



Summary: Hearing Screening France

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Table of Contents

- List of Tables..... 4
- 1. Glossary of Terms: Hearing Screening 5
- 2. Abbreviations 8
- 3. Background 9
 - 3.1. General 9
 - 3.2. Neonatal hearing screening 9
 - 3.3. Preschool hearing screening 9
- 4. Guidelines & Quality Control 10
- 5. Process: Screening, Diagnosis, Intervention 11
 - 5.1. Neonatal hearing screening 11
 - 5.2. Neonatal diagnostic assessment 11
 - 5.3. Preschool hearing screening 11
 - 5.4. Intervention approach..... 11
- 6. Protocols..... 13
 - 6.1. Neonatal hearing screening (well)..... 13
 - 6.2. Neonatal hearing screening (at-risk) 13
 - 6.3. Preschool hearing screening 14
- 7. Professionals..... 15
 - 7.1. Neonatal hearing screening (well)..... 15
 - 7.2. Neonatal hearing screening (at-risk) 15
 - 7.3. Preschool hearing screening 15
- 8. Results: Neonatal Hearing Screening 16
 - 8.1. Coverage and attendance rates 16
 - 8.2. Referral rates 16
 - 8.3. Diagnostic assessment attendance 16
 - 8.4. Prevalence / Diagnosis 16
 - 8.5. Treatment success..... 17
 - 8.6. Screening evaluation 17
- 9. Results: Preschool Hearing Screening..... 18
 - 9.1. Coverage and attendance rates 18
 - 9.2. Referral rates 18
 - 9.3. Diagnostic assessment attendance 18
 - 9.4. Screening evaluation 18
- 10. Costs: Neonatal Hearing Screening..... 19



10.1.	Screening costs	19
10.2.	Equipment costs	19
10.3.	Staff costs	19
10.4.	Diagnostic costs.....	19
10.5.	Amplification costs.....	19
10.6.	Social costs	19
11.	Costs: Preschool Hearing Screening	20
11.1.	Screening costs	20
11.2.	Equipment costs	20
11.3.	Staff costs	20
12.	References	21



List of Tables

Table 1: Screening process for well babies in France.	13
Table 2: Screening process for at-risk babies in France.	13
Table 3: Prevalence of permanent hearing loss among neonates in France (per 1000; source unknown).	16
Table 4: Percentage of infants with permanent hearing loss in France after neonatal hearing screening referral (2005-2007 pilot programme).....	16

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	<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>
Risk babies / Babies at-risk	<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>
Sensitivity	<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>
Specificity	<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>
Target condition	<p>The hearing loss condition you are aiming to detect via your screening programme. This includes:</p> <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	<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 France, neonatal hearing screening and preschool hearing screening are organized both nationally and regionally. In contrast, there are no regional variations in protocol for preschool hearing screening. It is important to note the nomenclature differences, that in France, children attend “preschool” prior to age 3 years, while hearing screening occurs during “maternal school” at the age of 3-4 years.

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

3.1. General

The country of France has an area of 633 208 km² and with a population of 66 993 000 as of January 2019 (L’Institut national de la statistique et des études économiques, 2019).

In France, all births are registered with the National Association for Prevention and Screenings at Birth (AFDPHE). The number of live births in France in 2018 was 758 000.

The World Bank income classification categorizes France as a high-income country (The World Bank, 2018). The gross domestic product (GDP) in 2015 was €34 900 per capita (L’Institut national de la statistique et des études économiques, 2019).

From the World Health Organization (WHO) Global Health Expenditure Database, health expenditure for France in 2015 was 4212 USD or €3735 per capita (World Health Organization (WHO), 2018).

An infant mortality rate in 2015 for France is indicated by the INSEE and United Nations to be 3.7 and 3.5 per 1000, respectively (United Nations Statistics Division, 2016; L’Institut national de la statistique et des études économiques, 2019).

3.2. Neonatal hearing screening

In France, neonatal hearing screening is conducted universally, with all babies in the country having access to hearing screening, though screening is not obligatory.

