Economic Evaluation of Treatments for Pediatric Bilateral Severe to Profound Sensorineural Hearing Loss: An Australian Perspective

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Objectives: In Australia, surgical treatment options for children with bilateral severe to profound sensorineural hearing loss exist in a continuum ranging from unilateral cochlear implantation (CI), sequential bilateral CI through to simultaneous bilateral CI, depending on the condition. When treatment options are mutually exclusive, the mean costs and benefits of each treatment group are summed together to obtain the total mean costs and benefits. This enables an incremental analysis of treatment options in the context of the treated populations.

The objective was to evaluate the cost-utility of current Australian CI treatment practices in children using domestic costs and consequences when compared with bilateral hearing aids (HAs).

Research Design: Economic evaluation including a Markov model based on secondary sources.

Setting: The base case modeled a government health payer perspective over a child’s lifetime. Primary and secondary school education costs were also assessed.

Intervention: Bilateral HAs compared with CI, including unilateral, sequential bilateral, or simultaneous bilateral CI weighted according to treatment.

Main Outcome Measures: Incremental costs per quality adjusted life year.

Results: Approximately 42% of children in Australia with unilateral CI did not transition to sequential bilateral nor undergo simultaneous bilateral implantation. This differs from previous economic evaluations that assumed 100% of children transitioned to sequential bilateral CI treatment or were treated with simultaneous bilateral CI.

The incremental cost utility of unilateral cochlear implantation compared with HAs was AUD 21,947/QALY. The weighted average incremental cost utility of the combined cochlear implantation treatment groups was AUD 31,238/QALY when compared with HAs.

Conclusion: Previous economic evaluations of cochlear implantation assumed 100% of unilaterally treated patients would transition to sequential bilateral or be treated with simultaneous bilateral implantation. This approach does not take into account the total treated population, where a proportion of patients are treated with unilateral CI. CI was cost effective when compared with HAs, and included children treated with unilateral, sequential bilateral, and simultaneous bilateral CI. The model was sensitive to the number of assessment and habilitation visits. Alternative health service models with cost efficiencies are needed to reduce after care costs.

Key Words: Australia perspective—Bilateral cochlear implant—Bilateral severe profound sensorineural hearing loss—Cost utility—Economic evaluation—Unilateral cochlear implant.

Sequential bilateral and simultaneous bilateral cochlear implantation (CI) provides an artificial binaural experience that permits bilateral cortical stimulation and the development of auditory pathways leading to the restoration of binaural hearing (1). Sequential bilateral and simultaneous bilateral CI is the standard of care in many countries for all children who qualify (2). In Australia approximately 58% of pediatric candidates underwent sequential bilateral or simultaneous bilateral cochlear implantation in 2014 (3).

CI can provide a hearing solution for people with bilateral severe to profound sensorineural hearing loss (SP SNHL) when hearing aids (HAs) do not provide sufficient benefit. Pediatric treatments may involve unilateral, sequential bilateral, or simultaneous bilateral CI with individually tailored habilitation programs to improve postsurgical outcomes. CI procedures are safe, effective, and cost-effective (4–6) and can result in significant changes to educational outcomes of children, including participation in mainstream education without additional assistance (7–9).

In addition to clinical safety and effectiveness, healthcare decision makers now rely on cost-effectiveness when making clinical decisions (10).

CHALLENGES IN MEASURING QUALITY OF LIFE GAINS IN BILATERAL CI

Improvements in quality of life (utility) can be measured through the administration of disease specific or generic measures (10–12). Unilateral CI delivers a substantial gain in utility when compared with HAs. A marginal gain in utility was measured for patients progressing from unilateral CI to sequential bilateral or simultaneous CI, despite patient preference for sequential and simultaneous bilateral CI (5–7,13). This marginal gain may underestimate patient preferences (5). There are no disease-specific utility measures that can more sensitively detect patient preferences for sequential bilateral or simultaneous bilateral CI. Similarly, no instruments are administered to young children with no communication or comprehension skills, and parents/caregivers respond on their behalf (5).

