National Consultative Ethics Committee for Health and Life Sciences

OPINION N°103

"Ethics and childhood deafness: consideration of information regarding systematic neonatal screening and the medical management of deaf children".

Members of the Working Group:
Annick Alpérovitch
Jean-Claude Ameisen
Pierre le Coz (rapporteur)
Roger-Pol Droit
Patrick Gaudray
Alain Grimfeld
Claude Kordon (rapporteur)
Haïm Korsia
Chantal Lebatard
Armand de Ricqlès
Philippe Rouvillois

Persons heard:
- Professor Christine Petit, Genetics of sensory deficits Unit, Neurosciences Department, Institut Pasteur
- Monsieur Jean-Louis Bancel, Member of the Steering Committee, "Le Livre Blanc: les sourds on la parole (The deaf have their say), published by ACFOS (Action connaissance formation pour la surdité), 2006.

Introduction

Society's view of deafness has changed, laboriously but favourably, in recent years. Although the teaching of sign language was authorised in 1991, it was only recognised officially as a language in its own right in 2005. This institutional recognition is taking place precisely at the same time as medical science is offering new possibilities of detecting hearing impairment and the correlative absence of oral language. Furthermore, ever more effective hearing aids (prostheses, implants, etc.) are becoming available.

These new technologies have the laudable ambition of improving a child's integration into the hearing world by developing capacity to hear and speak. However, these developments also give rise to an ethical debate that society cannot ignore. In particular, it would be regrettable if advances in early screening and audiophonology were to contribute indirectly to the reactivation of an ancient bias against deafness which, for many years, was seen as a mental handicap. Such prejudices could be propagated unintentionally by choosing screening and follow-up policies which are too restrictive for parents and deaf children, with the added risk that advances in the sophistication of screening and hearing aid techniques give rise to a public health policy that is overstandardised, too medically biased and indifferent to the human aspects of hearing impairment.

The negative perception of hearing impairment within society can undermine the principle that parents are free to make their own choices. If deafness is perceived as a severe handicap which must be diagnosed at the earliest opportunity so as to hasten the onset of treatment, do parents have any alternative to accepting what medicine has to offer? Although scientific and technological innovation is generally welcomed by public opinion, a section of the deaf population is concerned that parents' decisions could be called into question if early screening for hearing impairment policy was implemented too autocratically. They make the point that congenitally deaf people do not feel "handicapped" nor excluded from the rest of the population, that they are capable of leading a fully autonomous life by accessing the world of sign language and symbols thanks to the acquisition of a language characterised by the fact that is expressed by body and eye movement, smiles, facial expressions and gestures.

It was in this context of uncertainty regarding the direction to be followed by public health policies that the *Fédération Nationale des Sourds de France* (French national deaf persons' Federation) referred to CCNE on February 14, 2007 on the subject of early screening for hearing impairment. The Federation expressed surprise that France was "*ignoring the now global trend to cease considering impairment from a purely medical angle*". They were asking for CCNE's opinion on the risk of "*excessively early intervention*" following screening at birth. They asked the Committee how deafness should be viewed ("*a status, a sensorial deficit, or a disease*?) and drew attention to the danger of discrimination and stigmatisation of the population concerned caused by routine screening for deafness.

These concerns converge with those expressed in a referral the Committee received at the same time from the *Réseau d'actions médico-psychologiques et sociales pour enfants sourds (RAMSES)* (Medical and psychological action for deaf children network). This association raised the issue of whether screening for deafness should be performed in maternity units and clinics while drawing the Committee's attention to six French experiments on neonatal screening, "*in the absence of pædiatric psychiatrists and psychologists with competence in the field of infant health and with potentially serious consequences on early parent-to-child relationships which are crucial for the development of infants".* This referral also pointed out

that a certain number of international criteria for routine screening **such as the severity of the medical condition, the availability of treatment to prevent the onset of irreversible disorders** or the reliability of the test, were not being respected.

The two referrals[1] expressed divergent opinions on the conclusions of the Report drafted by the *Haute Autorité de Santé* (French National Authority for Health) in January 2007[2].

Another related question concerns the difficulty of replacing analog hearing aids with digital devices, which some severely and profoundly deaf people who are already fitted with analog devices, see as a dangerous step backward rather than an advance.

1. Preliminary considerations

1.1. The screening and treatment of deaf children raises ethical issues involving our cultural representation of deafness

Deafness cannot be seen as simply one of the sensory handicaps. Perceived as a communication disability, it is emblematic of the differences that challenge society's capacity to embrace, hear and understand.

The pejorative representations of deafness are perceptible in everyday language. For example, a common expression such as "a dialogue of the deaf " is a reminder that for society, deafness is synonymous with defeat, with insurmountable conflict and non-communication. The expression makes the implausible suggestion that deaf people are incapable of dialogue. This negative connotation has very ancient origins. It is not coincidental that in ancient Greek, the word *logos* means both reason and speech. The ancient definition "man alone of the animals has *logos*" puts *de facto* the deaf and mute in a situation of radical disparity. Banished to the frontiers of humanity, they hover on the edge of dementia and barbarity[3].

This Opinion cannot ignore the overall historical and cultural context, but its subject is not the status of deaf people in general. It focuses on *childhood bilateral and congenital deafness leading to difficulty in developing oral speech*. It is therefore concerned with profound and permanent neonatal deafness for which arises the question of the future fitting of a hearing aid, possibly a cochlear implant[4], in order to facilitate understanding through hearing and oralising.

1.2. To clarify the ethical issues of the discussion, two radically different situations must be distinguished:

[1] Note: The public announcement of the referral that the Fédération Nationale des Sourds de France addressed to the CCNE led a number of professionals and persons concerned by the discussion (in particular Jean-Louis Bancel and Dominique Farge) to send further information to the Committee.

[2] Haute autorité de santé, Service « évaluation médico-économique et santé publique », *Evaluation du dépistage néonatal systématique de la surdité permanente bilatérale,* Janvier 2007. Cf. en annexe 1 les conclusions et perspectives de ce rapport. (Evaluation of routine neonatal screening for permanent bilateral deafness).

[3] In Sanskrit, the root of the word for "mute" *mooka*, is derived from a root meaning "to constrain". No less significant is the Hebraic root of the word for "deaf and mute" *ilen*, which is also the root of the word for "violence", *alim*. This etymology suggests that to be reduced to silence is to be reduced to violence. He who does not respond when I speak to him, is guilty of violence. The Talmud states that someone who can neither hear nor speak cannot testify in a court of law since he cannot have a rational and objective view of the world. This is also the theme of Schlinck's book "The Reader", which depicts a woman who is employed as a guard in an extermination camp because she cannot read. Because she is illiterate, she can not, when she needs to take decisions, take any other course but to choose inhumanity and violence.

