



## **Summary: Hearing Screening Italy (Veneto Region)**

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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 Italy, hearing screening is performed and organized regionally. The first universal program for well and at-risk infants in Italy was implemented in 2003, though it is not yet conducted across the entire country. The majority of regions in Italy have universal neonatal hearing screening established; however, some regions do not yet have complete coverage, including Sicily, Calabria, Basilicata, Puglia, Sardinia, Abruzzo, Lazio and Trentino-Alto Adige.

The following report contains information with regards to hearing screening in the region of Veneto.

#### 3.1. General

The Region of Veneto has a total area of 18,345 km<sup>2</sup> with a population of 4 903 722 in 2017. In Veneto Region, all births are registered. The number of births is 36 587 per year, from 2017 data (UrbiStat, 2019).

The World Bank income classification categorizes Italy as a high-income country (The World Bank, 2018). The gross domestic product (GDP) in 2017 in Veneto Region was €30 710 per capita (Statista, 2019).

From the World Health Organization (WHO) Global Health Expenditure Database, health expenditure for all of Italy in 2015 was 2 709 USD or €2 421 per capita (World Health Organization (WHO), 2018).

Data acquired from the 2016 United Nations Demographic Yearbook indicates an infant mortality rate of 2.9 per 1000 for the country of Italy in 2015 (United Nations Statistical Division, 2016)

#### 3.2. Neonatal hearing screening

In the region of Veneto, neonatal hearing screening is conducted universally, with all babies in the region having access to hearing screening, as it is embedded in the Preventive Child Health Care screening system in Veneto. It is not obligatory, however, for parents to participate in neonatal screening. Screening is funded by the region as well as by parents. More specifically, the first step of screening is funded by the public health care system. Screening of step 2 is funded by the state when the screening occurs at the same maternity hospital as step 1. Otherwise, the cost of must be covered by the parents. The Regional decree indicates that screening should be free for all families, but this is not yet practically applied.

In Veneto, a different hearing screening protocol will soon be used compared to most other regions across the country. A recent change in protocol states that all infants in Veneto are to undergo one aABR screen instead of a multistage OAE protocol. With NICU babies, a combined OAE+aABR is recommended across Italy, while in Veneto the protocol has recently changed to only aABR.

#### 3.3. Preschool hearing screening

In Veneto, there is no preschool hearing screening programme. The majority of regions in Italy do not perform preschool hearing screening.

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

National guidelines for hearing screening are available, as well as regional decrees for the region of Veneto specifying explicit guidelines for the region (Official Bulletin of the Region of Veneto, 2018).

It was not indicated who had decided on the contents of the screening programme. The content of the screening programme has recently changed. Since 2015, hearing screening has become embedded into the mandatory medical services available for newborns, and in 2018 it was decided to adjust the protocol so that aABR is the single test used for all infants in Veneto.

A review of the hearing screening programme typically takes place every 1-3 years, depending on the region, though quality assurance of hearing screening programmes is not imposed by the government.

Information about the outcome of hearing screening is not collected across the entire region of Veneto. While the Regional decree indicates that monitoring of outcomes should be performed, this is not yet in practice. Currently, outcomes are only monitored at individual birth centres.

Annual reports are not available on a regional or national level. In Veneto region, each birth centre formulates their own annual report.

Research has been performed on hearing screening in Italy apart from auditing.

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

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

Well-babies are screened in the maternity hospital or child health care centre, and at-risk babies are screened in the hospital. Well-baby families and families of infants at-risk are invited for screening directly in person by health care professionals in the hospital. It is estimated that 99% of infants are born in maternity hospitals where the average length of stay after delivery is 2-3 days.

Hearing screening for both well and at-risk infants should be completed by 3 months of age. The goal is that a diagnostic assessment can begin by 3-months of age.

The target condition for screening for well- and at-risk babies is bilateral or unilateral hearing loss of > 35 dB HL.

