Contemporary Review

Bilateral Sequential Adult Cochlear Implantation: Who Should Receive Priority in the Context of a Constrained Health Care System?

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Resource allocation decisions have become increasingly necessary as the cost of health care habitually increases. Bilateral (second side) adult cochlear implantation (CI) is an example of a novel technology with accruing evidence of benefit, yet expense has limited universal employ. Currently at our centers, bilateral implantation is only provided under research protocol. In this article, we discuss the need for a principled approach concerning the distribution of a second device, both during this period of investigation and if ultimately an insured service. Allocation strategies, while extensively addressed in some arenas, have yet to be developed for second-side sequential adult CI. We advocate that physicians must assume an explicit role when both caring for individual patients as well as administering health care programs. We review social justice theories that inform resource allocation macrodecisions, and include a defence of age-based considerations. Our approach to patient selection for adult second-side CI sequentially considers clinical criteria (directly addressed in the article), a willingness to participate in rigorous research, and a 65 year cut-off. Ultimately, we employ random blinded selection for allocating bilateral CI among the remaining similarly situated individuals. This approach functions impartially and in a manner that is transparent for both patient and physician.

INTRODUCTION

Unilateral cochlear implantation (CI) has enormously improved the quality of life for the severely hearing impaired. In this article, we review the ethical basis for distribution of a second-side (bilateral) cochlear implant for adult patients in the setting of resource constraints. In Canada, bilateral simultaneous or sequential cochlear implantation in children is commonplace; however, routine second-side surgery in adults has yet to receive similar endorsement. As supporting evidence accrues, anticipated limitations in implant devices as well as surgeon/facility availability may expose patients to untenable wait times. The situation will be compounded as unilateral cochlear implant candidacy criteria are expanded and pediatric CI graduates with aging implant systems inevitably suffer device failure and require replacement.

The anticipated problematic access raises the issue as to how a scarce medical resource may be best allocated. The challenge to physicians is one of priority setting. As the working reflection of our hospitals’ cochlear implant programs, we suggest an allocation consisting of clinical eligibility requirements, including age prioritization, with ultimate selection from within the reduced patient population by random blinded selection. Recognizing that health care priority setting is now commonplace, we suggest that our principled clinical approach may aid other programs forced to make rationing decisions for health services which share features with bilateral cochlear implantation.

Second Cochlear Implant as a Social Good

The decision to fund any new treatment is complex and extends beyond the scope of this discussion. We will not address other economic and system-level factors relevant to the decision to insure a health service. Our position, which accords with the clinical experience of
many ENT surgeons,1 is that bilateral implantation provides patients with a significant hearing advantage, and evidence to this effect continues to accrue. Patients with a second implant experience improved sound localization,2–9 as well as better speech understanding in both quiet and noise.7–21 Only bilateral cochlear implantation can ensure that the ear with the best postoperative function has been implanted, and also that a patient has continuous auditory input should an isolated device fail (redundancy).

Framing the Questions
The issue of prioritizing access to a second CI reflects more general problems implicit in a publicly funded health care system. These include the need for a fair and principled means of allocating restricted services, and a clear role for physicians who must both care for individuals as well as administer health care programs. The priority Canadians place on health care22 does not alleviate the need for restricting the services that can be offered. Health care cannot usurp all other national considerations.

While direct and indirect service provisions for unilateral cochlear implantation are established in all provinces/territories, with similar access, the availability of bilateral cochlear implantation varies significantly by region. We anticipate multiple factors leading to the inability of programs to offer second CIs to all patients, highlighting the need for a fair means of distributing this limited resource. We also anticipate a conflict of interest within programs where physicians may be called upon to both plan for and execute prioritization decisions that impact their own patients. Both of these issues raise important ethical concerns that must be addressed.

