



Summary: Hearing Screening

China

Produced as part of Work Package 4

Date: 2019-03-18

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This project has received funding from the European Union's Horizon 2020 research and innovation programme under Grant Agreement No 733352

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.....	10
4. Guidelines & Quality Control.....	11
5. Process: Screening, Diagnosis, Intervention.....	12
5.1. Neonatal hearing screening.....	12
5.2. Neonatal diagnostic assessment.....	12
5.3. Preschool hearing screening.....	12
5.4. Intervention approach.....	12
6. Protocols.....	14
6.1. Neonatal hearing screening (well).....	14
6.2. Neonatal hearing screening (at-risk).....	14
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.....	16
8.6. Screening evaluation.....	16
9. Results: Preschool Hearing Screening.....	17
9.1. Coverage and attendance rates.....	17
9.2. Referral rates.....	17
9.3. Diagnostic assessment attendance.....	17
9.4. Screening evaluation.....	17
10. Costs: Neonatal Hearing Screening.....	18

10.1.	Screening costs.....	18
10.2.	Equipment costs	18
10.3.	Staff costs.....	18
10.4.	Diagnostic costs	18
10.5.	Amplification costs	18
10.6.	Social costs.....	18
11.	Costs: Preschool Hearing Screening	19
11.1.	Screening costs.....	19
11.2.	Equipment costs	19
11.3.	Staff costs.....	19
12.	References	20

List of Tables

Table 1: Process for neonatal hearing screening for well, healthy infants in China.....	14
Table 2: Referral rates for neonatal hearing screening (well babies) in China.....	16
Table 3: Prevalence rate (per 1000) of permanent hearing loss among neonates in China (roughly estimated).....	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	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 China, hearing screening is implemented regionally and organized both nationally and regionally. Specifically, the National Health Department designates where neonatal hearing screening should be implemented and guidelines for screening, and specifics such as tests, personnel and equipment is decided on at a regional or local level. The following report contains information with regards to childhood hearing screening across all of China.

3.1. General

The country of China has a total area of 9 597 000 km² and a population of around 1 395 380 000 as of December 2018. In China, each birth is registered. The number of live births in China was 15 230 000 in 2018 (National Bureau of Statistics of China, 2014).

The World Bank income classification categorizes China as an upper-middle-income country (The World Bank, 2018). The gross domestic product (GDP) was € 7 768 per capita in 2017 (National Bureau of Statistics of China, 2014).

From the World Health Organization (WHO) Global Health Expenditure Database, health expenditure in China in 2015 was 393 USD or €346 per capita (World Health Organization, 2018).

Infant mortality rate in the country of China was 1.4 per 1000 in 2015 (United Nations Statistics Division, 2016).

3.2. Neonatal hearing screening

In China, neonatal hearing screening is conducted universally, and participation is obligatory for parents. Hearing screening for well and at-risk babies started in 1996 and was fully implemented across the country in 2009.

In 2000, the Chinese government affirmed the significance and necessity of newborn hearing screening in the form of a law of the People's Republic of China on maternal and infant health care and began to carry out the work across the country (State Council of the People's Republic of China, 2001).

Prior to 2009, neonatal hearing screening was hospital-organized and each hospital decided on whether to implement neonatal hearing screening and how to run the programme. In 2009, the national government (Ministry of Health) implemented a scale-up neonatal hearing screening programme (Ministry of Health of the People's Republic of China, 2009; National Health Department, 2010). The goal of the scale-up programme was to gradually introduce universal neonatal hearing screening in hospitals across China.

Neonatal hearing screening is funded by regional hospitals and by parents. The cost is the same for all families, including for both well and at-risk babies, but it is not indicated. It is embedded in the Preventive Child Health Care screening system. Neonatal hearing screening is organized by the National Health Department, which designates the regions/hospitals that will perform screening.

National guidelines and screening protocol are available. Across China, the same protocol is followed for performing hearing screening; however, tests, screening professionals, and equipment are decided on by the hospitals.



3.3. Preschool hearing screening

There is no preschool hearing screening programme in China. Preschool hearing screening is not universally performed or organized. After neonatal hearing screening, follow-up is recommended, and screening may be done by a doctor in the hospital, but this practice is not embedded in the Preventive Child Health Care screening system. Any screening performed is funded by the parents.



