Paediatric Cochlear Implantation: A Challenging Ethical Dilemma

Les implants cochléaires chez les enfants : un dilemme intéressant sur le plan de l'éthique

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Abstract

Paediatric cochlear implantation must be understood in the therapy-research-therapy continuum as multidisciplinary and as "therapy-being-researched." In that perspective, a number of general ethical issues arise regarding, for example, harm/benefit ratio, confidentiality, and fairness in availability of this "therapy." Because the recipients of this service are children, particular attention must be given to assessing the "best interests of the child" in terms of such ethical concerns as well as to provision of integrated information (i.e., relevant to surgery, pre- and post-implant activity) for the benefit of those who will consent/assent to participation in these procedures. If paediatric cochlear implantation is to meet its goals, they must be clearly defined, with some accommodation made to an understanding of the interests of the deaf culture vis-a-vis this activity.

Résumé

Il faut considérer les implants cochléaires chez les enfants dans le continuum thérapie-recherche-thérapie comme une activité multidisciplinaire et comme une «thérapie en recherche». Dans cette perspective, un certain nombre de problèmes d'éthique se posent concernant, par exemple, le rapport dommage-avantage, le caractère confidentiel et l'équitabilité de la disponibilité de cette "thérapie". Comme les bénéficiaires de ce service sont des enfants, il est important d'évaluer l'intérêt de l'enfant en terme de préoccupations d'ordre éthique et de fournir des renseignements intégrés (par exemple, concernant la chirurgie, les activités avant et après l'implantation, etc.) au profit des personnes qui vont consentir à participer à ces interventions. Pour que les implants cochléaires chez les enfants donnent satisfaction, les objectifs doivent être définis clairement et assurer une bonne compréhension des intérêts des malentendants concernant cette activité.

Introduction

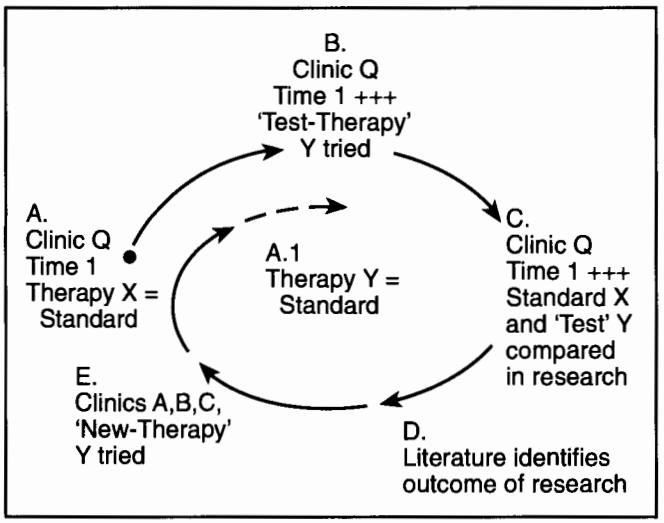
Consideration of the success of paediatric cochlear implantation prompts attention not only to its laudable scientific/technological achievement, but also to the ethical and social concerns surrounding its continuing development and initiation as standard clinical practice. In one perspective, use of the device is touted as removing the "barrier of silence" (Mecklenberg, 1988), with some commentators arguing that "it is unethical to deprive suitable cases of the opportunity to benefit from this recognized form of treatment" (McCormick, 1991, p. 146-7). Further to this point of view in the Canadian context: "Provincial governments should fund interdisciplinary cochlear implant programs in all areas of the country" (Durieux-Smith & Gagne, 1992, p. 93). Contrariwise, some argue that children who receive such devices are "victims" in "alarming danger" (Canadian Cultural Society of the Deaf, 1992); it may well be that they suffer "abuse" (Tait, 1992). In outspoken rejection of the use of paediatric cochlear implantation, the Canadian Cultural Society of the Deaf comments that, "As a matter of fact, (this procedure) forces the child to perceive himself or herself as an incomplete person who requires medical reparation in order to be acceptable to society" (Canadian Cultural Society of the Deaf, 1992, p. 3).

Each of these perceptions reflects an array of human values; each reflects commitment to an apparently different ethic regarding use of the process of paediatric cochlear implantation. In the best interests of children, attempts to reconcile these different views must continue. Such attempts will rest first on conceptual clarification regarding the general research/therapy interaction; second, on application of the ethical principles generally understood to be relevant in consideration of research/therapeutic activity; third, on consideration of paediatric cochlear implantation in terms of the research/therapy paradigm proposed; and fourth, on reflection regarding the ethical principles relevant to development and implementation of paediatric cochlear implantation, with negotiation among any competing ethical principles as required.

A Proposed Therapy-Research - Therapy Paradigm

Insofar as therapeutic practice is motivated by a desire to advance patients' well-being, research to improve such practice becomes an ethical and therapeutic imperative. Concep-

Figure 1. Conceptualization of the therapy-research-therapy interaction.