[4] Consisting of an electrode array implanted in the inner ear, a stimulator and a transmitter under the scalp, a cochlear implant is a technological device which receives , analyses and transmits sound to the auditory nerve. The device 's efficacy has improved in recent years and continues to improve, thanks to miniaturisation and enhanced sound processing. For further technical detail, see Annex 2.

- On the one hand, *a deaf child born into a hearing family* wishing to optimise the child's oral and auditory forms of communication. Despite the risks for a deaf child of educational denial or deficit, hearing parents are generally in favour of early medical management for their child.

In such cases, it is sometimes their eagerness to intervene which raises a problem. The urge to see their child's integration at the earliest opportunity into the hearing population can be fuelled by excessive trust in the power of technology, so that they adopt an overly unilateral approach, an exclusively organ-based vision of their child's deafness. It would be an error to believe that treatment consists solely in restoring a function that was accidentally inactivated. Eliminating *a priori* any contact with the world of the deaf, entirely rejecting sign language as a threat to the child's social integration and pinning all their hopes on technology and remedial surgery, would expose their child to the risk of absolute confidence in auditory restoration with the help of a device.

It is certainly true that there has been substantial technological progress as regards the management of deafness in recent years. However, it must not be forgotten that in the present state of advancement, there is no entirely satisfactory treatment. A deaf child with an implant does not become a normally hearing child. Restoration is generally incomplete and it is only through the use of auditory palliatives that the effects of congenital deafness can hope to be attenuated.

- On the other hand, *a child with a given genetic deficit born into a family of deaf people.* In this latter case, a different light will be cast on the objective. For the child's parents, the first priority for their child's integration is learning sign language, although this does not exclude *a priori* the need for access to the outside world using aids to help language acquisition. Unlike parents who can hear, deaf parents do not necessarily apprehend their child's deafness as an impediment to communication with them.

The difference between the circumstances of a deaf child, depending on whether parents are or are not deaf themselves, is therefore considerable. The only point they have in common is their concern as to whether they should give preference to one approach above another. Theoretically, a child can learn both sign language and an oral language. It would seem reasonable to consider that regardless of the parents' sensory status, it would be in the child's best interests to explore both of these dimensions of human communication. In practice, however, it must be recognised that defective information can contribute to a conflict between the two. The concept of early screening for deafness — which is viewed by some people as desirable while for others it is an unacceptable intrusion — is fraught with considerable ambiguity. It is judged to be beneficial in the first case because it can optimise medical monitoring and management of a deaf child. But in the second case it is rejected because the concept of "management" is seen as meaningless and based on an implicit devaluation of the child's status ("diseased", "handicapped", etc.), and by association, also of the parents' status. For this reason, it would be ethically reductive to deal with both situations on the same footing and the word "mandatory" ceases to be relevant, so that relations with parents could, with some justification, take account of this radical asymmetry.

1.3. Screening and fitting an aid must be considered separately:

Hastening access to cochlear implantation must not be the sole objective of early screening. The purpose of early screening is to develop a personalised management programme for the

child with due regard for the parents' biographic, psychological and social circumstances. Cochlear implants have an important, but non exclusive, role to play in the process of overall management for a deaf child. There are kinds of deafness for which they are not indicated. Their indication is total bilateral deafness, or profound (or possibly severe) deafness if verbal discrimination is under 50%. The ethical debate cannot therefore be limited to pragmatic considerations on how to prevent children from slipping through the screening net or being denied access to cochlear implantation.

2. Speech and intelligence: public perception bias regarding deaf-mute children

The concern expressed by many members of the deaf-mute population regarding the plan to carry out early and systematic screening for deafness is understandable in the light of historical data on the degrading treatment they have received in the past.
After numerous and regrettable attempts to force deaf people to hear and speak, they now aspire to respect for their condition, their freedom and their own way of life. We must not forget that, until quite recently, the idea prevailed that deaf children were not capable of developing normal intellectual capacities. The voicing of every new word was hailed as an intellectual breakthrough, even when the children could not understand what they were saying. The mark that these bitter memories left on the collective consciousness of the deaf population cannot be ignored.

That is why the primary ethical attitude is to pay attention to the testimony of deaf people when they say that their social and intellectual quality of life is in many ways comparable to what is enjoyed by other members of society[5]. The social interaction, relational development and cultural well-being of deaf people probably compares favourably with some of our fellow citizens suffering from loneliness and neglect.

To speak of deafness as "de-socialising" or as a "cognitive development disorder" is to confuse language with speech (which only one of the possibilities of expressing language). It has long been accepted that the human capacity to work with symbols and to communicate consists of — as Descartes demonstrated not a short while ago — "manipulating the signs of language", that is to associate arbitrary and conventional signifiers (sounds, graphics or gestures) to a purely mental signified (idea, concept, etc.).
This concept of the link between language and intelligence is shared by 80,000 profoundly and congenitally deaf people for whom signed language offers a broad range of possibilities to express with precision the content of emotional experience or states of the psyche. Listening to an interpreter translating the message expressed by a deaf person signing is proof enough that it is possible to speak as fast with hands as with a voice and to understand and use as many concepts as in any other language. The so-called "intellectual deficit" induced by bilateral deafness is for that matter denied by the fact that when they are properly educated, deaf-mute children are capable of reading, writing and engaging in higher education. It is the absence of access to appropriate schooling and not congenital deafness that explains the intellectual deficit suffered by some deaf children.

[5] The pleasure and enjoyment derived from learning sign language is often overlooked. An Austrian study ten years ago, showed that the perception of their physical, psychological and professional condition by those who are congenitally deaf or with hearing loss, was very comparable to the quality of life enjoyed by the population at large, even though they recognise that life is more difficult for them than for people who are not hard of hearing. The deaf who use sign language have many friends, lead an active social life, organise festive occasions, conferences and meetings which compensate for the initial obstacles to good quality of life. However, the quality of life of people who have lost their hearing is less satisfactory as they feel that they have suffered a loss of their capacity to express themselves leading to frustration and moral distress.

