MINISTRY OF HEALTH
MANATŪ HAUORA

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Sym Gardiner
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Ref: OIA H201401659

Dear Mr Sym Gardiner

Response to your request for official information

Thank you for your email of 27 April 2014 requesting the contents of the policy work about cochlear implants that was provided to the Minister of Health.

Please find the information being released by the Ministry attached. I have decided to withhold some of the information that falls within the scope of your request. This information has been withheld in order to:

- protect the confidentiality of advice tendered by Ministers of the Crown and officials as permitted by section 9(2)(f)(iv) of the Official Information Act 1982;
- protect information where the making available of the information would be likely unreasonably to prejudice the commercial position of the person who supplied or who is the subject of the information as permitted by section 9(2)(b)(ii) of the Official Information Act 1982.

You have the right to complain to the Ombudsman about my decision to withhold information. Information about making a complaint is on the website of the Office of the Ombudsman (www.ombudsman.parliament.nz). You can also contact the Office on freephone 0800 802 602.

Yours sincerely

pp

Michael Hundleby
Acting National Director
National Health Board

MINISTRY OF HEALTH
MANATŪ HAUORA

Health Report number: 20140282

Action required by: urgent

File number: HC453334

Health report

DISPATCHED

12 MAR 2014

Hon Tony Ryall, Minister of Health

cc. Hon Tariana Turia, Associate Minister of Health

Changes to Cochlear Implant Programme Policy and Funding

Executive Summary

i. The purpose of this Health Report is to seek your agreement to changes in cochlear implant policy and funding for children and adults that will result in better, sooner, and more convenient health care for people in New Zealand who are deaf or have severe hearing loss. The policy changes will enable:

- children aged 0-18 years of age who are new entrants to the cochlear implant programme to have simultaneous bilateral cochlear implants ✓
- all children under five years of age who have previously had a unilateral cochlear implant to have a sequential bilateral implant ✓
-
- children aged 0-18 years who have had a unilateral cochlear implant under the cochlear implant programme and a subsequent bilateral implant funded from non-government sources to have the ongoing costs of replacement processors and other support costs met by the Ministry of Health (the Ministry) for the second implant. ✓
-

ii. Current policy is for the Ministry to fund only one (unilateral) cochlear implant for 46 children and 40 adults per year, and to meet the life-long support cost and equipment maintenance costs. Surgery to implant the device is available for children as soon as they are assessed as meeting the clinical criteria, so there is no waiting time for children to receive an implant. However some adults face significant waiting times because funding levels currently do not meet demand, as service to children has been prioritised.

iii. For some time members of the Deaf community and their families, and the two Charitable Trusts who administer the cochlear implant programme, have been advising the Government that both policy and funding require revision. They consider the current policy is inconsistent with international evidence and developed world practice, which favours cochlear implants in both ears (bilateral implants) for children. For adults, their primary concern is waiting times, which in some cases can be over two years at both Charitable Trusts.

iv. The Ministry has recently reviewed the international literature regarding bilateral versus unilateral cochlear implants to establish the extent to which a bilateral implant improves hearing. The Ministry considers the evidence that bilateral cochlear implants can significantly improve children's hearing and spoken ability is compelling, particularly if the devices were implanted simultaneously in both ears in early infancy. The improvement in hearing and learning ability and being able to take in sound-based information like other children is in turn likely to produce significant improvements in the educational and labour market outcomes of deaf and hard of hearing children.

v. The Ministry has also undertaken a rapid economic evaluation of bilateral versus unilateral implants. For children five years and under, the cost of providing the quality of life gains compares favourably to that of most other interventions and therefore sequential bilateral implants represent relatively good value for money. However, the later in life that a cochlear

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implant is provided the less the hearing and spoken language gains are. Value for money of bilateral cochlear implants is therefore less for children aged 6-18 years, relative to those aged 0-5 years, and is even lower for adults. For those who have previously had a single implant, the longer the gap between the first and the second implant the less the hearing and speaking gains and value for money are.

vi. The report therefore recommends that as from 1 July 2014 cochlear implant policy be that new entrants to the programme aged 0-18 assessed as meeting the clinical criteria receive simultaneous bilateral implants without waiting. Transitional provisions are also recommended, for children who have already received one implant under the programme and for those whose bilateral implant was not funded by the New Zealand government. For adults (aged over 18 years), policy would continue to be that they are only eligible for a unilateral implant, but a maximum waiting time of six months would be specified.

vii. The funding required to implement these policy changes is estimated to total $1.1 million in 2013/14 (to be reallocated from within the 2013/14 Disability Support Services budget) and a total of $25.378 million for the seven years from 2014/15 to 2020/21. This constitutes an average of an additional $3.6 million per year in 2014/15 and each subsequent year.

viii. In the first instance, new funding is being sought as part of the 2014 Budget process. If, however, this is not agreed, you will need to decide whether or not changes to cochlear implant policy are more important than some existing health interventions or than some of the other new policy changes proposed for the new funding pool already agreed for Vote:Health in 2014/15 and out years.

ix. The following recommendations provide the detailed policy and funding changes that we seek your agreement to.