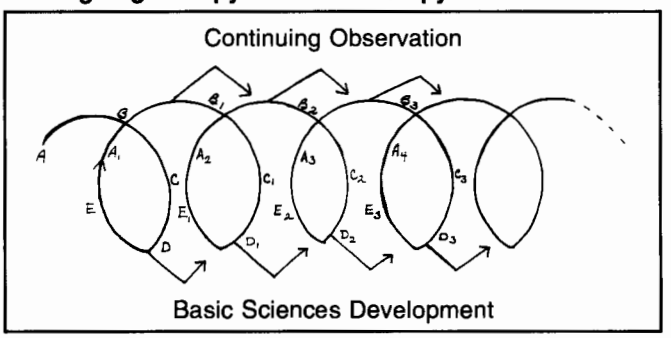


tually, then, today's accepted health care practice begets innovation; this innovation is formalized by way of research which is carried on until the innovation is rejected or approved as new practice. After some time/experience of use in various individual settings, this "new accepted practice" is finally accepted as standard practice, and it replaces its original forebear.

Applying the diagram in Figure 1, the use of therapy X (e.g., a solid plaster cast) has been recognized as standard practice in caring for a certain type of bone fracture for some time (A). However, on the basis of reading about new types of plastic substances now in use for setting non-human bones and having studied some of the theories of motion and healing on which use of this new plastic substance is based, the therapist suggests use of a plastic cast, Y, when that type of bone fracture next presents in clinic (B). Y might be used in an experimental way once or twice as a kind of test at (B); to set out its negative and positive qualities, however, Y will be subject to research procedures, perhaps as comparing X and Y in some randomized way (C). Presuming Y proves more satisfactory than X or any alternative, or that it is at least as satisfactory as X and any alternative, Y will be presented in the literature (D) and then tried as a "new practice" in various settings by different groups who become accustomed to it (E). With time/experience, the previously recognized standard practice (use of X) is set aside, and the standard practice for this type of bone fracture becomes use of Y, or Y may be seen as equally acceptable with X or other alternatives (Pattullo, 1981).

An important component of the continuum is ongoing openess to observation of behaviour (animal, human, manipulated inanimate substances) and application of such observa-

Figure 2. Observation and basic sciences development in the ongoing therapy-research-therapy interaction.



tion to the presenting query or situation. Such observation may be of activity which is almost predictable or apparently serendipitous (e.g., consider the original observation with reference to development of penicillin); application may appear orderly or it may be apparently spontaneous (e.g., consider the apparently contradictory application of the original observations in development of the early contraceptive pill). Of greater relevance than the exceptions here is the evident *constancy of observation* as practised along the continuum. Of importance here as well is the *continuing development* of the scientific infrastructure used in introducing modifications as the continuum develops. The constancy of observation and the continuing developments in the more basic sciences renders the therapy-research-therapy continuum ongoing as shown in Figure 2. Thus, the standard therapy Y, which challenged therapy X originally, may itself be challenged by Z and so forth.

Application of this general historical paradigm to paediatric cochlear implantation is possible only with some further specification regarding its various elements. Thus, definitions need to be assigned to the various stages of the continuum. *Therapy* is understood to be that part of health care science directed to the benefit of the patient through treatment and care of disease (e.g., activities like history-taking, examination, observation, investigation, diagnosis, prognosis, and the like employed in this pursuit). Such delineation of therapy from various other health care activities depends first on the distinctive *intention* directing the use of therapy, in this case, the desire to heal, cure, or act for the benefit of the patient using the modalities appropriate to such activity. Therapy is distinguished as well in terms of the *means* employed, that is, the medications or interventions demonstrated by research to be safe, efficacious, effective, and efficient, and accepted by the profession as standard. Finally, therapy is distinctive in its *outcome* or *result*; usually, therapy cures or heals. This is not to say that every therapeutic endeavour has the desired outcome; in a sense, each therapeutic intervention is experimental because each patient and each situation differs. However, even

though the future is not always predictable, therapy usually cures or heals.

Research is identified as the systematic inquiry for knowledge by use of the scientific method in the acquisition and subsequent evaluation of observations. Such delineation of research from various other health care activities depends first on its *intention*, defined to be pursuit of knowledge, which is generalizable, thus useful/beneficial for society, broadly speaking. Research also differs from other health care activity in its *means*, that is, use of activities which are novel, not standard, or use of standard therapies applied in novel ways, according to a protocol directed to demonstration of a stated hypothesis. Finally, research differs from other health care activities in terms of its *outcome*; the result of carefully conducted research should be an increase in knowledge such that even if the research fails, there is the new knowledge that this line of research is not productive for the goal intended.

Figure 3. Comparing therapy and research.

	Therapy	*Research*
Intention	Patient benefit (cure, maintain, rehabilitate, care)	Generalizable knowledge
Means	Standardized	'Novel' procedures (with standardized protocols)
Outcome	Patient benefit (cure, maintain, rehabilitate, care)	Generalizable knowledge

In terms of a diagram, the components of the definitions of therapy and research could be summarized as in Figure 3. Identified in terms of time and experience, *innovative* or *novel* therapy stands midway between therapy and research. This is experimental therapeutic practice attempted with 1-2 patients based on observation, basic science, and patient need. It is practised when standard means or procedures seem to have failed; its intention is therapeutic, but its outcome is uncertain. An example of innovative therapy is the use of the baboon heart as a transplant for Baby Fae. Again in terms of time and experience, the *pilot study* is an early research effort which moves beyond innovative therapy to make use of a few patients in an organized way so as to test toxicity, side effects, and the like. Use of the pilot study may help frame the hypothesis for more formal research study.

