

# Hearing and Vision Screening Program for newborns in Italy

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## Abstract

**Background.** The aims of this paper were to present data on the implementation and coverage of simultaneous Universal Neonatal Hearing and Vision Screening programmes and to evaluate the organization and management of these healthcare procedures in Italy.

**Materials and Methods.** Data were collected through a nationwide survey conducted in 2018. All maternity wards active in Italy in 2017 were included.

**Results.** HEARING SCREENING. Overall 427,365 newborns out of 448,386 (95.3%) received the hearing screening test (first level) in 391 out of the 409 maternity hospitals (95.5%), with a national mean referral rate of 3.63% (SD  $\pm$  4.58). A statistically significant increase ( $p < 0.034$ ) of newborns sent to audiological examination was found in maternity hospitals with Neonatal Intensive Care Unit (NICU) with “TEOAE only” protocol (9.32% SD  $\pm$  7.57), compared to those with “TEOAE/AABR” (3.0% SD  $\pm$  3.29).

VISION SCREENING. Overall 335,262 newborns out of 448,386 (74.7%) received vision screening (Red Reflex test) for vision impairment in 302 out of 409 maternity hospitals (73.8%), before nursery discharge. The mean referral rate, recorded in only 22 maternity hospitals out of 302 (7.2%), was 0.48% with a rate of lost to follow up of 0.75 %.

**Conclusions.** Our results show that implementation of simultaneous hearing and vision screening increased the coverage of both screening tests and is a new multi-disciplinary approach to sensorineural disability. The use of both ABR and TEOAE tests in the hearing screening decreases the number of newborns sent for audiological evaluation, with a notable reduction of costs.

The consideration that ocular problems are two to three times more common in deaf and hearing impaired children than their in hearing peers, confirms the importance of establishing guidelines for simultaneous hearing and vision screening, that favors the formation of a multi-disciplinary team (pediatrician, audiologist, ophthalmologist).

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## 1. Introduction

Sense organs play a key role in early child development, beginning in early fetal life and ending complete maturity several months after birth.

During the first year of life major neural networks are being formed in the brain (1).

Sensory information from the vision and hearing system are vital to children's development and support the achievement of optimal language, speech and educational outcomes (2). Studies on developmental plasticity of the neurosensorial system show that sensory activity leads to neural development, while sensory inactivity can lead to a loss of responsiveness (3).

Vision and hearing defects are the most serious forms of neonatal sensorineural disabilities with a high social impact, affecting 15.5 million children worldwide of whom 95% live in low- and middle-income countries (4).

Early detection of sensorineural defects in neonates, is crucial to vision and hearing development, cognitive, and psychosocial skills, as well as academic achievements later in life (5-11). Children with severe visual defects are at increased risk for on-going visual processing difficulties and lower IQ and these are a predictor of long-term impairments to academic achievements (6).

The implementation of a universal newborn hearing screening program (UNHS) has been recommended by the most important international organizations, such as the American Academy of Pediatrics (9), the National Institutes of Health (10), the Joint Committee on Infant Hearing (11).

The American Academy of Pediatrics recommended that all infants should have an examination of the red reflex of the eyes performed during the first 2 months of life by a pediatrician or other primary care clinician trained in this examination technique (12).

The World Health Organization and the United Nations Committee on the Rights of

Persons with Disabilities have invited various European and non-European countries to prepare specific universal neonatal selection programs for deafness and low vision, recommending that "all infants have access to screening within the first month of life according to standardized protocols" and that "States must provide early diagnosis and appropriate intervention to prevent further disabilities" (13, 14).

In Italy, a UNHS program was introduced in 2003 by the Italian Institute of Social Medicine, recently joined by the National Institute of Public Policies Innovation (INAPP Sensorineural Disabilities Prevention Research Group).

Nine national surveys were conducted in 2003, 2006, 2008, 2011, 2013, 2014, 2015, 2016 and 2017, which were the main source of information on the implementation and coverage of neonatal hearing screening in our country (15-20).

The present national survey aimed to verify the adequacy and appropriateness of the services for early prevention of sensorineural disabilities.

## 2. Materials and methods

### 2.1 Data sources

The source of the data used for the 2017 Italian UNHS and Universal Newborn Vision Screening (UNVS) survey were the statistics tables of the Italian National Institute of Health and the National Institute of Statistics, the Regional List of Hospitals activated in 2017, and the Italian Hospital Discharge Register.