The Ministry recommends that you:

a) **Agree** that the Ministry's cochlear implant programme be extended from 1 July 2014 so that eligible children: Yes /No

- aged 0–18 years and newly entering the programme receive simultaneous bilateral cochlear implants
- aged 0-5 years and who have previously had a unilateral cochlear implant funded through the programme be offered a second implant
- [redacted]
- aged 0-18 years and who have obtained a sequential bilateral implant outside of the New Zealand cochlear implant programme (e.g. privately, by fund raising or overseas) may access follow up services for the second implant such as processor replacement and habilitation through the programme.

b) [redacted]

c) **Agree** that from 1 July 2014 the following funding be allocated to the Ministry's cochlear implant programme: Yes / No

i. $920,000 per annum for surgery, device and two years of post-operative support for new eligible children 0-18 years of age

ii. $414,000 per annum for replacement processors and associated services necessary for these children to continue to benefit from their implant. in 2021 ?

d) **Agree** that from 1 July 2014 the following funding is allocated to the Ministry's cochlear implant programme for sequential bilateral cochlear implants: Yes / No

i. $2.15 million one-off in 2014/15 for sequential bilateral implants for children aged 0-5 years

ii. $120,000 per annum from 1 July 2014 for replacement processers and other support services for children who have already received sequential bilaterally implants that were funded from non-governmental sources.

e) **Agree** that in regard to waiting times for unilateral cochlear implants for adults (aged 18 and over):

i. [redacted]

ii. as a first step towards achieving this, in the remainder of the 2013/14 financial year, additional adult operations be authorised which are prioritised to adults who have been waiting two years or longer.

f) [redacted] Yes / No

i. [redacted]

ii. [redacted]

iii. [redacted]

iv. an additional $1.1 million be re-allocated from within the existing 2013/14 Disability Support Services budget to the cochlear implant programme for adult implantations to reduce the maximum waiting list time to two years by 1 June 2014.

g) **Note** that the Ministry will review the operation of the revised cochlear implant programme and will report to the Minister of Health the findings by 30 March 2016.

h) **Agree** that the additional costs incurred in 2014/15 and out years to implement the policy changes (as detailed in recommendations c), d) and f) i, ii, and iii above) will be provided from Budget 2014 funding [redacted] Yes / No

i) **Note** that the Ministry will work closely with the two Charitable Trusts to improve procurement practices regarding cochlear implants and external sound processors.

Don Gray
Deputy Director General
Policy Business Unit

Minister's signature

Date

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Health Report number: 20140282

Ministry of Health contacts

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Minister's feedback on quality of report

Very poor (1)	Poor (2)	Neutral (3)	Good (4) ✓	Very good (5)

Thank you for this. Cochlear implants make a real difference & I think these decisions will help a lot of people within limited resources.

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Advice

1. The purpose of this Health report is to provide you with advice on proposed changes to cochlear implant policy for children and adults, and on the additional funding required to implement the policy changes. The Ministry expects these will result in considerably better, sooner and more convenient cochlear implant services for people in New Zealand who are deaf or have severe hearing loss.

Current policy settings

2. Since the mid-1980's government policy in New Zealand has been to fund a cochlear implant in one ear (unilateral cochlear implant) for eligible infants, children and adults. This policy was based on the evidence available, which indicated that one implant could enable most people who are deaf or have severe hearing loss to hear effectively and for most pre-lingual children to develop good language skills. Funding unilateral rather than bilateral implantation also ensured that the maximum number of people assessed as being able to benefit from a cochlear implant (children and adults) were able to receive one.

3. Under current policy, people eligible for Ministry funding for a single cochlear implant are those who:
   - have severe to profound hearing loss
   - are not helped by standard hearing aids
   - have been assessed as likely to benefit from a cochlear implant
   - are eligible for publicly funded health and disability services
   - live permanently in New Zealand
   - do not qualify for cochlear implant funding through ACC.

4. The current contracted funding of $7.388 million per year allows 86 people to receive a unilateral implant each year. Of these, 16 are babies and infants aged less than two years of age, 30 are children aged 2-18 years and 40 are adults (over 18 years of age). In addition to the surgery and cochlear implant device, the funded service also includes follow-up services such as replacement of externally-worn sound processors. These cost approximately and require replacement around every six years. For deaf children, the habilitation costs are met from Ministry of Education funds.

5. For children funded through the cochlear implant programme in New Zealand, they are also covered for the cost of any repairs, batteries or spare parts for their speech processors. Adults (aged 19 years or older) do not have these costs covered as this is considered to be something they can plan to save for from their own resources.