Ethical Considerations for the Therapy-Research-Therapy Paradigm

The ethic of therapy has a long history comprising a variety of principles and rules, such as *primum non nocere* (first, do no harm), preserve the patient's confidential information as such, honour the patient's choice, and the like. Such principles and rules are found in the various codes of ethics for the health care professions (e.g., medicine, nursing, dentistry). The ethic of research has been well-detailed in numerous documents, for example, *The Nuremberg Code* of 1947 and *The Declaration of Helsinki* (as amended in Hong Kong, 1989) (Annas & Grodin, 1992). In Canada, formal ethical expectations regarding involvement of human subjects in scientific research have been identified by the Medical Research Council of Canada (MRC) in 1987. The group's document is the authoritative source for details of the ethics review required for its funding of such research; the direction it provides is the source used by other Canadian health care services funding groups. Of similar importance is the direction provided by the Canadian Social Sciences and Humanities Research Council (SSHRC) (1992). Like the MRC, this group mandates ethics review for the funding it provides (e.g., in the areas of psychology and education); the direction it provides is the source used by other Canadian social sciences/humanities groups.

So as to meet the requirements of mandatory ethics review in either instance, the researcher/research group must first propose "good science." The MRC document (1987) states that, "Ethical research must be scientifically sound, so that observing the integrity of the scientific method is part of the ethics of research." Insofar as such research involves human subjects[1], the researcher/research group must also demonstrate attention to certain ethical concerns, for example, respect for person (including considerations of choice, confidentiality, privacy), probability of harm/benefit (both long and short term) to the participating individual and to society/the individual's group, and fairness in the selection of participants. Briefly, in the view of both the MRC and SSHRC, research involving human subjects must be scientifically grounded as well as ethically humane.

Certain of the ethical requirements regarding research with human subjects have been given further clarification in Canada by way of legal judgments. Thus, *Halushka v. University of Saskatchewan* (1965) offered careful direction as to the information to be provided for the research subject participating in a clinical research endeavour not designed as part of a patient's medical treatment. *Weiss v. Solomon* (1989) addressed the responsibility of the research ethics board vis-a-vis information to be provided a patient participating in a research trial related to personal therapy. When the research subjects

involved are children, as in the case of both uni-disciplinary and multidisciplinary research concerning paediatric cochlear implantation, the need for ethical vigilance is intensified. In point of fact, the MRC document has been interpreted by some as providing overly strict limitations here, thus effectively reducing Canadian researchers' options in the matter of research involving children[2].

Taking a slightly different perspective on this point, *Research Involving Children* (National Council on Bioethics in Human Research, 1992) identifies paediatric research as a matter of justice and caring for children, recognizing that there can be no potential improvement in their well-being in the absence of such research. At the same time, the National Council, in common with the MRC, identifies the need for careful assessment of the probability and magnitude of harm and benefit to the individual child, group, and society in ethics review of paediatric research protocols. Both documents offer comment on the need for balance among such factors; NCBHR provides a method to be used for that purpose.

Once harm/benefit and their probability have been weighed in ethics review, however, the critical question of consent for children's participation in research must be addressed. For those children deemed incapable of understanding relevant information about the proposed research and not sufficiently mature to process such information in terms of their "life-goals" or "sense of self," parents/guardians must act in this regard. The fact remains that the incapable child may disagree with the decision of the parent/guardian; thus both the MRC and National Council documents refer to the need to obtain the child's assent, as possible, and to honour the child's semi-knowledgable objection as relevant. Older children may be judged able, in their own right, to consent/refuse/withdraw as regards participation in the research proposed. Overall, then, there are several possibilities along the consent spectrum vis-a-vis involvement of children in research: permission from parents alone, permission from parents with assent from the participating child, and consent from the older child.

When children are involved in research, there is also need to attend to their particular concerns regarding privacy and confidentiality. While such need is more apparent in the case of adolescents, younger children, too, may have a strong need for privacy; the researcher must make provision for meeting such a need. Any limitation on confidentiality or privacy with regard to the research participant should be made known prior to commencement of the research activity as part of the information conveyed to the individual responsible for permission/consent in this matter.

With reference to ethics review of research involving children, the NCBHR (1992) document notes the need for representation of recognized child health care staff among review board members. It suggests as well that an advocate—"a person who knows the child very well, an adult 'best friend' (such as the teacher, nurse, religious leader, family physician, child psychologist, social worker)" (p. vi; 44) be available to the child and/or parents for optional discussion of the child's participation in the protocol prior to permission/consent being given for research participation.

Paediatric Cochlear Implantation in the Therapy-Research-Therapy Interaction

As often noted in the literature, paediatric cochlear implantation is a multidisciplinary activity, in terms of both development and clinical implementation. Such activity actually comprises the many activities of various disciplines and researchers, as well as the activities of many clinicians and commercial organizations. By reason of the common focus of these various endeavours, paediatric cochlear implantation is thus presented as if it were a single entity. Such use of the term *paediatric cochlear implantation* in the singular, as a collective noun, ought not to obscure the existing differences among the various individuals/groups involved, whether in regard to achievements, sophistication of research projects, or rate of application of relevant research. Equally, the achievement, sophistication of research project, or rate of application of relevant research within any one discipline or group working on any one aspect of paediatric cochlear implantation cannot be seen to be the conceptual equivalent of the enterprise as a whole. This is only to say that the success of any one part of the paediatric cochlear implantation process is not to be seen as the success of the whole of paediatric cochlear implantation.