The universal program for well and at-risk babies was first implemented as an experimental programme in 2005. In 2012, neonatal hearing screening was mandated by law, and in 2013 the ministerial degree was published and funding allowed programme implementation across the country. Neonatal hearing screening is not embedded in the Preventive Child Health Care screening system. The programme is funded through the state and health ministry, which dedicates 18€ per infant for neonatal hearing screening. This funding is included in the birth package.

3.3. Preschool hearing screening

In France, preschool hearing screening exists nationally and is embedded in the general Preventive Child Health Care system. In contrast to neonatal hearing screening, there are no differences in preschool hearing screening across regions. It is estimated that preschool hearing screening in France started many years ago.



4. Guidelines & Quality Control

Neonatal hearing screening in France follows the national hearing screening guideline, specifications and funding. The national hearing screening guideline states that childhood hearing screening must be organized by law; however, regional health agencies (ARS) may adapt these guidelines to their own regional specifications. Therefore, tests performed and referral criteria for well babies may differ across the country. In contrast, protocols for at-risk infants follow the national guidelines.

For example, regions may use aABR, OAE or both methods for screening. Additionally, some regions may only refer well-infants to diagnostic assessment with a failed result in both ears, while other regions may have a different strategy for follow-up for infants who fail the screening unilaterally.

Preschool hearing screening in France follows a national guideline.

The content of the neonatal screening guidelines was developed by the health ministry. Since its initiation, the guidelines have not been revised. The process and funding for revision of the guidelines if needed in the future is not indicated.

Quality assurance is imposed on by the national government. Data and quality monitoring of screening performed in maternity hospital is performed regionally.

Annual reports are not available on a national level for neonatal hearing screening, and data are only available from the experimental program from 2005 to 2007.

Studies have been performed on hearing screening in France, including its effectiveness.



5. Process: Screening, Diagnosis, Intervention

5.1. Neonatal hearing screening

According to 2005 statistics, 99% of children are born in a hospital or maternity clinic, and 1% of births take place at home (L'Institut national de la statistique et des études économiques, 2005). The percentage of children admitted to the NICU in France is roughly estimated to be 4.3%.

Well-babies and at-risk babies are screened in the maternity wards or neonatology unit in the hospital.

Families are invited directly in person in the hospital, where the average length of stay after delivery is calculated to be 4.2 days. Neonatal hearing screening should be completed before discharge from the maternity ward or neonatology unit. Well-baby screening should be completed with a referral for a diagnostic evaluation before 1 month of age. For infants at-risk, the recommended maximum age of screening is not defined in protocol.

In France, at risk infants are defined using the criteria stipulated by the Joint Committee of Infant Hearing (2007), as well as any infant admitted to the NICU. In contrast to well-infants, all regions follow the mandatory national procedure for at-risk infants. Babies who meet these conditions are screened using a different protocol because of the increased risk of auditory neuropathy. It is estimated that 4.3% of infants are screened with the at-risk protocol, as this the percentage of transfer at birth.

The prevalence of CMV infections among neonates is not described but the prevalence of meningitis is 1.4 per 10000 for children under age 5.

The target condition for screening for well and at-risk babies is a hearing loss of greater than 35 dB HL. Whether unilateral or bilateral hearing is targeted varies across regions. In Ile de France, bilateral hearing loss is targeted, while in other regions both unilateral and bilateral hearing losses are targeted.

5.2. Neonatal diagnostic assessment

The diagnostic assessment of well-babies should be performed before 3 months of age; however, with moderate hearing losses it may take longer to achieve the complete and correct diagnosis. Clinical ABR is performed to diagnose hearing impairment.

5.3. Preschool hearing screening

School-age hearing screening takes place at maternal school when the child is 4 and 6 years old.

Children are invited to participate in hearing screening at the schools by school doctors.

It is estimated that the target condition for preschool-age screening is a hearing loss is a unilateral or bilateral hearing loss of at least 25 dB HL.

5.4. Intervention approach

In France, treatment options available include grommets, hearing aids, bone conductive devices, and cochlear implants. Other services include speech therapy. It is estimated that infants are fitted with hearing aids from less than 6 months of age or 6-12 months of age. It is also estimated that infants are fitted with cochlear implants from 1-2 years of age.



