



# NEONATAL HEARING SCREENING IN ALBANIA



PROBLEMS, ORGANIZATION AND ACCESS TO HEALTH SERVICES;  
RECOMMENDATIONS

This material is published in the framework of the project “Improving life conditions of people with hearing impairment in Albania” financed by Italian Agency for Cooperation and Development and implemented by Save the Children in partnership with Independent Forum of Albanian Women.

Expert

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# **NEONATAL HEARING SCREENING IN ALBANIA: PROBLEMS, ORGANIZATION AND ACCESS TO HEALTH SERVICES; RECOMMENDATIONS**

*Position Paper*

*Tirana, June 2022*

## Acronyms:

- ABR Presence test of evoked auditory potentials of the cerebral trunk
- NUHS Neonatal Universal Hearing Screening
- HCSO Health Care Service Operator
- IPH Institute of Public Health
- J.C.I.H Joint Committee on Infant Hearing
- PHC Primary Health Care
- HC Health Center
- TEOAE Transient Evoked Otoacoustic Emissions
- TORCH Congenital infection with toxoplasmosis, rubella, cytomegalovirus, herpes simples.
- NIC Neonatal Intensive Care

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## Introduction

This document is designed for all supervisors of the Albanian health system and for health personnel who provide care for children after birth in the primary, secondary, and tertiary health care services.

Its goal is to shed light on the issue of congenital hearing loss, how to screen and diagnose it, to inform about the legal basis and the relevant protocol approved by the Ministry of Health and Social Protection and to conduct an analysis of the direct costs and economic benefits of investing in this screening program, as well as to make other recommendations for organizing the provision of this service at the regional and national level.

## I. Framework

Listening means having contact with the people and the environment around you, perceiving the voice, the words, the noises, and everything that further affects the psyche and emotions of the individual. Hearing loss is one of the most common health problems present at birth, being more common than any other condition detectable in this period of life (1).

Throughout the world, on average, 1-3 out of every 1,000 children are born completely deaf, while many others are born with milder degrees of deafness. Hearing loss of any level can occur when there is a problem in the outer and/or middle ear, which can slow down or stop the transmission of sound waves. These are: congenital defects that cause changes in the structure of the ear canal and middle ear; accumulation of wax in the ear; damage or rupture of the eardrum; objects that block the ear canal; and damage to the eardrum by numerous infections. Hearing loss also occurs when the nerve endings that transmit sound through the ear are damaged.

The causes of congenital hearing loss or early onset of hearing loss vary between countries, but at least half of these types of hearing loss are due to genetic mutations (syndromic and non-syndromic). Others suffer hearing loss during the early years of childhood (2).

The prevalence of these disorders increases up to 10-20 times in newborns admitted to intensive neonatology therapy and in infants with other risk factors (e.g. low birth weight, family history of deafness, cranio-facial abnormalities, intrauterine infections, passing meningitis, taking ototoxic drugs during pregnancy, children treated with mechanical ventilation over 5 days, etc).

While congenital hearing loss affects about 3 in 1,000 children, so does the number of children who acquire hearing impairments in the months following their birth. Hearing loss that manifests after birth is classified as *acquired*, *progressive*, and with a *delayed onset*.

There are many factors that occur after birth and that can contribute to hearing problems.

Another important aspect of deafness in newborns is the fact that about 50% of children with hearing loss do not have any known risk factors for this health condition (3). Therefore, if the screening was performed only in newborns with risk factors, in about half of them the diagnosis would be established late and, consequently, the relevant intervention would be delayed. So, the problem lies in identifying as early as possible the largest possible number of children with permanent bilateral hearing disorders.

It is important to understand that for a child, listening and speaking are essential tools for learning, playing, and developing social skills, so early diagnosis and rehabilitation are essential for them. Children learn to communicate by imitating the sounds they hear. If they have hearing loss that is

not diagnosed or treated in time, they lose the language spoken to them and communication with the people around them.

This can lead to delays or underdevelopment of spoken language and cognitive skills, leading to later intellectual and academic problems as well as emotional and social development.

