

■ Economic Evaluation of Cochlear Implants in Children

■ Évaluation économique des implants cochléaires chez les enfants

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Abstract

This paper presents a framework for the economic evaluation of cochlear implants in children in the Canadian setting. The development of the framework was guided by a pilot study in one pediatric centre. The charts of 18 children who received cochlear implants were reviewed to summarize communication and education outcome data as well as detailed information on the clinical services provided. Results are documented in communication outcomes and educational placement following three years of implant use. The health related costs of pre-implant assessment, surgery, and post-audiological management were detailed over a three-year period. In addition, a focus group interview with parents of children who received implants identified family-related costs. The framework is a comprehensive model that can be applied in other Canadian settings in economic evaluations of pediatric cochlear implantation.

Abrégé

Cet article présente un cadre d'évaluation économique des implants cochléaires chez les enfants au Canada. Une étude pilote menée dans un centre pédiatrique a guidé l'élaboration de ce cadre. Les auteurs ont passé en revue les dossiers de 18 enfants ayant reçu des implants cochléaires en vue de tracer un portrait de leurs aptitudes à la communication et de leurs résultats scolaires. Cet exercice visait aussi à fournir de l'information détaillée sur les services cliniques qui leur ont été offerts. Les résultats sont exprimés en fonction des aptitudes à la communication et du parcours scolaire après trois années d'utilisation des implants. Les coûts de l'évaluation avant l'implantation, de la chirurgie et de la gestion auditive après l'implantation ont été examinés sur une période de trois ans. De plus, un groupe de discussions dirigées avec les parents des enfants ayant reçu un implant a servi à préciser les coûts pour les familles. Ce cadre est un modèle exhaustif qui peut servir à mener des évaluations économiques de l'implantation cochléaire dans d'autres milieux canadiens.

Key Words: cochlear implantation, pediatric, economics, cost-effectiveness, outcomes

Severe to profound hearing loss is associated with significant social and economic costs to individuals with hearing impairment, their families, and society in general (Downs, 1997; Mohr et al., 2000). In a burden of illness study, Mohr et al. (2000) estimated that the societal costs for early onset severe to profound hearing loss exceeds \$1 million (US dollars) per individual. Special education resources accounted for about 21% of total costs for all individuals with severe to profound hearing loss. Despite significant investments in hearing technology and rehabilitation, poor communication and academic outcomes have traditionally been reported for children with significant hearing loss (Carney & Moeller, 1998).

In the past decade, cochlear implants have become a routine treatment option for children and adults with severe to profound hearing loss, essentially replacing conventional amplification as the hearing technology of choice. Studies on the effectiveness of cochlear implantation have shown that children with implants have

greatly improved access to auditory information and acquire spoken communication skills (O'Donoghue, Nikolopoulos, & Archbold, 2000; Waltzman, Cohen, Green, & Roland, 2002). There is also evidence that cochlear implantation leads to changes in educational placement from special education classes to mainstream settings (Daya, Ashley, Gysin, & Papsin, 2000; Koch, Wyatt, Francis, & Niparko, 1997). However, in contrast to traditional amplification devices, the costs of cochlear implants are considerably higher. This may result in a rationing of cochlear implants in countries with socialized medicine, forcing health care providers to restrict access for some individuals. In Canada, the availability of cochlear implant devices in both pediatric and adult settings has been somewhat restricted with certain provinces allocating devices on a quota system. The potential consequences of these decisions are different candidacy criteria, different levels of access and different standards of care in various parts of the country.

Public demand for new technology continues to grow at a rapid pace and the requirement for cochlear implant technology is no exception. Parents and providers have fuelled the demand for a device that can enhance quality of life through improved access to sound. Candidacy criteria have broadened to include children with additional disabilities and children with more residual hearing. Confronted with shrinking resources, this increased demand creates a need for guidelines on the use of this technology. Current health technology assessment is concerned not only with the effectiveness of an intervention but equally with the costs associated with these interventions compared to another. In Canada, cochlear implants have never been subject to a cost-effectiveness study despite the rationing of the device for a number of years. The long term cost effectiveness of cochlear implantation may have the greatest impact on public health policy and practice decisions. Decisions regarding access and benefit from this technology have been left with individual health care providers.