### 2.2 Data collection

Data were collected through a questionnaire during the period January-March, 2018. The questionnaire was sent to all the 409 public maternity hospitals (public hospitals and private maternity hospitals active within the National Health System),

operated in Italy in 2017 and was filled in either by the chief of the Hospital or by the UNHS UNVS program coordinator.

For each maternity hospital participating in the survey, the following data were collected:

2.2.1 -Hospital profile: geographic location of the hospital; total annual births; category of newborn units (i.e., level I or basic neonatal care, level II or specialty care, and level III or subspecialty NICU (Neonatal Intensive Care Unit)).

2.2.2 - UNHS program data: number of newborns screened for hearing loss; hearing screening and re-screening protocols used; percentage of infants referred for audiologic evaluation, congenital CytoMegalovirus (cCMV) infection management, referral rate.

2.2.3 - UNHS program structure and functions: program co-coordinator and staff performing the screening.

2.2.4 - Communication: staff responsible for informing the parents about the results of the screening tests and the type of information given to parents.

2.2.5 - UNVS program data: number of newborns screened for ocular disease; red reflex screening and re-screening protocols used; percentage of infants referred for ophthalmology evaluation.

2.2.6 - UNVS program structure and functions: program co-coordinator and staff performing the screening.

2.2.7 - Communication: staff responsible for informing parents of the results of the red reflex test and the type of information given to parents.

### **2.3 Data analysis and statistical evaluation**

The present data for 2017 were compared to the previous screening survey in 2016.

The primary variables analyzed and compared were the percentage of maternity hospitals performing UNHS UNVS and the percentage of newborns screened. These

variables were compared for data grouped in five main geographical areas, i.e., North West (Piedmont, Aosta Valley, Lombardy and Liguria); North East (Trentino, Veneto, Friuli and Emilia); Center (Tuscany, Umbria, Marche and Latium); South (Abruzzo, Molise, Campania, Calabria, Basilicata and Apulia); and Islands (Sardinia and Sicily).

Statistical evaluation was done through the Chi-Square Test ( $\chi^2$ ) using the SPSS statistical software package (SPSS Statistical Data Analysis, SPSS Inc. Chicago, ILL, 2017). Statistical significance was accepted at  $p < 0.05$ .

## **3. Results**

Census period: from February to June 2018. Census coverage estimated  $> 98,3\%$ .

A total of 448,386 babies (corresponding to 96.5% of 464,281 total live births in 2017), were born in the 409 maternity hospitals participating in this survey (Fig. 1).

### **3.1 Hearing Screening**

A total of 391 out of 409 maternity hospitals (95.5%) underwent UNHS during the three days in the nursery (first level).

Figure 2 shows the coverage rate of UNHS, in 2003, 2006, 2008, 2011, 2013, 2014, 2015, 2016, 2017.

Table 1 shows the extent of UNHS screening in different areas.

Overall 427,365 newborns out of 448,383 (95.3%) received hearing screening test at first level. In the North-West area, the coverage was 98.2% (114,070 out of 116,134 births), 98.6% (83,131 of 84,087 births) in the North East, 97.7% (85,435 out of 87,431 births) in the Center, 89.6% (98,209 of 109,560 births) in the Southern area, and 90.9% (46,520 of 51,171 births) in the Islands (Tab. 1) (Fig. 3).

#### **3.1.1 Hearing screening protocol**

UNHS programs implemented in Italy are based on transient evoked otoacoustic

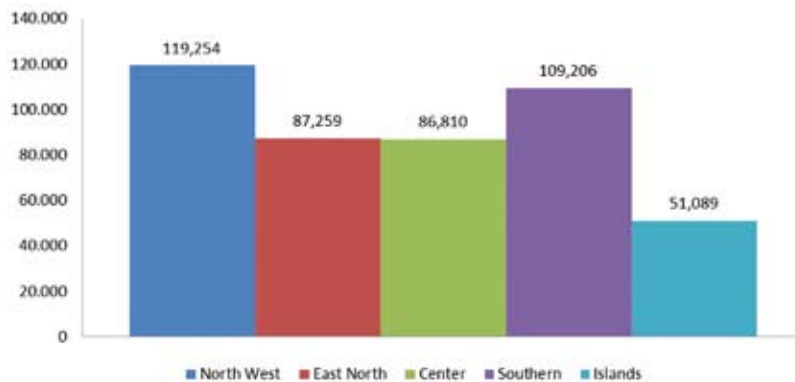


Figure 1 - Total children born in Italy for macro area. (Year 2017)