6. Since 2009, some people who have lost their hearing because of meningitis have had two electrodes funded by the Ministry. The other element, which is the externally worn bilateral processor, is self-funded. This policy was implemented after it became apparent that in many cases of severe or profound deafness following meningitis, subsequent cochlear ossification (where the cartilage in the ear hardens into bone) prevented implanting an electrode in the second ear if this was required.

7. As children need adequate auditory input as soon as possible to develop adequate hearing and language, it is vital that hearing loss is diagnosed soon after birth and managed well before six months of age. A national new-born screening programme and early intervention programme protocol was introduced in 2007 to help ensure early detection of hearing loss. This is now functioning well throughout the country, with approximately 60,000 new born babies being screened each year through the hearing programme. Those few who are found to be entirely deaf or who have profound hearing loss are then referred to the cochlear implant programme.

8. The cochlear implant programme is delivered for the Ministry under contract through the Northern Cochlear Implant Charitable Trust and the Southern Hearing Charitable Trust. The Trusts purchase the implants from manufacturers, assess children and adults for eligibility, liaise with surgeons (mostly in the private sector although some implantations take place in

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District Health Board facilities), and provide ongoing habilitation, processer replacements and other on-going support services that people with cochlear implants require.

9. For children there is no waiting time for implantation, after being assessed as eligible. For adults there is a waiting time, and this continues to be an issue despite additional one-off funding being allocated in 2011/12 and 2012/13 ($1m and $2.6m respectively). In 2013/14 an additional 20 adult implants per annum ongoing were funded, bringing the annual budget for the cochlear implant programme up to $7.388 million. There are now 159 adults on the waiting list across both Trusts, with currently 22 adults waiting longer than two years, and the longest wait of those on the list currently being 2 years and 11 months.

10. The growing waiting list numbers and waiting times reflect a growing number of adults who are deaf or have severe hearing loss being assessed as able to benefit from a cochlear implant. With cochlear technology advancing and increased public awareness, demand for this procedure is continuing to increase.

Recent international evidence

11. Unilateral cochlear implants were the standard of government-funded care for children with severe to profound hearing loss in most countries for many years and there is now a large body of research on the hearing and speech outcomes. An implant in one ear clearly gives deaf people the ability to hear sound when they couldn't before and can markedly improve hearing for some. However, for many who have severe to profound hearing loss in the non-implanted ear, the evidence shows that they still often experience significant difficulty understanding soft speech or speech in noisy environments, and they have difficulty locating sound in groups and the direction that speech/noise is coming from. This can also have consequences for the development of speech.

12. In 2009 the United Kingdom's National Institute for Clinical Excellence (NICE) undertook a review of the evidence of the difference to hearing and speech that a bilateral cochlear implant provided, relative to a unilateral one. At that stage there were relatively few studies available, and most had relatively small sample sizes. The NICE review concluded that provision of bilateral cochlear implants did result in a small additional benefit over single implants, but this benefit was achieved at a relatively high cost. Despite the NICE value for money concerns, the United Kingdom government opted to fund simultaneous bilateral cochlear implants for children and eligible adults in 2010.

13. Since the 2009 NICE review, the evidence base about the relative effectiveness of bilateral cochlear implantation has grown rapidly. Government policy changes in almost all other developed countries to fund bilateral cochlear implants for eligible children has provided many more cases to study.

14. Recently the Ministry commenced a comprehensive review of what is now a substantial body of international evidence comparing unilateral and bilateral implants, particularly for children. There is now a considerably more compelling case for offering parents the opportunity for their child to have simultaneous bilateral implants as soon after birth as possible. Compared to having only one implant, infants with two implants generally have life-long better hearing in noise, are better able to locate the direction of sound, incur less listening effort, hear more clearly due to increased volume of sound, and have better spoken language.

15. The evidence regarding educational attainment, labour market outcomes and quality of life, however, is not so conclusive. For some people, on some measures, those with bilateral implants have better outcomes - but this is far from always the case.

Economic analysis

16. The Ministry undertook rapid economic analysis of moving from unilateral to bilateral cochlear implants. Preliminary results indicate that simultaneous bilateral cochlear implants, when compared to a unilateral implant, are cost-effective but the results vary significantly by age.

17. For children aged five or less who receive simultaneous bilateral implants in early infancy, thereby maximising the quality of life gains, the return on investment will be very high.

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18. For children aged five or less who receive sequential bilateral cochlear implants (where there is already a single implant), these are likely to be as or more cost-effective than many other New Zealand health interventions that have been evaluated to date.

19. A high proportion of the vocabulary and spoken language skill gains are achieved when children are aged five and under. Therefore children aged six and over who have already received one implant, a subsequent second implant is likely to be less cost-effective than most other evaluated health interventions options. The quality of life gains from a sequential bilateral implant achieved by adults will be even lower, making the cost-effectiveness lowest for this group. For adults, it is likely that money spent on bilateral implants would gain a higher quality of life return per dollar invested by being spent on other health interventions found to be more cost-effective.