A cost-effectiveness study of pediatric cochlear implantation would involve comparing the costs and benefits of cochlear implantation with an alternative intervention. Such a study is likely not possible in Canada as an appropriate comparison group of children who use hearing aids is no longer available. However, it is important to document economic costs associated with the intervention to guide decision makers concerned with the increased costs and effectiveness of new and existing programs.

Studies measuring the cost effectiveness of cochlear implants in adults with postlingual deafness have found cost-utility ratios (cost per Quality of Adjusted Life Years) that compare favorably with other medical and surgical interventions (Cheng & Niparko, 1999; Harris, Anderson, & Novak, 1995; Wyatt, Niparko, Rothman, & deLissovoy, 1996). Cost-utility analysis relates the net cost of an intervention to the net gain in quality of life resulting from the program or services. It is well recognized, however,

that findings for adults cannot automatically be applied to decision making for children. Cochlear implantation involves a comprehensive process including pre-implant assessment, surgery and post-implant management. The economic evaluation of cochlear implantation in children presents special issues particularly related to post-operative rehabilitation. The majority of adults who receive cochlear implants have post-linguistic deafness and the benefits in communication functions are observable very soon after implantation. In contrast, most children who receive implants have congenital or pre-linguistic hearing loss. The rehabilitation process for children is extensive and variable in method and intensity between implant centers, and the desired communication and social outcomes may not be apparent for several years.

Economic concerns have prompted investigators in a number of countries to examine the cost-effectiveness of pediatric cochlear implantation (Cheng et al., 2000; Severens, Brokx, & van den Broek, 1997; Summerfield, Stacey, Roberts, Fortnum & Barton, 2003). In a cost-utility analysis of cochlear implants in children in the United States, Cheng et al. (2000) reported that cochlear implants improved the quality of life in children with profound deafness and reduced the costs of childhood deafness for society. The reduction in costs was largely accounted for by the shift towards mainstream educational placements that presumably reduce resource use compared to specialized self-contained classes. These reduced education costs generated a savings of \$65,555 (1999 US dollars) per child. It is unknown whether the special education services in a Canadian mainstream setting would result in a similar reduction in educational resources.

It is difficult to directly apply study results from one country to another given the differences in health care systems, costs of services, and health and educational service delivery models. In a multi-center study of 12 programs in the United Kingdom, Barton, Bloor, Marshall, & Summerfield (2003) showed that even with centralized cochlear implant services, there was great variability in costs between programs, ranging from €9,482 to €47,173 over a child's lifetime of 73 years. The authors of this study highlight the wide variation in the estimated lifetime costs of cochlear implantation in children based on cost data reported in five previous studies ranging from €50,257 in a US study (Cheng et al., 2000) to more than €124,350 in a study from the Netherlands (Severens et al., 1997). They stress the importance of factoring in ongoing implant maintenance costs in economic evaluations as these accounted for 22% of the total United Kingdom cochlear implant budget with a projected rise to 64% over a 15-year period for a projected annual volume of 222 pediatric implantations. These examples suggest that although there is a small body of literature on the economic evaluation of pediatric cochlear implantation, generalization of the results to another decision-making context is problematic.

Cochlear implants are typically provided to children with the premise that access to auditory information which is not available from less expensive conventional amplification will translate into improved communication and academic outcomes, mainstream educational placements and ultimately better social and economic opportunities. In addition to speech recognition and language outcomes, a comprehensive assessment of the cost-benefit of cochlear implantation for children must consider educational placements and costs, academic and social functioning and eventual employment status (Durieux-Smith, Delicati, Brewster, Fitzpatrick & Phillips, 1995; Francis, Koch, Wyatt, & Niparko, 1999). We propose that a comprehensive cost-benefit analysis of cochlear implantation in children must quantify direct medical, rehabilitative and educational costs borne by public systems as well as direct and indirect costs for families.