Early detection of hearing loss, followed by timely and appropriate intervention, can significantly reduce and even eliminate the negative consequences of hearing loss for the affected individual, family, and the whole society (4).

## II. Screening programs and their organization

Considering the fact that congenital hearing loss is quite difficult to identify in the absence of screening tests as the child is very young, the recommended strategy to identify these newborns is universal screening for hearing loss immediately after birth (4).

Neonatal hearing screening provides early detection of hearing problems, moderate, or severe bilateral hearing disorders present at birth ( $> = 40$  dB HTL between 0.5 and 4 kHz) through a few simple tests.

Early detection and diagnosis, in this case, is a vital element in providing deaf or hard-of-hearing infants with adequate support so that they can enjoy equal opportunities in society.

Neonatal Universal Hearing Screening (NHS) is widely recommended, mandatory in most developed countries, and it consists of hearing testing for all newborns. Neonatal hearing screening programs are offered in hospitals as most births occur in hospitals. Screening procedures (screening tests) can be performed by a nurse, audiologist, doctor, or other professional trained in this field (5).

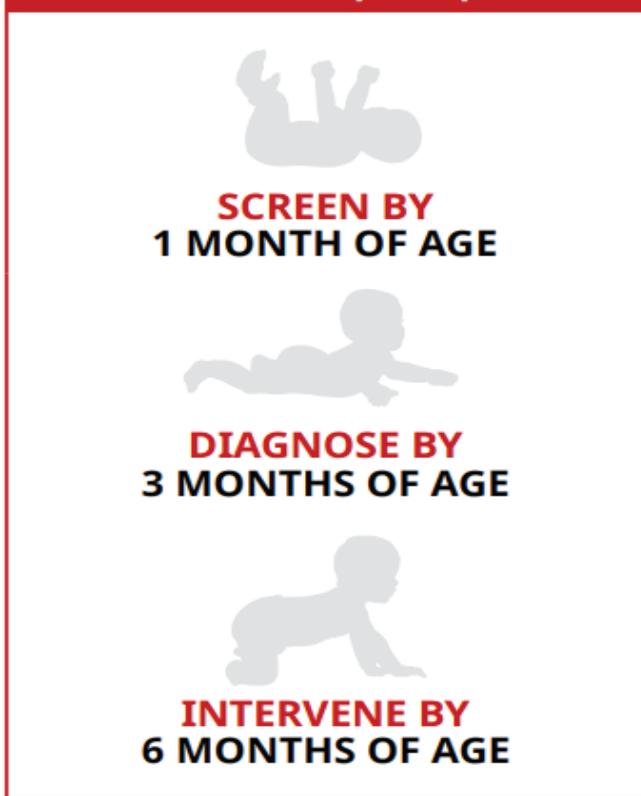
Generally, screening is performed before the baby leaves the hospital, 24-48 hours after birth, and this screening can be performed at any time of the day and in different places away from the noises of the surrounding environment (in the nursing, mother's room, or specific room for hearing assessment), which vary by the organization of the hospital departments. The screening test lasts a few minutes and is not at all painful or invasive for the baby.

Almost 50 years ago, Wilson and Junger (1968) proposed the principles of public health screening programs. These principles have been universally accepted as the basic criteria of public health screening programs and are still used today (6).

It is also recommended by the Joint Committee on Infant Hearing (J.C.I.H) that a baby should:

- ✓ complete maternity screening procedures within the first month of life,
- ✓ complete diagnostic tests within the 3rd month of life
- ✓ complete treatment interventions within 6 months of life, and these are known as principles 1-3-6 (7).

### Box 1.1 The 1-3-6 principle



(5)

Newborns who do not pass the screening test should go through a complete audiological diagnosis as soon as possible, but no later than the third month of life. Some hospitals perform diagnostic tests for infants who do not pass the screening test, while others refer infants to other institutions. Providing appropriate medical, audiological, and educational services to infants and children born with hearing problems is an incredibly complex and multidimensional undertaking.