Because of the absence of cognitive and communication disorders, parents whose child has inherited their own hearing impairment do not generally consider audition and oralisation defects as a handicap to be overcome. For this reason they are reluctant to view the interventions proposed by post-natal medicine as being "treatment". For the same reason, they find it perplexing that public health authorities keep recommending the inclusion of early and systematic screening programmes into French procedure. Parents of deaf children feel justified in detecting as the background of this type of programme the classic bias that cognitive and psychosocial development is dependent on oral training. The idea central to early detection of deafness is that the earlier deafness is known, the quicker action can be taken, concentrating efforts on oralisation through prostheses and implants. As Benoît Drion remarks "*The great majority of deaf people are vehemently opposed to this type of screening. When they are asked for their reasons, it transpires that it is not so much the screening itself which bothers them as the healthcare programmes that are its natural follow-up and point in the direction of cochlear implants*"[6].
It would be untrue to say that all ENT doctors burn with the urge to enrol a deaf child into a healthcare programme. However, the problem cannot be broached in its full complexity while ignoring the beliefs, the representations and the concerns that are still very much alive in some quarters because of the occasionally unreasonable efforts, deployed in the course of the last two centuries, by the medical professions seeking to bestow hearing on the deaf.

In effect, the social importance of orality may have obscured the value of signed communication. Focused on the oral form of communication, a certain number of healthcarers — and non-deaf parents — were less attentive to the interactive capacities of very young children, to the quality of their visual communication, to their non-verbal body language and possibly to their difficulties with reading.

As a result, profoundly deaf children were kept away from institutions and associations which could have enhanced their sign language acquisition capacity, so that there was a risk of leaving lastingly unexploited their capacity to communicate. As the delay in learning sign language is increased, there is a proportionate increase in the risk of trapping the deaf child in a position of inferiority compared to a hearing child. If the process is institutionalised, the delay in learning to communicate is aggravated instead of being improved. Adult deaf people who were subjected to education focusing on auditory and speech development — during the 100 years when the French sign language was prohibited — are able to testify that this denigrating perception of deafness was more of a handicap than their sensorineural deficit itself. It is easy to imagine the discomfort experienced by a deaf child known by the doubtful label: "hearing-deaf" (sourd entendant).

3) Ethical issues arising out of systematic neonatal screening

The ethical issues are different depending on whether parents themselves are or are not deaf:

- <u>In the first case, which is the majority (90%), of children born into a hearing family,</u> the question of screening does not arise as such. The only remaining question is when. In earlier times, contact between the mother and the maternity unit medical team was sufficiently prolonged to allow for more than just a short talk to explain test procedures. There was time enough to provide counselling to deal with the psychological consequences of the diagnosis. But today, the circumstances in which a child comes into the world are not what they used to be. There has been progress on sanitation and safety, but regression in terms of human

[6] Drion B., « La traversée du miroir », in *Ethique et implant cochléaire, que faut-il réparer ?*, Presses Universitaires de Namur, 2006, p. 26

contact and interaction. Announcing too early that a child is profoundly deaf in this context is all the more unacceptable because a premature test can be inaccurate. At this point, the most extreme precautions must always be taken when informing a mother of a diagnosis of deafness. This dehumanising violence attached to automatic screening is even more incomprehensible when there is no urgent need for any immediate somatic treatment. In other words, the consequences of screening for total or profound bilateral deafness can in no way be compared to the consequences of screening for diseases for which any delay in diagnosis may have immediate and serious outcomes. It should be regarded simply as a preliminary *exploration* designed to enhance the quality of parental guidance by a speech and language therapist and psychological support in the few weeks following birth. If deafness is suspected during the neonatal period, the audiophonological test should be repeated two days later, then again two weeks later and at the latest, at two or three months; at which time the risk of a false positive is almost nil[7].

In the case of deaf parents, systematic neonatal screening may seem intrusive.
Understandably, since the population of deaf people has been exposed to a long-established tradition of prejudice, coercion and stigmatisation, the prospect of making neonatal screening for deafness mandatory meets with a degree of reluctance. Unless this history of social exclusion is brought to mind, it is impossible to comprehend that, confronted with the "remedial" approach to deafness, a section of the deaf population is tempted to put forward a "socio-cultural" approach and refuse a definition of deafness equivalent to a *deficit* requiring a *therapeutic* approach.

However, although the historic background of the status of deaf people, as well as the erroneous suspicion of a deficit are ample justification for a scrupulous, prudent, vigilant and humble approach, as the Committee has had occasion to recall in a recent Opinion on screening for genetic diseases[8], the main criterion justifying postnatal decisions must in every case be the child's direct interest.

It is again the child's interest which much serve as a guiding principle for any consideration of whether universal screening for permanent deafness with neonatal onset is appropriate. Is there a danger that the attempt to improve the condition of the congenitally deaf child actually aggravates it? Is a medical team practising an early screening test for deafness at the child's place of birth transgressing the ethical principle of 'not doing harm' which is the very foundation of medical practice? In any event, neonatal screening does not solve every aspect of the problem.

In its referral document to CCNE, the French Federation of the Deaf underlines the dangers of a public health policy based on generalised screening for deafness at birth. It is not so much the very principle of screening that is questioned, as the conditions of its implementation. Along the same lines, the RAMSES Association considers that the brutality

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[7] Apart from the risk of needlessly compromising the quality of the child's initial contacts with his parents, the strategy of screening in the birth clinic is fraught with serious difficulty:
- The risk of false positives (mistaken suspicion of a non-existent deficit) is much greater in the first few hours of the life of a baby. According to current estimates, numbers are:
- 1/ 1.5 to 5% of cases under study, using the otoacoustic emissions method (duration of the test: 3 to 4 minutes);
- 2/ 1% of cases under study, using the automated auditory evoked potential method (duration of the test: 6 to 7 minutes and slightly more expensive equipment).

This means that currently there are likely to be 8,000 to 40,000 unfounded suspected cases per year in France, i.e. 90 to 98% erroneously diagnosed auditory deficiency in children who are tested, whereas 800 to 1000 per year are really deaf. This number of false positives drops very sharply when the newborn tests are repeated a few days later.

[8] CCNE Opinion n° 97 on Ethical issues arising out of the delivery of neonatal genetic information after screening for genetic disorders.

of an announcement immediately following a child's birth ("your baby may be deaf") introduces "*a major risk of generating psycho-pathological childhood disorders and obstructing the development of language*".

There are no scientific publications to support this statement, but it can rely on empirical observations by specialists on infant health and by experts on the emotional processes of bonding in the period of time when early mother and child relationships are still very fragile. The RAMSES Association points out that "*puerperal psychotic decompensations or severe post-partum depressions may occur at this time*". The disruptive effect of announcing the existence of a communication handicap at this point could have "*a pathological outcome in the short or long term*" and all the more so since there is no certainty that neonatal screening would be followed by appropriate psychological counselling.

