Prioritization of Reimplantation in Previously Successful Cochlear Implantation Following Natural Device Failure

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Introduction: Cochlear reimplantation procedures account for approximately 5% of all implant cases and may be caused by internal device failure, skin flap complications, or an unexpected decline in auditory performance. This issue, in concert with changing demographics, expanded audiometric candidacy criteria, adult bilateral implantation, and implantation for unilateral hearing loss, all place escalating pressure on device availability and resource allocation in a publically funded health care system.

Objective: The predictable and problematic access to a scare medical resource requires rigor in establishing program priority and formal policy. We present a single cochlear implant center's working reflections and an attempt at a principled approach to rationing health care decisions.

Methods: Different approaches to health care rationing are examined and discussed. We describe a method of allocation that is currently employed by a large Canadian quaternary care center and ground this method in important principles of distributive justice as they apply to health care systems.

Results: We elect to recognize device failure as analogous to sudden sensorineural hearing loss, with the associated need to expedite reimplantation. We consider this an ethical approach grounded in the egalitarian principle of equality of opportunity within cohorts of patients.

Conclusion: Porting the practice from sudden sensorineural hearing loss, the time-sensitive need for hearing restoration, and maximized communication outcomes, dictates prioritization for this patient population. The predicted evolution of health systems globally and the shape of future medical practice will be heavily influenced by both the macro and micro level resource-dependent decisions implant centers currently face. Key Words: Cochlear—Device failure—Ethics—Hearing—Implant—Loss—Rate—Revision—Sensorineural—Sudden.

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Cochlear implantation is immensely successful in the habilitation/rehabilitation of the severely hearing impaired. In Canada, adult patients are conventionally queued for surgical restoration. These individuals often suffer an untenable wait for initial cochlear implant (CI) surgery as a corollary to provincially mediated device allocations, as well as surgeon availability.

There is now the added pressure of previously successful implant recipients requiring reimplantation as their internal hardware fails. Currently, reimplantation procedures account for approximately 5% of all implant cases and may be caused by internal device failure, skin flap complications, or an unexpected decline in auditory performance (1,2). This trend, in concert with changing demographics, expanded audiometric candidacy criteria,

adult bilateral implantation, and implantation for unilateral hearing loss, all place escalating pressure on device availability and resource allocation in a publically funded health care system.

The predictable problematic access to a scare medical resource requires rigor in establishing program priority and formal policy. We present a single CI center's working reflections and an attempt at a principled approach to rationing decisions.

NEED FOR AN EXPLICIT POSITION

A consistent, principled, and transparent protocol is required for reimplantation cases. Any approach can be characterized as a tradeoff between multiple core ethical values. There are existing conditions that result in disparate prioritization of a waiting patient. Pediatric patients have an accelerated timeline as do sudden sensorineural hearing loss (SNHL) patients. The former is clearly to maximize central auditory abilities while the latter has a dramatically reduced rehabilitative course with near instant audition. Sudden sensorineural hearing loss is unique in that the abrupt change in auditory function presents an significant psychosocial burden and negative

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impact on quality of life (3,4). There is also the physiologic need to rapidly implant a potentially fibrotic cochlea in patients with meningitis (5).

Whenever a patient is forced to wait to receive a medical good the justifications to address the delay in treatment should be explicit to the patient, the system, and the political context. An ideal system would be one based on objective data that would consistently result in the same prioritization given to any individual patient.

THE DUTY OF THE PHYSICIAN

The subject of medical resource rationing is overly familiar in a publically funded health care system. Provincially funded implant programs are implicitly mandated to positively impact an individual with an expectation of fiscally accountable allocations. Each province independently prescribes the funding envelope for CI surgery. This results in differential wait times across Canada. The competing needs of a patient are uniquely at odds with the needs of a fiscally conservative program, requiring physicians to both plan for and execute prioritization decisions that may negatively impact their own patients.

The Hippocratic Ideal incorporates the obligation to patients as fiduciary (in Latin: fidere, 'to trust') (6). Within a fiduciary relationship, a person places their trust in a professional, and trusts that the professional will always act in their best interests; irrespective of the potential impact that such actions might have on other persons (7). Juxtaposed is the evolving role of physician as a health care resource manager (8). This change has been supported by the Royal College of Physicians and Surgeons of Canada and internationally by the World Medical Association's international code of medical ethics (6,9).

THEORIES OF DISTRIBUTIVE JUSTICE

There are a host of approaches to best allocate a social good across populations (10).

A utilitarian approach attempts to maximize benefit for the patient, the community, and the health system. Here, the benefits to society supersede the individual (11,12). The substantial benefits to the individual and the community, extending to include even the tax base, are considered and contrasted against exceptional device cost. This approach is problematic in the need for the physician to ascribe value to the individuals' contribution and worth.

A deontological approach surmises that health care entitlements arise from ascribed patient rights. There are no value judgements, but rather equally situated individuals who have an equal right to health services (13). These theories can be operationalized to CI surgery through patient lottery selection or queuing. A physician can still maintain their fiduciary obligation as it is impartial and transparent in application while still satisfying the role of physician as health manager. These

systems, however, do not address duration, severity, and the psychosocial and/or functional impact of hearing loss on an individual.

There is a more recent theory that attempts to apply social justice theories to macro level health economics. Inherent within this construct is the idea that not all health care resources can be provided to all patients (14). There is an implicit age-based bias; that age imparts natural limitation to function and under conditions of scarcity, disbursements should mirror age-associated norms (14). Health service delivery must consider the entire span of an individual's life and allocate accordingly. This schema acknowledges the inherent discrimination; however, age-related transitions through life apply to all individuals, regardless of sex or race. This approach can be applied to CI surgery as severe hearing loss is dramatically more common at the extremes of life.

OUR APPROACH

We elect to recognize device failure as analogous to sudden SNHL, with the associated need to expedite reimplantation. This preferential queuing is in recognition of the rapidly altered ability to hear with the associated impact on function and the reality that many of these individuals had to experience a queuing process when receiving their first implant.

Porting the practice from sudden SNHL, we recognize the time-sensitive need for hearing restoration and maximized communication outcomes, balanced with the significant accommodations required for work and home life. However, to be accelerated in the queue, a patient needs to have significant listening needs. This can include employment, volunteer, or familial needs. This caveat is an explicit attempt to not impede surgery for other patients with severe hearing loss who have significant auditory requirements.

We consider this an ethical approach grounded in the egalitarian principle of equality of opportunity within cohorts of patients. In doing so, patient waits are based on a principle of equity rather than equality. This does not afford a similar surgical wait for all patients but rather all similarly situated individuals. Within these cohorts, allocations can be either through lottery or time-based rationing, where we elect for the latter. These individuals have previously suffered the burden of a queue and it would seem unfair to have to wait twice.

This approach will aggravate the wait times for those with gradual onset of profound hearing loss. As such, it will be important to monitor the adjusted wait times for the global surgical waitlist and attempt to procure additional funding to offset this change.

SUMMARY

We have elected to explicitly disclose our current practice as we think that pragmatic discussion around the fair allocation of a limited resource is substantive and

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timely. The predicted evolution of health systems around the globe and the shape of future medical practice will be heavily influenced by both the macro and micro level resource-dependent decisions we currently face. We think that physicians must assume a leadership role in this discussion, and failure to do so may compromise our future influence in such matters. We describe a method of allocation that is currently employed by a large Canadian quaternary care center and ground this method in important 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.

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