In Veneto, 9% of infants are considered at-risk, as having one of the risk factors indicated by the Joint Committee of Infant Hearing (Joint Committee on Infant Hearing, 2007). Infants admitted into the NICU are screened with a different protocol than well babies because of the higher risk of being affected by auditory neuropathy / auditory dyssynchrony). They are included in a follow-up programme with one or two tests per year, depending on the risk factor. Well babies with at least one risk factor for hearing impairment undergo the well-baby screening protocol, but are followed up by 6 months (aABR screening) and 18 months of age (full assessment). Infants positive for CMV are referred for diagnostic ABR assessment, regardless of the results of the screening test.

The prevalence of CMV in Italy varies between 0.15% and 0.51% as indicated by the Portal of Epidemiology for Public Health (National Center for Disease Prevention and Health Promotion , 2019).

The incidence of meningitis in Italy can be divided into meningitis by *Neisseria meningitides* (4.8 per 100 000 infants < 1 year old), meningitis by *Streptococcus pneumoniae* (5 per 100 000 infants < 1 year old), and meningitis by *Haemophilus influenza* (3.75 per 100 000 infants < 1 year old). Specifically, for the Veneto region in 2016, the incidence of meningitis by *Neisseria meningitidis* for children 0-4 years of age was 1.7 per 100 000 children, the incidence of meningitis by *Streptococcus pneumoniae* was 8.63 per 100 000 infants < 1 year old, and the incidence of meningitis by *Haemophilus influenza* was 7.67 per 100 000 infants < 1 year old (National Institute of Health, 2017).

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

The diagnostic assessment tests performed after neonatal hearing screening referral are auditory brainstem response testing, as well as tympanometry, DPOAE, and a medical (ENT or audiologist) examination. Diagnostic testing should be performed by 3 months of age (or corrected age) for well and at-risk babies.

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

Not applicable.

### **5.4. Intervention approach**

In Italy, 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 6-12 months of age or older.

The hearing aid fitting criteria in Veneto region is a bilateral or unilateral hearing loss of >30 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 neonatal hearing screening protocol in the Region of Veneto for well infants is currently a 3-step OAE-OAE-aABR protocol. This is the protocol that is performed predominantly across Italy. However, recently (Spring 2018) a Regional Decree was published indicating that the protocol will be changed. Instead, a one stage aABR protocol will be performed on all infants (Official Bulletin of the Region of Veneto, 2018).

**Table 1:** Screening process for well babies in Veneto Region, Italy.

Test	Age	Referral Criteria	Device	Unilateral Referrals?	Location
OAE1	24-72 hours	8x peaks of alternating-signs	Accuscreen PRO	Yes	Maternity hospital
OAE2	1 month		Accuscreen PRO	Yes	Maternity hospital
aABR	(same session as OAE2)	35 dB nHL	Accuscreen PRO	Yes	Maternity hospital

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

Table 2 describes the 2-step OAE+aABR screening protocol currently used in Veneto Region of Italy. As with well infants, the 2018 Regional Decree (Official Bulletin of the Region of Veneto, 2018) is also relevant for NICU infants, whereby one aABR will soon be performed instead of the current multi-stage screening approach.

**Table 2:** Screening process for at-risk babies in Veneto Region, Italy.

Test	Age	Referral Criteria	Device	Unilateral Referrals?	Location
OAE+aABR1	36-42 weeks; depends on health of newborn	35 dB nHL	Accuscreen Pro	Yes	NICU
OAE+aABR2	1 month	35 dB nHL		Yes	Hospital Clinic / NICU

### 6.3. Preschool hearing screening

Not applicable.

## **7. Professionals**

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

Screening for well babies is performed by nurses.

Screening staff, both doctors and nurses, are trained on hearing screening via a 6-hour course for nurses and an 8-hour course for doctors. Training is certified and updated every 1-3 years.

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

Screening for NICU infants is performed by audiometric technicians or audiologist physicians. See 7.2 for training requirements.

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

Not applicable.