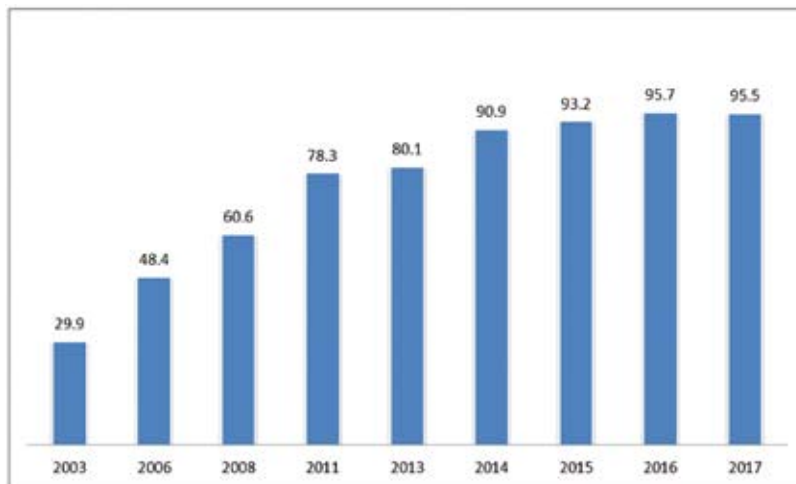


Figure 2- Increase of Maternity Hospitals performing UNHS over the years

Table 1- Coverage of Hearing Screening Program for each Geographic Area

| No. | Geographic Area | Maternity Hospitals | Maternity Hospitals with UNHS | %    | Total births in maternity hospitals | Newborns screened | %    |
|-----|-----------------|---------------------|-------------------------------|------|-------------------------------------|-------------------|------|
| 1   | North West      | 99                  | 99                            | 100  | 116,134                             | 114,070           | 98.2 |
| 2   | East North      | 70                  | 70                            | 100  | 84,087                              | 83,131            | 98.6 |
| 3   | Center          | 76                  | 76                            | 100  | 87,431                              | 85,435            | 97.2 |
| 4   | Southern        | 108                 | 96                            | 89.8 | 109,560                             | 98,209            | 89.6 |
| 5   | Islands         | 56                  | 50                            | 87.5 | 51,171                              | 46,520            | 90.9 |
|     | Italy           | 409                 | 391                           | 95.5 | 448,383                             | 427,365           | 95.3 |

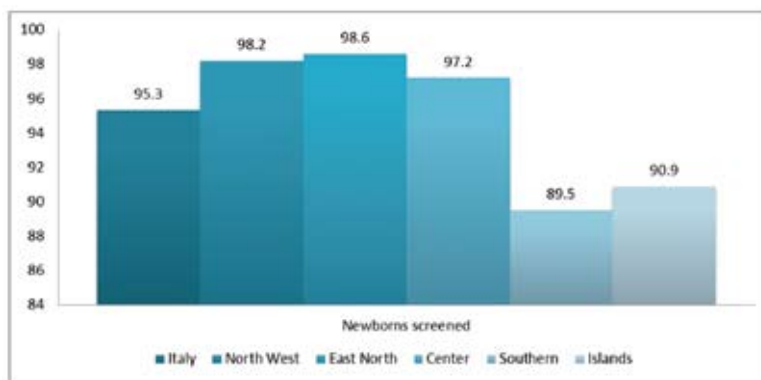


Figure 3 - Percentage of newborns screened for hearing impairment for Macro Area

emissions (TEOAE) and automated auditory brainstem response ABR (AABR). Both technologies are non invasive, provide objective measures of the health status of the auditory function, and are used worldwide for UNHS.

TEOAEs are acoustic signals generated by the outer hair cells of the cochlea in response to a train of click stimuli. The presence of a TEOAE response is a strong indicator of normal functioning of the peripheral hearing system. The ABR test measures through surface electrodes the auditory brainstem response to rapid clicks. The AABR test is based again on the acquisition of ABR responses but in this last case the presence or absence of a physiologic response is detected automatically through a template matching algorithm. The AABR test (like the conventional ABR) gives objective information regarding the status of the peripheral auditory system, the eighth nerve, and the brainstem auditory pathway. TEOAEs reflect the status of the auditory system from periphery up to the cochlea, they cannot detect neural conduction disorders or auditory neuropathy/dyssynchrony that is associated with prolonged NICU stay.