A growing number of European countries have introduced universal screening for newborn hearing loss into their standard procedures. In some countries, screening is used nationally, which may or may not be mandatory. In some other countries, screening is carried out in certain regions at the national level.

The Joint Committee on Infant Hearing (2007, 2019) sets the evaluation criteria for NHS programs, which recommend a coverage of 95% of neonates and refer less than 4% of them for diagnostic evaluation (8).

### III. Situation in the world and Albania

The literature provides us with a good database of international reports, but also from Albania.

Sloot et al. (2015) reported that 33 out of 38 European countries implement a NHS program. In 2019, it turned out that at least 26 European countries, including some countries in the region, offer hearing screening for more than 90% of their neonates. In addition, it turns out that 98.2% of births were screened in the US; in 43 countries, universal screening of births is mandatory by law; while in other countries it is implemented even though the law has not yet been passed for approval (9).

In neighboring countries such as Italy, this type of screening was first introduced in 1997 in some of its regions, reaching in 2011 a national coverage of 78.3%. In 2017, the government issued a decree law that made screening compulsory all over the nation (11).

In 2018, the WHO declared that, based on neonatal hearing screening programs, the prevalence for Central and Eastern European countries (including our region) was 1.5%.

Meanwhile, in the Balkan region, neonatal hearing screening programs are not mandatory. In these countries, there are several hospitals that offer such programs, most with universal programs that use different screening protocols and methods; in public hospitals though, this is often missing. Specifically, in Greece, Serbia, Bulgaria, Bosnia and Herzegovina, and Croatia, there are mainly universal screening programs, while in Macedonia there are selective screening programs, but still the coverage in these countries is not high enough and the digits are very fragmented (11).

In Albania and Kosovo, hearing screening is regularly offered in some private hospitals, while in public hospitals it is offered irregularly, depending on the duration of the pilot projects. Information on the prevalence encountered in private hospitals is missing (11).

During the last 20 years, in Albania, there have been several attempts by medical professionals to introduce newborn screening for hearing as a service for young infants. Until 2008, only a few partial studies were conducted in Albania to assess the incidence and prevalence of hearing deficits.

During the period 2005-2006, specialists from the ENT service at UHC "Mother Teresa", supported this time by the University of Ferrara, in Italy, performed selective screening among 1561 newborn children with high risk factors and hospitalized in intensive care in the maternity of Tirana. (12)

In 2008, the Italian Ministry of Foreign Affairs approved and financed in Albania, through the Italian Development Agency, a project for "Early Diagnosis and Social Integration of Deaf Children" (AID 8670), which was implemented by the "MAGIS" NGO. For three years, a universal type of hearing

screening program was implemented in the 3 regions with the largest number of births such as: Tirana, Fier and Shkodra, which covered about 17000 out of 35000 births per year. A total of 47,341 neonates were tested for the presence of hearing impairment through the OAE test, with the inclusion in the screening procedures of 86% of all neonates in these maternities. At the end of this project, after completion with further diagnostic examinations (follow up), 2.32 babies per 1000 births resulted to have permanent hearing impairments (1, 14).

Another study was conducted in Tirana during the period November 2009 - May 2011 where a random sample of preschool children from 40 public urban and rural kindergartens in Tirana was examined for the ability to listen, discussions were carried out about the importance of performing screening procedures in schools, mainly for preschool children, and an audiological surveillance system was established that monitors cases of progressive deafness or those at risk for late-onset deafness, which accounts for about 20-30% of children with hearing loss. In this study, 400 children (49% male) aged 4-6 years (born during 2003-2007) were examined through tonal audiometry, tympanometry, and objective examination of the ear, nose, and pharynx to detect possible structures and/or diseases that contribute to hearing impairment as well as the collection of information on previous history of diseases of the ENT sphere and their basic socio-demographic characteristics. The findings suggested that the prevalence of hearing loss in this age group (4-6 years) was relatively high (16%) (13).