The present research was designed to serve as a pilot study for a comprehensive economic evaluation of cochlear implants in children in a Canadian setting. Using cases implanted in one Canadian pediatric cochlear implant center, the objectives of this study were 1) to identify, in an exploratory way, the direct and indirect costs of cochlear implantation in children, 2) to define the expected benefits of cochlear implantation in children, and 3) to develop a framework to study the economic evaluation of cochlear implants in children in a Canadian setting.

Method

Study Design

This pilot study involved a retrospective chart review of resource use and clinical outcome measures for children implanted at one Canadian pediatric center between 1993 and 1996. The study included all children consecutively implanted during this 3-year period who resided in the local area (within driving distance to the hospital outpatient clinic) and who had used an implant for at least 3 years. A total of 18 children met the criteria and a comprehensive review of their clinical charts was conducted to determine the feasibility of collecting data related to costs and benefits retrospectively over a period of three years. The implant center is a publicly funded health care facility in the province of Ontario where the provincial Ministry of Health determines the annual allocation for cochlear implant devices. During the period for which data were collected, the allocation for pediatric implantation was five devices annually for a total catchment area of approximately 1 million people. In addition to the chart data, qualitative data were collected through a focus group interview with parents of four of the implanted children. The Research Ethics Board of the Children's Hospital of Eastern Ontario approved the study.

Study Population

The 18 children meeting the criteria for this study had pre-linguistic hearing loss with an average age of diagnosis of 2.3 years (range 2.5 months to 9.0 years), and average age of implantation of 6.7 years (range: 1 year 10 months to 15 years 7 months). One child had been diagnosed with a moderate to severe loss at age 3 which progressed to a profound loss by age 9. All children had used a cochlear implant for at least 3 years (range 3.5 to 7.3 years); 17 of 18 used a Nucleus 22 device for the entire study period and one Nucleus 22 user was re-implanted at 2 years post-implant with a Nucleus 24 device due to device failure. At the pre-implant stage, 8 of 18 children were enrolled in auditory-verbal therapy programs and 10 were in programs with an emphasis on sign language. All received weekly auditory-verbal therapy sessions through the implant center for at least two years post-implant. Children of school age at implantation or entering school during the period covered by this study also received rehabilitation services through the educational setting.

Data Collection

Medical Costs

Resources employed in providing cochlear implant services were identified through hospital statistics, review of clinical chart entries for the 18 participants and discussion with clinicians regarding the time allocated for various types of clinical audiology and rehabilitation visits. Rehabilitation services provided by the educational system (local school board) were not included as part of the medical costs.

A data sheet was developed for the collection of basic demographic information, pre-implant and post-implant history, and the recording of outcome measures. Data collection included information on variables known to have an impact on outcome, including age of onset of deafness, age of hearing aid fitting, age of implantation, and mode of communication. All speech recognition results were recorded. The data sheet also included information (for example, number of days in hospital, number of visits to outpatient clinics, etc.) that was used to calculate the costs associated with cochlear implantation. Direct medical costs were calculated by determining the costs associated with each phase of cochlear implantation. The phases included candidacy assessment, surgery and hospitalization and post-implant follow-up. Post-implant follow-up included initial device fitting, programming and maintenance as well as rehabilitation. Micro-costing was used to calculate the outlays for each individual resource in order to estimate, as accurately as possible, the total resource costs including personnel, facilities and equipment for each child implanted.