4. Guidelines & Quality Control

There are national guidelines for hearing screening in China developed by the National Health Department of the People's Republic of China (2010).

The content of the general hearing screening programme was decided on by audiologists/ENT specialists and the public health organization (National Health Department), and there have not been any changes since the initial publication in 2009. The public health organization would make decisions on future revisions, if applicable.

Quality assurance of hearing screening programmes is not imposed by the government and information is only collected locally in hospitals performing screening. Annual reports are not available.

There has been research performed on hearing screening programmes in China (Huang, et al., 2012; Chen, et al., 2012; Tobe, et al., 2013; Chen, et al., 2017; Wenjin, et al., 2017), and articles published investigating the effectiveness of neonatal hearing screening in China (Tobe, et al., 2013; Chen, et al., 2017).



5. Process: Screening, Diagnosis, Intervention

5.1. Neonatal hearing screening

Newborn hearing screening is available in both urban and rural areas. Well and at-risk babies in urban areas are screened in the hospital or NICU. In rural areas, screening can be carried out in town health care centres or in regional medical institutions.

Parents/caregivers of well and at-risk babies are invited to participate directly in person in the hospital. Parents/caregivers of infants that are discharged from the hospital are invited to participate in screening via a telephone call. The hospital will phone the family and instruct them to perform hearing screening as soon as possible.

Neonatal hearing screening should be completed within 42 days after birth.

At-risk infants are defined as those with low birth weight (less than 1500 g), born premature (28 to 37 weeks gestation), low body weight due to malnutrition, NICU stay greater than 5 days, family history of permanent childhood hearing impairment, intrauterine infection (CMV, rubella, herpes, syphilis, toxoplasmosis), craniofacial malformation (including ear canal malformation), hyperbilirubinemia, meningitis, neonatal asphyxia, respiratory distress, ECMO, mechanical ventilation for more than 48 hours, maternal use of ototoxic drugs or drug abuse, present or suspected syndrome involving hearing impairment.

These infants are screened with the same protocol as well babies in the hospital; however, they are referred for the second step of screening regardless of the results of the initial screen.

The prevalence of meningitis and CMV in China are unknown. The prevalence rate of CMV is difficult to ascertain, as only approximately 40-60% of individuals with CMV show associated symptoms.

The target condition for screening for well and at-risk babies is a bilateral or unilateral hearing loss \geq 25 dB HL

5.2. Neonatal diagnostic assessment

The diagnostic assessment after neonatal hearing screening referral should be performed by 3 months of age according to the guidelines for all of China. Diagnosis and treatment institutions designated by the provincial health and family planning administrative department for further diagnosis within 3 months after birth.

5.3. Preschool hearing screening

As specified, there is no preschool hearing screening programme in China. Hearing testing around preschool age is performed in public hospitals, and children are invited to participate directly via a telephone call. Testing is performed by doctors.

The target condition for preschool hearing screening is not indicated.

The prevalence of chronic otitis media with effusion in China is 7.3 to 30.7% (Liu, et al., 2018).

5.4. Intervention approach



In China, treatment options available include hearing aids, bone conductive devices and cochlear implants. Infants are fitted with hearing aids from 6 months of age or older and with cochlear implants from 1-2 years of age or older.

The fitting criteria in China for a hearing aid is hearing loss of at least 60 dB HL. Children with a hearing loss from 25-60 dB HL are observed for habilitation potential, and children with a hearing impairment greater 60 dB HL are advised to wear hearing aids after 6 months of age.



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 2-step OAE-aABR/ASSR protocol is in effect, whereby the first OAE is performed in the maternity hospital before the 3rd day of life. If the infant fails the first test, a secondary screening occurs within 42 days after birth. A subsequent fail would warrant a referral to the ENT department for a diagnostic assessment.

Table 1: Process for neonatal hearing screening for well, healthy infants in China.

Test	Age	Referral criteria	Device	Unilateral Referrals?	Location
OAE	48-72 hours	Not indicated	Not indicated	Yes	Maternity hospital
aABR/ASSR	42 days	35 dB nHL		Yes	

6.2. Neonatal hearing screening (at-risk)

The screening process for at-risk infants is the same as for well infants, with the exception that all infants considered “at-risk” are referred to step 2 screening at 42 days of age, regardless of the results of the OAE test in the hospital.