The Fiduciary Duty of the Physician
The public expects that a physician’s first duty is to the patient, a notion supported by the authors of this article. This value corresponds to the Hippocratic ideal that a physician must attend to the needs of the patient at hand. This concept has been codified in the Declaration of Geneva and the International Code of Medical Ethics: “a physician shall owe his patients complete loyalty and all the resources of his science.”23 The physician’s obligation is fiduciary (Latin fidere “to trust”). Within a fiduciary relationship, a person places their trust in a professional, expects that conflicts of interest will not threaten the professional relationship, and trusts that the professional will always act in their—the patient’s—best interest. Within this construct, the physician cannot look at the aggregated good for society or consider third parties. The physician must act in the interests of their immediate patient, irrespective of the impact that such actions might have on other statistical persons who may also have a need.24 However, the Hippocratic ideal has been challenged on several grounds.25 It may prescribe an overly narrow focus that has physicians subverting their role as socially conscious physicians/citizens. Weighing the needs of patient populations and the availability of health services represents a shift in the perceived function of physicians in society. This new role of physician as a health care resource manager has been supported in Canada by the Medical Council of Canada26 and the Royal College of Physicians and Surgeons of Canada,27 and internationally by the World Medical Associations International Code of Medical Ethics.28 The American Medical Association’s Code of Medical Ethics section on allocation of limited medical resources acknowledges the need for such decisions, but asserts that these decisions should not compromise fiduciary duty.29 However, a more recent publication on allocation of donated organs emphasized the ethically justifiable role that physicians must assume as resource managers.29

Theories of Distributive Justice and their Application to Cochlear Implantation
Distributive justice concerns how social goods such as health care should be dispersed across persons.30 Specific theories describing how to achieve justice abound, though none have met with uniform consensus. We describe several theories that have received considerable attention in the ethics literature, and summarize their potential application to the problem of distributing a limited supply of second CIs.

A utilitarian approach aims to achieve best possible outcomes. Some utilitarian approaches consider societal contribution.31 Here, primacy is given to notions of public interest, the common good and the welfare of the community,32 prioritizing benefits to society over benefits to the individual. The considerable cost of cochlear implantation can be seen as justification for this selective process. Unfortunately, this utilitarian approach is faced with the insurmountable predicament of requiring clinicians to adjudicate the value of an individual’s societal contribution: such a judgment requires information not attainable from a brief patient encounter and is outside the realm of physician expertise.

In contrast, deontological theories suggest an individual’s claim to a health service arises from rights rather than maximizing best outcomes. Egalitarian theory suggests an individual’s rights claim arise from patterns of distribution: all equally situated individuals should have an exactly equal right to health care services. In the instance of a second cochlear implant, true egalitarians would assert that each individual ought to have an exactly equal chance at receiving this benefit. The means of satisfying this principle would include a lottery based system or applied queuing.33 Either allows for clinicians to maintain their fiduciary obligation and still operates within the confines of a fixed number of devices to be implanted. This approach is impartial, transparent, and straightforward to operate. However, a simple lottery does not consider important factors such as how long the patient has had hearing loss, the severity of the loss, and how important hearing is to their function.

An alternate form of egalitarianism championed by John Rawls permits instances of inequality when they benefit those “worst off.”34 Within the context of bilateral cochlear-implant candidacy considerations, the
individual with the poorest functional status after first implantation ought to receive the second implant. To an extent, this paradigm is currently employed, as patients classified as being deaf-blind now universally receive bilateral implantation. Use of objective measures of hearing loss also helps avoid problematic value judgments. This avenue has the virtue of being transparent to both physician and patient. However, the framework does not aid decision making when individuals have equally limited hearing, and it presumes that our measures of hearing assessment are sufficiently accurate and reliable. Regrettably, identifying the “worst off” is difficult.

Other justice theories employ age considerations in health care rationing. One such theory has been championed by Norm Daniels. His book *Just Health Care* addresses ethical issues surrounding macro-level decisions pertaining to health policy and applies social justice theory to health care.35 Noting that all health care systems operate under the confines of limited resources, he argues that not all therapies can be provided to all individuals at all times. Daniels contends that access to health services should be age-based, recognizing that age imparts natural limits to normal functioning, which should lead to natural limits to accessing health care services. He also emphasizes that health insurance schemes must plan for needs across the whole span of an individual’s life, such that it is prudent to save certain resources for certain periods of a life span. This reasoning leads Daniels to conclude that some health services are inappropriate for certain periods of life and further, that under conditions of scarcity, age should be a means of allocating health services. He points out that on the surface, restricting services based on age appears unappealing because it is discriminatory. Daniels maintains that age-based rationing is not akin to racism because we all must anticipate getting older. Moreover, Daniels points out that the basis of racism or sexism is unfair because of the irrelevant nature of race or sex to the discrimination process. In contrast, age is highly relevant for considering equal access to health care, since any individual’s opportunities naturally change as they approach death. For this reason, Daniels concludes that age based restrictions, while discriminatory per se, should not be considered unfair in the allocation of health services. Daniel’s theory is relevant to the management of hearing loss, since hearing is expected to decline as a person ages. Nonetheless, we recognize that an individual’s age is a somewhat crude means of assessing future longevity, although it does approximate anticipated future opportunities.