Determination of candidacy included assessments in audiology, auditory-verbal therapy, psychology and social work, in addition to otologic and medical pre-operative evaluations. Hospital financial services

personnel were consulted to ensure the accuracy of the calculation of costs for cochlear implantation. For the calculation of direct costs, the number of hospital visits and the service providers involved were recorded. Costs of clinic resources per visit were calculated by dividing the annual cochlear implant budget for personnel by the number of visits per year. A percentage of 29.4% of the personnel costs was used to estimate facility and equipment costs. This is a composite overhead for the hospital, a standard allocation set annually by the Ontario Ministry of Health, which includes all facility costs, including capital costs. Physician professional fees were based on the standard provincial billing rates.

Implantation costs included the cost of the cochlear implant device, surgery costs including the surgeon's and anesthesiologist's professional fees and hospital inpatient costs. The type of device implanted, the number of days in the hospital and the number of post-operative outpatient visits were recorded for each child. The total cost of the hospital stay was calculated by multiplying the number of overnight stays in the hospital by the per diem fee which encompasses all the surgery costs, exclusive of the medical fees and in-hospital post-operative care.

Post-implant follow-up included clinic visits for the initial fitting and programming of the implant, ongoing mapping sessions and speech perception testing. The service delivery model at this clinic included weekly auditory-verbal therapy sessions, a family-centred intervention program aimed at teaching children and their families to maximize auditory communication skills (Fitzpatrick, 1997). School-age children were eligible to receive weekly therapy sessions at the implant center for a period up to 2 years post-implant while preschool age children received therapy from the clinic until they entered the educational system typically at age 5. The number and frequency of sessions varied depending on the child's progress and availability of other therapy resources.

Family Direct and Indirect Costs

Data related to family costs were collected qualitatively through a focus group interview with the parents of four children from the sample. The parents were asked to detail the out-of-pocket financial costs not covered by the health care or educational systems, including the cost of private cochlear implant insurance. Open-ended questions were used to collect information on stresses specifically related to cochlear implantation and the benefits and changes in the quality of life associated with use of the cochlear implant. Data were analyzed by two interviewers to identify the primary themes.

Benefits

A short-term benefit commonly associated with cochlear implants is improved speech recognition. A variety of speech recognition measures appropriate to the child's age and linguistic level were administered pre-implant, 6 months post-implant and at annual intervals as part of the clinical protocol. Speech perception data

were extracted from the clinical records. Information on educational placement pre- and post-implant was also extracted from the clinical charts or through discussion with the child's therapist. Benefits reported by parents through the focus group interview were also recorded.

Results

Direct Health System Costs

A summary of the direct costs of cochlear implantation in a sample of 18 children from pre-implant evaluation to 3 years post-implant is shown in Table 1. The mean number of visits for each post-implant service is provided. All costs have been converted to 2004 financial levels. Total costs per child were \$ 64,171.46 (Canadian). Costs per child for pre-assessment varied depending on the number of assessment visits, whether sedation was required for a CT scan, whether magnetic resonance imaging (MRI) was required and whether there were additional pre-surgical medical assessments required (e.g. cardiology). None of the children in this cohort had an MRI and none required additional medical assessments.

Post-implant follow-up includes clinic visits for device fitting, ongoing programming and troubleshooting sessions, speech perception testing, and rehabilitation. The number of visits varies per child depending on a number of factors; for example, the number of visits can increase if there are programming problems or equipment malfunctions. The total number of auditory-verbal therapy (AVT) sessions per child over 3 years was 59.2 (range 14 to 121) for an average total cost per child of \$18,418.02 (range \$4,353 to \$37,631). In this clinical setting, the total number of visits varies with age at implantation ($r = -.54$, $p < .05$) and therefore so do the direct health care costs. Preschool children generally had more sessions at the hospital as rehabilitation was also provided in the school setting for school-age children. For this pilot project, only the rehabilitation costs for the clinical program were recorded.