## 8. Results: Neonatal Hearing Screening

### 8.1. Coverage and attendance rates

The coverage rate for well-babies in Veneto Region is >95%. This is based on data from 2011 of the coverage rate in Northwest Italy, encompassing Veneto region (Bubbico, Tognola, & Grandori, 2017) and the coverage rate from 2016 in the Province of Padua, within Veneto region (Dhima, 2018). These coverage rates were 97.1% and 97.8%.

For at-risk infants, it is estimated that all infants (100%) are offered hearing screening.

The number of well infants that missed being *offered* screening is not specified, and therefore, attendance rate for the initial screening step is not known. However, attendance rates for step 2 in the Province of Padua was 94.5% and 80.6% for well babies and NICU babies in 2016 (Dhima, 2018). Attendance rate for step 3 would be theoretically 100% as this screen occurs during the same appointment.

### 8.2. Referral rates

Referral rates are calculated from data collected in the Province of Padua in 2016 and are presented in Table 3.

**Table 3:** Referral rates for neonatal hearing screening (well babies) in the Province of Padua within the Region of Veneto in 2016 (Dhima, 2018).

Test	Referral Rate
OAE1	3.9%
OAE2-aABR*	7.5%

Referral rates assume 100% attendance at each step. \*Represents referral rate after OAE2 and aABR (if necessary) performed at the same appointment.

The final referral rate for well and NICU babies was 1.06% and 10.1%, respectively (Dhima, 2018).

### 8.3. Diagnostic assessment attendance

The attendance rate at the diagnostic assessment for all infants (well and NICU) was 93.8%, and the percentage of infants that completed the diagnostic assessment was 93.7% in 2016 out of the number of infants referred. This figure represents 2.3% of all newborns screened (Dhima, 2018).

### 8.4. Prevalence / Diagnosis

The prevalence values of permanent hearing loss among neonates for all of Veneto Region of Italy are not presented; however, 1.2% of newborns in the Province of Padua are detected with a hearing impairment (Dhima, 2018).

Data on the prevalence of bilateral auditory neuropathy for both well-babies and NICU-babies in Veneto Region is not indicated.

### 8.5. Intervention

In Veneto Region, it is not indicated how many infants with neonatal hearing impairment are fitted with hearing aids or cochlear implants per year.

### **8.6. Screening evaluation**

Data are not indicated regarding the false positives, false negatives, sensitivity or specificity of neonatal hearing screening in Veneto Region. Data are also not indicated regarding the positive predictive value of a refer result.



## **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. Screening evaluation**

Not applicable.

## 10. Costs: Neonatal Hearing Screening

Neonatal hearing screening in Veneto Region is free of charge for parents. There is no financial reward when parents attend hearing screening or a penalty for refusing screening.

A cost analysis was performed and published in the 2013 study (Martini, Marchisio, Bubbico, Trevisi, & Perletti)

### 10.1. Screening costs

In Italy, the cost of hearing screening is €6200 per 1000 births per year in one birth centre, or €6.20 per neonate, according to the 2013 study (Martini, Marchisio, Bubbico, Trevisi, & Perletti); however, the live costs result in a total of €13.22 per infant

### 10.2. Equipment costs

*(Information extracted to protect commercially sensitive data)*

The cost of one aABR performed at the first step would be €10.

### 10.3. Staff costs

The salary of a professional performing hearing screening is not indicated. In Veneto Region, there are 38 birth centres and 4 hearing screening nurses in each hospital, plus 3 other professionals per birth centre (doctors and specialist nurses). Therefore, there are approximately 152 nurses who perform hearing screening and 114 other professionals involved in screening in Veneto Region. The cost of training hearing screening professionals is unknown.

### 10.4. Diagnostic costs

The cost for a diagnostic ABR assessment is €35 according to the 2013 cost analysis; however, the current costs are €46 for the diagnostic ABR, plus €30 for an audiological/ENT consultation.

### 10.5. Amplification costs

In Veneto Region of Italy, all children are treated for hearing loss.

The cost for hearing aid and cochlear implant intervention in Veneto Region is not indicated.

### 10.6. Social costs

Social costs are not provided.

## **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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