Another study conducted during 2018 in the two maternity hospitals of Tirana, Kukës and Pogradec is the EUSCREEN conducted by the Medical University of Tirana in the framework of the EU Research and Innovation Program Horizon 2020 [grant agreement No. 733352]. The protocol implemented was the same as the protocol implemented by the project we are analyzing, namely OAE-OAE-aABR. During it, in 2018, 10,925 (94.9%) out of 11,507 newborns were tested in the four regions involved. Of the 1115 (10.2%) neonates who did not pass the first test, 361 (32.4% of them) did not return for the second test, and 31 babies out of 90 (34.4%) did not show up for the third test (aABR) (14).

Finally, in the framework of the implementation of the project funded by AICS based in Tirana "Improving the living conditions of people with hearing disabilities in Albania - AID 12145", Save the Children Albania, in cooperation with the Ministry of Health and Social Protection<sup>1</sup> and institutions depending on where the project is being implemented, has performed:

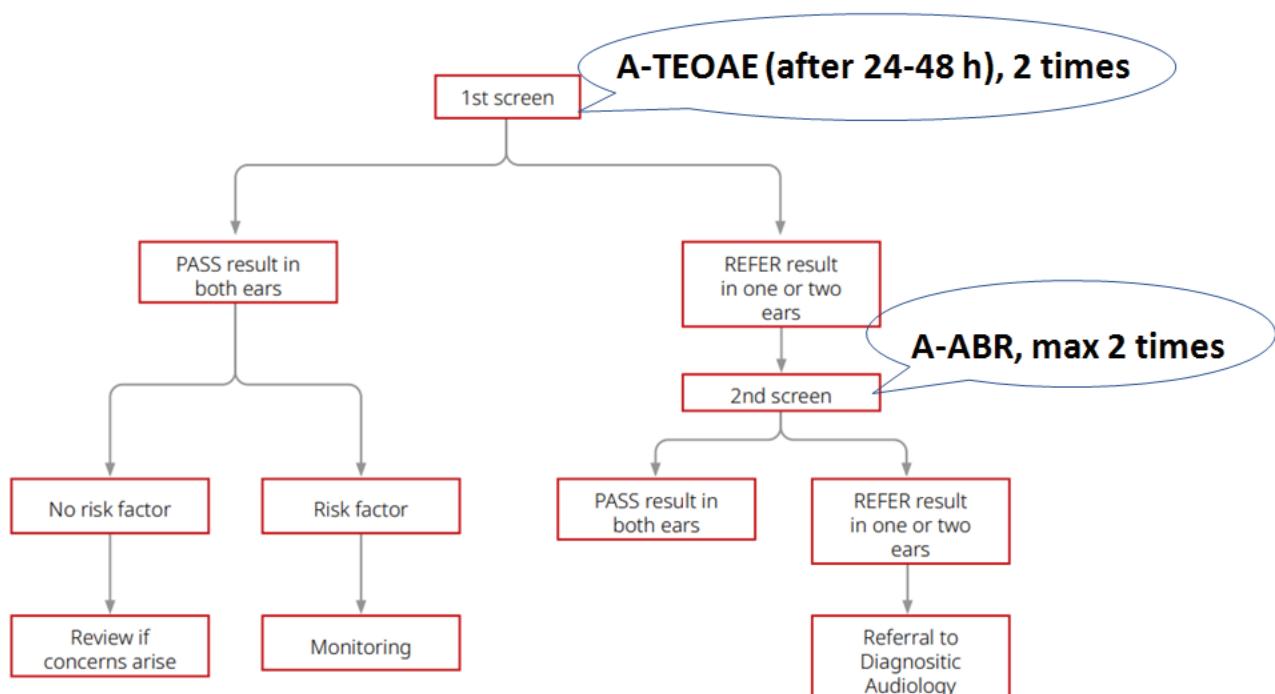
1. Technical-scientific direction and supervision of the implementation of the Universal Newborn Hearing Screening Program (NUH) and the referral system of patients from the Regional Hospitals of Durrës, Fier, Elbasan and Korça;