Family Costs

The costs described by families that were not covered by the public health or education systems were organized into two main categories of direct and indirect expenses. The primary direct costs included private cochlear implant insurance and extended warranties as well as charges for the maintenance and replacement of external equipment. Indirect costs were related to travel and parking expenses, child-care fees for special appointments, time out of the labor force and time away from work to attend clinic visits. Family stress related to the cochlear implantation process also evolved as a central theme during the focus group interview with parents. The initial decision-making around surgery, the assessment period and the waiting time for surgery were sources of anxiety during the pre-implant phase. Complications post-surgery and device failure concerns were identified as stresses related to the surgical intervention. During the post-implant period,

Table 1

Summary of direct medical costs of cochlear implants for 18 children

Phase		Average cost per child	Mean number of visits per child (range)	
Assessment		\$3,074.02		
Implantation	Hardware	\$28,525.00		
	Surgery	\$1,810.54		
	Hospital Stay	\$3,202.34		
	Post-op outpatient follow-up	\$46.28		
Post-implant follow-up				
Year 1	Programming and assessment	\$3,472.86	11.2 ± 3.9	(6 to 20)
	Rehabilitation*	\$9,260.96	29.8 ± 10.2	(14 to 47)
Year 2	Programming and assessment	\$1,390.36	4.5 ± 2.2	(1 to 9)
	Rehabilitation*	\$6,803.17	21.8 ± 14.1	(3 to 42)
Year 3	Programming and assessment	\$987.89	3.2 ± 3.3	(0 to 13)
	Rehabilitation	\$5,598.04	18.0 ± 10.2	(5 to 34)
Total Medical cost per Implanted Child		\$64,171.46		

*Only the costs of rehabilitation at the implant center are included; rehabilitation costs in the educational setting are *not* included

certain stresses were related to the technology and included speech processor device problems and the troubleshooting of defective equipment. Other stresses were more specific to the child and included teasing by peers and limitations for sports and play activities due to the use of a cochlear implant. Finally, parents also discussed the time pressures of frequent visits to the implant center for speech processor programming and therapy.

Benefits

Communication

Speech recognition results were available for 16 of the 18 children in the sample. One child was French speaking and comparable outcome measures were not available; a second child moved and was lost to follow-up. As the speech perception measures varied across participants, the results were translated into speech perception categories on an ordinal scale (Geers & Moog, 1987). Cheng, Grant and Niparko (1999) adapted this scale to include 6 speech perception categories, ranging from detection (category 1) to open-set speech recognition (category 6). Geers and Moog (1988) suggested that children who attain Category 3 or higher, thereby demonstrating some word recognition (measured by scores on closed-set word tests), have the potential to

develop intelligible speech and spoken language. The results in Figure 1 indicate that 12 of 16 children attained Category 4 or higher by 3 years post-implant.

A second expected benefit of cochlear implantation is that children who have improved access to hearing will develop or improve auditory-verbal communication skills. Of the 10 children who were communicating with sign language only pre-implant, four have become auditory-verbal communicators and three use a combined oral-sign system (Table 2). The three children who continued to communicate using sign language only were age 7 or older at implantation.

It is also expected that children with enhanced oral communication skills can move from more "self contained" or specialized educational settings to inclusion with hearing

peers. Educational placement information is not available for one child who moved during the 3-year period of the study. Of the other 17 children, 13 attended partial or full mainstream classes by 3 years post implant (Table 3). The three children who remained exclusively in a self-contained classroom were implanted after age 7 and used sign language as their primary communication mode prior to implantation. One child implanted at age two, who presented with developmental concerns, did not show significant gains in speech perception abilities; he required sign language and was only partially main-streamed by 3 years post-implant.

Quality of Life Benefits

Formal measures of psychosocial or quality of life benefits were beyond the scope of this preliminary research project. During the focus group discussion, parents shared their perception of the benefits provided by a cochlear implant. These ranged from the ability to hear environmental sounds and increased safety and distance hearing to more rapid progress in speech and language as well as improved speech intelligibility. Parents also noted several benefits that were more apparent in the academic setting. These included the need for fewer support services at school and improved concentration. After implantation, children were more relaxed, more confident and better advocates for themselves.