It is estimated that hearing aid fitting criteria in France is a sensorineural bilateral or unilateral hearing loss of >30 dB HL. For conductive hearing loss, hearing aids be appropriate depending on the aetiology.

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 process for well babies in France is indicated in Table 1. The neonatal hearing screening process is partly defined in a national protocol; however, each region also has its own protocol. Some maternity clinics have aABR equipment, in which case they may perform aABR as their first and/or second step. Other clinics have only OAE equipment.

Some regions perform a third screening test (control screen) less than month after discharge from the maternity hospitals. Other regions do not perform this control screen and refer to a diagnostic assessment at discharge.

Some regions recommend follow-up after one year for infants that fail neonatal hearing screening unilaterally. Other regions refer unilateral failed screens for a diagnostic examination.

Table 1: Screening process for well babies in France.

Test	Age	Referral criteria	Device	Unilateral Referrals?	Location
OAE / aABR	24-72 hours	Various / 35 dB nHL	Varies	Regional variation	Maternity ward
OAE / aABR	Before discharge	Various / 35 dB nHL	Varies	Regional variation	Maternity ward
OAE / aABR (some)	< 1 month	Various / 35 dB nHL	Varies	Regional variation	Diagnostic centres

6.2. Neonatal hearing screening (at-risk)

The neonatal screening process for infants at risk is similar to well-babies except that aABR is mandatory for each step, as per the national guidelines.

Table 2: Screening process for at-risk babies in France.

Test	Age	Referral criteria	Device	Unilateral Referrals?	Location
aABR	24-72 hours	35 dB nHL	Varies	Regional variation	Maternity ward / Neonatology unit

aABR	Before discharge	35 dB nHL	Varies	Regional variation	Maternity ward / Neonatology unit
aABR (some)	< 1 month	35 dB nHL	Varies	Regional variation	Diagnostic centres

Recommendations for referral and follow-up after screening for at-risk infants vary by region. For example, at-risk infants that fail screening unilaterally may be directly referred for diagnostic assessment or they may be followed-up after 3-4 months of age. Regional programmes may also request that all at-risk infants follow up for later retesting (e.g., after 1 year of age).

6.3. Preschool hearing screening

Hearing screening (age 3-4) in maternity schools is performed with pure-tone audiometry screening; however, there is no national protocol for how pure-tone screening should be performed.

7. Professionals

7.1. Neonatal hearing screening (well)

Screening for well babies is performed by nurses or nurse auxiliaries/assistants in the hospitals. Training is required per the national guideline but organized by regional networks. The length of training varies across regions. For example, a training session may be 3 hours of theory plus one half day to one full day of practical training. The training is not accredited or certified.

7.2. Neonatal hearing screening (at-risk)

Screening for at-risk infants in NICUs is performed by NICU nurses. See 7.1 for training details.

7.3. Preschool hearing screening

Screening for 3-4-year-old children in maternity schools is performed by school doctors.



8. Results: Neonatal Hearing Screening

Results for neonatal hearing screening in France were studied during the experimental program from 2005 to 2007 in preparation of national implementation. Since implementation, national data have been aggregated by InVS / Public Health France.

Regional programs are responsible for monitoring and evaluation. Therefore, data are available via annual reports specific to individual regions; however, these data represent only those individual regions and not France as a whole.

8.1. Coverage and attendance rates

In France, 100% of infants should be invited for neonatal hearing screening, though the actual percentage is unknown. The coverage rates were 98% in Ile de France region in 2016.

While attendance rate is not documented, refusal is considered exceptional.

8.2. Referral rates

Passing or referral rates for the neonatal screening on a national level are unknown.

Data from the national experimental program in 2005-2007 had a 1.8% referral rate for well-babies; however, this is not reflective of true rates, as aABR as used at each stage of screening. The referral rate for at-risk was 5% from experimental program data.