The simultaneous use of both ABR and OAE tests in birth screening provides much

more useful information than when each of these tests is used alone (11).

All national pediatric hospitals in Italy use a two stage hearing screening protocol: the first screening stage at day 2 after birth is followed by new screening test before hospital discharge if a “pass” response is not obtained from both ears; the second follow-up screening is 3-4 weeks later in the case of failure at the first stage. Children who fail the second stage follow-up screening are then referred for audiologic evaluation.

For the second screening, the babies are invited back to the maternity hospitals. This visit is connected with other follow-up procedures.

Maternity hospitals use three different technological set up to perform the two-stage screening protocol:

A “TEOAE only” set up - TEOAEs are used both in the first and in the second screening stage.

B “TEOAE/(AABR or ABR)” set up - TEOAEs are used in the first screening, followed by either AABRs or ABRs for the new screening before hospital discharge (first stage) and either TEOAEs or AABRs in the second stage screening.

C “AABR only” set-up - AABR test is used both in the first and in the second screening stage.

The “TEOAE only” is the protocol preferred by 70.8% (277 out 391) of Italian maternity hospital, followed by “TEOAE/AABR” set up which is used in 27.3% (107 out 391 hospitals), and finally the “AABR only”, which is used in 1.7% (7 out 391 hospitals).

In the maternity hospitals with a NICU the use of the two different protocols is almost equal, “TEOAE/AABR” was preferred in 51%, and “TEOAE only” in 49%.

### 3.1.2 Personnel performing hearing screening

In Italian maternity hospitals, the hearing screening test (first stage) is performed by nurses in 256 hospitals (65.6%), followed by technicians in 83 (21.4%), and finally by pediatricians 52 (13%).

### 3.1.3 Congenital cytomegalovirus (cCMV) management

Congenital cytomegalovirus (cCMV) infection remains a leading cause of childhood hearing loss. Although cCMV saliva screening in cCMV infants identifies infected infants for early monitoring and intervention, routine cCMV screening currently is not performed in Italy. In this survey the alternative approach used by maternity hospitals was investigated.

Only 21 %of maternityhospitals tested all infants who do not pass their newborn hearing screening at I level with TEOAE to

CMV DNA investigation in urine by PCR within the first 3 weeks of life.

### 3.1.4 Referral rate

During the stay in first level nurseries only 122 out of 391 (31.2%) maternity hospitals had recorded data on annual referral rate for all 152,229 newborns screened (35.6% of total).

The overall mean referral rate was 3.63%, with a wide variability from 0 to 24.64% (SD = 4.58%).

In the whole sample only 30 out of 130 (23%) maternity hospitals equipped with an NICU had recorded the annual referral rate in a standardized fashion.

4,555 newborns (out of 91,577 screened) had reported a referral test (mean referral rate = 4.97%  $\pm$  6.7%), during the stay in neonatal intensive care unit.

A statistically significant increase ( $p < 0.034$ ) of number of newborns send to audiological examination (2,663 out 28,557) was found in NICU with “TEOAE only” set up protocol (9.32% SD  $\pm$ 7.57) compared with those with “TEOAE/AABR” set up (1,892 out 63,020) 3.0% (SD  $\pm$ 3.29).

## 3.2 Universal Newborn Vision Screening UNVS

In Italy in 2017, a total of 302 out of 409 maternity hospitals, (73.8%) used universal newborns vision screening during three days in nursery (first level) (Tab. 2).