The possibility that the psychological repercussions for the newborn of a premature deterioration of the emotional climate of birth could be underestimated is a legitimate concern which furthermore draws attention to the fact that the process of screening for congenital disorders in a very young child raises issues which are not purely technical and medical. *In fact, it is precisely this inclination to oversimplify and view this practice as a simple medical and technical management problem which raises the ethical question*: what are the benefits that can reasonably be expected from neonatal screening for deafness? To steer clear of setting up a routine, impersonal, one-size-fits-all screening procedure, the objectives must be set out with extreme precision.

The ethical dimensions of the problem were pointed out by the European Group on Ethics in Science and New Technologies to the European Commission in its Opinion dated March 16, 2005[9]. The Group stated that "*The technological drive to promote cochlear implants raises ethical questions concerned with how this drive impacts on the individual and on the deaf community (and on the signing community in particular)."* Among the symbolic impacts induced by the insertion of congenital deafness into the national policy for neonatal screening, should be mentioned the listing of deafness in the category of "severe impairments" alongside with phenylketonuria, congenital hypothyroidism, sickle cell anæmia, congenital adrenal hyperplasia and, more recently, cystic fibrosis. By the same token, deafness becomes "a public health problem" (the prevalence of total or profound deafness with neonatal onset is 1/1000). In view of the indiscriminate therapeutic policies and abuses of the past that are mentioned above, the deaf population's unease concerning the symbolic meaning conveyed by this categorisation comes as no surprise.
CCNE draws attention to the possible psychological impact of certain classifications when they are used in reference to screening for deafness, ("severe impairment", "handicap", "public health problem", etc.) on a population whose social recognition is still fragile and imperfect (in France and almost everywhere else worldwide).
The European Group on Ethics recommendation to pay attention "*to the psychological, linguistic and sociological issues*", in order to avoid too conventional an approach to normality, seems to be well advised in the circumstances.

However, despite the difficulty of arriving at an objective definition, it would be wrong to conclude that the notion of handicap is purely subjective. Communication with others is not simply a possibility that may be added to the life of a human being. We do not become human alone; it is our relationship with others that makes us human. Since the absence of

[9] Ethical aspects of ICT implants in the human body, EGE, rapporteurs: Prof. Stefano Rodotà and Prof. Rafael Capurro; ec.europa.eu/european_group_ethics/archive/2001_2005/activities_en.htm

any possible oral communication deprives deaf people of one of the major resources of inter-human communication, it must be allowed that efforts to develop a child's auditory potential are based on genuinely ethical intentions.

Moreover, the fact that someone with a sensory disability does not have an intimate perception of it is no reason to refrain from any attempt to attenuate or remedy its effects. For that matter, pædiatricians and ENT doctors can testify that some deaf couples consult them on whether they should consider a hearing aid for their deaf child.

There should therefore be no confusion between recognising fully the dignity of sign language and viewing deafness as simply a distinctive sensory characteristic. It is certainly possible to argue that deafness is not a *handicap* as such, but it can hardly be denied that it is a deficit with leads to a *situation of handicap*. Can it be ignored that it does deprive a person of the capacity to communicate with the overwhelming majority of his or her fellows? Auditory deficit creates a situation of handicap as regards the practice of the oral languages used by 99.9% of people in a given society and renders inaccessible all the realms of music.

Removing that situation of handicap created by bilateral auditory deficits would suppose that sign language is learned by every child in every school. This does seem rather unlikely since motivation to learn a language is always proportionate to the frequency of possible use of that language.

The legitimacy of a screening programme in France is all the more justified because the *average age of diagnosis for profound deafness is currently much too late* (16 months, since 1987). Added to the direct prejudice to their child, a delayed diagnosis can cause a great deal of emotional distress for some parents who feel guilty that they were unable to detect earlier their child's hearing impairment.

It will probably always be difficult to arrive at a consensus on the best time to screen. Some experts on early childhood consider that the relationship between children and their parents should not be disturbed prematurely by a traumatic diagnosis that cannot lead to any immediate treatment. Others consider that these efforts to protect parents from plain facts can be detrimental to the child's best interests which must be and always remain the central consideration. The alternative to conventional medical paternalism is enlightened psychological paternalism.

4) The decision to use a hearing aid: the parents' decision, the child's best interests

Should screening *ipso facto* lead to fitting the child with a hearing aid? Clearly, the progress in techniques available to correct auditory deficits was the development that led public health authorities to recommend neonatal screening today. But the object of the screening test does not reside solely in evaluating the need for a hearing aid or the time when one should be fitted. It also serves to evaluate the child's auditory capacities, as early as is necessary. It the test is taken too early and the result is positive, the screening procedure may well be an inopportune intrusion into the parental relationship. Too late, however, is there not a risk of delaying unnecessarily the fitting of an aid or of an implant? Some practitioners deplore that out of 1,500 new cases of deafness (of all kinds) diagnosed every year in France, less than a third of the children for whom this is a therapeutic indication are fitted with a cochlear

implant[10]. Very much on the same lines, the authors of the "*Livre Blanc sur la surdité*" (White paper on deafness), warn that "if residual auditory function does not receive very early stimulation, learning language is irreversibly delayed: hearing in the first two years of life is a condition for normal language acquisition"[11]. A delayed diagnosis is therefore an evident loss of opportunity for the child concerned.

The question arises of whether refusal by parents to accept implantation for their child (regardless of their own sensory status) when it could facilitate access to oral expression, should not be regarded as depriving the child of facilities which could enhance relational development. We have of course already mentioned the pernicious error which consists in reducing language to the use of the spoken word and correlating an individual's degree of intelligence to his degree of hearing. And yet, is not access to speech, for all human beings, a way of diversifying their palette of interaction with the environment?

There are sensitive periods for the construction of a language, be it spoken or signed: around a year and a half for phonological representations; from 2 to 3 years of age to elaborate a grammatical system; around 5 or 6 years of age to acquire an extensive vocabulary and create a hierarchical organisation of the lexicon. It is therefore important to understand that delaying the time when a cochlear implantation is made is a serious decision. In any event, the offer made to parents to resort to an implant is justified in view of the advantages for some of them to be aware of the sense they wish to favour to optimise communication with their child (sight in particular). Early knowledge of their child's deafness gives such parents the possibility of themselves learning sign language at the earliest opportunity, thus serving their child's best interests.

The decision to fit a child with a hearing aid must, in the final analysis, be taken by parents who must choose the treatment which they consider to be most appropriate in the particular case of their child. Different problems arise in making this decision, depending on whether the parents of deaf children are deaf themselves. If they are, they may have doubts regarding the benefit their child could derive from a hearing aid or a cochlear implant, particular at this early stage in the child's development. Such reticence is linked to the difficulty in recognising in their child a "handicap" (or a "pathology") which they do not recognise in themselves.

