in Clinical Medical Center University of Rijeka. May not be used universally in Croatia.

6.3. Preschool hearing screening

Summary Hearing Screening: Croatia



Not applicable.

7. Professionals

7.1. Neonatal hearing screening (well)

Screening for well babies is performed by nurses supervised by pediatricians in the maternity hospitals. There is no specific training programme for screening professionals, and staff are trained amongst themselves. At the implementation of neonatal hearing screening in Croatia, a training video was developed and supplied to maternity hospitals with the screening equipment (Marn & Kekić, 2016). This training video is still in use for training new screening staff.

7.2. Neonatal hearing screening (at-risk)

Screening for at-risk infants is performed by pediatricians. Training is the same for NICU-staff as for staff performing well-baby screening.

7.3. Preschool hearing screening

Not applicable



8. Results: Neonatal Hearing Screening

8.1. Coverage and attendance rates

Coverage rates were supplied and sourced from Marn and Kekic (2016). Calculated from 2003 to 2014, coverage rates were provided separately for the step 1 and step 2 across maternity hospitals in Croatia.

Note that, while some data are collected across all maternity hospitals in Croatia, not all maternity hospitals have continuously supplied data for each year across this 12-year time-period. However, given that many maternity hospitals have provided data for several years, these rates are considered representative for the country of Croatia. Also, note that fewer maternity centres have supplied data for step 2 of screening, and therefore the step 1 coverage rate is based on a larger amount of data than the step 2 coverage rate.

The coverage rate for the first step of screening in Croatia is 97%. That is, out of the total number of births for all hospitals supplying data (including both well-infants and NICU-infants), 97% have a screening result for the first step (Marn & Kekić, 2016).

The number of infants that missed being *offered* step 1 screening is not specified, and therefore, attendance rate for step 1 is not known.

The attendance rate for step 2 is 81.4%. That is, out of the infants referred from the maternity ward/NICU, 81.4% return for step 2 screening at one month of age (Marn & Kekić, 2016).

8.2. Referral rates

Referral rates for the neonatal screening are sourced from Marn and Kekić (2016). Calculated rates are from data sent to HURDOS from 2003 to 2014. Percentages are separated into referral rates for step 1 and step 2.

Table 3: Referral rates for neonatal hearing screening (both well and NICU babies) in Croatia (Marn & Kekić, 2016).

Test	Referral Rate
Step 1 (OAE1/aABR1)	3.5%
Step 2 (OAE 2/aABR2)	22.7%

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

In total, the referral rate for well-babies to a diagnostic assessment after the screening process is approximately 0.7% (Marn & Kekić, 2016). The referral rate is the number of infants referred from step 2/3 of screening out of the total infants screened in step 1. Note that 19.6% of infants were lost between steps 1 and 2.

The referral rate for at-risk infants is not calculated separately.

8.3. Diagnostic assessment attendance

Data are not available for the compliance rate for a diagnostic assessment after neonatal hearing screening. The compliance rate to a diagnostic assessment is roughly estimated to be > 80%. In other



words, more than 80% of the infants referred from step 2/3 of the screening attend a diagnostic examination.

8.4. Prevalence / Diagnosis

The prevalence values of permanent hearing loss among neonates in Zagreb, Croatia are presented in Table 4. These prevalence values were determined during the implementation of neonatal hearing screening in Croatia, and measured in Zagreb only (Marn, 2005). Therefore, prevalence presented here may not represent the entire country of Croatia. It is unknown if more recent prevalence data are available. Prevalence was determined in 2004 based on a sample of 10 687 infants.

Table 4: Prevalence of permanent hearing loss among neonates in Zagreb, Croatia (Marn, 2005).

	Bilateral		Unilateral	
	≥ 40 dB HL	≥ 80 dB HL	≥ 40 dB HL	≥ 80 HL
Prevalence per 1000 (Marn, 2005)	0.84		0.84	

Prevalence values were calculated based on data from screening implementation. Therefore, the percentage of infants diagnosed with permanent hearing loss after neonatal hearing screening would be identical to the prevalence figures presented. Again, this data represents the Zagreb area and may not represent all of Croatia.

The prevalence of bilateral auditory neuropathy in Croatia is not available.

8.5. Treatment success

Data are unavailable regarding the number of children with neonatal hearing loss that are fitted with hearing aids in Croatia. It is calculated that 15 children with neonatal hearing loss are fitted with cochlear implants per year (Vešepić, 2018).

8.6. Screening evaluation

The percentage of false negatives is unknown. The percentage of false positives after neonatal hearing screening is unknown.

For well and at-risk infants, the positive predictive value of a refer result is unknown.

Data on sensitivity is unavailable. Specificity is > 99%, based on the referral rate being 0.7% (Marn & Kekić, 2016). This figure represents both well-babies and at-risk babies.



9. Results: Preschool Hearing Screening

9.1. Coverage and attendance rates

Not applicable

9.2. Referral rates

Not applicable

9.3. Diagnostic assessment attendance

Not applicable.

9.4. Prevalence / Diagnosis

Not applicable.

9.5. Screening evaluation

Not applicable.



10. Costs: Neonatal Hearing Screening

Neonatal hearing screening in Croatia is free of charge for parents. There is no financial reward when parents attend hearing screening, and there is no penalty for those who do not attend hearing screening.

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

10.1. Screening costs

There are no data available for the screening costs for well- and at-risk babies in Croatia.

10.2. Equipment costs

The cost of OAE and aABR screening devices are unknown. It is expected that they are only replaced when broken or fail to function. The maintenance and disposable cost for OAE or aABR is unknown.

10.3. Staff costs

Data are unavailable on how many hearing screening professionals exist in Croatia, though the salary is roughly estimated to be €14 500 annually or €7-8 per hour. The educational cost for hearing screening professionals is unknown.

10.4. Diagnostic costs

The cost for a diagnostic assessment is €21 per OAE, €35 per ABR, €41 per ASSR, €4 per tympanometry, and €15 for a clinical assessment.

10.5. Amplification costs

In Croatia, all children are treated for hearing loss.

For hearing aids, the estimated cost is €300, which is covered by health insurance. Higher-end technology can be paid out of pocket. Each visit to the ENT/audiologists for assessment and treatment costs €15-30. It is estimated that children require 2-3 follow-up visits per year.

For cochlear implants, it is roughly estimated that the cost of the device is €13 000, plus €600 for the operation. As indicated, each visit to the ENT/audiologist for assessment and treatment costs €15-30. It is roughly estimated that approximately 10 visits are required for the first year of implantation and 2-3 visits for each subsequent year (Velepik, 2018).

10.6. Social costs

Specialized schools specifically for deaf and hard of hearing students are not available in Croatia. Children with hearing impairment attend regular schools unless they have multiple disabilities or additional impairments preventing them from attending mainstream schools. The number of children attending these schools and cost information are unknown.

In mainstream schools, professionals are available to support children who are deaf or hard of hearing.

The cost of special support in mainstream schools for deaf and hard of hearing students is not known.



11. Costs: Preschool Hearing Screening

11.1. Screening costs

Not applicable.

11.2. Equipment costs

Not applicable.

11.3. Staff costs

Not applicable.



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