CHALLENGES IN MEASURING COST-EFFECTIVENESS OF BILATERAL CI

The United Kingdom, the United States, and Canada developed different approaches to assessing cost-effectiveness (4,5,7,13–15). The UK adopted an incremental analysis comparing the second implant with the first implant. They assumed 100% of children implanted unilaterally would transition to a sequential bilateral implant (4,5,7). In 2015, a study by Hanvey showed 48% of children referred for sequential bilateral or simultaneous bilateral treatment according to NICE Guidance did not transition to a sequential bilateral CI or were not treated with simultaneous bilateral CI for clinical reasons (16,17).

In 2013, Semenov et al. (14) reported on an economic evaluation in the US context using a decision analytic model comparing unilateral CI with HAs. Chen et al. (15) reported on an economic evaluation of adults in the Canadian context using the Health Utility Index (HUI3). In a departure from the UK method, Chen et al. (15) demonstrated the cost-effectiveness of sequential bilateral CI when compared with no treatment.

Incremental analysis involves the weighted average costs and consequences of the treatment regimes in one discrete population, compared with the average costs and consequences of the comparator treatment in another discrete population (10–12). This is illustrated in Figure 1 where a decision to treat surgically creates a CI treatment population with mutually exclusive and exhaustive treatment options, compared with a decision of no surgery, which creates a treated population with bilateral HAs. The decision point is surgery compared with no surgery.

This method of evaluation was applied to treatments such as for eye laser surgery or cancer treatments (18,19). These theoretical underpinnings were applied in this economic evaluation.

CLINICAL PRACTICE TREATMENT PATHWAYS AND THEIR USE IN ECONOMIC EVALUATIONS

Treatment pathways help understand the evaluated treatments in context with existing treatments. This defines treatment populations, the proportion of patients treated, and identifies the most appropriate comparator (10–12).

The objective was to evaluate the cost-utility of current Australian CI treatment practices in children using domestic costs and consequences compared with bilateral HAs.

METHODS

This publication follows the reporting structures set out by the consolidated health economic evaluation reporting standards (20).

Australian Clinical Practice

In Australia CI is covered by public and private health care systems (21). Since 2005, the decision to implant one or two CI, and when to implant, was based on the clinical presentation of the child (3). Australia is well placed to report the proportion of children implanted unilaterally, sequentially, or simultaneously. In the Australian context not all children were treated with a second (contralateral) implant (3).

Target Population and Subgroups

The population of interest was children presenting with bilateral SP SNHL who qualified for CI. Treatment pathways derived from a major CI clinic in Australia described the surgical treatments depending on clinical presentation (3,21).

All children with bilateral SP SNHL were first treated with HAs to assess hearing benefit. If insufficient clinical benefits...
were obtained, the child was assessed for treatment with one or more CIs. Children with unambiguous profound SNHL in both ears were treated with simultaneous bilateral CI (2). Children with profound deafness in one ear and severe SNHL in the other ear were initially treated with unilateral CI. Degeneration of hearing in the other ear was monitored, and should hearing degenerate it may lead to treatment with a sequential bilateral CI. Children with stable SNHL in the other ear may present no clinical or medical need for a second CI (3).

Bimodal configurations were not included as published data was not available in Australia at the time of publication to inform on the proportion of unilaterally implanted children who also wore an HA in their contralateral ear. No published stated health preferences were available for this group.

**Setting and Location**

The study simulated the treatment pathway of bilateral SP SNHL through newborn hearing screening and school-based hearing screening programs in the Australian setting. Australia also has standardized referral processes for children across the country because of a national Hearing Services Program administered by Australian Hearing (22).

**Study Perspective**

The Australian health care system formed the perspective of the model base case scenario. Only direct costs were included in the model. Primary and secondary school costs were included in a scenario analysis from a wider governmental perspective.

**Comparators**

CI as a surgical treatment sits alongside HAs and no treatment. There are no other viable treatment alternatives. Bilateral CIs were the appropriate choice of comparison.

**Time Horizon**

Costs and consequences were evaluated over the child’s lifetime. A life tables approach was adopted using Australian life tables reported by the Australian Bureau of Statistics (23). It was assumed mortality of children treated with CI was not different from the Australian population.

**Discount Rate**

Costs and outcomes discounted annually at 5%, the standard rate as determined by the Australian Medicare Services Advisory Committee (10).

**Choice of Health Outcomes**

Cost per quality adjusted life year (AUD/QALY) gained.

