



## **Summary: Hearing Screening**

### **Slovenia**

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**Allison Mackey & Inger Uhlén**  
Karolinska Institutet, Stockholm Sweden

**Hearing screening representative for Slovenia:** Saba Battelino, University Medical Centre Ljubljana, University of Ljubljana, Faculty of Medicine

**General information provided by:** Mojca Juricic, University of Ljubljana, Faculty of Medicine, Dep of Public Health

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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>	<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>
<b>Risk babies / Babies at-risk</b>	<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>
<b>Sensitivity</b>	<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>
<b>Specificity</b>	<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>
<b>Target condition</b>	<p>The hearing loss condition you are aiming to detect via your screening programme. This includes:</p> <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>	<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 Slovenia, neonatal hearing screening is organized nationally through the National Institute for Health and implemented across all 14 maternity hospitals.

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

#### 3.1. General

The country of Slovenia has a total area of 20 273 km<sup>2</sup> and a population of 2 065 895 as of January 2017 (Statistical Office of the Republic of Slovenia, 2018). In Slovenia, each birth is registered. The number of live births in Slovenia was 20 641 in 2015.

The World Bank income classification categorizes Slovenia as a high-income country (The World Bank, 2018). The gross domestic product (GDP) was €19 262 per capita in 2015 (Statistical Office of the Republic of Slovenia, 2018).

From the World Health Organization (WHO) Global Health Expenditure Database, health expenditure in Slovenia in 2015 was 1 772 USD or €1 528 per capita (World Health Organization, 2018).

Infant mortality rate in the country of Slovenia was 1.8 and 1.6 per 1000 in 2014 and 2015, respectively (United Nations Statistics Division, 2016; Statistical Office of the Republic of Slovenia, 2018).

#### 3.2. Neonatal hearing screening

In Slovenia, neonatal hearing screening is conducted universally, with all babies in the country having access to hearing screening, though participation is not obligatory for parents. Neonatal hearing screening for well babies started and was fully implemented on in Slovenia in 2005 and was fully implemented in 2006. For infants at risk, screening was implemented in 2009, but it is unknown when it was implemented across the country. Neonatal hearing screening is funded through health insurance and is embedded in the Preventive Child Health Care screening system.

Neonatal hearing screening is organized by the Ministry of Health, who distributes funding. Each maternity hospital is responsible for training staff, managing equipment, and sending data to the National Institute of Health.

National guidelines are not available, nor is an official screening protocol across the country. Across Slovenia, maternity hospitals use the same protocol for performing TEOAEs and reporting results: however, there may be differences in rescreening and follow-up. Family physicians responsible for referring infants may refer to primary or secondary ENT clinics for rescreening before referral to audiological (tertiary) centres. However, in Ljubljana or Maribor, family physicians may refer directly to the audiological centre without intermediate rescreening at the ENT centre. It is unclear whether there are differences in protocol across NICUs in Slovenia.

#### 3.3. Preschool hearing screening

In Slovenia, preschool hearing screening is not universally performed. Depending on the region, some type of test may be performed on preschool children. In Ljubljana, group audiometry is performed; in Celje, pure-tone audiometry is performed; and in the other 12 regions a whisper test may be



performed. While early accounts of screening preschool-aged children in Ljubljana dates back to the 1960s, screening is not performed across the entire country.



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

As indicated, official national guidelines for hearing screening and screening protocol do not exist in Slovenia.

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

Quality assurance of hearing screening programmes is not imposed by the government; however, pass/refer information from maternity hospitals is collected by the National Institute for Health. Maternity hospitals are obligated to release the results of their individual neonatal data, including figures such as weight, APGAR scores, and neonatal hearing screening results. Data are automatically sent to the National Institute of Health. Other data collection is not systematically performed, but only when hospitals or the university are interested in collecting their own data.

Annual reports are not available. There have not been any studies on hearing screening programmes in Slovenia, nor has there been research performed on the effectiveness of screening in Slovenia.