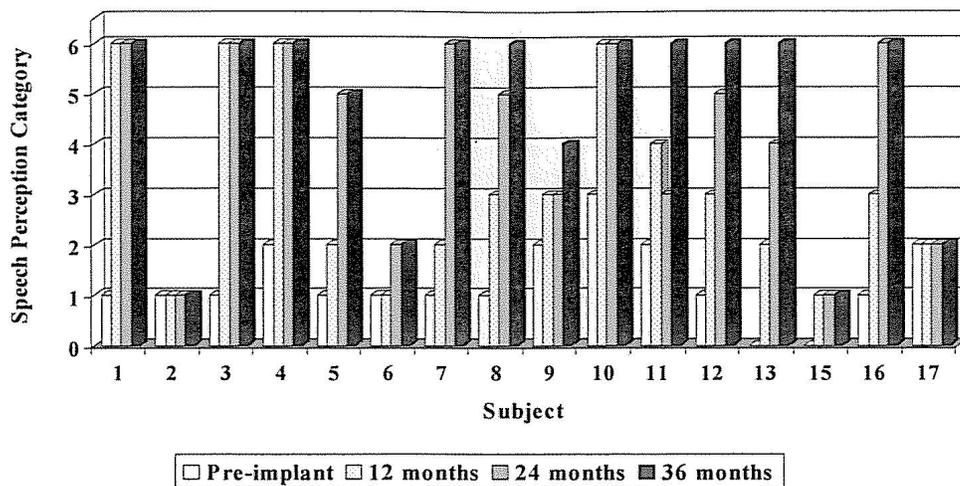


Figure 1. Speech perception category as a function of implant use

Table 2

Communication modes pre-implant and 3 years post-implant

Pre-implant	Post Implant		
	Auditory-verbal	Signing-oral	Signing
Auditory-verbal	6	0	0
Signing	4	3	3
Totals	10	3	3

Table 3

Educational placements pre-implant and 3 years post-implant

Pre-implant	Post Implant		
	Mainstreamed	Partial Mainstream	Self-contained
Mainstreamed	4	0	0
Self-contained	4	2	3
Preschool	1	2	0
Totals	9	4	3

Economic Evaluation Framework

Figure 2 presents a framework for the economic evaluation of cochlear implants in children in the Canadian setting based on the models of Carter and Hailey (1995), Summerfield and Marshall (1999) and Francis et al. (1999). This model identifies the costs according to the three phases of implantation: pre-implant assessment, implantation, and post-implant follow-up. The post-implant follow-up is further divided into device

programming/assessment costs, therapy through the health system, therapy through the educational system, and family costs. The consequences of pediatric cochlear implantation in this model include short-term and medium-term outcomes. Longer-term outcomes such as academic performance, social integration, learning and employment opportunities will take many years to determine in a pediatric population. It is expected that the more measurable short and medium term benefits will result in positive longer-term outcomes.

Discussion

In this study, a retrospective chart review was conducted to identify and document the costs associated with cochlear implant surgery and management. The findings of this study have been used primarily to guide the development of an economic evaluation model rather than to generate a cost analysis of pediatric cochlear implantation. The findings are subject to certain limitations which may affect the results of future cost-analyses projects. The data were collected retrospectively on children implanted during the first three years of the cochlear implant program. Cochlear implant programs have evolved over the past 10 years and costs and procedures may have changed. For example, in the program studied, more children now undergo MRI during the pre-implant assessment and the length of inpatient stay has decreased. Furthermore, the age of implantation has continued to decrease and younger patients may require more audiological time for speech processor programming and troubleshooting. However, there is no evidence that the