With that caveat in mind and speaking of paediatric cochlear implantation conveniently as one (multidisciplinary) activity, can this procedure be said to be standard therapy (Point A, Figure 1)? The answer must be negative on several counts. While the intention of those working in the area is patient benefit (improvement in hearing, language, speech, etc.) and the procedure might thus be seen to be therapeutic, the various means used are not yet recognized as standard by all the various professional groups involved, nor is the outcome beneficial (i.e., in the sense in which the term is applied to recognized therapy: a usual result, generally predictable).

Speaking of means, for example, and first with reference to the device alone, the electrodes may be inserted within or outside the cochlea; the signals may be transmitted through either one or several independent channels; only certain features of the speech signal may be transmitted or the input signal may be transmitted to the electrodes without extracting specific speech cues. As well, there are different types of

criteria for patient selection used in different centres; outcome evaluations have not been standardized; there are various approaches used for pre- and post-implant education. Thus, the means cannot be considered standard.

Speaking of outcome, the NIH Consensus Development Conference commented (1988): "Few medical interventions yield outcomes as varied as those for cochlear implantation" (p. 4). The results mentioned vary from those who can "communicate face-to-face with comparative ease, and even a few (about 5%) who can carry on normal conversation without lipreading" to those who "can barely distinguish between simple environmental sounds such as car traffic and the doorbell" (p. 4). In children, "the potential and possibly long-term effects of the implant, either beneficial or deleterious, are unknown" (p. 6).

If paediatric cochlear implantation does not belong in the therapeutic category as already defined, should it be considered innovative, that is, as a temporary modification of existing therapy based on observation and advances in basic sciences (Point B, Figure 1). Apparently not because the implant device, together with (re)habilitation, is being widely used; once the devices received FDA approval (and similar approbation in Canada), the procedures (not just the device or the method for its implanting) moved formally to a more sophisticated level of investigation. Perhaps, then, paediatric cochlear implantation should be seen as still in the pilot study portion of the research phase (Point C, Figure 1). As already noted, at least part of the procedure (i.e., the devices) received U.S. and Canadian approval after research involving numerous patients; in that one aspect, at least, paediatric cochlear implantation is not now in a pilot study phase. Further, many more advanced studies with numerous research subjects are being conducted concerning use of paediatric cochlear implantation. The hypotheses being studied exceed in scope the usual concerns for safety and efficacy that characterize pilot studies. There is interest, for example, in the matter of efficacy in improving the user's quality of life and in comparison of the effects of cochlear implants with alternative methods of treatment.

If paediatric cochlear implantation is not to be seen as therapy, not to be seen as innovative therapy, not to be seen as a pilot study, can it be called research (Dickens, 1975)? It certainly meets the criterion of intention (search for knowledge) as well as the criterion of non-standardized means (those being used are still in stages of comparability, with data sought and stored on an ongoing basis for use in future endeavours). Further, its outcome is uncertain (but always results in an increase of knowledge). True, the various successes of the researchers are appearing in the literature (Point D, Figure 1); and some of the devices are no longer considered experimental (Cochlear Corporation, 1990) or investigational (Yin & Segerson, 1986), although they are still in the process of improvement. As noted, however, such partial successes do not equate with success of the whole; the overall activity here seems to be an energetic search for new knowledge which is needed to solve that larger puzzle.

In this energetic search, certain therapies (i.e., approved systems, together with trial methods of selection, teaching, etc.) are being used not only with the intention of benefitting the patient, but also with the intention of resolving the therapy question, that is, finding the optimal procedure (device plus pre- and post-implant activity). Would this activity not, then, best be identified as research about therapy[3]? This blending of therapy and research is certainly the image suggested pre-FDA and Canadian approval of the devices used. For example, Boothroyd (1986) comments that, "the responsibilities of the implant teams to the accumulation of clinical research data cannot be overlooked ... There is an urgent need for preparation of a data base ... only with such a data base can we hope to remove the many uncertainties that now attend decisions on candidacy and prediction of outcome" (p. 351). Tyler (1986) speaks in the same vein, "Although our primary concern is patient care, carefully designed research is necessary" (p. 433). Clark (1992) makes the same point in speaking of work with the first of the implant patients at his center: "To achieve a balance between acquiring knowledge and helping a patient is necessary with many research projects, and the two goals are not incompatible" (p. 99).

Given these comments, and there are more like them in the current literature, it seems reasonable to suggest that this activity is first of all intended to be therapeutic, but that this therapy (i.e., use of approved devices together with certain trial non-medical activity) is practised with the clear understanding that there is still much uncertainty here and that the therapy being used is part of a greater research effort. With specific reference to children, there is evidently need for further research regarding the effects of growth on the implant; long-term studies are simply not yet available. Mohay (1991) notes: "The selection of children for audiological assessment remains a problem" (p. 372); House (1991b) comments, "Cochlear implant patients ... show wide variations in their responses to these systems" (p. 1), (indicating the need for further research in this area). Quittner and Steck (1991) note that, "As the (new) procedure is proven safe and beneficial from a medical standpoint, the research emphasis typically shifts into related areas" (p. 89); in this connection, they list a variety of areas in which research is ongoing. A particular problem relates to children with behaviour problems who "may have problems completing the rehabilitation process and using the device effectively. This is the focus of a research project currently in progress" (p. 94). Another area in particu-

lar need of research relates to the stress for the parent and the child that is associated with the rehabilitation process (Quittner et al., 1991). Again, Carney (1991) asks that research move beyond device efficacy so as to address questions of perceptual development.