**The Need for an Explicit Position**

There is a need for a principled rationing strategy when providing a second cochlear implant. As clinicians, we require such a strategy to guide the difficult allocation decisions that arise out of clinical studies, demonstrating benefit with bilateral sequential implantation. Such a strategy will be especially needed if government/insurance bodies elect to insure bilateral adult implantation. Should this expectation be realized, demand will outstrip supply; limitations in the number of facilities/surgeons that perform this procedure, as well as anticipated quotas as a corollary of expense, will both prevent timely implantation. Otologists will be required to prioritize patients, underscoring the importance of examining how different allocation schemas might aid distribution of a limited supply of cochlear implants. As such, physicians must balance their fiduciary role with that of manager of health services.

In our experience, creating a decision-making framework for which of our postlingually deafened adults is offered a second cochlear implant has been a difficult undertaking. Currently, at Sunnybrook Health Sciences Centre in Toronto, there are over 300 unilateral implantees (a total pool of over 1,000 unilateral implant recipients within the program) who are considered appropriate candidates for sequential bilateral implantation. This pool reduction stems from consideration of compliance, otologic status of the nonimplanted ear, vestibular function, ability to meet fiscal requirements of implantation (replacement processor cost), and overall health status. Currently, age is not a contraindication for unilateral implantation, and it does not enter into candidacy assessment, such that a candidate of any age is offered unilateral implantation in an expeditious fashion.

**Our Approach to Allocation**

Our approach addresses the challenge posed by a resource limited environment, and sequentially involves the above delineated clinical criteria, and both a willingness to participate in rigorous research and an age cutoff. Ultimate selection from this reduced candidate pool is by random blinded selection/lottery. Bilateral implantation is only provided under research protocol.

This approach functions impartially and in a manner that is transparent for both patients and physicians. Random blinded selection is a fair distribution paradigm when deciding among a group of similarly situated individuals.30 Our two programs have taken the position to not provide a second cochlear implant to those over 65 years. While recognizing that such a policy discriminates by age, for reasons accounted by Daniels, it should not be judged unfair. In most instances this policy will maximize the duration of benefit experienced by implantees. An age cutoff of 65 will additionally prioritize individuals whose expected needs include employability. Bilateral cochlear implantation serves to increase the likelihood of assisting an individual in the work environment by improving speech in noise, providing redundancy in input, and mitigating against fatigue.

We clearly recognize that this schema is imperfect. However, we strongly desire a system that does not involve nonmedical evaluative judgments on the part of the clinician, as well as a model that is simple and impartial in its application. While conceding that these clinical exclusion markers are problematic, we feel that those not being included in the eligible group should still anticipate a reasonable auditory disposition with their
singer device. As such, these individuals are not overly disadvantaged by this process. Our proposed age cutoff will require reassessment if and when resource scarcity abates.

CONCLUSION

We have elected to explicitly disclose our current practice as we believe that pragmatic discussion around the allocation of a limited resource is increasingly substantive and timely. The predicted evolution of health systems around the globe, as well as the shape of future medical practice, will be heavily influenced by both the macro- and microlevel resource-dependent decisions we currently face. We believe that physicians must assume a leadership role in this discussion, and failure to do so may compromise our future influence in such matters. In conclusion, we describe a method of allocation that is currently employed, and we ground this method in principles of distributive justice as they apply to health care systems. This model of allocation will be of interest to other cochlear implant programs and other similarly situated bodies that are also called upon to ration health care services.

BIBLIOGRAPHY