Stakeholder pressure for policy and funding changes

20. As deaf children and their families have become more exposed to both the research evidence and the lived experience of those with bilateral implants[1], there has been growing pressure to revise the Ministry's cochlear implant policy and funding.

21. Organisations representing the Deaf community support the availability of bilateral cochlear implants in early infancy rather than unilateral implants as a choice available to adults and the parents of children who are deaf or have severe hearing loss.

22. The 2Ears2Hear parents group headed by Sym Gardiner has been particularly active, lobbying you, the Ministry and other decision-makers on this subject. As you know, he recently presented a petition to the Health Select Committee signed by 1338 people requesting that the House of Representatives fund bilateral cochlear implants for children who are clinically assessed as needing them.

23. It should be noted that some Deaf community members in New Zealand, as overseas, strongly oppose making cochlear implants more available to deaf and profoundly hard of hearing children. They are concerned that implanting cochlear implants in infancy denies deaf children the choice of their identity as a deaf person. They see this as the government imposing a narrow medical model of what is 'normal' and desirable. They feel this devalues those who live within deaf culture, where sign-language rather than spoken language is the norm. In their view, it sends a strong signal that to be deaf is not OK, while mistakenly giving the impression that a profoundly deaf person cannot have a happy or successful life.

24. Both Charitable Trusts are supportive of the Government funding bilateral cochlear implants for children. While not advocating bilateral implants for adults, the Trusts are very concerned about the growing size of their adult waiting lists for unilateral implants resulting in most adults now facing long waiting times.

Proposed new policy and funding implications

i) Simultaneous bilateral cochlear implants for children from 1 July 2014

25. In light of the international evidence, and the results of the preliminary economic analysis, the Ministry proposes that children aged 0-18 years who meet the existing cochlear implant eligibility criteria be eligible for simultaneous bilateral cochlear implants from 1 July 2014. To achieve this, the Ministry recommends that an additional $920,000 per annum be allocated to the Disability Support Service's cochlear implant programme for 2014/15 and out years.

26. Each year the additional funding will enable 46 children to receive bilateral cochlear implants, when clinically recommended, and associated follow-up services. Based on recent trends, this should be adequate to cover the number of new child referrals received each year.

[1] According to information recently provided by the two Charitable Trusts, 81 of the 271 people 0-18 years of age who have had a government funded unilateral implant since 2003 have subsequently had a second implant in their other ear, which was self-funded or funded through fundraising.

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ii) *Sequential bilateral cochlear implants for children from 1 July 2014*

27. There are currently 271 children who have already received one implant through the Ministry's cochlear implant programme, most of whom are over five years of age. There are likely to be some further children who had unilateral cochlear implants overseas and then moved to New Zealand. There are also a further 81 children aged under 18 who had an initial cochlear implant under the programme and have processor replacement and other support costs met by the Ministry for that implant, and who have subsequently already obtained a self-funded or fundraising-funded sequential bilateral implant, for which they currently meet the ongoing costs for replacement processors and other support.

28. The evidence suggests that as children age, the effectiveness of a second implant reduces, particularly after five years of age. There are still likely to be some improved hearing outcomes after this age, up to adolescence, with the extent of this varying from case to case. The evidence also shows that the longer the time between having the original implant and the second one, the less the hearing and spoken language gains. This is partly because over time the brain adapts to single ear hearing, and reversing this adaption gets more difficult the longer single ear hearing has been operating.

29. In light of these findings, the Ministry proposes that from 1 July 2014 a second implant is offered to all children up to five years of age who have a unilateral cochlear implant which was funded through the programme. This will require allocation of an additional $2.15 million of one-off funding to the programme in 2014/15.

30.

31.

32. Finally if funding of bilateral implants for all new child entrants to the programme is approved for children who received their implant through the programme., it is recommended that children aged 0-18 years who received bilateral implants outside of the programme (privately, by fund raising or overseas) and who fit the programme eligibility criteria may access follow up services through the programme from 1 July 2014. This will require an additional $122,000 per annum to be allocated to the cochlear implant programme from 2014/15 onwards.

iii) *Adults' access to cochlear implant services (waiting times)*

33. While children are scheduled for a unilateral implant once they have been assessed as meeting the eligibility criteria, current funding levels translate to 40 adults receiving a unilateral implant each year, which is less than the number of adults annually assessed as needing surgical implantation. Consequently at the end of February 2014 there are 156 adults waiting for a cochlear implant – 74 on the Northern Trust waiting list and 82 on the Southern Trust waiting list. Twenty four of those on the adult waiting list have been waiting for two years or more, with the longest wait currently being 2 years and 11 months at both Trusts.

34.

[redacted]

[2] Costing is based on 30% of the existing 228 children aged 6-18 being clinically assed as eligible for a sequential bilateral implant over the seven years commencing 2014/15 (10 per year).