8.3. Diagnostic assessment attendance

Non-compliance after referral from neonatal hearing screening is a recognized problem in France. National compliance to referral for diagnostic assessment is unknown; however, data from the experimental program from 2005-2007 showed that 85% of referred infants comply with diagnostic assessment referral, which is 1.53% of all infants screened.

8.4. Prevalence / Diagnosis

The known prevalence values of permanent hearing loss among neonates in France is presented in Table 3 based on calculated estimates.

Table 3: Prevalence of permanent hearing loss among neonates in France (per 1000; source unknown).

	Bilateral		Unilateral	
	≥ 40 dB HL	≥ 80 dB HL	≥ 40 dB HL	≥ 80 dB HL
Prevalence (per 1000)	1.26	0.6	0.7	unknown

The percentage of infants diagnosed with permanent hearing loss in France after the experimental program from 2005 to 2007 is presented in Table 4.

Table 4: Percentage of infants with permanent hearing loss in France after neonatal hearing screening referral (2005-2007 pilot programme).

	Bilateral		Unilateral	
	≥ 40 dB HL	≥ 80 dB HL	≥ 40 dB HL	≥ 80 dB HL
Pilot programme (2005-2007)	10.8%	5%	7%	unknown



8.5. Treatment success

An estimation from the experimental program data is that 880 children per year are fitted with hearing aids and 400 children per year are fitted with cochlear implants after neonatal hearing screening.

8.6. Screening evaluation

Recent data are unavailable with regards to the false positive or negatives associated with neonatal hearing screening for well babies or at-risk babies. However, from experimental program data, the false positive rate was 1%. Recall that the experimental program used a 2-step aABR.



9. Results: Preschool Hearing Screening

9.1. Coverage and attendance rates

Information on preschool or school age hearing screening is unknown.

9.2. Referral rates

Information on preschool or school age hearing screening is unknown.

9.3. Diagnostic assessment attendance

Information on preschool or school age hearing screening is unknown.

9.4. Screening evaluation

Information on preschool or school age hearing screening is unknown.



10. Costs: Neonatal Hearing Screening

Neonatal hearing screening in France 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 been a cost effectiveness analysis completed in France.

10.1. Screening costs

Neonatal hearing screening costs around €18 per infant (including well and at-risk infants), with approximately 800 000 births per year, equating to almost 15 million euros per year. This cost includes equipment, disposables, and salaries. The cost also includes both initial screening and rescreening in the maternity ward. Rescreening that occurs outside the maternity ward costs €48 per child.

10.2. Equipment costs

Equipment costs are unknown but included in the screening costs.

10.3. Staff costs

Staff costs are unknown but included in the screening costs.

10.4. Diagnostic costs

The cost for a diagnostic assessment is not indicated.

10.5. Amplification costs

In France, all children with hearing loss are treated. Children may not be fitted with cochlear implants if deaf parents refuse this type of intervention; however, this is rare.

The total cost for bilateral hearing aids is estimated to cost around €4000. The device itself is €2500 plus an assessment, including genetics, imaging, programming is €1500. The cost of speech therapy is €500.

For cochlear implants, the cost of the first year of treatment is €31039. This includes pre-implantation (€930), TDM and MRI (€450), the surgery and implant (€26 918) and the cost of post-implant maintenance (€901). For the second year, the cost is €901. Cost data for cochlear implants are sourced from the Assistance Publique –Hôpitaux de Paris (2017).

Hearing devices and cochlear implants are fully reimbursed. Bone conductive devices are not reimbursed, especially for unilateral hearing loss.

10.6. Social costs

According to the Ministry of Health, there are 105 specialized schools in France, which may have around 5500 children. Most children with hearing impairment are in mainstream schools with special support and speech therapy. Medico-social institutions and departments of schools for the deaf support deaf children integrating into mainstream schools. Costs are not available.



11. Costs: Preschool Hearing Screening

11.1. Screening costs

Screening costs for preschool or school-age hearing screening are unknown.

11.2. Equipment costs

Screening costs for preschool or school-age hearing screening are unknown.

11.3. Staff costs

Screening costs for preschool or school-age hearing screening are unknown.



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