## **5. Process: Screening, Diagnosis, Intervention**

### **5.1. Neonatal hearing screening**

In Slovenia, infants are screened in the hospital. It is estimated that 99% of infants are born in hospitals each year and 0.3% are born at home. The average length of stay in the maternity hospital after birth is 2 days. Families are invited to participate in screening directly in person at the hospital. For at-risk infants, it is estimated that a doctor invites families to participate.

The target condition for screening is not documented in guidelines; however, the common target for neonatal screening is a bilateral hearing loss of at least 30 dB as defined by both automatic screening instruments and by hearing aid fitting protocols in Slovenia.

There is no set age in protocol by which neonatal hearing screening for well infants and infants at risk should be completed. Screening is performed in the hospital for all infants.

At-risk infants are defined as those admitted to the NICU, are premature, or have hypoxia, hypoglycemia, or sepsis.

Data are unavailable on the childhood/infant prevalence of CMV infections or meningitis in Slovenia.

### **5.2. Neonatal diagnostic assessment**

The diagnostic assessment for well infants should be completed by 3-6 months of age (ideally by 3 months), and for at-risk infants should be completed before 4-12 weeks of age. Continued monitoring may be performed, depending on the case.

### **5.3. Preschool hearing screening**

The target condition is a hearing loss of at least 30 dB HL.

### **5.4. Intervention approach**

In Slovenia, treatment options available include grommets, hearing aids, bone conductive devices, and cochlear implants. Children are fitted with hearing aids from < 6 months of age and with cochlear implants from 6-12 months of age.

According to insurance regulation, fitting guidelines for hearing aids in Slovenia is at least a 30-dB pure-tone average at 500, 1000, 2000 and 4000 Hz.

## 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 screening protocol for well infants in Slovenia is described in Table 1. As described previously, after referral from the maternity ward, infants may first be rescreened in a general ENT clinic before being referred further to the tertiary audiological centre. In Ljubljana or Maribor, family physicians may refer infants directly to the tertiary audiological centre.

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

Test	Age	Referral criteria	Device	Unilateral Referrals?	Location
OAE1	24-72 hrs	4 dB SNR for 3/6 freq (Maico, 2017)	Maico Screener	Yes	Maternity ward
<i>optional OAE rescreen</i>				Yes	General ENT centre
OAE2/3 (+ Tymp)	>10 days			Yes	Audiological centre

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

Infants at-risk are screened with aABR. This protocol has been in effect for the last 2 years.

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

Test	Age	Referral criteria	Device	Unilateral Referrals?	Location
aABR	< 2 weeks after birth (36-42 weeks); before discharge	35-45 dB	Maico Screener	Yes	NICU

### 6.3. Preschool hearing screening

Hearing screening protocol for preschool-age children is not universal and differs across region in Slovenia. Screening generally takes place around the age of 5 to 6 years.

In some regions, group audiometry or pure-tone audiometry is performed. In other regions, the whisper test is performed. Testing occurs at the Child Health Care Centre and is performed by a pediatrician or a nurse. The referral criteria differ, depending on the test performed, and may be 25-30 dB for audiometry and a distance of 5 meters for the whisper test.

## **7. Professionals**

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

Screening for well-babies is performed by nurses. There is no specific training programme for screening professionals. Nurses are trained by more experienced nurses in the maternity ward or NICU.

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

Screening for at-risk infants is performed by specialist nurses or pediatricians. Some specialized nurses are trained in the audiological centre in Ljubljana. However, no specific training is officially required.

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

Preschool-age screening is performed by a pediatrician or nurse.



## 8. Results: Neonatal Hearing Screening

### 8.1. Coverage and attendance rates

In Slovenia, neonatal hearing screening results are delivered to the National Institute of Health by maternity hospitals. Coverage rate is defined as the total number of test results received out of the total number of live births. From 2006 to 2012, the coverage rate has ranged from 95.8 to 96.3%. Reports from the National Institute of Health from the last 5 years has indicated coverage rates of approximately 98%, though actual data could not be acquired.