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35. It will be possible to promptly deal with those waiting for the longest waiting times by reallocating an additional $1.1 million (one-off) from the existing 2013/14 Disability Support Services budget to the cochlear implant programme for adult implantations. This would allow 22 implantations to be undertaken for all those adults who have been waiting for two years, by 1 June 2014.

Overview of funding implications and sources

36. Table 1 below sets out the estimated costs of the proposed funding changes to the cochlear implant programme.

Estimated costs of proposed changes to cochlear implant programme

	Number of people benefitted	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21
Children - additional cost of moving to bilateral implants									
New simultaneous*	46 (each year)		920,000	920,000	920,000	920,000	920,000	920,000	920,000
New sequential** for 0 - 5 yrs children	43		2,150,000						
[redacted]									
Additional support for children with privately funded second implant (processor replacements)	81		122,000	122,000	122,000	122,000	122,000	122,000	122,000
Adults - cost of reducing waiting times for unilateral implants									
[redacted]									
Reduce maximum waiting time to 2 years	22	1,100,000							
[redacted]									
Estimated total		1,100,000	[redacted]						

Notes
* 'New simultaneous' involves the children getting two implants at the some time, with the cost of one covered by baseline funding, and the additional costs of the second implant only included in this table.
** 'New sequential' refers to the additional cost of providing a second implant to children who already have a single implant.

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37. The financial information provided in Table 1 is based on current costs for cochlear implants and external sound processors. There is an expectation that, with more than double the volume in numbers of implants there will be an ability to negotiate more favourable prices for this technology through improved procurement practices.

38. For 2013/14 the funding of $1.1 million to provide implants for the 22 adults who have waited the longest can be reallocated from underspending within other parts of the baseline Disability Support Services funding. [redacted]

39. The proposed policy change will also impose additional habilitation costs for deaf children on Vote:Education, but the magnitude of these are difficult to estimate at this point. The Ministry of Education will investigate the cost implications and if these significantly exceed existing budgets further funding may be required to cover these costs.

40. In regard to the source of Vote:Health funding: if you are not able to gain agreement to additional new Vote:Health funding on top of that already being sought for other new health initiatives, you may wish to scale back the extent of increased funding on cochlear implants (for example by providing bilateral cochlear implants to a narrower group of children, or by opting for a longer waiting time for adult unilateral implants).

41. If new money cannot be obtained through the Budget 2014 process, the proposed changes to the cochlear implant policy (or a scaled down version) could be funded through:
   a. reprioritisation of initiatives proposed for Budget 2014
   b. reprioritisation within existing baselines.

Further longer term policy work required

i) Charitable Trust structure and operation of new policy

42. At the outset of the programme the Ministry recommended that two Cochlear Implant Charitable Trusts were established, one in each island. The rationale for this was that they

would be better able to raise funds and meet the needs of their own communities than one large trust. The Ministry is generally impressed with the services that they deliver for their catchment populations. However, each has evolved its own distinct ways of working.

43. It was always intended that at some point there would be a review of the two trust model to confirm how effective and efficient it was, and whether to continue with it as is, make minor changes, or move to a different model for the long term. The Ministry's view is that in order to ensure both Trusts focus on implementing the new policy in the next year, it would be best not to undertake the review of the Charitable Trust approach until the last half of 2015/16. This would also be the appropriate time to undertake an initial review of implementation of the new cochlear implant policy recommended in this paper, should you agree to it.

ii) Purchasing

44. Currently the Northern Cochlear Implant Trust and the Southern Hearing Charitable Trust use two providers of cochlear implant devices. One Trust offers children only one implant brand, the other allows the surgeon to choose which to use. The Trusts separately endeavour to negotiate reductions in the cost of the devices from the manufacturers. We understand preliminary discussions about what the price reductions might be if the government moved to bilateral implants indicate likely cost savings because of the higher volumes being purchased.

45.

Managing some Deaf community concerns about policy changes

46. An announcement that provision of bilateral cochlear implants will become the new norm for children will not be welcomed by some within the Deaf community. They consider that deafness is not something which needs to be 'cured' through the use of cochlear implants, because it is possible to lead a happy and productive life without hearing or spoken language. They are concerned that the history, culture and language (sign) of Deaf culture may be eroded as cochlear implants become the norm.

47. Given the majority of deaf children are born to hearing parents, Deaf adults consider it vital that these parents have ready access to information that enables them to make informed choices about cochlear implants that recognise Deaf culture. Finally, given the evidence that children with cochlear implants can feel like they do not truly belong in either deaf or hearing culture, the Deaf community is concerned that if children are not given the opportunity to learn sign language, this may further exacerbate their difficulties in feeling they are a part of the Deaf community.

48. To deal with these concerns, when the policy is announced it will be important to note that parents' families and carers responsible for the decisions regarding the implantation of a child have access to information to ensure they are able to make informed choices that recognise Deaf culture. It can also be noted that the Ministry, through the two Trusts, also provides access to New Zealand Sign Language classes for those who receive a unilateral cochlear implant. Going forward, this option would continue for those who are implanted bilaterally.