**Measurements of Effectiveness—Estimating Resources and Costs**

The model considered presurgery assessment costs including specialist consultations, audiological hearing assessments, and audiological speech assessments. Surgical and hospital costs included direct and overhead costs for ward, nursing, other clinical staff, pharmacy, imaging, theater, hospital bed costs, as well as implant and sound processor costs (24). Postsurgical costs included fitting and programming of the sound processor, specialist follow-up consultations, audiological hearing assessments, speech assessments, ongoing maintenance over time including outpatient costs, spare parts, replacements and repairs, failure rates, and nonuse of the implant (25).

The frequency of surgical, audiological, and speech assessment visits before surgery was assumed to be 3 surgeon visits, 5 audiological assessments, and 10 speech assessments per patient (expert opinion, personal communication, 2015). The frequency of postsurgical assessment visits in the first year was assumed to be 5 surgical consultations, 1 fitting visit, 7 audiological assessments, and 11 speech assessments (expert opinion, personal communication, 2015). It was assumed one audiological assessment and one speech assessment occurred annually after the first year. It was also assumed the CI sound processor and HAs were updated every 5 years.

Costs were based on published Medicare Benefit Schedule (MBS) item numbers for relevant procedure codes as at July 1, 2015 (25). Prostheses costs were based on the Prostheses List Billing Codes published as at August 28, 2015 for a cochlear implant and sound processor (26). Hospital costs were informed by the National Hospital Cost Data Collection report for hospital costs, round 16, published by the Australian National Independent Hospital Pricing Authority (24).

Sequential bilateral implantation involves a second completely separate episode of care in hospital, whereas simultaneous bilateral CI occurs within one episode of care. It was assumed cost efficiencies were associated with simultaneous bilateral CI in preoperative diagnostics, theater, ward, nursing, pharmacy, other clinical staff, and bed costs as they occur only once for both CIs.

For the HA group, costs associated with maintenance of bilateral CIs were negligible. The cost for bilateral HAs was the median cost from a range offered by Australian Hearing, a Commonwealth statutory entity that provides hearing services to eligible clients.

**Failure Rates and Nonuse of Implant in the Model**

A cumulative annual failure rate of 1% was calculated on the basis of 30 years of CI experience at a major Australian CI clinic (21). In contrast, previous models assumed a failure rate of 20% in the absence of published evidence (4). Raine et al. (27)
reported 11 of 155 children did not use their implant, a percentage of 7.1%, for implant nonuse. Although this figure is thought to be high for Australia, it is used in the absence of published local data.

**Currency, Price, Date, and Conversion**
Currency is Australian dollars. Costs were based on published fees as at July 2013 and are presented in Table 1.

**Choice of Model**
A Markov model was used to analyze the cost utility of cochlear implants in Australia. The model assumed five health states; bilateral HAs, unilateral CI, sequential bilateral CI, simultaneous bilateral CI, and death as illustrated in Figure 2. All individuals with bilateral SP SNHL started in the hearing aid state, and transitioned to either the unilateral CI health state or the simultaneous bilateral CI health state. Once in the unilateral CI health state, individuals either remained in that state or transitioned to the sequential bilateral health state, or the death state. A proportion of children in each of the CI health states experienced implant failure or chose not to use their implant. For implant failures, children underwent revision surgery consisting of an explant and optional reimplantation (10). In 2013, all implant failures in Australia were successfully reimplanted.

Children in the surgical (CI) and nonsurgical (HAs) treatment populations were aged 0 to 18 years. Patients in the implant groups proceeded to a state where the implant was in place and functional, no further implant after implant failure, or not used (10). The model allocated costs and utility to time spent in each state (10). One cycle in each health state was equivalent to 1 year.

**Analytical Methods**
The analysis reports cost and QALYs gained over a lifetime for patients who received cochlear implantation compared with HAs. Mean costs and QALYs of each CI health state were summed to obtain the total mean cost of the CI treated populations. This approach enabled each mutually exclusive CI treatment option to be considered in the context of the treatment population. It also enabled an incremental analysis of the total CI treatment population when compared with nonsurgical treatment consisting of bilateral HAs.

Sensitivity analysis explored the degree to which the model was robust to plausible uncertainty around assumptions and data sources chosen.

