



Summary: Hearing Screening
Spain (Autonomous Community of Valencia)

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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 hearing screening in the Autonomous Community of Valencia (Comunitat Valenciana), hereafter, the Valencian Community, which includes the provinces of Castellon, Valencia, and Alicante.

3.1. General

The Valencian Community has a total area of 23 255 km² with a population of 4 959 968. The birthrate in the Valencian Community is 43 450 per year (Generalitat Valenciana, 2016).

The World Bank income classification categorizes Spain as a high-income country (The World Bank, 2018). The gross domestic product (GDP) in 2015 was €20 586 per capita in the Valencian Community 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 Valencian Community, each birth is registered with the law office. Data from the Generalitat Valenciana (2016) indicates an infant mortality rate of 3.18 per 1000 for the Valencian Community in 2015. 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 Valencian Community, 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 2000, and by 2008/2009, neonatal hearing screening was implemented across the region. Neonatal hearing screening is embedded in the Preventive Child Health Care screening system. Screening is funded through the state and organized through the regional government via an auditory screening committee within Public Health entitled “salud publica: cribado auditivo” containing a group of experts.

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. Within the Valencian Community, all public hospitals follow the same protocol.

3.3. Preschool hearing screening

The well child control programme contains some indications about hearing. There is a current mandate that pediatricians ask the family about hearing status and a tuning fork test is occasionally performed. However, preschool hearing screening is not performed universally in the Valencian Community. Further sections in this report will state “not applicable” with regards to information about preschool hearing screening.



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.

The content of the hearing screening programme was decided on by the Valencian Community government through a panel of experts and has not been changed since its implementation. The revision process is performed when needed through a meeting of experts and is funded by the state.

Quality assurance of hearing screening programmes is not imposed by the government; however, information is collected about hearing screening outcomes through a database specific to the Valencian Community.

Annual reports are available, but with some delays. The most recent data from 2013 were published in 2015 (Dirección General de Salud Pública, 2015). Other research has been performed on hearing screening in the Valencian Community apart from auditing (e.g. Sequi-Canet, Sala-Langa, & Collar del Castillo, 2016; Sequi-Canet, Sala-Langa, & Collar del Castillo, 2014).



5. Process: Screening, Diagnosis, Intervention

5.1. Neonatal hearing screening

Well-babies and at-risk babies are screened in the hospital. Well-baby 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 estimated that 90% of infants are born in a hospital or maternity clinic in the Valencian Community and 10% of births take place at home. The average stay in the maternity hospital after birth is estimated to be 48 hours (2 days).

Neonatal hearing screening for both well- and at-risk babies should be completed before 1 month of age.

In the Valencian Community, approximately 3% of infants are screened differently than well-babies. The definition of at-risk infants is obtained from the 2007 publication by the Joint Committee of Infant Hearing (Joint Committee on Infant Hearing, 2007). Infants with risk factors are screened at least once with aABR, with or without TEOAE screening. The exception is infants with a family history of hearing loss in the well-baby nursery who are screened with TEOAE.

The prevalence of CMV infections among neonates is estimated to be <1%. The prevalence of meningitis (all cases) is estimated to be <3 cases per 10000.

The target condition for screening for well- and at-risk babies is a hearing loss of >40 dB HL.

5.2. Neonatal diagnostic assessment

The diagnostic assessment tests performed after neonatal hearing screening referral are tympanometry, clinical ABR, TEOAE/DPOAE, and ASSR. Testing should be performed by 3 months of age.

5.3. Preschool hearing screening

Not applicable.

5.4. Intervention approach

In the Valencian Community, treatment options available include grommets, hearing aids, bone conductive devices and cochlear implants. Infants are fitted with hearing aids from 6-12 months of age and cochlear implants from 1-2 years of age.

The hearing aid fitting criteria in the Valencian Community is a bilateral hearing loss of >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 protocol for neonatal hearing screening for well babies is described in Table 1. A two-step OAE screening programme is in effect, whereby the first step of OAE screening takes place in the maternity ward and the second step occurs before the infant is 1 month of age. The first OAE step may include one or two OAE tests depending on when the first test occurred and when the infant is discharged. If two OAE tests are performed, these would both be included under OAE1.

Table 1: Screening protocol for well babies in the Valencian Community.

Test	Age	Referral criteria	Device	Unilateral Referrals?	Location
OAE1*	24-72 hours	Base program [†]	Otodynamics ILO	Yes	Maternity hospital
OAE2	<30 days	Base program	Otodynamics ILO	Yes	Hospital (outpatient)

*Step 1 (OAE1) takes place before hospital discharge. If OAE1 fails and time allows, a repeat screening will be performed before discharge. This rescreen is still included under Step 1 (OAE1).

[†]Default referral criteria according to the Otodynamics EchoPort EZScreen Manual (Otodynamics, 2017) is 3 out of 5 bands with a criteria of 6 dB SNR, and confirmed in Sequi-Canet, Sala-Langa & Collar del Castillo (2016).

6.2. Neonatal hearing screening (at-risk)

The screening protocol for at-risk infants is described in Table 2. As indicated previously, infants that undergo screening with the at-risk protocol are those with risk indicators defined by the Joint Committee on Infant Hearing (2007). These infants may or may not also undergo OAE screening in addition to aABR screening. The exception is infants in the well-baby unit with a family history of hearing loss who are screened according to the well-baby protocol.

Table 2: Screening protocol for at-risk babies in the Valencian Community.

Test	Age	Referral criteria	Device	Unilateral Referrals?	Location
aABR	2-8 weeks (36-42 weeks gestation)	35 dB nHL	Various	Yes	NICU

6.3. Preschool hearing screening

Not applicable.