49. The Ministry of Education is working with the Audiology Society to develop information about New Zealand Sign Language and making education resources accessible. There will be a new role of a sign language facilitator to work alongside the family at the beginning of a child's life supporting parents who choose the New Zealand Sign Language Path.

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BILATERAL COCHLEAR IMPLANTS IN CHILDREN: AN EVIDENCE SUMMARY

This summary of the international evidence on bilateral cochlear implants in children is organised as follows:

- Section 1: an introduction and overview to the review (page 2)
- Section 2: a brief summary of the current New Zealand policy (pages 2 – 5)
- Section 3: a summary of international policy and practice regarding bilateral cochlear implants (pages 5 – 8)
- Section 4: details of the evidence summary of the impacts of bilateral cochlear implants (pages 9 – 17) regarding :
    - Hearing in noise
    - Localisation
    - Speech perception
    - Communication skills
    - Educational attainment
    - Implications of implanting bilaterally:
    - Impact of early implantation and time between implant
    - Sequential vs Simultaneous
    - Risk
    - Identity
- Section 5: conclusions regarding the implications of the results of the evidence summary for future New Zealand cochlear implant policy (pages 17–18)
- Section 6: details of the methodology of the review evidence summary questions (pages 18-19)
- Section 7: details of the material included in the summary review (pages 19–52).

In addition there are three appendices to this report:

- Appendix 1: Glossary (page 53)
- Appendix 2: References and Grey Literature (pages 54 – 59)
- Appendix 3: Search Strategy (pages 60).

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1. INTRODUCTION AND OVERVIEW

A cochlear implant is a surgically implanted electronic device that provides a sense of sound to a person who is severely hard of hearing or profoundly deaf. While it does not restore normal hearing levels, it can significantly benefit users by providing access to sound. This enables people to acquire and understand spoken language and to speak intelligibly.

Cochlear implants were first developed in the 1970s, and were initially provided to deaf adults. Overseas the first child received an implant in 1980. In New Zealand the first child received one in 1986.

Disability Support Services (DSS) within the Ministry of Health (the Ministry) currently funds a cochlear implant in one ear for eligible infants, children and adults. The Ministry's position has been that one implant is highly effective in achieving the goal of ensuring a person can hear effectively and for most children to develop their language skills at the crucial early stage. The Ministry has chosen unilateral over bilateral implantation to ensure that the maximum number of people who could benefit from a cochlear implant (children and adults) are able to receive one.

The Ministry's Disability Support Services is, however, aware that there is now a body of research indicating there may be some additional benefits from bilateral cochlear implants over unilateral cochlear implants. As a result, many countries have changed their policy in favour of funding bilateral cochlear implants. Disability Support Services has therefore asked the Disability Policy Team of the Ministry of Health to undertake a review of existing evidence to inform future decisions on New Zealand's cochlear implant policy.

2. CURRENT NEW ZEALAND COCHLEAR IMPLANT POLICY & OUTCOMES

2.1 *Eligibility criteria*

As noted in the introduction, New Zealand's policy is to fund a cochlear implant in one ear for eligible infants, children and adults. The eligibility/referral criteria for children to receive a unilateral cochlear implant in New Zealand are:

- Children who have recently suffered from meningitis which has caused a sensorineural[1] hearing loss should be referred urgently following diagnosis
- Children who have a bilateral severe hearing loss or worse, from 1 kHz to 8 kHz on ABR testing, or on an unaided test
- Children with limited aided speech information above 2 kHz (as seen on speech-mapping)
- Children with a severe reverse sloping hearing loss or worse, or those whose speech and language is not progressing adequately

[1] **Medical Definition of** sensorineural: of, relating to, or involving the aspects of sense perception mediated by nerves <*sensorineural* hearing loss>

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- Children with auditory neuropathy spectrum disorder who are not progressing in their speech and language development

- Children older than three who are referred should have documented evidence of difficulty developing oral language

- Children over the age of four with no oral language will be considered and discussed only on a case-by-case basis

- A child older than five with no language is unlikely to benefit from a cochlear implant

- Children who have not heard and are over the age of five are not likely to benefit from a cochlear implant or achieve oral-aural communication and would not be considered a candidate for a single cochlear implant.

2.2 Service elements and costs

The funded cochlear implant service, which costs about $50,000 per patient, includes:

- The assessment
- The device (an implanted electrode and a sound processor which is worn externally)
- The surgery
- Audiology
- Maintenance and support
- Associated on-going support services
- Rehabilitation for adults or habilitation for children
- Device replacement.

The funded service includes follow-up services such as replacement sound processors. These follow-up services ensure the cochlear implant works well throughout the wearers' lives.

For children, the funded service also covers the cost of any repairs, batteries or spare parts for their speech processors. Adults (aged 19 years or older) do not have these costs covered.