Parameters varied in the sensitivity analyses included the number of pre and postassessment visits, education costs, 95% confidence intervals for costs, and discount rate.

**Transition Probabilities**
The proportion of children treated with simultaneous bilateral CI in 2012 to 2013 was 32.9%. The proportion treated with unilateral CI was 67.1% whereas 34.3% of the unilateral group were treated with sequential bilateral CI (28). These percentages informed the weightings used in calculating mean costs and consequences.

Transition probabilities calculated from annual proportions by using the following formula:

\[ P = 1 - e^{-rt} \]

where \( P \) is the probability, \( e \) is the base of the natural logarithm, \( r \) is the rate, and \( t \) is time, which in this model is consistent with the cycle time of 1 year (10).

**TABLE 1. Costs—base case and education costs**

<table>
<thead>
<tr>
<th>Service/Device Costs</th>
<th>Unit Costs</th>
<th>Hearing Aid Costs</th>
<th>Cochlear Implant Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialist consultation—initial</td>
<td>$85.55</td>
<td>$85.55</td>
<td>$85.55</td>
</tr>
<tr>
<td>Specialist consultation—subsequent</td>
<td>$43.00</td>
<td>$43.00</td>
<td>$86.00</td>
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<tr>
<td>Audiology hearing assessment</td>
<td>$115.35</td>
<td>$230.70</td>
<td>$576.75</td>
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<tr>
<td>Audiology speech assessment</td>
<td>$49.20</td>
<td>$98.40</td>
<td>$492.00</td>
</tr>
<tr>
<td>Subtotal</td>
<td>$457.65</td>
<td>1,240.30</td>
<td></td>
</tr>
<tr>
<td>Direct costs—excl. prostheses</td>
<td>$6,398.65</td>
<td>$0.00</td>
<td>$6,398.65</td>
</tr>
<tr>
<td>Overheads</td>
<td>$3,222.37</td>
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<td>3,222.37</td>
</tr>
<tr>
<td>Cochlear implant or cochlear hybrid implant</td>
<td>$13,500.00</td>
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<td>13,500.00</td>
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<tr>
<td>Cochlear sound processor—initial</td>
<td>$11,500.00</td>
<td>$0.00</td>
<td>11,500.00</td>
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<tr>
<td>Hearing aid</td>
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<td>$6,000.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Subtotal</td>
<td>$6,000.00</td>
<td>$34,621.01</td>
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<tr>
<td>Follow-up consultation</td>
<td>$43.00</td>
<td>43.00</td>
<td>$215.00</td>
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<td>Fitting of sound processor (1 h)</td>
<td>$192.45</td>
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<td>First 12-month audiology assessments</td>
<td>$115.35</td>
<td>346.05</td>
<td>$922.80</td>
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<tr>
<td>First 12-month speech assessments</td>
<td>$49.20</td>
<td>147.60</td>
<td>$492.00</td>
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<tr>
<td>Annual audiology follow-up for 5 years</td>
<td>$115.35</td>
<td>461.40</td>
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<tr>
<td>Annual speech follow-up for 5 years</td>
<td>$49.20</td>
<td>196.80</td>
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<tr>
<td>Replacement sound processor after 5 years</td>
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</tr>
<tr>
<td>Replacement hearing aid after 5 years</td>
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<td>6,000.00</td>
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<tr>
<td>Australian hearing support for cables and batteries</td>
<td>$498.00</td>
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<td>Subtotal</td>
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<td>Education costs per year</td>
<td>28,401.50</td>
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<tr>
<td>Total</td>
<td>$13,844.95</td>
<td>$48,881.76</td>
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*Education costs when 52% of children with CI were in mainstream schools without support. When 85% of children with CI were in mainstream school without support, education costs were $16,717.64 for children with CI.
CI indicates cochlear implantation.
Health Utilities for the Health States
Utility is an index measure from 0 to 1 integral to the calculation of QALYs, where 0 equates with death and 1 equates with perfect health. Utility scores to populate the model in this study came from the published literature from the UK (4,5,7). These included a baseline utility of 0.23 (5) for HAs, an incremental gain of 0.145 for unilateral CI when compared with HAs, and an incremental gain of 0.063 for sequential bilateral CI when compared with unilateral CI (5). No utility gain comparing simultaneous bilateral CI with HAs is available from the published literature for children. A utility gain of +0.145 + 0.063 represents the incremental gain obtained by summing the gains together (5). The utility gain for simultaneous bilateral CI was assumed to be the same as the utility gains obtained from sequential bilateral CI.