The ethical issue arising out of a refusal to accept a hearing aid is therefore limited to a relatively restricted population, since over 90% of profoundly deaf children's parents live in the "hearing" world. Parental decision in the event of a medical offer of cochlear implantation is therefore based on the principle of informed consent.

It is essential that parents be informed of the risks of the operation, of the investment demanded by the follow-up, adaptation and also uncertainties regarding the chances of success. Added to the classic risks of surgery (and those of anæsthesia to begin with), are more specific risks connected to the in-dwelling intrusion of a technological device in a sensitive area of the child's body. Information to parents must include the facts that implants are battery-powered and need to be changed or recharged quite frequently in the present state of the art and that technical advances will certainly be modifying currently available techniques so that their child will have to adapt to them at some time in the future.

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[10] Cf. on this debate the interview with Prof. Bernard Meyer in *Le Quotidien du Médecin, N°8119, Tuesday March 6, 2007* in the article *« L'implant cochléaire a 50 ans : l'IFIC à l'écoute des patients ».* ("50 years of cochlear impants: IFIC hears the patients".)

[11] *Le livre blanc sur la surdité de l'enfant. Les sourds ont droit à la parole,* (White paper on childhood deafness. The deaf have a right to speak). ed. Acfos, Action connaissance, formation pour la surdité, 2e éd., Paris, nov. 2006.

How should members of the medical professions concerned react when confronted with parents who reject any treatment for their child because they consider that for themselves, deafness is neither a handicap nor a pathology? What should be said to those who consider that "correcting a deficit" conceals a lack of respect for differences?
The Committee considers that in such a case, respect of their autonomy must be the rule. Fitting an aid can no more be forced than can be screening. Unless parents are willing to undertake the wearisome follow-up procedures after a cochlear implant, the outcome is bound to be a failure. All the more so since an error of indication can never be excluded. If for example, deafness is not an isolated symptom but only one part of a more complex genetic syndrome that is not discovered immediately, the cochlear implant might well turn out to be a useless or inadequate hindrance that disturbed the child's development unnecessarily.

Generally speaking, the possibility that the apparatus could turn out to be an inappropriate indication for a particular child should be sufficient deterrent to exerting any pressure on parents (or even legal interference as a last resort, in the name of protection of children's welfare).

This does not mean that healthcarers must give up any notion of discussion with parents who are reluctant to accept a prosthesis or an implant. Respect for the principle of autonomy does not absolve the medical profession from accountability. All the issues must be brought up in unhurried debate with the parents. Could the rejection of implantation compromise the child's future? Could the child blame those who took the decision in his stead for having deprived him of the scientific and technical possibilities that were available for a different kind of integration into society? Seen from that angle, does respect for the parents' decision lead to confiscating the child's freedom? Is it possible to presume that the child would have consented to the parents' rejection of diagnosis or therapy?

It is true that the evidence seems to point to the fact that the earlier they are fitted (6 months to a year), the better deaf children are capable of intelligible speech. Some people are of the opinion that the auditory benefit of a cochlear implant is enhanced if it was preceded with a specifically targeted stimulation of the cerebral areas concerned [12]. Nevertheless, fitting a child with a device at the very beginning of life is not a trivial procedure. Subjective and relational elements play a part. Today's deaf adults sometimes complain that their childhood was taken away from them so that "speech could play a primary role". They have had to submit to the burden of medical follow-up and intervention, genetic counselling, urgent calls to consult a surgeon, non-stop education and rehabilitation as and when implants needed to be adjusted.

Confronted with this intrusion of medical technology in the relationship between children and their parents and relatives, the importance of the quality of life in the first few years and its repercussions later on must be kept in mind. Early fitting of a device can cause pain and distress for both parents and children. Even if they do notably improve hearing, implants cannot be trivialised and viewed in the same light as a simple prosthesis to remedy a functional failure[13].

5) When and how to screen and consider using a hearing aid?

[12] Govaerts P., et al., *Outcomes of cochlear implantation at different ages from 0 to 6 years.* Otol Neurotol, 2002; 23; 885-890

[13] A prosthesis amplifies sound, but the implant bypasses the natural auditory channel and electrically stimulates living matter, transforming nerve centres and giving them new capabilities.

Because of the diversity of questions raised by the evaluation of auditory capacities, the optimal time to do so is still open to controversy and the subject of contradictory discussion:

- Concerning the systematic nature of neonatal (or prenatal) screening, CCNE has already make known its opinion on possible adverse effects, in particular in its recent Opinion on screening for heterozygosis in cystic fibrosis (Opinion n° 97). Systematic practices end up becoming a routine and expose parents of the child being screened to normative judgemental opinions by members of the medical profession if parents happen to reject or question the standard procedure. The evaluation of auditory capacity differs from other types of screening. Furthermore, it would be a mistake to consider than an auditory deficit is like a disease with a preventable outcome.

- The main justification for neonatal screening is a practical consideration, i.e. that it would represent, taking into account the current organisation of our healthcare system (in particular follow-up deficiencies) the safest way of taking care of all children. Mothers and their newborn babies are both present and available. Should the time spent in the maternity unit be taken as an opportunity to test and be sure the child is not lost to screening? We all know that the time spent there is extremely brief and ill-suited to counselling on any kind of screening. The *later* interview which the perinatal project includes in the protocol should make it a more effective process, but unfortunately, the protocol is seldom applied. Systematic use of the later interview would therefore seem to be all the more necessary since the average initial stay in the maternity unit has been drastically shortened (early screening for many disorders would be much facilitated if the initial stay had been kept at 4 to 7 days). If auditory deficit is found, there should be a check before leaving hospital involving a longer stay for the mother.

- The difficulty that a mother has in consenting to systematic screening in psychologically distressing circumstances cannot be ignored since, if deafness is in fact discovered the test does not lead to any actual therapeutic action until several months later. For example, the time which is currently considered to be most appropriate for performing a cochlear implant is between 9 to 10 months or a year. There is therefore a long period of latency which, in the opinion of all non deaf parents who have had to deal with this situation, a particularly stressful experience, particularly in the absence of any parental guidance programme.

However, these criticisms of the neonatal screening process are not decisive. Some arguments could put them in perspective:

- Information on the evaluation of auditory capacity at birth could conceivably be given to parents *earlier on, in the prenatal period,* so as to mitigate the "thunderbolt" effect when announced immediately after birth. Information about a risk is always a source of anxiety, even in the event of a potential risk with a low probability (1/1000). It is therefore important to associate the information with reassurance regarding the possibility of early audiophonic or orthophonic treatment, generally effective when parents favour the strategy of fitting the child with an aid.