The 2013/14 Ministry budget is $7.388m per year for cochlear implants and associated costs. This equates to:

- 40 cochlear implants for adults
- 30 cochlear implants for children and
- 16 cochlear implants for babies.

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2.3 *Service providers and waiting lists*

There are two organisations providing cochlear implants in New Zealand. The Southern Cochlear Implant Programme has funding from the Ministry to provide 23 implant systems for children each year. In 2012/13, however, they only received 19 referrals for children so they reallocated the remaining 4 implant systems to adults. The Southern Cochlear Implant Programme also provided an additional 10 privately funded implant systems for children.

The Northern Cochlear Implant Trust received funding for 24 implant systems for children in 2012/13. All 24 were allocated to children. They funded 6 private cochlear implants for children, which were all for bilateral implants. Children do not have to wait for an implant and adults wait on average 2 years.

In 2011/12 and 2012/13 an additional $1m and $2.6m was allocated respectively to reduce adult waiting times (increasing the budget to $7.388m).

2.4 *Early intervention*

The Ministry recognises that to develop speech and language children need adequate auditory input as soon as possible. Hearing loss should be diagnosed soon after birth and managed well before six months of age. A national new-born screening programme and Early Intervention Programme protocol is in place to help ensure early detection of hearing loss. Approximately 60,000 new born babies are screened each year through the hearing programme. If a cochlear implant is to be implanted, it is preferable that this is done before 12 months of age.

2.5 *Bilateral implants available for those patients with hearing loss from meningitis*

Since 2009, some people who have lost their hearing because of meningitis have had two implants funded by the Ministry. This policy was implemented as it was becoming clear that in many cases of severe or profound deafness following meningitis, subsequent cochlear ossification (where the cartilage in the ear hardens into bone) prevented sequential insertion of a second electrode if this was required.

2.6 *Unilateral cochlear implants in New Zealand*

There are currently 1000 cochlear implant users in New Zealand and around 270 of those users are children. Currently, 46 of those users are under five years of age. Some of those users have received bilateral implants through private funding.

Unilateral cochlear implants have been implanted in children and adults in New Zealand and internationally for many years and have become the standard of care for children with severe-profound hearing loss in New Zealand. The evidence suggests that if implanted early with a single cochlear implant, pre-lingual children have good language outcomes and post-lingual children and adults regain useful hearing and communication. Developments in technologies over recent years mean that individuals can hear better in noise, listen to music, and use their processors during sporting activities. However, a unilateral cochlear implant wearer with severe-profound hearing loss in the non-implanted ear still can experience significant difficulty understanding soft speech or speech in noisy environments, difficulty locating sound in groups, or the direction of speech/noise.

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2.7 *Focus of evidence summary*

This evidence summary looks at three main aspects of the existing national and international information and research regarding cochlear implants in children and adults:

- What different countries offer to profoundly deaf and hard of hearing infants and children (Section 3)
- The findings of the international literature on the impact bilateral cochlear implants have on different aspects of hearing and oral language (Section 4)
- Conclusions regarding the policy implications of the findings from the international literature (Section 5).

3. INTERNATIONAL COCHLEAR IMPLANT POLICY & PRACTICE

The first part of our evidence summary looked briefly at what different countries offered to profoundly deaf and hard of hearing infants and children in regard to cochlear implants.

In recent years internationally there has been an increasing trend towards implanting bilateral cochlear implants in infants and children, as the following table shows. Countries such as the United Kingdom, Ireland, Canada and Australia all now implant bilaterally for infants and children. In some countries certain adults are also eligible, for example adults with additional needs.

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Provision of bilateral cochlear implants for children	*Provision of unilateral cochlear implants for children*
• Argentina • Australia (mix of insurance and small govt funding) • Canada • Cyprus • Japan • Norway • Sweden • Switzerland • UK • Italy • Denmark • France • Holland (insurance) • Iceland • Ireland • Belgium • Germany • Singapore – via insurance • Spain • USA – via insurance	• Cuba • New Zealand • Saudi Arabia • Iran • Libya • Taiwan • Japan

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A report into worldwide trends in bilateral cochlear implants (Peters et al 2010) reviewed implant manufacturers' databases which indicate that in 2010 there were 4986 children (0-18 years) worldwide with bilateral implants. The same study also estimates that 78 percent of worldwide bilateral implantations are for children. The age group three-ten years are the most highly represented group and it is more common for children under three years to receive simultaneous bilateral operations (on both ears on the same day) than for the group of children aged three-ten years, who are more likely to receive a sequential bilateral implantation (one operation on one ear followed at a later date by a second operation on the other ear).

Highlights of policy and practice in selected countries are as follows:

3.1 Ireland

The Irish Government is introducing a new sequential bilateral cochlear implant service to benefit unilaterally implanted children eligible for a second implant, and simultaneous implantation for children who are born profoundly deaf from now on. In 2014 around 100 children are expected to benefit from the additional cochlear funding (3.2 million euros), with 50 sequential and 50 simultaneous bilateral cochlear implants to be fitted.