7. Professionals

7.1. Neonatal hearing screening (well)

Screening for well babies is predominantly performed by pediatric nurses. In a few hospitals, pediatricians or ENT physicians also perform screening. All screening staff (including nurses, pediatricians and ENT physicians) undergo training for a few days. The head of the nursing staff typically performs the in-house training, except in large hospitals where there is a dedicated team for training new staff.

7.2. Neonatal hearing screening (at-risk)

Screening for at-risk infants is also performed by nurses, pediatricians, or ENT physicians, and training is similar to that for well-baby screening.

7.3. Preschool hearing screening

Not applicable

8. Results: Neonatal Hearing Screening

8.1. Coverage and attendance rates

Results presented reflect the situation in public hospitals in the Valencian Community. Private hospitals perform neonatal hearing screening; however, data on their performance are not available.

Coverage rates were provided separately for the step 1 (OAE1 or aABR) and step 2 (OAE2) of screening. Table 3 provides an overview of coverage rates available. The rates are presented for all newborns, both well and at-risk infants, as well as specifically the at-risk infant group. Data were provided for the year 2015, as well as for the combined years of 2010-2017, and for both the entire Valencian Community and specific to H.F. Borja Gandia hospital (Sequi-Canet, 2018a; 2018b).

Table 3: Coverage rates for each step of neonatal hearing screening for all infants and for infants considered at risk.

		All Newborns		At-Risk Newborns	
		2015	2010-2017	2015	2010-2017
Valencian Community	Step 1	92%	86.5%	99.6%	98.9%
	Step 2	86.5%	87.5%		
H.F. Borja Gandia Hospital	Step 1	98%	99.9%	100%	100%
	Step 2	88.6%	85.7%		

If incorporating both step 1 and step 2 of screening for all newborns into a single coverage rate for the entire Valencian Community, the total coverage rate for both steps of screening can be estimated as 91.1% (2015) and 85.7% (total 2010-2017).

Attendance rate for neonatal hearing screening is defined as the percentage of infants who completed the screening out of all babies offered screening. The number of infants that missed being *offered* screening is not specified, and therefore, attendance rate is not known.

8.2. Referral rates

Referral rates for the neonatal screening are calculated estimations from data provided from both 2015 and the total numbers from 2010-2017 (Sequi-Canet, 2018a; 2018b). Figures are calculated for all newborns (including risk- and well-infants).

Table 4: Referral rates for neonatal hearing screening (all neonates) in the Valencian Community (2015).

	Referral Rate	
	2015	2010-2017
Step 1	8.4%	7.4%
Step 2	14.8%	16.2%

Referral rates assume 100% attendance at each step. Step 1 includes both OAE and aABR when applicable. Step 2 includes OAE2 for well infants.

In total, the referral rate to a diagnostic assessment after the screening process is 1.08% (2015) and 1.05% (total 2010-2017). This figure, calculated from the total number of infants referred from step 2 out of all infants screened in the step 1, does not account infants lost between the two steps of the screening process.

8.3. Diagnostic assessment attendance

The compliance rate for a diagnostic assessment after neonatal hearing screening for all neonates (well and at risk) was 72.3% in 2015 and 76.1% from the years 2010-2017 combined (Sequi-Canet, 2018a; 2018b).

8.4. Prevalence / Diagnosis

The prevalence values of permanent hearing loss among neonates in the Community of Valencia are not known, as results are divided between normal vs. abnormal and bilateral vs. all. Therefore, data available indicates the prevalence of all hearing loss, including both permanent and transient, among neonates (Sequi-Canet, 2018a; 2018b).

Table 5: Prevalence of all hearing loss (permanent and transient) among all neonates in the Valencian Community (per 1000).

	All Newborns		At-Risk Newborns
	Bilateral	Unilateral	Bilateral & Unilateral Combined
2015	0.96	0.72	25
2010-2017	0.93	0.75	29

The prevalence of bilateral auditory neuropathy in the Valencian Community is not available.

8.5. Treatment success

Data is unavailable regarding the number of children with neonatal hearing loss that are fitted with hearing aids or cochlear implants in the Valencian Community.

8.6. Screening evaluation

The percentage of false negatives is roughly estimated to be less than 1%. Data provided indicates a total of 18 children have received an abnormal diagnostic test after normal screening results from 2010 to 2017. The percentage of false positives after neonatal hearing screening is calculated to be about 1%.

The positive predictive value of a refer result (all newborns) was 14.3% for 2010-2017 combined and 13.2% for 2015 (Sequi-Canet, 2018a; 2018b).



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 Valencian Community is free of charge for parents. There is no financial reward when parents attend hearing screening, nor is there a penalty for those who refuse hearing screening.

There has not been a cost effectiveness analysis completed in the Valencian Community.

10.1. Screening costs

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

10.2. Equipment costs

(Information extracted to protect commercially sensitive data)

The cost for disposables for OAE screening is negligible and the cost for aABR disposables is around €5-10 per infant screened.

10.3. Staff costs

Data is unavailable on how the number of hearing screening professionals, their salary, or the cost of their education.

10.4. Diagnostic costs

The cost for a diagnostic assessment is not indicated.

10.5. Amplification costs

In the Valencian Community, all children are treated for hearing loss.

Data on the costs of hearing aids or cochlear implants is unavailable.

10.6. Social costs

Information on specialized schools specifically for deaf and hard of hearing students in the Valencian Community is unknown. However, there are some institutions that oversee the management of deaf children, including both government (Aula Instituto Valenciano de Audiofonología) and family institutions (ASPAS- FIAPAS).

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

The cost of special support for deaf and hard of hearing students is not known. Some indirect figures can be relayed. For example, one article shows that 1.2 million euros was allocated for the cost of maintaining the IVAF-Luis Fortich School for deaf and hard-of-hearing students (Elperiodic.com, 2012).



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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