- Although early knowledge of the child's hearing impairment can disrupt the relationship with parents at a critical stage, the trouble avoided early on can reappear in just as distressing a form in a later phase of the child's development. The natural spontaneity of communication may be blighted, but it can also be improved in the longer term by better adjustment to the transmission of the messages that parents wish to send to their child. Founded on lucidity,

exchange with the deaf child can be more carefully aligned with touch and vision. Parents can communicate via lip movement, thus facilitating their child's later approach to lip reading. There is also the possibility for them to learn sign language so that they can communicate using gestures in the first few months of their child's life.

The manufacture of implants has made great progress in recent years, in particular through combining electrodes capable of transmitting signals of specific frequencies to others capable of breaking down these frequencies according to the Fourier analysis principle. But the results, although they are considered in some quarters to be "the most effective form of neural prosthesis" available today, are far from perfect. They give access to learning phonation, but with differing degrees of intelligibility depending on which language is being used, and they are still ill suited to the restitution of music. New technological developments are under way and they can be expected to improve still further the performance of auditory prostheses.

The question of the safety of cochlear implants is also worth raising. Even though fatalities in association with this technique are rare, the risk of infection or even meningitis in implanted children cannot be excluded. In this connection, the Committee points out that, as is the case for any surgical procedure involving a minor, cochlear implantation requires consent from *both parents (sometimes with discrepant auditory capacities)*.

Finally, it must be emphasised that, increasingly, digital prostheses are replacing their analog counterparts, so that the industrial transformation resulting from this transfer compromises maintenance on older models. This perverse effect of technological progress can lead to considerable discomfort, and sometimes a risk of auditory confusion, at the time of transfer from one generation of device to the next. Complaints from people concerned by the disruption seem to indicate that manufacturers and the authorities are not considering the consequences of this change. It would be regrettable if market forces were to be the sole judge of the advantages of a technological advance without obtaining input from those concerned or their associations on the complexities of various situations.

Generally speaking, the accelerated evolution of technologies raises another *sui generis* ethical issue as regards in-dwelling prostheses, implants or their equivalents. At a time when new generations of technological devices are being developed, inter-generational (both structural and functional) compatibility must be ensured between these new devices and the permanent part of the implant which is the technological/biological interface (that will never be changed for people with lifelong implants). Incompatibilities would be unacceptable between successive standards as has been the case in the past, from one generation to the next, for interchangeable photographic lenses or connectivity between computers and peripherals (3 years on average).

6. Summary

- The authorities must fully assess the extent of the current diagnosis delay which would be the justification for a national awareness raising campaign aimed at professions specialising in early childhood care, parents and parents to be.

- In opposition to certain healthcarers inclined to reduce deafness to its purely mechanistic and neurological dimensions, and therefore to underestimate the relational and psychological aspects, there is sometimes a community-based trend claiming that

auditory deficits are no more than a simple cultural particularity. Nevertheless, a brief review of the customs and appurtenances of daily life is sufficient evidence of the integration problems that deafness imposes on those concerned. Deafness is not an identity freely selected in the midst of a multicultural society. It is a component of an identity but cannot alone embrace the rich complexity of a person's identity.

- While due respect must be given to the rights of parents to choose the treatment offered to their child, and with due regard for the practical, ethical and legal difficulties that could arise out of imposing an external decision on parents in the absence of any life-threatening situation, CCNE is of the opinion that some regard must be given to ensuring that children with total or profound bilateral congenital deafness are not deprived of their right to treatment which can preserve their capacity to communicate with other linguistic communities. Not providing treatment for a sensory deficit at a time when it can be helpful is an irreversible loss of opportunity for a deaf child. So that deafness does not inhibit communication, the necessary information and education must become available much sooner than is now the norm, i.e. 16 months of age on average.

- Rejecting an appropriate hearing aid (prosthesis or implant) compromises the acquisition of verbal language if it then begins beyond two years of age. The ethical principle which must apply is that of equity for children, that is respect for their right to benefit fully from medical progress.

- CCNE insists on the need to remember the lessons of the past in order to gain a better understanding of the apprehensions of deaf persons and the need to *involve them in healthcare decisions*. Neglecting the symbolic and psychological effects of what is said or done, maintaining confusion between language, speech and intellectual capacity, would be the continuation of an ancient tradition of mistreatment. Deaf children and their parents deserve more respect for their dignity, their singularity and their liberty than is the case today. This evidence of respect would give them the feeling that they can, at any time, change their minds as a result of ongoing experience and information on new evaluations and technologies.

- This does not mean that the Committee subscribes without reservation to the opinion that wearing an implant has a negative impact on the deaf community and the capacity of deaf children to become an integral part of it. This would be tantamount to formulating the problem at the outset as an alternative: *either* a technical substrate, *or* learning sign language. As a previous CCNE Opinion pointed out (Opinion n° 44) *hearing aids and the learning of sign language are complementary and should be combined.* **It may be regrettable that the recommendations contained in the above Opinion have not been acted upon** despite the fact that the outcome of schooling and higher education for the deaf in Scandinavian countries pleads in favour of bilingualism.

- *Screening and its consequences are only meaningful if effective follow-up measures are also instituted.* The medical and psychological follow-up of deaf children and its funding are public health priorities. At present, the prerequisites for *medical* follow-up exist since it is now possible to determine with reasonable precision the time slots during which fitting with a prosthesis or an implant will be effective. But the provision of psychological assistance needs to be improved and practical arrangements

(pedagogical, cultural and psychological) for systematic screening for deafness in the maternity unit need to be carefully prepared by the various members of the healthcaring team.

- In the present state of affairs, mass screening for neonatal deafness on the first day of life, in an anonymous and impersonal form, would probably do more harm than good. Although early detection of auditory disorders constitutes *a priori* an advantage for a profoundly deaf child, nevertheless the *systematic* aspect of screening within two days of birth could cause an anxiety crisis for that child and the child's parents when results are revealed although it is a known fact that there can be no immediate therapeutic action. In particular, in large maternity hospitals with a shortage of qualified personnel, damaging distress could be generated by automatic and uniform revelations without sufficient consideration for the psychic impact on hearing parents. There is also reason to fear that automatic screening could serve as a substitute for subsequent high-quality management of the condition. Believing that the problem of childhood deafness will be solved by technical check-up on the first day of a child's life could be contrary to the child's interest because of the risk of neglecting deafness with later onset.