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1. Memoranda of Understanding have been signed with the Ministry of Health and Social Protection as well as the Regional Hospitals of Durrës, Fier, Elbasan and Korça and UHC

2. Implementation of the specialized audiological diagnostic program for newborns referred to the University Hospital Center by the regional hospitals who could not pass the screening test;
3. Implementation of the hearing prosthesis program for the beneficiaries of the screening program diagnosed with hearing impairment, according to the availability of prosthetic equipment;
4. Development of diagnostic activities, supply of prosthetic equipment, and follow-up of students of the “Institute of Deaf Students”, according to the agreement to be signed between the parties.
5. Conduct on-the-job training for doctors and nurses involved in the NUH Program.
6. Implementing an information and awareness program for families and the community on issues related to hearing impairments and treatment modalities;
7. Implement an advocacy campaign to review and update the “National Clinical Practice Protocol and Hearing Assessment for Children 0-6 Years Old”.

This project started its implementation in April 2021 and, in the duration of one year, has tested 4730 (90%) out of 5525 newborns in these maternity hospitals. Of these, unilateral or bilateral referrals resulted in 214 (4.5%) infants who were recommended to be presented for diagnosis at UHC. The



protocol implemented in this project was OAE-OAE-aABR and then the REFER uni or bilateral infants were referred for diagnosis to UHC.

So far, about 110 babies have been presented and tested at UHC, and many others have made appointments for the following months. The low number of attendees has several reasons: the pandemic situation, delays in the preparation of the audiological cabinet at UHC, or the positive reaction of infants to the mother's voice over time. Other reasons are the long distance from Tirana, travel costs, change of contact number, etc.

So far, 4 infants (0.7% of neonates) have resulted in severe hearing impairment and have been referred for prosthetics and speech therapy to experts selected by Save the Children.

On the other hand, the short time of implementation of the intervention may have affected the low number of attendees; experts say they are sure that there will be other children who will be present for diagnosis and prosthesis in the coming months.

Regarding the above, the evidence shows that the pilot projects implemented for hearing screening in newborns in Albania, have enabled not only the necessary equipment to be made available, but also the creation of the necessary scientific, financial, and administrative experience to implement such programs and screening at the national or regional level.

## IV. Strategic and legal background

The national health strategy 2021-2030, with the aim of meeting the Objectives of Sustainable Development has the vision of health protection, improvement, and promotion; Increasing the welfare and productivity of all citizens in Albania; Ensuring the provision of quality and affordable health care for the Albanian population and ensuring sustainable progress in public health and health care (15).

Investing in health systems for the entire population helps identify the best actions to improve and protect health, based on human rights, social, and cultural values, with an impact on increasing the economic, environmental, and cultural well-being of all people.

It should be noted that in Albania, maternal and child health has a strong and well-established legal basis and has been the focus of all strategies or other action plans of the health system or other non-health sectors (see Annex to Laws).

Prevention is an art form to prepare an individual with full opportunities to benefit from life and to offer these benefits even to the next generation.

So, screening for newborn hearing as a form of second prevention provides early identification of hearing loss and enables early interventions that improve language development and healthy development and well-being.

The protocol of universal hearing screening in newborns was first prepared in Albania in 2013 and approved by the Ministry of Health in 2014 as the “National protocol of clinical practice for the assessment of hearing and vision of neonates”, part of the PPK package and UPK of Child Rehabilitation and Development 0-6 years in primary health care (16).

The protocol was then revised in 2020 and by letter of the Ministry of Health and Social Protection no. 17967/1, dated 30/04/2021, with the subject “Approval of the Guide, Protocol, Information Sheet and Obtaining the Patient Consent in the Hospital for the Service of the ENT Service”, these documents were forwarded to the respective hospitals.

## V. Cost estimation analysis

Worldwide, untreated hearing loss accounts for more than 980 billion USD annually. This includes costs related to health care, education, income losses, and social costs. Many of these costs can be facilitated through the use of cost-effective interventions, such as the Baby Screening Program (5).