Parameter Estimation
Presurgical assessment and surgical costs were assumed to occur each time a child transitioned from one model health state to the next. Maintenance costs consisted of postsurgical assessment costs and were assigned to each health state. They were assumed to exist annually for the rest of the child’s life. The cost of the replacement sound processor every 5 years was averaged over 5 years to obtain an annual cost.

Transition probabilities were assumed to remain constant, as pediatric CI surgeries in Australia have reached a steady state, with relatively little variation in patient population year on year for the past 5 years.

A scenario analysis involving the attendance of children with CI in mainstream schools without assistance was undertaken to measure the cost-effectiveness of CI in terms of the ability of children to avoid attendance in special classes or special schools for the deaf and hard of hearing.

RESULTS
Incremental Costs per Quality Adjusted Life Year—Payers Perspective
Estimated cost/QALY over a lifetime horizon is reported in Table 2. The discounted lifetime costs for bilateral HAs were AUD 37,046. The discounted lifetime costs for unilateral CI were AUD 73,289, and the discounted lifetime costs for the total CI treatment population were AUD 109,506.

The estimated cost utility for bilateral HAs was AUD 8,094/QALY. The incremental cost utility for unilateral CI compared with bilateral HAs was AUD 21,849/
QALY. The incremental cost utility of the total CI treatment population was AUD 31,798/QALY when compared with bilateral HAs.

**Education Costs—Scenario and Sensitivity Analysis**

It costs an average of AUD 15,169 per year to educate a student in a mainstream school in Australia (29). An additional cost of AUD 13,232 applies to educate students in special classes within mainstream schools or separate special schools (29). Approximately 52% of children with CI regularly attended mainstream schools without assistance, whereas 44.7% attended special classes within mainstream schools or attended separate special schools (30). The proportion of children in mainstream schools without support was a major driver of the education model. It was assumed 100% of children with severe to profound SNHL using HAs attended special classes or special schools.

As reported in Table 2, costs were applied to the model on the basis of 52% attendance in mainstream schools without assistance. The costs for bilateral HAs increased to AUD 233,211 yielding an incremental cost utility ratio (ICUR) of AUD 50,951. The total CI treatment population costs increased to AUD 287,377 resulting in an ICUR of AUD 23,770/QALY when compared with bilateral HAs.

A sensitivity analysis assumed children with bilateral CI and unilateral CI required less assistance than children with HAs. When it was assumed 85% of children with CI did not require assistance in mainstream schools, the ICUR for bilateral HAs was the same, at AUD 50,951 (31). Costs for the total CI treatment population were AUD 250,560 yielding an ICUR of AUD 7,614/QALY, when compared with bilateral HAs. When it was assumed that 70% of children with CI did not require assistance in mainstream schools, the ICUR for the CI treatment population was AUD 14,957/QALY when compared with bilateral HAs.

**Parameter Analyses—One-way Sensitivity**

Different parameters were adjusted to assess the impact they had on the model. These are represented in Table 3. This model was stable for all changes in parameter estimates, remaining below a cost/QALY threshold of AUD 50,000/QALY.

Changes in the model occurred when all children assumed to transition to a second implant. The ICUR increased to AUD 39,822/QALY. This was an expected outcome. Sequential bilateral and simultaneous bilateral CI remained marginally cost-effective when a threshold of AUD 50,000/QALY was applied.

A discount of 3% in costs and benefits over the model horizon resulted in an ICUR of AUD 25,754/QALY, whereas a discount of 6% resulted in an ICUR of AUD 34,697/QALY. When visit schedules were altered to one visit per therapist in each assessment phase, the ICUR became AUD 30,831/QALY. When visits were doubled from the assumed base case the ICUR increased to AUD 35,245/QALY.

When it was assumed that the failure rate doubled to 2% annually, the ICUR for the CI treatment populations was AUD 34,040/QALY when compared with bilateral HAs, and when nonimplant use was assumed to be 3.5%, the ICUR for the CI treatment population was AUD 29,959/QALY when compared with bilateral HAs.