To sum up, the Committee considers that the conditions for ethical generalisation of neonatal deafness screening are not present today. It fears excessive medicalisation of deafness, reducing the condition to solely functional and organic dimensions and simultaneously polarising on purely technological management. Cochlear implants cannot be viewed in the same light as an ordinary prosthesis replacing a neutral body part. Unlike ordinary prostheses, it affects an organ which is closely connected to subjectivity and identity.

When it could help to learn oral language, cochlear implantation must however be considered as in the child's best interests which include a fundamental right to benefit from medical progress. Their welfare must not be dependent on choices which have the effect of maintaining them in a situation of impairment made irreversible by lack of an early diagnosis. The fact that a deaf child is intrinsically neither "sick" nor "handicapped" is in no way a reason for failing to explore all the technological possibilities of communicating with parents and other children who are not deaf.

There is however every reason to inform parents earlier on the conditions of access to a diagnosis for severe deafness at the child's birth to spare them the risk of a revelation coming as a shock for which they are psychologically unprepared. Similarly, the conditions presiding over the choice of a hearing aid and of a specific procedure must not be contrary to the principle of informed decision which, in the last resort must be the parents' prerogative.

7) Recommendations

Bearing in mind the above considerations, the National Consultative Ethics Committee recommends:

- On the subject of the generalisation of neonatal screening:

1) Screening for profound deafness must be performed as early as is necessary, making certain that all requirements for reliability and accessibility of the test are respected. Despite improvements in the technical performance of the test, ***the greater***

number of errors made with first-day testing is a problem. The Committee therefore considers that excessively early testing is too unreliable for systematic evaluation of auditory capacity on the first or second day of life to be generalised. *In newborns, the optimal time for evaluating auditory capacity only begins after the third of life and continues beyond the neonatal period (28 days).* The Committee therefore considers that it would be preferable to develop the concept of oriented detection of auditory capacity disorders rather than to opt for generalised neonatal screening.

2) *Oriented detection of this nature would be more helpful in identifying a population of children for whom more in-depth examination is needed.* ***But in any event, early screening should not be an automatic and psychologically unsupported procedure.*** Unlike systematic screening, oriented detection in the maternity units is an individual and optional procedure. The attention of pædiatricians should also be drawn to the importance of recommending oto testing using automated auditory evoked potentials if there is the slightest clinical indication for it. It would be paradoxical if the outcome of neonatal screening was a subsequent lack of concern for the child's medical management.

3) When the child's parents are deaf, *there is a risk that making routine screening mandatory could lead to rejection and to conflictual situations which could be of disservice to the child. In such cases, information must precede detection and it should explain the therapeutic possibilities but also the advantages for the child of gaining access to the general hearing population through oral language.* ***Parents must be able to access and participate in the creation of counselling teams charged with providing information and guidance in the choices to be made, so as to reconcile to the fullest extent possible the two ethical imperatives: recognition of the primacy of parental choice and the preservation of the child's rights and best interests in the future.***

4) Another very important point is to make sure that parents are aware of the usefulness of a bilingual education combining sign language and oral acquisition with the help of appropriate devices. The non deaf parents of congenitally deaf children must also be put in touch with members of associations so that they can be adequately informed on how to access bilingual training. On this point, the Committee confirms the conclusions outlined in a previous[14] Opinion, recommending that sign language be taught to deaf children even when the prognosis for hearing recovery through implants seems favourable.

5) In order to improve the evaluation of auditory capacity, quality of information must be enhanced at several levels:

° Precise and simple data should be given to mothers during pregnancy so that, in the event of their child being diagnosed for deafness, they are not totally unprepared and uninformed.

° Pædiatric follow-up should integrate more information so that clinical signs can be identified in good time for children who could benefit from treatment to compensate for auditory deficit (for example, children should react to their name between 7 and 8 months of age). An effort to raise awareness in

[14] CCNE Opinion n° 44 on cochlear implants in prelingual deaf children. *December 1, 1994.*

pædiatricians and doctors in both private and hospital practice would enable them to pass on to parents data based on precise technical and empirical evidence.

° *Explicit instructions should be available for the auditory evaluation capacity apparatus in maternity units, so that it is clear how it is best used and in particular that there is a high risk of error if measurements are made too early in the life of a child.*

6) Cochlear implants are now one of the reliable therapeutic options and they perform better than traditional prostheses. As such, they must be governed by the rules of free and informed consent and it would be improper to refer to them as being experimental. However, and in so far as auditory deficits are not life-threatening, parents' decisions must be the outcome of logical and well-argued discussion, not of persuasive pressure.

7) The divergent opinions of the various specialists on early childhood concerning the advisability of systematic neonatal screening and the controversies on the practical aspects of medical management could surely be the subject of explanation and discussion. Developing a "sharing culture" through the creation of pluridisciplinary working groups and ethical committees (for example within the ethical reflection procedures provided by the law dated August 6, 2004) could help to avoid particularly unwelcome and futile disputes on decisions which condition the future and quality of life of children. More frequent and regular discussion between members of the medical professions specialising in hearing problems and associations of deaf people are needed to improve mutual understanding. Serene elucidation of the values under discussion could help to steer clear of two symmetrical pitfalls: medicalisation which ignores the cultural vision of a sensory deficit on the one hand and a community set in its hostility to any kind of medical practice, on the other.

The ethical issue of neonatal screening for deafness goes well beyond the purely functional and organic dimension. A person's humanity is achieved through a wide range of social interactions and exchanges with fellow human beings in which oral language obviously plays a major role. *But we must remember that even with a hearing aid, a deaf child cannot hear as well as others do. The rich contribution of sign language remains an essential component of communication even after implantation . Implants and sign language are not in opposition; on the contrary their association is essential.*

- <u>On the specific issue of the transfer from analog to digital of auditory prostheses for those already using a hearing aid, CCNE recommends the following:</u>

As long as transferring from analog to digital is difficult and complex, analog equipment must continue to be produced. Health authorities and manufacturers of aids must make sure that follow-up and maintenance continues to be provided for existing devices — for as long as it is needed —when products using new technologies which are not compatible with the previous generation of equipment, are put onto the market.