These various comments lead to the conclusion that, while safety and efficacy of the devices have been demonstrated to the satisfaction of the regulatory bodies, the question of effectiveness of paediatric cochlear implantation as a whole has yet to be demonstrated to the satisfaction of the professional bodies. Paediatric cochlear implantation (devices plus ancillary activity) is thus a therapy-being-researched. This type of research about therapy (or therapy-being-researched) has been formally recognized in the NCBHR report (1992): "that type of research in which it can be foreseen that the substance of the inquiry (e.g., use of a drug or physiologic test for some of the research subjects) will likely provide direct benefit to (at least some of) the research subjects" (p. vii). Such research might be planned in advance (e.g., in use of the randomized clinical trial) or, as in the case of paediatric cochlear implantation, may be a study of the various attempted therapies after the fact. The dual nature of such activity (i.e., both therapeutic and research) must be reflected in making any ethical comments about its ethical dimension.

Ethical Reflection on Development and Implementation of Paediatric Cochlear Implantation

There appear to be three separate but related points to consider here: (1) satisfaction of ethical standards for pursuit of an activity identified as therapy-being-researched; (2) satisfaction of the requirements of justice in the matter of availability of a procedure thought to be beneficial to some patients; and (3) reconciliation of different cultural viewpoints regarding use of this procedure. With reference to the first concern, the ethical requirements here comprise a blend of the two kinds of ethics activity already mentioned (i.e., the ethic of therapy and the ethic of research). Any initial ethical uneasiness regarding the priority as between the two activities involved should there be some conflict between them was established in the earlier MRC document (1987), which identifies that concern for patients' well-being is to take precedence over pursuit of research goals.

With specific reference to paediatric cochlear implantation in this context, ethical requirements relevant to this activity have been formally expressed best in the MRC *Guidelines for research on somatic cell gene therapy in humans* (1990). While gene therapy and paediatric cochlear implantation are by no means identical, such gene therapy has also been identified as therapy-being-researched, and the two procedures do share numerous characteristics common to that grouping. The analogy here can be made clearer on recognition that both activities proceed with therapy as an intention, but with the understanding that the therapy is under continuing review and development. Both are recommended for early use in a population of children still under identification, and in both cases, the long term results are unknown. Both procedures involve insertion of a foreign substance within the body, with the paediatric cochlear implant being removable, but with long term effects of its surgical insertion apparently not reversible. Both activities will have a profound effect in terms of life—gene therapy on physical survival at least and paediatric cochlear implantation on life in terms of cognitive, emotional, and social development. While there are obvious differences here, paediatric cochlear implantation seems to resemble the gene therapy procedure more closely than it does, for example, kidney transplant (no longer a therapy-being-researched), the Baby Fae transplant (innovative therapy, as already noted), other recognized therapies (standard medications, dental restorations, recognized prostheses like eyeglasses), pilot studies, or randomized clinical trials. Use of the (genetic) *Guidelines* (1990) here seems defensible and, because they are current, there is no need to "re-invent the wheel."

The principal ethical concerns identified in this more recent MRC document are those that arise in any provision of therapy or in any research pursuit; comments regarding them here are tailored to the dual context presented by therapy-being-researched. The document stresses first the research aspect of such activity; it calls for research review of any proposal in this area prior to its implementation. Attention is directed as well to three other aspects of interest: consent, evaluation of research and benefit, and confidentiality.

Further to consent, with modification of terms used for procedure and problem, the discussion put forth in the *Guidelines* (1990) is well-suited for application to the practice of paediatric cochlear implantation. For example: "On the one hand it seems appropriate to treat individuals as soon as they have been diagnosed to maximize the potential for therapeutic benefit if gene transfer is successful; the risks of performing gene transfer will not be reduced by waiting, and delay will almost certainly cause greater harm to patients through irreversible accumulation of the effects of the disease. On the other hand, the younger the subjects, the less able are they to consent" (*Guidelines*, 1990, p. 24). The document includes a listing of the elements of information to be understood by the participant/participant's parents prior to agreeing to the procedure; these elements, common to any research protocol information sheet, include statement of "the available alternatives and the harms and benefits associated with these; the probability that any of the potential harms and benefits will

manifest themselves" (p. 25). The difficulty of withdrawing from the procedure is mentioned here as is the need for "full disclosure of risks ... the patient's or proxy's perceptions of potential harms may differ markedly from those of the physician ... Because the proposed ... intervention may be the child's last hope, parents and guardians may be willing to ignore the risks and to focus instead on the possible good; they may therefore be too eager to consent to their child's participation ... Their hope must be tempered by an adequate understanding of the risks involved. Feelings of guilt ... may influence some parents to downgrade the risks ... On the other hand some parents may inadvertently become over-protective and thus overrate the risks. Provision should therefore be made ... to ensure the availability of in depth counselling to ensure full understanding by the subject or legal guardian of what is proposed" (p. 26-7). The authors of the report stress that the child's wishes here must be respected; "children should be encouraged to participate in the consent process to the extent to which they are capable" (p. 27), and attention should be given to their assent/dissent/objection concerning participation in this procedure.

The usual requirement for evaluation of harm/benefit and the probability of benefit applies here: The foreseen benefits must outweigh the foreseen harms. Consideration is to be given to harms/benefits with regard to both the individual and society more generally; long term monitoring is seen as essential. Confidentiality is also discussed; this is a matter of particular concern because there may well be public interest in this area.