Table 2 - Coverage of Vision Screening Program for each Geographic Area

| No. | Geographic Area | Birth Hospitals | Birth Hospitals with UNVS | %    | Total births in maternity hospitals | Newborns screened | %    |
|-----|-----------------|-----------------|---------------------------|------|-------------------------------------|-------------------|------|
| 1   | North West      | 99              | 77                        | 77.7 | 116,134                             | 91,467            | 78.7 |
| 2   | East North      | 70              | 45                        | 64.2 | 84,087                              | 49,056            | 58.3 |
| 3   | Center          | 76              | 66                        | 86.8 | 87,431                              | 81,131            | 92.7 |
| 4   | Southern        | 108             | 65                        | 60.1 | 109,560                             | 67,810            | 61.8 |
| 5   | Islands         | 56              | 49                        | 89.2 | 51,171                              | 45,798            | 89.4 |
|     | ITALY           | 409             | 302                       | 73.8 | 448,383                             | 335,262           | 74.7 |

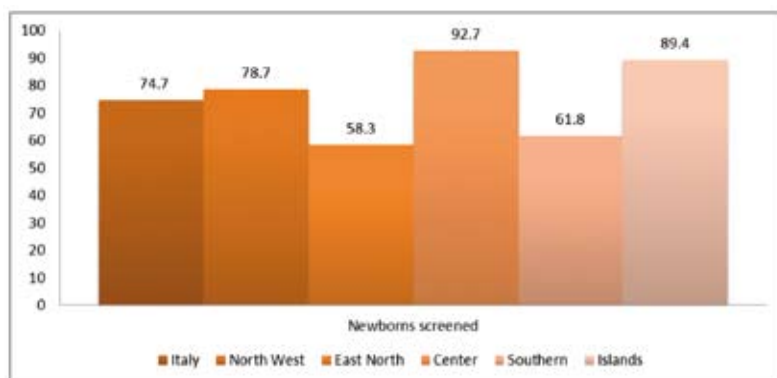


Figure 4 - Percentage of newborns screened for vision impairment for Macro Area

Overall 335,262 newborns out of 448,386 (74.7%) were screened for vision impairment.

In the North-West area, the coverage was 78.7% (91,467 out of 116,134 births), 58.3% (49,056 of 84,087 births) in the North-East, 92.7% (81,131 out of 87,431 births) in the Center, 61.8% (67,810 of 109,560 births) in the Southern area, and 89.4% (45,798 of 51,171 births) in the Islands (see Fig. 4 and Tab. 2).

### 3.2.1 Vision screening protocol

Following the recommendations of the American Academy of Pediatrics, the UNVS programs implemented in Italy are based on the red reflex test (12).

The test is performed using a light (a direct ophthalmoscope), at a distance of about 50 cm, pointing the light towards the pupil of the child. The red reflex is produced when the eyes are looking directly at the light of the ophthalmoscope that illuminates the blood-rich retina.

A strong indicator of a normal eye system is if the color of the reflection is red and identical in both eyes.

This non-invasive technique is a quick screening tool for even the most apprehensive child. A normal red reflex can rule out intraocular pathology; an abnormal reflex indicates the need for urgent ophthalmology consultation.

All national pediatric hospitals in Italy use a two-stage vision screening protocol: first screening before hospital discharge, if a “pass” response is not obtained from both eyes, children are then referred for ophthalmologic evaluation.

### 3.2.2 Personnel performing vision screening

The first stage of red reflex screening in maternity hospitals with a well babies nursery is performed by pediatricians in 81.9 % and by ophthalmologists in 18.1 %, while in maternity hospitals with NICU it is performed by pediatricians in 72.2 % and by ophthalmologists in 27.8 %.

### 3.2.3 Red reflex and pupils dilatation

Although rare complications have been reported using various agents to dilate the pupils in infants, the majority of maternity hospitals (73%) used the red reflex test in spontaneous mydriasis in a darkened room and using pharmacological mydriasis in 27%.

### 3.2.4 Referral rate

Only 22 maternity hospitals out of 302 (7.2%), had recorded data on the annual number of referrals, a total of 29,450 out 335,262 newborns screened positive (8.7% of total), at first level during the stay in the nursery.

The overall mean rate of referral was 0.48% (144 out of 29,450), and a rate of loss to follow up of 0.75 % (222 out of 29,450).

No data is available from birth hospitals with NICU.

#### 4. Discussion and conclusion

The present study is the first analysis of simultaneous hearing and vision screening to detect sensorineural impairment in children early.

The coverage of the neonatal hearing screening program had reached the required goal of 95%, while the performance indicators (referral rate in NICU) still fell below the international benchmark. There is a need to address the identified causes through more suitable protocols to identify characteristics and risk factors for NICU infants.

The implementation of simultaneous hearing and vision screening, introduced for first time in 2017, yielded an unexpected high red reflex rate (74.5%).