The reason for lifelong hearing control is well described in the first World Hearing Report released in 2021. The report shows that increasing hearing screening and early intervention over the next 10 years require an additional 1,33 USD annual investment per person. The resulting health benefit over the 10-year period would avoid nearly 130 million USD DALYs (years of life adjusted for the disabled), benefit 1.4 billion people, and lend a return of approximately 16 USD for every dollar invested (5).

This Report also recommends that WHO member states undertake urgent and evidence-based policies to prevent, identify, and rehabilitate hearing loss.

Based on WHO recommendations, rapid identification and intervention in infants is possible only through neonatal hearing screening (NHS) (5, 17).

We have currently made an estimate of the direct costs of screening and diagnostic costs, including the analysis:

- cost of human resources (in maternity and UHC, medical, and nursing staff)
- operating costs for the purchase of consumables
- staff training
- various awareness campaigns
- 5% depreciation of equipment
- 3% inflation calculated for each year

The approximate estimated values are as follows:

- ✓ For screening with the TEOAE/ABR cohort of 27 850 births/for 2021 (18), the cost is estimated to be approximately 14,122,000 ALL/year, with a screening coverage of 90%
- ✓ Considering that it is estimated that a maximum of 4.5%, or 1228 babies, go for more in-depth diagnosis with diagnostic ABR/audiometry/tympanometry at UHC, the cost for a complete diagnosis at UHC is estimated to be approximately 22,562,000 ALL/year

According to the literature, in the last 3-4 years, a significant part of the regional hospitals in the country has already been provided with the necessary facilities for hearing screening, and staff training has already taken place. Specifically, within the project implemented by Save the Children, the Regional Hospitals of Durres, Fier, Elbasan and Korça were provided with facilities implemented by OAE-aABR, and the pediatric hospital at UHC was equipped with a complete cabinet for the diagnosis of children. Also, within the EUScreen project, it was invested to facilities in 4 hospitals (2 University Obstetric Hospitals in Tirana, a regional hospital in Kukës and a municipal hospital in Pogradec) as well as a cabinet in the French hospital in UHC. So, we can say that at least 6 out of 12 regional hospitals have at their disposal the necessary facilities to provide this service in most of the country by establishing and implementing a referral system.

In order to extend this program to all regional hospitals in the country, considering that the approximate investment cost for screening equipment OAE for a regional hospital is in the amount of 1 000 000 ALL/equipment, the investment cost for screening equipment in the 6 remaining regions will be about 6 000 000 ALL.

Expenditures of the screening program at regional level for 12 regions vs the total of secondary services according to the Budget Program 2022-2023 are in the amount of 0.06% (in an increase of inflation 3% every year), according to the table below (no.1).

| Program   | Product code | YEARS          |                |                |
|---|--------------|----------------|----------------|----------------|
|   |              | 2022           | 2023           | 2024           |
| Secondary Health Care Services <sup>2</sup>   | 91304AA      | 23,055,703,000 | 23,519,703,000 | 23,278,503,000 |
| TOEA/ABR screening at maternity level   |              | 14,122,624     | 14,546,303     | 14,982,692     |
| Percentage of screening service in maternity ward vs total of hospital health care services |              | 0.06%          | 0.06%          | 0.06%          |

In total, based on equipment costs, human resource costs, consumables costs, and direct screening costs for the whole country (taking into account data from four region hospitals with three diagnostic levels for 2021 cohort babies), the costs amount to approximately 36,600,000 ALL/for 27,850 births (table 2).

2. <https://www.financa.gov.al/programi-buxhetor-afatmesem-2021-2023-faza-iii/>

These expenditures, in the percentage of total costs of secondary services according to the Budget Program 2022-2023, are in the value of 0.16% - 0.17% (in a 3%/every year inflation increase).

| Program   | Product code | YEARS          |                |                |
|---|--------------|----------------|----------------|----------------|
|   |              | 2022           | 2023           | 2024           |
| Secondary Health Care Services  | 91304AA      | 23,055,703,000 | 23,519,703,000 | 23,278,503,000 |
| Baby Hearing Screening Service  |              | 36,683,831     | 37,784,346     | 38,917,876     |
| Percentage of screening and diagnostic service vs total Hospital Health care services |              | 0.16%          | 0.16%          | 0.17%          |

Meanwhile, based on the study on cost-effectiveness measured by Cost for Quality-Adjusted Life-Year (QALY), conducted by EUScreen in 2021, which calculates not only direct costs for diagnosis, but also future costs (for patient treatment, for the timely use of hearing aids, additional costs for specific education and further family interventions, as well as gained Quality of Life (19), it results that the application of such a program is cost-effective, as recommended by the WHO.

