



## **Summary: Hearing Screening**

**Malta**

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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 Malta, there is no universal neonatal hearing screening program.

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

#### **3.1. General**

Malta has a total area of 316 km<sup>2</sup> with a population of 475 701 in 2017 (National Statistics Office, 2019).

In Malta, all births are registered. The number of live births in Malta in 2014 was 4308 (Department of Health Information and Research, 2015).

The World Bank income classification categorizes Malta as a high-income country (The World Bank, 2018). The gross domestic product (GDP) in 2017 was €24 016 per capita in Malta (The World Bank Group, 2019).

From the World Health Organization (WHO) Global Health Expenditure Database, health expenditure for Malta in 2015 was 2250 USD or €2006 per capita (World Health Organization (WHO), 2018).

An infant mortality rate of 7.4 per 1000 is reported for Malta in 2016 (United Nations Statistics Division, 2016).

#### **3.2. Neonatal hearing screening**

In Malta, neonatal hearing screening is selective, with only babies in the single NICU in Malta having access to hearing screening. Neonatal NICU screening is funded through state, but participation is not obligatory for parents. Neonatal NICU hearing screening in Malta was started and fully implemented in 2005, as there is only one NICU in the country. It is not embedded in the Preventive Child Health Care screening system.

In Malta, at-risk infants are defined as those admitted to the NICU. Data is unavailable on the prevalence of CMV or meningitis in Malta.

#### **3.3. Preschool hearing screening**

Preschool hearing screening does not exist in Malta.



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

National guidelines for child health care do not exist in Malta, and there is also no general hearing screening programme.

Quality assurance or data collection on hearing screening is not performed and there have been no annual reports or studies performed on hearing screening in Malta.



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

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

In Malta, it is roughly estimated that the percentage of children admitted to the NICU is less than 10% (NICU specialist resident, 2017).

At-risk babies are screened in the NICU located in the main state hospital by audiology assistants. Families are invited to participate in screening via information provided directly at the hospital.

Babies should be screened before discharge from the hospital.

The target condition for screening for at-risk babies is not quantified. Once referred with OAEs, hearing loss is assessed for any degree or severity.

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

Infants referred from neonatal hearing screening to diagnostic assessment are tested with a secondary OAE and ABR. The ABR is performed under chloral hydrate sedation, if indicated.

There is no criterion for when the diagnostic assessment of well-babies should be completed; a diagnostic assessment is performed once there is a possibility of a hearing loss of any degree or severity. No timeline is indicated.

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

Not applicable.

### **5.4. Intervention approach**

In Malta, treatment options available include grommets, hearing aids, bone conductive devices, and cochlear implants. Infants are fitted with hearing aids from less than 6 months of age or older, and infants are fitted with cochlear implants from 6-12 months of age or older.

The hearing aid fitting criteria in Malta is at least a 40-45 dB hearing loss in one or both ears (Department of Audiology / Otolaryngology, 2017).

## 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)

Hearing screening for well babies does not exist in Malta, though implementation plans are in progress.

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

A two-step OAE protocol is in effect in the NICU in Malta. See Table 1 for details.

**Table 1:** Screening process for at-risk (NICU) babies in Malta.

<b>Test</b>	<b>Age</b>	<b>Referral criteria</b>	<b>Device</b>	<b>Unilateral Referrals?</b>	<b>Location</b>
OAE1	Immediately	Waveform peak fit (8/8 peaks detected)	Madsen Accuscreen	Yes	NICU
OAE2	Before discharge			Yes	NICU

### 6.3. Preschool hearing screening

There is no preschool hearing screening.



## **7. Professionals**

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

Well baby neonatal hearing screening is not yet performed in Malta.

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

Screening of at-risk infants is performed by audiology assistants. There is currently no specific training, but staff are given hands-on experience.

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

There is no preschool hearing screening.

## 8. Results: Neonatal Hearing Screening

### 8.1. Coverage and attendance rates

In Malta, coverage and attendance rates for well babies was 0%, as there is no neonatal hearing screening program for well babies.

All babies in the NICU are invited for neonatal hearing screening. The coverage rate for NICU infants is 100% (as of April 2017).

### 8.2. Referral rates

Data on passing rates after neonatal hearing screening of at-risk infants in Malta is not available.

In total, the referral rate for at-risk babies to a diagnostic assessment after the screening process is less than 10%<sup>1</sup>.

### 8.3. Diagnostic assessment attendance

The compliance rate for a diagnostic assessment after neonatal NICU hearing screening is unknown. The percentage of infants who receive a diagnostic evaluation after neonatal hearing screening referral is estimated to be around 100%, though the occasional patient is lost despite several reminder attempts.

### 8.4. Prevalence / Diagnosis

The prevalence values of permanent hearing loss among neonates in Malta is unknown, as only infants at-risk in the NICU are screened. It is roughly estimated that the total percentage of NICU graduates that are diagnosed with a hearing loss is less than 5%.

The total numbers of children diagnosed with a hearing loss of a certain severity in Malta were provided and categorized by age group. In total 4 children fell into pre-school age of  $\leq 5$  years. The population statistics in Malta report a total population of 13518 children between 3-5 years of age (National Statistics Office, Malta, 2018), which would indicate a total prevalence of 0.29 per 1000.

There are 2 children  $<5$  years of age diagnosed with auditory neuropathy. It is unclear if these children are well, healthy babies or not. It is also unclear if auditory neuropathy is bilateral or unilateral.

### 8.5. Treatment success

Children with hearing impairments are fitted with hearing aids, depending on the severity of the loss, except if parents refuse. Children with profound hearing loss are fitted with cochlear implants. In 2016, 4 children were fitted with cochlear implants including 1 unilateral and 3 bilateral.

### 8.6. Screening evaluation

The false negative rate for neonatal hearing screening is unknown, though the false positive rate is roughly estimated to be less than 5%.

Sensitivity, specificity, and positive predictive values are unknown, though it is estimated to be high.

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<sup>1</sup> Referral rate is calculated as an average across the year, of the number of infants referred out of the total number of infants tested. Note that in January 2018, 2 infants failed the screening out of 21 infants tested.



## **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**

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

### **10.1. Screening costs**

Data on neonatal hearing screening costs are unavailable. All costs are covered by the government.

### **10.2. Equipment costs**

*(Information extracted to protect commercially sensitive data)*

The cost of maintenance is around €700 per year for diagnostic equipment, which lasts around 12-15 years. The costs for OAE disposables are around €500 for 750 tips (Engineering department of MDH, 2017).

### **10.3. Staff costs**

In Malta, there are 4 screeners for a population of 420 000. The salary costs per year for hearing screening professionals is €15 000 per year (Staff and salary section of MDH, 2017). The training costs are unknown.

### **10.4. Diagnostic costs**

The cost for a diagnostic assessment is not provided.

### **10.5. Amplification costs**

In Malta, all eligible children are treated for hearing impairment. The cost of a hearing aid ranges between €100 and 150, though this cost is covered by the government. The cost of a cochlear implant is €15 000, which is also covered by the government (Audiology Unit, 2017).

### **10.6. Social costs**

There is 1 specialized school in Malta for the deaf and hard-of hearing. The number of children that attend this school is unknown. Children in mainstream schools receive special support through a teacher of the deaf and audiologist in the education department.

The costs for schooling (specialized or mainstream) is also unknown.





## **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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