



Summary: Hearing Screening

Spain (Principality of Asturias)

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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	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.
Risk babies / Babies at-risk	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.
Sensitivity	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%.
Specificity	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%.
Target condition	The hearing loss condition you are aiming to detect via your screening programme. This includes: <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	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 Spain, hearing screening is performed nationally, yet organized regionally. The following report contains information with regards to childhood hearing screening in the Autonomous Community or Principality of Asturias.

3.1. General

The Principality of Asturias has a total area of 10 604 km² with a population of 1 034 960 in 2016. The birthrate in the Principality of Asturias is 6600 per year, from 2015 data (Asturian Society of Economic and Industrial Studies, 2017).

The World Bank income classification categorizes Spain as a high-income country (The World Bank, 2018). The gross domestic product (GDP) in 2015 was €21 595 per capita in the Principality of Asturias (Asturian Society of Economic and Industrial Studies, 2017) and €23 300 per capita in Spain (Datosmacros.com, 2018).

From the World Health Organization (WHO) Global Health Expenditure Database, health expenditure for all of Spain in 2015 was 2 354 USD or €2 026 per capita (World Health Organization (WHO), 2018).

In the Principality of Asturias, each birth is registered. Data from the Asturian Society of Economic and Industrial Studies indicate an infant mortality rate of 1.86 per 1000 for the Principality of Asturias in 2015 (2017). Data acquired from the 2016 United Nations Demographic Yearbook indicates an infant mortality rate of 2.7 per 1000 for the country of Spain in 2015 (United Nations Statistical Division, 2016).

3.2. Neonatal hearing screening

In the Principality of Asturias, neonatal hearing screening is conducted universally, with all babies in the region having access to hearing screening, though screening is not obligatory for parents. The universal program for well and at-risk babies was first implemented in 2002 across the entire region. Neonatal hearing screening is not embedded in the Preventive Child Health Care screening system. Screening is funded by the region.

Each region across Spain is responsible for organizing its own protocol, though a national committee (CODEPEH) publishes recommended guidelines. Regions use the different protocols for screening well and at-risk babies, though for at-risk infants nearly all regions use aABR. There are no differences in neonatal hearing screening protocols across the Principality of Asturias for either well babies or at-risk babies.

3.3. Preschool hearing screening

In the Principality of Asturias, preschool hearing screening is not performed.



4. Guidelines & Quality Control

National recommended guidelines for hearing screening exist in Spain, published by CODEPEH (Comisión para la Detección Precoz de la Hipoacusia Infantil (CODEPEH), 1999; Trinidad-Ramos, de Aguilar, Jaudenes-Casaubon, Nunez-Batalla, & Sequi-Canet, 2010). These recommendations may be used for the development of regional protocols.

Regional guidelines and a protocol for hearing screening exist in the Principality of Asturias. The content of the hearing screening programme was decided on by the public health organization.

Quality assurance of hearing screening programs is not imposed by the government; however, information is collected about hearing screening outcomes. Hospitals regularly send hearing screening information via email to a generalized database of all hospitals in the Principality of Asturias. Neonatal hearing screening outcomes collected from maternity hospitals are reviewed annually. It is unknown how the review and revision process is funded. The content of the programme has not been changed since its start.

Annual reports are available based on data collected from maternity hospitals. It is unknown if other research has been performed in the Principality of Asturias apart from this annual auditing.



5. Process: Screening, Diagnosis, Intervention

5.1. Neonatal hearing screening

Well-babies and at-risk babies are screened in the hospital. Well-babies are invited to participate in neonatal hearing screening via a letter, and at-risk families are invited to participate in neonatal screening directly in person in the hospital by pediatricians, nurses and sometimes ENT physicians. It is roughly estimated that 99% of infants are born in maternity hospitals, where the average length of stay is 2 days after delivery.

Neonatal hearing screening for both well and at-risk babies should be completed before 3-months of age.

In the Principality of Asturias, 1.4% of infants have an increased risk of auditory neuropathy and are screened differently than well-babies. At-risk infants are defined as those with hypoxia, family history of hearing loss, and hyperbilirubinemia.

The prevalence of CMV infections or meningitis among neonates is unknown.

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

5.2. Neonatal diagnostic assessment

The diagnostic assessment after neonatal hearing screening referral, including clinical ABR, should be performed before 6 months of age.

5.3. Preschool hearing screening

Not applicable.

5.4. Intervention approach

In the Principality of Asturias, treatment options available include grommets, hearing aids, bone conductive devices and cochlear implants. The average age infants are fitted with hearing aids is 8.42 months of age. Infants are fitted with cochlear implants from 1-2 years of age.

The hearing aid fitting criteria in the Principality of Asturias is a hearing loss > 40 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 process for neonatal hearing screening for well babies is described in Table 1. A 3-step OAE protocol is in effect, whereby the first OAE is performed in the maternity hospital before discharge. If the infant fails the first OAE, rescreening occurs at 15 days after birth and again by 3 months.

Table 1: Screening protocol for well babies in the Principality of Asturias.

Test	Age	Referral criteria	Device	Unilateral Referrals?	Location
OAE1	24-72 hours	Bimodal statistical probability	Echo-screen	Yes	Maternity hospital
OAE2	15 days			Yes	Maternity hospital
OAE3	<3 months			Yes	Maternity hospital

6.2. Neonatal hearing screening (at-risk)

The screening process for at-risk infants is described in Table 2. As indicated, infants with hypoxia, family history of deafness, or hyperbilirubinemia undergo the at-risk protocol. These infants are initially screened with OAE. In cases where the OAE is a pass, an aABR is performed.

In cases where OAE is a fail, a second OAE is performed at 15 days and a third OAE is performed at 3 months.