## VI. Recommendation

- Early detection allows the initiation of early interventions, which can improve the speech, language, and social development of the child affected by this health condition. The Albanian Government, in implementation of the national health strategy and the fulfillment of the Millennium Sustainable Objectives, must be committed to continuing the provision/maintenance of this service in all regional hospitals of the country, especially in hospitals already provided with testing equipment, with staff trained and aware of the importance of this service provision.
- The managers of the regional hospitals where this project is offered should take measures to ensure that the staff are familiar with the Clinical Protocols and Guidelines, as well as for the work continuation and the regular reporting of the screening results to the hospital directorates and then to MOH. They should also set monitoring indicators for the progress of the screening program.
- We recommend that the screening protocol be unified in all regional hospitals and that measures be taken to ensure that it is rigorously applied to all newborns after the mothers have been informed about its importance and the way of its implementation.
- Establish a clear referral system that tracks the results of screening from the maternity ward to the infant/family doctor/family doctor for further monitoring. This should be done by noting it in the Baby Health Notebook that accompanies the baby after leaving the maternity ward. If the screening results are negative (REFER/FAIL), the child should be referred for a complete audiological diagnosis in the pediatric hospital at QSUT maximum within the first 3 months of life.
- In the event that the child is born outside or inside a hospital structure where this service is not provided, the Central Directorate of the Health Care Operator should organize the provision of the service so that all newborns in the country can receive this service. This would require screening to be provided in a quiet outpatient setting within regional maternity hospitals.
- Screening test can be performed on the newborn within a few minutes and the costs of implementing universal hearing screening on newborns in our country are low, so we suggest that policy-makers and decision-makers take this fact into account and find the space to fund Universal Hearing Screening in Albania as a cost-effective intervention with long-term and multi-planned benefits for children, their families, and the health system in general.

- We also recommend the continuous training and appropriate structuring of the team that performs universal screening of newborns and guarantees screening every day of the week. The training is also very valuable for the child counseling staff and family doctors.
- Like many other countries, Albania should already have programs that perform Early Identification and Intervention (EII). For the neonatal universal screening program to be effective, the health system's investments in audiological surveillance that monitors progressive or at-risk cases of late-onset deafness, which accounts for about 20-30% of children with dementia, should not neglect hearing loss and a new organization of the pediatric audiological service, so that hearing-impaired young infants and their families can be followed in a complex, systematic, and competent way. We also recommend performing screening procedures in schools, mainly for preschool children.
- In regions that have had experience with hearing screening, delays in diagnosis are often attributed to parents being uninformed at the appropriate level and/or a lack of family physicians during routine visits. Awareness campaigns dedicated to hearing loss, the reasons for its impairment in the newborn, and the importance of controlling or combating stigma, should be part of the tasks of health institutions responsible for the health education of the population and training of staff caring for the well-being and development of children.
- It is also necessary the ongoing training for specialist audiologists, audiometrists, speech therapists, audioprosthетists, etc. as these professional figures are missing largely or completely from our education and health system, in order to diagnose and treat these children early on to ensure their language and cognitive development.
- We suggest that all children with speech delays be included in regular follow-up by pediatricians through visits and questionnaires to parents, as well as referred for specialized follow-up to audiologists/ENT. This would require a mandatory training course for pediatricians on audiological follow-up of children.
- Finally, children with deafness should be guaranteed access to diagnostic and hearing aids such as prostheses and cochlear implants, so the health system should be able to offer and refund these devices.

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