### 8.2. Referral rates

The referral rates for neonatal hearing screening of well, healthy infants are presented below in Table 3. OAE1 is performed in the maternity hospitals and data collected are from all of Slovenia and sourced from the National Institute of Health.

Data from OAE2/3 are collected by the audiological centre in Ljubljana. Note that this test is labeled OAE2/3 due to the fact that some infants may be rescreened at primary ENT centres before referral to the audiological centre. In 2012, approximately 1.5% of infants born in the region were referred to the audiological centre in Ljubljana.

**Table 3:** Referral rates for neonatal hearing screening (well-babies) in Slovenia

Test	Referral Rate
OAE1	1.8% (National Institute of Health. 2006-2012)
OAE2/3	69% (Ljubljana audiological centre data, 2015)

Referral rates assume a 100% attendance at each step.

Two referral rates can be interpreted from these data. First, the referral rate from the composite data collected from maternity hospitals (OAE1) across all of Slovenia is, on average 1.8%. Second, a referral rate from the data collected from the Ljubljana audiological centre can be calculated. Ljubljana region comprises 1/3 of the infants born in Slovenia. Given that around 1.5% of infants in the region are received at the Ljubljana audiological centre for secondary or tertiary rescreening (2012 data) and 31% of these referred infants continue to show a “no pass” on TEOAE (2015 data), the final referral rate for a full diagnostic evaluation can be estimated to be 0.56%.

In Ljubljana, there is an agreement with the NICU that at-risk infants are referred to the audiological centre. While there is no actual data, it is roughly estimated that around 10-20% of at-risk infants are referred for audiological assessment. Data from the maternity hospital in Ljubljana show that for premature babies, the OAE referral rates were 11.96% for infants <28 weeks, 1.68% for infants 28-32 weeks, and 3.86% for infants 33-37 weeks.

### 8.3. Diagnostic assessment attendance

The compliance rate for a diagnostic assessment after neonatal hearing screening is unknown. After referral from the maternity ward, individual infants are not tracked.

### 8.4. Prevalence / Diagnosis

Out of the infants referred to the audiological centre for tertiary rescreening in Ljubljana in 2014/2015, 69% had normal OAE results (as indicated previously), 8.5% were diagnosed with a permanent



hearing loss of 35-80 dB and eligible for hearing aids, 1.5% were diagnosed with a permanent bilateral hearing loss of  $\geq 80$  dB, 7% were diagnosed with single sided deafness, and 14% had a conductive or fluctuating hearing loss.

Given these figures, and that 129 infants were referred out of the 8600 infants born in Ljubljana region in 2014-2015, prevalence rates can be estimated in Table 4 below.

**Table 4:** Prevalence of permanent hearing loss among neonates in Ljubljana, Slovenia (estimated from data collected in the Ljubljana audiological centre).

	Bilateral		Unilateral	
	$\geq 40$ dB	$\geq 80$ dB	$\geq 40$ dB	$\geq 80$
Prevalence per 1000 (Ljubljana audiological centre)	1.5	0.23		

Data from the audiological centre in Ljubljana from 2006 and 2012 indicate the age at which hearing aids and cochlear implants are fit for the first time. For children between the ages of 2-6 years, 96 children received hearing aids for the first time and 66 children received cochlear implants. Additionally, 199 children under the age of one year received hearing aids and 74 children under the age of one year received cochlear implants for the first time.

If one were to make the assumption that a similar number of children already have hearing aids/cochlear implants in the 2-to-6-year age range, one may calculate that a total of approximately 435 children from 2-6 years of age have either a hearing aid or cochlear implant. This figure is not exact, however, as some children are fit with a trial hearing aid first before cochlear implantation, and therefore, some children fit with a hearing aid before the age of 1 year may then be implanted at the age of 2-6 years.

However, from a sample of 125 000 children between 2-6 years of age, one can still estimate a prevalence rate range of between 3.0 and 3.5 per 1000 for permanent hearing loss of  $>30$  dB HL and thus eligible for hearing aids or cochlear implants. One can also calculate from cochlear implant data a prevalence of 1.12 per 1000 for a bilateral hearing loss of  $> 80$  dB HL (eligible for cochlear implants).