These formalized statements of ethics concerns about therapy-being-researched are instantiated in much of the literature concerning paediatric cochlear implantation. For example, there is continuing comment about the timing of the procedure (Berlin & Luxford, 1987); this raises the question of consent for it by those other than patients should the patient be too young. McCormick (1991) speaks against delay here; Simmons (1985) remarks that "earlier is not necessarily better" (p. 62); Mecklenberg (1988) notes that, given the notions of critical periods for language development and neural plasticity, waiting for informed consent by the child may sacrifice the opportunity to process the patterns of input speech. Again, in addition to consideration of risks of harm in surgery itself (Belal, 1986; Berliner et al., 1990), of possible harm in surgery and in use of the implant (Burgio, 1986; Mecklenberg et al., 1991), and of "the potential of damage to an already non-functioning auditory system" (Mecklenberg, 1988, p.164), potential non-medical harms to the individual in not pursuing this procedure are well-discussed. Boothroyd (1987), for example, remarks: "Without proper intervention (presumably including cochlear implantation) ... (there can be) ever expanding deficits of linguistic, social, emotional, and intellectual function and eventually, of vocational opportunity" (p. 84). Concern is also expressed for a balance of potential individual harms with potential individual benefits (Berliner et al., 1988). For example, if only environmental sounds can be distinguished, is surgery justified?

The related need to organize all the relevant components of paediatric cochlear implantation so as to achieve success is well recognized (thus, indicating the harm in not doing so): "If all the components are in place, a cochlear implant has the potential of having a significant impact on the intellectual, academic, and social development of a deaf child" (Kileny et al., 1991, p. 146). Boothroyd (1987) makes this point succinctly: "Deafness is a multidimensional problem. It does not respond well to unidimensional solutions" (p. 84) (cf. American Academy of Otolaryngology, 1991). Despite its promise, then, the matter of benefits from the implant procedure must be qualified. Realization of such benefits depends on a combination of factors: appropriate patient selection (i.e., on physical and psychological aptness), on success of surgery, on type of implant as suitable for this patient, on success of post-implant rehabilitation (Alpiner, 1986; Berliner et al., 1990; Boothroyd et al., 1991; Eisenberg et al., 1986; Geers & Moog, 1988, 1992; House, 1986a; Maddox et al., 1986; Moog & Geers, 1991; Northern, 1986; Tyler & Kelsay, 1990). Stated conservatively, consensus as to problems/ successes concerning the various aspects of cochlear implantation activity is still uncertain (DeFoa & Loeb, 1991). Not to be ignored in any discussion about harm/benefit is the social benefit of this research, which is well-stated. Quoting Loeb, Mecklenberg (1988) comments, "An artificially imposed prohibition ... would foreclose the most important source of data needed to answer the very difficult theoretical and technical questions" (p. 167). Gagne (1992) identifies the social benefits of research even more precisely: It will be helpful so as "to develop efficient and cost-effective post-implant rehabilitation services" (p. 126).

In considering the material in the literature relevant to consent as well as to harm/benefit, together with the recommendations regarding ethical concerns in the MRC documents noted, the importance of adequate informing and voluntary consent to the procedures involved in paediatric cochlear implantation is apparent. The question is: How are patients/ parents informed? Do they truly understand the nature of the procedure, its potential for harm/benefit, the alternatives to it? How is the information conveyed to them?

The clinical trials of paediatric cochlear implants conducted pre-FDA (and Canadian) approval were not conducted in Canada; the detailed research consent form used in those trials is not on file with the Canadian agency that gave approval to the use of such implants[4]; it is not clear that there

is any multidisciplinary consent form, either of a therapeutic or research kind, now being used in Canada. In fact, the consent form relevant to cochlear implantation used in numerous Canadian institutions is most general; it refers only to surgical concerns. As a *general surgical* consent form, it thus may not identify the fact, for example, that patients who have received a cochlear implant should not undergo a Magnetic Resonance Imaging procedure nor the fact that "long term effects from any electrode insertion trauma or from chronic electrical stimulation are unknown" (Cochlear Corporation Consent Form, Clinical Trials). As a surgical consent form, it need not identify the many non-surgical procedures essential to any success with such implantation, nor need it list the many other special concerns arising from that fact (e.g., the time needed for testing, the alternatives available).

Presumably, all this information is conveyed prior to surgery for the implant during assessment sessions by various members of the multidisciplinary team. The question remains whether this means is satisfactory so far as the whole process of a particular therapy-being-researched is concerned. If there are individual explanations and consents for each of the various research parts of this overall procedure, will information from each of the services somehow be integrated for the prospective patient? Will it be possible from these various sessions to have full comprehension of all the parts of the process as necessary for truly informed, voluntary consent? Will parents be sufficiently knowledgeable to recognize that the surgery is insufficient unless the other ancillary services are also both available and well-developed?

At this point, use of the description *multidisciplinary* with reference to the procedure must be made applicable in practice as well as in theory (Phillips, 1992), as must the understanding that there are many parts of this therapy which are less-well standardized than the process of surgical implantation. If it is unethical to provide the device in the absence of adequate assessment and follow-up (Gagne, 1992), parents must understand the interrelatedness of the various components. To this end, a detailed information sheet with comprehensive consent assured and formalized in some way is imperative. Not only would such an information sheet provide a record that all was explained and was, at the time, understood by both parents and therapists, but it also would send the message that paediatric cochlear implantation is, indeed, more than a surgical procedure only.