When utility gains from unilateral to sequential bilateral CI were amended to +0.03 on the basis of published evidence by Barton, and applied similarly to the simultaneous bilateral treatment group the ICUR for the total CI treatment populations increased to AUD 34,814/QALY when compared with bilateral HAs (4,7).

**Sensitivity Analysis**

Probability sensitivity analysis included Monte Carlo simulations for all health states. The simulation generated random inputs within a defined range and 1000 iterations were run. A Gamma distribution within a 15% standard error range was used for utilities and transition probabilities. These ranges were based on assumed variations in costs and consequences in the absence of patient level data.

The scatterplot graph for simultaneous bilateral CI compared with bilateral HAs appears in Figure 3. It plots the results of the 1,000 Monte Carlo simulations for each health state. This shows the model is robust and confirms the combined CI health states were cost effective when compared with bilateral HAs in the Australian context, when a cost-effectiveness threshold of AUD 50,000/QALY was applied.

**DISCUSSION**

This evaluation demonstrated CI health states were cost-effective when a cost-effectiveness threshold of AUD 50,000.00/QALY was applied. CI was more cost-effective than bilateral HAs when education costs...
were included. More children attending mainstream school without assistance was more cost-effective when compared with assisted schooling and special schools for the deaf.

The effects of bilateral CI on the level of assistance required in the classroom are yet to be established in the published literature. More research is needed.

Previous economic evaluations assumed 100% of children treated unilaterally would transition to sequential bilateral CI or be treated with simultaneous bilateral CI (4,5). Hanvey (16) demonstrated children in the UK referred for bilateral CI were treated unilaterally for clinical reasons, indicating there is a place for unilateral CI in a unilateral CI framework.

In the Australian context children were treated according to mutually exclusive and exhaustive treatment options that depended on the clinical presentation of the child. This demanded a different approach to measuring incremental cost-effectiveness, where the mean costs and consequences of the patient population in the proposed surgical interventions were evaluated incrementally against the mean costs and consequences of the alternative, nonsurgical treatment option.

This model was robust in its measurement of the costs and consequences associated with CI. Failure rates reported by Wang et al. (21) were the first of their kind in reporting the results of CI failures over a 30-year period in an experienced Australian clinic. Previously published economic models assumed failure rates and revision surgeries, and assumed annual maintenance costs such as cables, coils, and batteries. These consequences were available from published sources in Australia (21). When failure rates were doubled, the ICUR for the CI cohort did not alter dramatically when compared with bilateral HAs.

The major drivers of this model were visit frequencies for clinical assessments and the proportion treated with sequential and simultaneous bilateral CIs.

Given the number of visits can significantly influence costs associated with treatment, strategies that reduce the number of clinic visits are warranted to reduce the burdens associated with SP SNHL. Technologies that enable children to be fitted with their sound processors quicker, and technologies that enable clinicians to trouble shoot without the need for a clinic visit should introduce cost efficiencies into the clinic and reduce the overall costs associated with CI treatments. Future research that evaluates the potential cost-savings of such technologies merits attention.

This evaluation is limited by the use of secondary sources for patient level data and health utilities. Clinical studies with economic endpoints are required for a deeper understanding of the treatment benefits. Utilities were based on UK studies in the absence of any utility data from Australia. Australia and the UK both share high income status from a global and WHO perspective, suggesting that UK utilities may be appropriate proxies for an Australian population (32).

Basing the utility gain for simultaneous bilateral CI on the Summerfield et al. (5) data is likely to underestimate the benefits of simultaneous bilateral CI. In the absence of other direct evidence, this incremental gain in utility was applied in the model.

Bimodal listening data is not available in the Australian context which prevented analysis of this important population subgroup. Productivity impacts were not included in this model. Parental absence from work and impact on employment studies are needed. Fiscal models are also needed that analyze government welfare payments to people who are deaf, compared with taxes paid to government for people with CI who work. Health resource utilisation is not included in the model because data was not available. Linked data to major claims databases, hospital records, disease registries, and primary care should be investigated to obtain the “true” impact of hearing loss on the health care system, and more broadly on society.

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