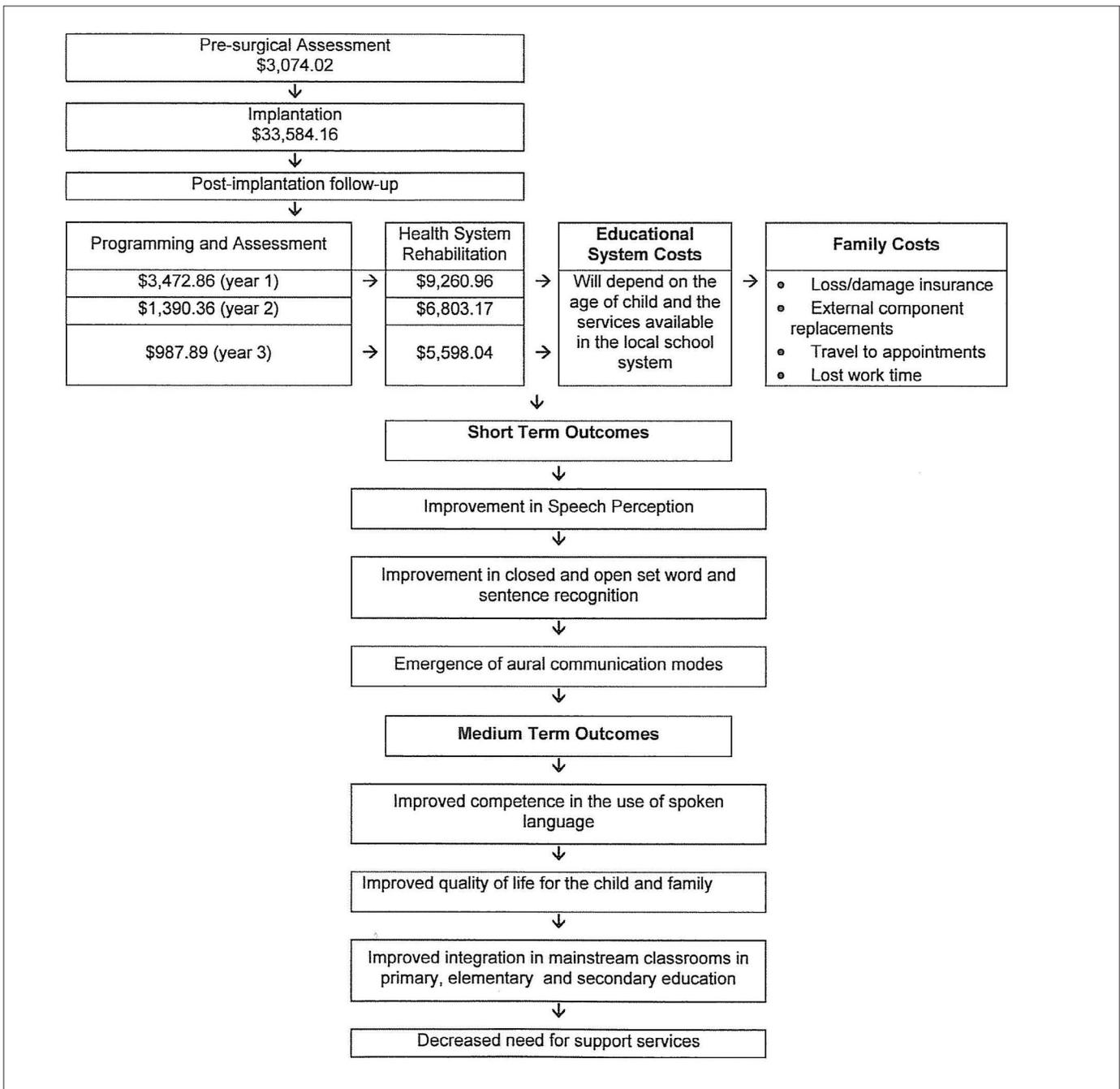


Figure 2. Model of costs and benefits of cochlear implants in children

majority of components of service delivery required in the assessment, surgical management and post-implant intervention of children with cochlear implants have significantly changed.