6.3. Preschool hearing screening

Not applicable.



7. Professionals

7.1. Neonatal hearing screening (well)

Neonatal hearing screening for well babies is performed in the maternity hospitals by nurses or audiologists. During step 2, audiologists and ENT physicians interpret the results of the aABR/ASSR and refer for further evaluation when warranted.

There is no specific training for hearing screening staff. Audiologists and ENT physicians have 3 years of background education.

7.2. Neonatal hearing screening (at-risk)

In addition to the professionals described in 5.1, screening for at-risk infants is may also be performed by neonatologists.

7.3. Preschool hearing screening

Not applicable. Hearing testing at preschool age is performed by doctors.



8. Results: Neonatal Hearing Screening

8.1. Coverage and attendance rates

The coverage rate for well and at-risk babies was estimated to be 90% in the year 2000 (source unknown). The attendance rate is roughly estimated to be 80%.

8.2. Referral rates

The referral rates for neonatal hearing screening of well, healthy infants are presented below in Table 2 based on published literature from China (Gou, et al., 2018; Chen, et al., 2017).

Table 2: Referral rates for neonatal hearing screening (well babies) in China.

Test	Referral Rate
OAE	89-90% (Chen, et al., 2017; Gou, et al., 2018)
aABR/ASSR	86% (Chen, et al., 2017)

In total, the final referral rate to a diagnostic assessment for well, healthy babies reported is roughly estimated to be 8%.

8.3. Diagnostic assessment attendance

Out of the well infants referred from neonatal hearing screening, it is roughly estimated that 91% complied with referral and completed a diagnostic assessment.

8.4. Prevalence / Diagnosis

The prevalence rates of permanent neonatal hearing loss in China is roughly estimated in Table 3.

Table 3: Prevalence rate (per 1000) of permanent hearing loss among neonates in China (roughly estimated).

	Bilateral		Unilateral	
	≥ 40 dB HL	≥ 80 dB HL	≥ 40 dB HL	≥ 80 dB HL
Rough estimations	2	0.6		

Data for other prevalence rates are unavailable or unknown.

8.5. Treatment success

In China, it is unknown how many children per year are fitted with hearing aids. Approximately 30 000 children are fitted with cochlear implants, roughly estimated.

8.6. Screening evaluation.

Estimations were provided. The percentage of false negatives is estimated to be 0.1%, and the percentage of false positives is estimated to be 7%. Other figures are not known.



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

Screening is free of charge for parents. There is no financial reward when parents attend hearing screening, nor is there a penalty for those who do not attend hearing screening.

A couple cost analyses of neonatal hearing screening in China have been completed (Tobe, et al., 2013; Huang, et al., 2012); however, these articles represent only part of the complete analysis.

10.1. Screening costs

The total screening costs for the neonatal hearing screening programme is not known. It is estimated that each screening test costs around 100-120 RMB or €13-15.

10.2. Equipment costs

(Information extracted to protect commercially sensitive data)

Maintenance costs are variable, and devices are often replaced every 10 years. The costs for disposables are unknown.

10.3. Staff costs

Data are unavailable regarding the number of professionals performing hearing screening in China.

The annual salary for a screening professional is roughly estimated to be €7842. The total cost for training hearing screening professionals (complete university education for ENT physicians and audiologists) is €13 069, including books.

It is possible that nurses could be trained to perform hearing screening.

10.4. Diagnostic costs

The total cost of diagnostic confirmation is not indicated.

10.5. Amplification costs

In the China, not all children with hearing loss are treated due to payment problems.

Costs for amplification were provided based on rough estimations. The cost for hearing aid intervention is €1307 for the first year (with device), and €653 for additional years (including consultations). The cost for cochlear implant intervention is €19 604 to €33 981 for the first year (including device), and €653 for additional years (including consultations). Additionally, bone conductive devices cost €15 683.

10.6. Social costs

The number of schools for the Deaf and Hard of Hearing in China is unknown. It is unknown how many children attend this school. In mainstream schools, extra support is not provided to children with hearing impairment. All costs for mainstream or special education schools are unknown. A rough estimation is that the cost per child per year across all schools is €1306.



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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