However, for both screenings there are still critical issues regarding disparities in coverage from region to region.

Currently, early monitoring and routine intervention CMV screening is not yet performed in our country.

An alternative approach is performed, for all infants who do not pass their newborn hearing screening at first level to CMV DNA testing in urine by PCR within the first 3 weeks of life.

In the biomedical research field, the multi-disciplinary approach has always been successful especially in the face of complex health problems.

Our results show that implementation of simultaneous hearing and vision screening, increased the coverage of both tests and is a new multi-disciplinary approach in sensorineural disability research.

A recent study indicates that in 43.6%

of deaf and hearing impaired children, ophthalmic abnormalities were found, which is two to three times that of their hearing peers (21).

This finding confirm the importance to established guidelines for simultaneous hearing and vision screening that favors the formation of a multi-disciplinary team (neonatal audiologist, ophthalmologist), who can better face the diagnostic and therapeutic challenges in relation to sensorineural pathologies.

In addition, the present study highlighted weaknesses of monitoring and control of data in our country, especially regarding the variations in the degree of completeness of the referral rates, that has an impact on national estimates and health costs (18).

The strength of this study was the employment of telephone recalling, which enabled to maximize the response rate to the survey in all Italian birth centers.

The high number of questions allowed to investigate in depth two very specific topics (hearing as well as visual neonatal screening) on a large scale and in one go, thus containing survey costs.

Not all sections of the questionnaire were always filled up though and the answers provided were sometimes unconvincing.

The Joint Committee on Infant Hearing (JCIH) acknowledged the need to standardize data definitions and reporting practices (11).

Implementation of a centralized data tracking system for each child, will improve health system efficiency.

There is a lack of data regarding national simultaneous vision and hearing screening program.

This study represents a new multi-disciplinary approach to sensorineural disability field research.

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## Riassunto

### *Screening uditivo e visivo neonatale simultaneo in Italia*

**Premesse.** Gli obiettivi di questo studio erano di presentare i dati sull'implementazione e la copertura dei programmi di Screening Uditivo e Visivo simultaneo nei neonati e di valutare l'organizzazione e la gestione delle procedure sanitarie in Italia.

**Materiali e metodi.** I dati sono stati raccolti attraverso un'indagine a livello nazionale condotta nel 2018. Sono stati inclusi tutti i reparti di maternità attivi in Italia nel 2017.

**Risultati.** SCREENING Uditivo. Complessivamente 427.365 neonati su 448.386 (95,3%) hanno ricevuto il test di screening dell'udito (primo livello) in 391 su 409 centri nascita (95,5%), con un tasso di refer medio nazionale del 3,63% (DS  $\pm$  4,58). Un aumento statisticamente significativo ( $p < 0,034$ ) di neonati inviati alla valutazione audiologica è stato riscontrato nei centri nascita con Unità di Terapia Intensiva Neonatale (UTIN), che avevano adottato un protocollo impostato solo su "TEOAE (test retest)" (9,32% SD  $\pm$  7,57), rispetto a quelli con protocollo "TEOAE / AABR" (3,0% SD  $\pm$  3,29).

SCREENING VISIVO. Complessivamente 335.262 neonati su 448.386 (74,7%) hanno ricevuto lo screening visivo (test del riflesso rosso) in 302 su 409 centri nascita (73,8%), prima della dimissione dal nido. Il tasso medio di refer, registrato solo in 22 ospedali su 302 (7,2%), è stato di 0,48% con un tasso di dispersione al follow-up di 0,75%.

**Conclusioni.** I nostri risultati mostrano che l'implementazione dello screening simultaneo uditivo e visivo ha aumentato la copertura di entrambi i test di screening, rappresentando un nuovo approccio multidisciplinare alla disabilità neurosensoriale. L'utilizzo di entrambi i test ABR e TEOAE nello screening uditivo, consente di diminuire il numero di neonati inviati alla valutazione audiologica, con una sensibile riduzione dei costi. Considerando che nei bambini sordi e ipoacusici i difetti visivi sono molto frequenti, da due a tre volte rispetto ai loro coetanei udenti, si conferma l'importanza di stabilire linee guida nazionali per lo screening uditivo e visivo simultaneo nei neonati, che favoriscano la formazione di un team multidisciplinare di esperti (pediatra, audiologo, oculista).

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