In addition, the costs related to special rehabilitation and support services for implanted children enrolled in the school system were excluded from this analysis because of the difficulty of accessing the data within the scope of this project. However, the service delivery model described in this paper included specialized therapy at the clinic in the early years post-implantation. This service was not available to school-age children who used conventional

amplification and therefore constitutes an additional cost associated with an implant. Intervention models, in particular, vary across centres; therefore rehabilitation costs may need to be treated differently in determining the costs of models of care.

A clinical population of 18 children has been used as an example to outline the specific costs for the various cochlear implant program components so that reasonable generalizations can be made to other program models. Using a small sample from one hospital clinic to generate the proposed framework enabled us to identify with reasonable accuracy the specific services and costs

attributable to cochlear implantation for this group of children. The attributes and desired outcomes of the program could then be incorporated into the resulting framework. Improved overall outcomes might be anticipated for children more recently implanted largely due to earlier age at implantation and possibly due to technological advances.

The expanded candidacy criteria for pediatric cochlear implantation raise new questions that can have an impact on economic evaluations of the intervention. Children with disabilities in addition to their hearing loss represent a growing number of cochlear implant candidates (Holt & Kirk, 2005). Investigations examining the communication development of children with multiple impairments have documented slower rates of progress than for children without additional disabilities (Holt & Kirk, 2005; Waltzman, Schalchunes & Cohen, 2000). These children may require additional resources and the goal of spoken communication may not be realistic for some. It is important to investigate whether cochlear implantation results in a better quality of life for these children and potential longer-term savings for society. Further research is required so that appropriate expectations for outcome and intervention needs can be adjusted in future models. Secondly, children with greater amounts of residual hearing are being implanted. The impact on outcome and costs for these children, some of whom start the process with foundations in oral language, needs to be better understood. Thirdly, children are receiving implants at younger ages including during the first year of life. This may have consequences for intervention and longer-term outcomes.

Summary

This pilot project presents a framework for the economic evaluation of cochlear implants in children. The framework was constructed based on the health care costs and program components for a subset of 18 children who were implanted in a Canadian facility. Information was obtained from parents on additional direct and indirect costs to families. Anticipated short- to medium-term benefits were documented, including improved speech recognition, auditory-verbal communication and mainstreamed school placements. Families also described quality of life changes post-implant.

The ability of cochlear implants to reduce education and societal costs will be a key factor in pediatric cost effectiveness (Severens et al., 1997). While studies suggest that the cost-utility of pediatric cochlear implantation is acceptable compared to other procedures (Cheng et al., 2000; Summerfield et al., 2003), the existing cost data is not necessarily applicable to the Canadian context.

The above model is proposed as a framework that can be adapted to study the economic evaluation of cochlear implants across Canadian centres. It can provide valuable information regarding the comparison of costs across clinics and inform long-term program planning. "The objective of economic evaluation is to be an *aid* to decision

making, not a complete basis for making decisions" (Drummond, O'Brien, Stoddart, & Torrance, 1997, p. 290). Although costs are not the only determining factor in providing health care, economic information coupled with value judgments can assist providers and decision-makers in making the most efficient use of resources.

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The Editor of *JSLPA* is responsible for planning the annual content of four issues of the Journal (Spring, Summer, Fall and Winter), and coordinating the collection, peer-review process, and disposition of submissions, in addition to the organization and copy-editing of manuscripts, working in close cooperation with CASLPA's National Office. The Editor is expected to devote, on average, 1.5 days/week to activities related to *JSLPA*. Funding is allocated for part-time administrative assistance. This is a three-year contract position subject to an annual review. The Editor reports directly to CASLPA's Communications Manager. The stipend is \$15,000/year paid in quarterly installments subject to meeting production deadlines. For a complete job description and further information on the Journal, visit <http://www.caslpa.ca/english/resources/jslpa.asp>.

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