December 6, 2007

ANNEX 1: CONCLUSION OF THE REPORT BY THE HAUTE AUTORITE DE SANTE (French National Authority for Health

"Systematic screening for neonatal permanent hearing impairment using automated otoacoustic emissions and automated auditory evoked potentials has been recommended for all infants before three months of age in the United States and in Europe.
Such recommendations were formulated on the basis of studies concluding that early identification and treatment were associated with better language acquisition and communication capacities, compared to the absence of screening and delayed treatment. The US Preventive Services Task Force recognised however that the quality of methodologies in these studies was poor.
New studies using better methodology have been published in the last few years. In 2005, a randomised comparative study showed that systematic screening for neonatal hearing impairment could be used for diagnosis and onset of treatment before the age of six months, regardless of the severity of the condition. In 2006, a controlled retrospective study by the same author showed that diagnostic confirmation and early treatment before the age of nine months produced better outcomes as regards language acquisition compared to later interventions addressing children with an average age of eight years.
By implication, and in the absence of direct evidence in 2006, it is safe to assume that systematic screening for congenital hearing impairment improves the language acquisition chances of congenitally deaf children of school age, since diagnosis and medical management of the condition occur earlier .
Scientific proof of the long term efficacy of systematic screening for neonatal hearing impairment is difficult to obtain since other factors besides screening, such as the degree of parental involvement, may impact on the development of communication skills and such factors are difficult to evaluate. A comparative retrospective cohort study could provide some degree of enlightenment, clearing the main confusion factors (age, severity of hearing loss, age at the time of diagnosis, age at onset of treatment, type of intervention, degree of parental commitment) and using validated language analysis scales. Systematic screening for neonatal hearing impairment can be stressful if the test report is positive. The possible repercussions of parental anxiety, or of a change in parental behaviour, on the child's development or on the quality of the parent-child relationship have remained relatively unexplored and are the subject of controversy. The results of the Amiens Research and Teaching Hospital project, undertaken as part of the clinical research hospital programme (*PHRC*), will probably document this aspect of systematic screening for neonatal hearing impairment. In economic terms, international studies tend to converge in favour of systematic screening. In France, a short term model ranked strategies by their degree of efficacy and their cost, so that recognised priorities could orient decisions.
Experiments in France (projects as part of PHRC and local projects) and abroad have shown that systematic screening for neonatal hearing impairment prior to hospital discharge was possible provided it was rigorously organised, in particular as regards the availability of personnel in the maternity unit, with meticulous follow-up of positively screened newborns and counselling for parents as soon as there is any indication that a positive diagnosis is likely. The outcome of the experimental *CNAMTS* (*Caisse Nationale d'Assurance Maladie des Travailleurs Salariés* - French national health system) programme will provide an assessment of the feasibility of systematic screening for neonatal hearing impairment in maternity units on a larger scale.

ANNEX 2 : TECHNICAL ASPECTS OF COCHLEAR IMPLANTATION

A cochlear implant consists of an external removable part and a surgically implanted internal part.

The external part includes a microprocessor and a micro-magnet. The microphone amplifies, filters and compresses the sound signals. The microprocessor (which is battery-powered) provides an analog transduction of the sound supplied by the microphone. The data is processed through frequency bands of 125 - 8000 Hz. The microprocessor transforms sound into electrical impulses using a particular algorithm (Fourier). The transmitter, which is held in place on the scalp with a magnet, allows data to pass through the skin to the implanted part of the device.

The internal part consists of a microprocessor-receiver-stimulator and an electrode array. The microprocessor is placed behind the ear and the electrode array is placed inside the cochlea. Information is then transmitted to the auditory nerve through the cells of the spiral ganglion. Implants use 15 to 22 channels to stimulate the various cochlear frequency regions. Sound signals can be processed in various ways which determine the coding strategy. Two parameters can be modified: the number of frequency regions to be analysed and the speed of stimulation. Electrodes are never all stimulated simultaneously. One pair of electrodes is chosen for a given frequency range so that it will be all the more selective if the number of pairs is large. Increasing the amount of processed information generally has a negative impact on the speed of processing. Manufacturers have therefore worked out a compromise between the number of channels that can be activated, maximum peaks and processing speed.

ANNEX 3 : METHODS FOR NEONATAL SCREENING OF AUDITORY FUNCTION

During the first eight weeks of life, two tests can be used to identify neonatal hearing impairment.

1. Otoacoustic emissions (OAEs)
This designates low-intensity sounds produced by the inner ear and collected in the external auditory canal after stimulation of the ear with clicks. The test takes under a minute per ear and provides binary results. Repeatability is high with deviation less than 1%. Testing with OAEs is generally a two stage procedure. Reliability of the test increases with time after birth, ranging from 85% on the first day of life to 97% on the fourth day. The test cannot be interpreted in the event of hospitalisation in an intensive care unit. After two successive tests, at a month's interval, the rate of false positives is as low as 1.4%. 75% of children for whom the first test result was doubtful turn out to have normal hearing.

2. Automated Auditory Evoked Potential Measurements (AAEP)
This is an exploration of the inner and middle ears, the auditory nerve and the auditory pathways in the brainstem. Here again, response is binary. This is the method chosen for the feasibility programme for neonatal hearing impairment screening in France. The test takes 3 to 4 minutes and both ears are stimulated simultaneously. The child must be asleep before three electrodes are placed on the scalp and two eartips pasted around the ears.
A second test is systematically proposed prior to hospital discharge for children with a positive result to their first test. The second test takes 10 to 11 minutes.
Screening programmes must always consist of a two-step procedure to minimise the number of false positives and reinforce the positive predictive value (PPV) which is a more sensitive indicator than the rate of false positives.
For this reason, although OAEs are faster and cheaper, AAEP has a higher PPV. Using OAEs as a first line test and AAEP as the second line is economically sounder than repeating AAEP, but there is a risk of false negatives and PPV is less good than with a AAEP repeat. Auditory neuropathies will not be detected by the first OAE filter.

ANNEX 4: NEONATAL SCREENING IN OTHER COUNTRIES

- Germany

30% of newborns are screened and of these, 50% were tested for hearing by six months of age. 100% of those who are diagnosed with profound bilateral hearing impairment are listed for treatment by six months of age.

- Italy

30% of newborns are screened and of these, 50% before 1 month of age (half of which before, and the other half after they leave the maternity unit). Of the screened newborns, 95% undergo an audiometric test (of which 25% before three months of age). For 100% of children diagnosed with profound bilateral hearing impairment, intervention is planned by six months of age.

- Netherlands

80% of newborns are tested before 1 month of age, followed by an audiometric test before 3 months if necessary, followed by intervention in 95% of cases involving known early bilateral deafness.

- United Kingdom

The Newborn Hearing Screening programme was launched in 2003 with the aim of testing all newborns. Currently, some 50% are tested. Of these, 65% are tested prior to leaving the maternity unit and 25% afterwards, but before 1 month of age. Of the newborns who are tested, 80% undergo an audiometric examination.

- United States

90% of newborns are tested in over two thirds of the States, both in States which have legislation prescribing tests and those which do not.

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