Data are unavailable on the prevalence of bilateral auditory neuropathy in well- or at-risk-babies.

### 8.5. Treatment success

It is estimated that 70 children (all ages) are fitted with hearing aids each year and 15 children are fitted with bone conduction devices in Slovenia. On average 9.2 children are fit with cochlear implants per year (averaged across 10 years) at the audiological centre in Ljubljana. This figure does not represent all of Slovenia, however, as there is also a small centre in Maribor that fits cochlear implants.

### 8.6. Screening evaluation

The percentage of false negatives is roughly estimated to be  $<10\%$ . From data collected in Ljubljana, 75-78% of infants who fail the initial OAE neonatal hearing screening have normal hearing. With an initial referral rate of 1.6% from the maternity hospital, the false positive rate can be calculated to be 1.2 to 1.25%.



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

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

In Slovenia, it is roughly estimated that approximately 20-40% of children are invited for a health check from paediatricians, and approximately 10-20% of children attend a preschool hearing screening.

### **9.2. Referral rates**

It is roughly estimated that 0-5% of children are referred for follow-up after preschool screening.

### **9.3. Diagnostic assessment attendance**

The rate of compliance for a diagnostic follow-up after referral from preschool screening is unknown.

### **9.4. Screening evaluation**

False negatives and positives are roughly estimated. The percentage of false negatives was estimated to be 10-40% and the percentage of false positives was estimated to be 20-40%.

The positive predictive value of a 'refer' result after neonatal hearing screening for at-risk infants is roughly estimated to be 40%.

## 10. Costs: Neonatal Hearing Screening

There has not been a cost effectiveness analysis completed in Slovenia. There is no financial reward when parents attend hearing screening, and there is no penalty for those who do not attend hearing screening.

### 10.1. Screening costs

It is estimated that costs are €36 550 per year for neonatal hearing screening in Slovenia, based on a calculation from the birth rate and information that health insurance covers €1.7 per child screened, including both well and at-risk infants.

Given that approximately 10% of infants are admitted to the NICU, the annual costs for screening infants in the NICU is approximately €3 655, which is included in total aforementioned cost.

### 10.2. Equipment costs

*(Information extracted to protect commercially sensitive data)*

There is no rule stipulated to how often a device is scheduled to be replaced. The cost for disposable eartips is approximately 20 cents per infant.

### 10.3. Staff costs

It is roughly estimated that there are approximately 50-70 nurses in Slovenia that perform neonatal hearing screening in maternity wards and NICUs. The salary costs per year for hearing screening professionals is unknown. The training costs are unknown.

### 10.4. Diagnostic costs

Diagnostic costs are not indicated.

### 10.5. Amplification costs

In Slovenia, all children are treated for hearing impairment unless parents refuse cochlear implantation. The cost for bilateral hearing aids is €3000 (or 2x €1500). The cost for a bone conduction device is €6 100. Data are not available for the costs of follow-up and fitting appointments, including after the first year.

The cost for cochlear implant fitting is €21 000 according to a national tender agreement. Data are not available regarding follow-up costs, including after the first year.

### 10.6. Social costs

There are 3 specialized schools in Slovenia for deaf and hard-of hearing students based on national data. It is estimated that 10% of children with hearing impairment attend specialized school in the initial years and then transfer to mainstream schools. Children with hearing impairment are supported in schools with individualized work, social workers and speech-language pathologists for up to 5 hours per week. Costs are unknown.



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

### **11.1. Screening costs**

It is roughly estimated that, in Ljubljana, preschool hearing screening (group audiometry), costs approximately €10 per child. With 2100 children entering their first year of school in Ljubljana, the approximate cost for Ljubljana is around €21 000.

### **11.2. Equipment costs**

Information not indicated.

### **11.3. Staff costs**

Information not indicated.



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