A second ethical concern raised regarding the implementation of the paediatric cochlear implant procedure must also be considered, and that is the matter of fairness. The device and surgery alone are expensive; additionally, "all cochlear implant recipients should be provided with post-implant ancillary aural rehabilitation services" (Gagne, 1992, p. 126)—not available cheaply! In certain parts of Canada, such programs are provided by provincial health care resources; in Ontario, for example, such activity is funded by way of inclusion in the overall institutional (hospital) budget. In terms of Canadian health care system legislation, however, if/when such implantation is seen to be a necessary health care service, it should be available. Thus, while the opportunity for implantation surgery may be provided in certain specified centres and while individuals may be prepared to travel distances to have such surgery, one must ask how shall the essential pre- and post-implant services be made available in the more remote areas not only because such services are costly, but also because there seem to be too few personnel to provide the services required. Still speaking of availability, will there be equal opportunity in all provinces of Canada when therapy in this area is recognized as standard? Indirectly, this leads to the macro-question: What funding priority should such programs have in any provincial health budget or in the provincial budget more generally?

To consider the problem of fairness in another way: For those Canadians who will have the service available to them, it will be available at no direct cost to the individual. The costs will be borne by the Canadian publicly funded system. A question raised frequently in the literature is: What about those persons in other parts of the world who might desire this service and could benefit from it, but for whom the service is unavailable in fact, or unavailable because they cannot afford it (Tyler et al., 1992)? A somewhat different concern about fairness can be raised by those who might object to the standards used in selecting candidates for the procedures. Those working in this area seem to agree that criteria other than otological and audiological must be considered here (Gagne, 1992). Thus, for example, "The committee felt that it was probably reasonable to accept, postpone, or reject a child for implantation based on parental attitudes .. This factor should take precedence, i.e., whether the parents will fully cooperate in the rehabilitation program" (Downs, 1986, p. 391). Again, Stark (1986) speaks of a "grading system" which could be used in selecting among candidates (based presumably on outcomes to date and outcomes still subject to research); Yaeger and Joyce (1989), among others, point to the need to provide the procedures only for children with "normal mental abilities." To complicate the problem further, there is recognition that product development is expensive and that a certain level of use of it is necessary to recover costs, much less to make a profit. It could well be, then, that there is pressure to over-recommend paediatric cochlear implantation.

It is clear that parental support is needed to help in a good adjustment to the use of the procedures; it seems reasonable to suggest that children with less than a certain level of mental ability may be confused or frightened by use of the procedures;

it seems fair to say that those who bear the cost of development should be fairly re-imbursed. The ethical justification of any such labelled under-inclusion or over-inclusion will be complex; its presentation for public acceptance will be difficult. Careful attention to this question must be a high priority on the agenda of those working in this area. In the cases of those not selected as candidates for these procedures, presuming the procedures are standardized and the individuals wish to have such procedures, as well as in the case of those who wish the procedure but find it not available to them in their province/locality, there may even be certain legal implications about equality under the Canadian *Charter*. The matter of fairness here is certainly not a trivial one.

Even as the multidisciplinary group works to develop and extend the opportunity of hearing to prelingually and postlingually deaf children by way of paediatric cochlear implantation, many individuals are working to prevent the use of any such procedures. For some, there is question of potential harm outweighing potential benefit; for some there is concern about early cochlear implantation with potentially unknown deleterious effects; some challenge the methodology used in providing reports of purported benefits of the procedures; some query any involvement of children in research activity; some question the possibility of coercion here because young children cannot consent to the procedures for themselves; some question the use of public funding for this purpose, given the many other needs in the community; some point to the experience of deaf adults, many of whom, it is alleged, overwhelmingly decline the use of such prostheses (the inference is that parents should wait until children can decide for themselves); some note the difficulty in listening and discriminating among sounds, given the distorted auditory signal provided by the cochlear implant (Gibson, 1991; Harrison, 1991). Many of those raising such concerns are members of the deaf community, and various groups and individuals within that community have stated their negative views regarding the use of paediatric cochlear implantation formally, by way of position papers and statements in the professional literature, as well as by way of statements in the popular media (e.g., World Federation of the Deaf, National Deaf Children's Society - London, National Association of the Deaf - U.S.) In Canada, the Canadian Cultural Society of the Deaf and G. Malkowski, the only deaf member of Ontario's provincial parliament, have been particularly outspoken on this matter.

While each of the arguments/queries raised reflects concern about a particular human value, and thus raises an ethical issue (e.g., of harm/benefit ratio, of fairness in the use of resources, of truthfulness in the matter of research, of freedom of choice, of concern for the well-being of children), the most basic of the concerns raised appears to be one of recognition of the identity and autonomy of the deaf culture. That concern is clearly stated by the Canadian Cultural Society of the Deaf (CCSD): "The unique culture of the deaf is (to be) appreciated and preserved for posterity just as all ethnic cultures are appreciated and preserved in society as a whole" (p. 3). Again, "Members of the deaf community usually do not regard themselves as disabled, but prefer to see themselves as members of a minority group with a language and culture of their own" (Mohay, 1991b, p. 719); they have no need for sound. In such a perspective, "deafness requires *acceptance* by the society's mainstream, rather than a ceaseless quest for medical and technological solutions" (CCSD, 1992, p. 3); "the hearing society must acknowledge the rights of deaf individuals to achieve personal fulfillment on their own terms" (CCSD, 1992, p. 4). Having taken this basic stance, many members of the deaf community are not only opposed to medicalization of deafness, but also "resent hearing people imposing their values upon (deaf people) without consultation, even on issues which have direct relevance to deafness" (Mohay, 1991b, p. 719).