After at-risk infants pass neonatal hearing screening, a follow-up process is then initiated until the child is 3-years of age.

Table 2: Screening process for at-risk babies in the Principality of Asturias.

Test	Age	Referral criteria	Device	Unilateral Referrals?	Location
OAE+ aABR	2-8 weeks (36-42 weeks gestation)	Bimodal statistical probability / 35 dB nHL	Echo-screen	Yes	Hospital
OAE2	15 days			Yes	Hospital
OAE3	3 months			Yes	Hospital

6.3. Preschool hearing screening

Not applicable.



7. Professionals

7.1. Neonatal hearing screening (well)

Screening for well and at-risk babies is performed by nurses. Nurses undergo a specific one-week training on hearing screening, which is not accredited or certified. The training is not updated, monitored or revalidated.

7.2. Neonatal hearing screening (at-risk)

Screening for at-risk infants is also performed by nurses.

7.3. Preschool hearing screening

Not applicable.

8. Results: Neonatal Hearing Screening

8.1. Coverage and attendance rates

The coverage rate from 2014 to 2017 in the Principality of Asturias was calculated to be 98% (Database, 2017). The coverage rate is the percentage of infants screened out of the number of live births in the Principality of Asturias.

From the 2015 report (García, 2015), the participation rate for well babies for the first stage of screening was reported to be 99.2%. The participation rate for stage 2 was 90.7% (out of 6778 well infants that were referred from stage 1, screening results were recorded for 6148 infants), and the participation rate for stage 3 was 88.8% (out of 1393 well infants referred from stage 2, 1237 infants participated in stage 3). Therefore, 786 well infants, or 11.6%, were lost-to-follow-up between stages 1 and 3 of the screening protocol.

8.2. Referral rates

Referral rates are calculated from data collected from 2002 to 2014 (García, 2015) and are presented in Table 3.

Table 3: Referral rates for neonatal hearing screening (well babies) in the Principality of Asturias (García, 2015).

Test	Referral Rate
OAE1	7.8%
OAE2	22.7%
OAE3	60.9%

Referral rates assume 100% attendance at each step.

In total, the referral rate to a diagnostic assessment after the screening process is 0.88% (García, 2015). This is determined from the total number of infants referred from OAE3 to a diagnostic assessment out of the total number of infants screened in step 1. This referral rate applies to all infants, and not just for well, healthy infants.

The referral rate specifically for at-risk infants is unknown.

8.3. Diagnostic assessment attendance

The compliance rate for a diagnostic assessment after neonatal hearing screening referral was 88.5%, as calculated from all the infants referred to a diagnostic assessment from 2002 to 2014 (García, 2015).

8.4. Prevalence / Diagnosis

The prevalence values of permanent hearing loss among neonates acquired from 2016 data in the neonatal hearing screening database in the Principality of Asturias are presented in

Table 4.

Table 4: Prevalence of permanent hearing loss among neonates in the Principality of Asturias (Database, 2017).

Bilateral		Unilateral	
≥ 40 dB HL	≥ 80 dB HL	≥ 40 dB HL	≥ 80 dB HL



Prevalence per 1000 neonates (Principality of Asturias Database, 2017)	3	1.16	0.5	0.4
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The prevalence of bilateral auditory neuropathy in the Principality of Asturias is 7 per 100 000 (Database, 2017).

8.5. Treatment success

The number of children with neonatal hearing loss that are fitted with hearing aids is, on average, 39 per year. The number of children with neonatal hearing loss that are fitted with cochlear implants is, on average, 5 per year (ranging from 3-7 per year) (García, 2015).

8.6. Screening evaluation

The percentage of false negatives is estimated to be less than 1%. The percentage of false positives after neonatal hearing screening is roughly estimated to be 1%.

For well babies, the positive predictive value of a refer result is roughly estimated to be 40%.

The results of screening at-risk infants are unknown.



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 the Principality of Asturias 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 the Principality of Asturias; however, an economic evaluation was completed from the data reported from 2002 to 2014 (García, 2015).

10.1. Screening costs

The total screening costs per year (calculated from the report citing data from 2002 to 2014) was €94 488, which equates to €14 per infant screened. When dividing by expenditure, 67.4% is allocated to personnel, 27.4% to equipment and 5.2% to general costs (García, 2015).

10.2. Equipment costs

The cost of OAE and aABR screening devices is included in the total screening costs. Data on the cost for disposables and maintenance is not available.

10.3. Staff costs

It is estimated (via calculation) that there are 9 hearing screening professionals per million population. Salary and training costs are unknown, but are included in the total screening costs.

10.4. Diagnostic costs

The total cost of diagnostic confirmation is €47 130 per year, which equates to a cost of €871 per child tested (García, 2015).

10.5. Amplification costs

In the Principality of Asturias, all children with hearing loss are treated.

The total cost of treatment is €227 137 per year, which equates to €8554 per child treated with hearing aids and €24 918 per child treated with cochlear implants (García, 2015). These costs include costs associated with hearing testing and management.

10.6. Social costs

In the Principality of Asturias, there are 7 primary schools and 5 secondary schools for deaf and hard of hearing (Asturias Government). Information is available in the hearing screening report on the children attending special schools, mainstream schools, or special education centres. From the 2013-2014 school year, 168 children attended mainstream schools, 39 children followed the auditory integration model, and 20 children followed the special education model (García, 2015).

In mainstream schools, social services extra support is provided to children with hearing impairment.

The cost for a normal hearing student in a mainstream school is €6435 (Asturias Government); however, the cost for special support in mainstream schools or the cost for a hearing-impaired student in a specialized school 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.

11.4. Diagnostic costs

Not applicable.



12. References

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