Within such a context, the view that deaf people will regard cochlear implantation as a tool, not as a measure to fix a defect, but to add to one's repertoire and to "use if you choose" (Ad Hoc Committee on Ear Surgery: The Greater Los Angeles Council on Deafness, quoted by House 1986b) is quite understandable. Within such a context, fear about losing this culture, should these deaf people come into the hearing world as second-class hearing citizens (i.e., as using the cochlear implant, but still hearing impaired) is quite understandable (Mohay, 1991b). Within such a context, use of paediatric implantation in children could easily be understood as a loss of young people to this particular culture, as can the view that "many deaf people consider the implant a rejection of children by their parents" (Tait, 1992, p. C-1).

So far as deaf adults are concerned, there is no question of their freedom to accept or refuse use of cochlear implantation. When children are the population of concern, however, the ethical principle of "best interests" must prevail. With reference to children, is paediatric cochlear implantation at such a stage of development that parental non-provision of such implantation could be seen as contrary to the best interests of the child? If so, then parents/guardians who do not allow such use could be seen to be abusive or negligent. Are those involved in this practice ready to support this view and to take appropriate steps to notify authorities identified as providing protection for children in such cases? When therapists are indeed ready to take the "protect from abuse" stance, it will be a mark that this therapy has, indeed, become standard. The question raised earlier has a quite different application here: What are the rights of the "distinct society of deaf people" under the Canadian *Charter*, and what in fact, are the obligations of the larger community to this group (and its child-members)?

Conclusion

The development and initial clinical use of the paediatric cochlear implant have introduced a number of medical, scientific, and technological challenges. When considered in the context of ethical, legal, and social concerns, these challenges are even more pronounced. Response to such challenges requires recognition in concept as well as in practice that: (1) the activity in question is truly multidisciplinary, and (2) the activity is truly therapy-being-researched.

The approved device, unimplanted, cannot fulfill the intention of its designers; further, the implanted device cannot be effective in the absence of a variety of services, many of which are still in early stages of research/development. There is without doubt a therapy-research imperative motivating those who wish to benefit children as they attempt to improve on earlier therapies; this intention alone does not render paediatric cochlear implantation (the device *and* the ancillary services) standard therapy. Even though there is acceptance of the device and the surgery which implants it, so long as the needed ancillary services are still in the process of research and until there is professional acceptance of some recognized criteria in these areas, the procedure-as-a-whole must be seen as a kind of research, and thus subject to certain research ethics requirements. In the case of children, these include concern for consent, harm/benefit ratio, fairness and confidentiality, and particularly, the best interests of the child.

As paediatric cochlear implantation moves along the development/clinical application continuum, that is, as it becomes standard therapy, recognized to be such by the various professional groups involved, a number of other ethical questions, presenting as legal and social queries, must be addressed. In most general terms, these comprise consideration of the limits of societal respect for the concerns of a minority cultural group, particularly insofar as respect for such a group might be seen to endanger the children who are members of it, as well as concerns about the availability of such procedures.

In terms of future development of paediatric cochlear implantation, clarification of the goal for such activity will be most important. Is the aim to provide sound for those who cannot hear? Is it to "give the deaf child, who cannot effectively use hearing aids, enough hearing so that he or she can be educated in a much less restrictive environment than in a residential school for the deaf" (Schloss, 1987, p. 310)? Is it to assist in development of the whole child? Is it to provide children the opportunity to choose either a deaf or a hearing community, or both (Mecklenberg, 1988)? Is it to somehow negate a group's cultural aspirations? Presuming the best interests of the child to be a common intention for all those involved here, some further and extended dialogue is essential as to the agreed direction for this activity. Once this is identified, the ethical difficulties implicit in such work will become more manageable, if not easily resolved.

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Notes

[1] The ethics of animal research is not included in this discussion. Cf. Midgley, M. (1983). *Animals and why they matter*. Harmondsworth, Penguin Books; Singer, P. (1975). *Animal liberation*. 2ed. NY, New York Review/Random House 1990.

[2] The laws/regulations/ethical recommendations re: research involving children differ from country to country. Cf. National Commission for the Protection of Human Subjects Biomedical and Behavioral Research. (1977). Research Involving Children, Report and Recommendations, 77-0004. Wash., D.C.: DHEW; Nicholson, R.H. (Ed.). (1986). *Medical research with children*. Oxford: Oxford Univ. Press.

[3] There is some controversy concerning use of the term, *therapeutic research*. Cf. Lynch, A. (1988). The therapeutic/non-therapeutic research distinction: Why/why not? In J.M. Nicholas (Ed.), *Moral priorities in medical research: The second hannah conference* (163-174). London: The University of Western Ontario; Rolleston, F. & Miller, J.R. (1981). Therapy or research: A need for precision. *IRB, 3* (7), 1-3; Capron, A.M. (1981). A concluding and possibly final exchange about 'therapy' and 'research' (letter). *IRB, 3* (7), 10-11, with replies from Levine, R.J. and Capron, A.M.

[4] Personal communication. Dr. Magwood, Bureau of Radiation and Medical Devices, Ottawa. January, 1993.