The Irish National Cochlear Implant Center (NCIC) in Beaumont Hospital estimates that around 200 unilaterally implanted children may be eligible for a second cochlear implant at the moment[2].

3.2 England and Northern Ireland

In 2009, the United Kingdom's National Institute for Health and Clinical Excellence (NICE) recommended that all suitable children have simultaneous bilateral cochlear implants, or a sequential bilateral implant if they had received the first before the guidelines were published. NICE Guidance[3] is issued as follows:

> **Simultaneous** bilateral cochlear implantation is recommended as an option for:
>
> 1. children
> 2. adults who are blind or who have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism for spatial awareness
>
> IF they are severely to profoundly deaf (as defined below) AND do not receive adequate benefit from acoustic hearing aids.
>
> Severe to profound deafness is defined as hearing only sounds that are louder than 90 dB HL at frequencies of 2 and 4 kHz without acoustic hearing aids. Adequate benefit from acoustic hearing aids is defined for this guidance as:
>
> - for adults, a score of 50% or greater on Bamford–Kowal–Bench (BKB) sentence testing at a sound intensity of 70 dB SPL
> - for children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability.
>
> Acquisition of cochlear implant systems for bilateral implantation should be at the lowest cost and include currently available discounts on list prices equivalent to 40% or more for the second implant.
>
> **Sequential** bilateral cochlear implantation is not recommended as an option for people with severe to profound deafness.
>
> People who had a unilateral implant before publication of this guidance, and who fall into one of the categories described in the simultaneous bilateral cochlear implantation section, should have the option of an additional contralateral implant only if this is considered to provide sufficient benefit by the responsible clinician after an informed discussion with the individual person and their carers.

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3.3 Australia

In Australia, the funding for cochlear implants is a combination of private and public funding. A cochlear implant costs between AUD$25,000-$30,000 for the surgery and implant.

Private health insurance generally covers the cost of the implantation with the exception of the excess charges. However, there is often a 'gap' charge applied that can be up to a few thousand AUD dollars.

[2] http://www.irishhealth.com/article.html?id=21851
[3] http://www.nice.org.uk/nicemedia/live/12122/42854/42854.pdf

Sydney Cochlear Implant Centre (SCIC) receives funding from the NSW Health Department for a limited number of cochlear implants for public patients (around 45 per year).

In terms of bilateral implantation, a paper developed by the Western Austrian Ear Nose and Throat Advisory Group in 2011[4] noted that bilateral implantation is the treatment of choice in paediatric patients with bilateral severe to profound sensorineural hearing loss who are unable to obtain bimodal benefit. Only those patients who have suboptimal outcomes or special cases e.g. meningitis, mondini are considered for second / bilateral surgery.

The group noted that the situation is inequitable and recommended that funding is increased to allow for more bilateral implantation.

3.4 Canada

In 2007/08, the provision of bilateral cochlear implants was approved for children who meet the requirements.

Cochlear Implant Program in Canada – for children in all provinces this provides for:

- Surgery and implant devices for bilateral cochlear implants up to 18 years of age
- Replacement parts (i.e. batteries, microphones, headpieces) for children up to 18 years of age
- One processor upgrade for children while they are of school age.

The programme also provides for bilateral surgeries for adults who are not yet approved for coverage.

Transportation costs, accommodation and meals for cochlear implant clients are the responsibility of the individuals. However, some financial assistance to cover part of these costs may be available through the government's Medical Transportation Assistance Program.

3.5 Developing countries

Deaf people in many developing countries are still receiving unilateral single-channel cochlear implants as the cost of manufacturing the multi-channel processors, which are the standard in developed countries, is too prohibitive. It is estimated that of 1 million children in India with profound hearing loss only 5000 have received a unilateral cochlear implant.[5]

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[4] http://www.healthnetworks.health.wa.gov.au/docs/1301_CG_AdultCochlearImplantation.pdf
[5] http://www.dnaindia.com/money/report-costly-cochlear-implants-beyond-reach-of-masses-1409419

4. SUMMARY OF FINDINGS RE BILATERAL COCHLEAR IMPLANTS

A bilateral cochlear implant provides individuals with access to sound information from both ears. They may improve speech perception in quiet and in noise, as well as sound localisation, along with other benefits which are discussed below.

The William House Cochlear Implant Study Group[6] released a position statement in 2008. The group strongly endorses bilateral cochlear implantation in clinically appropriate adults and children and states that bilateral cochlear implantation is now considered as accepted medical practice.

The evidence indicates that when hearing with two ears, sound quality and speech perception is improved with main improvements being seen when background noise is present. It is also easier to locate the source of a sound. When locating sound the listener uses difference in the timing and level of sound to each ear. This localisation ability allows the listener to locate sounds in a group of sounds in the environment. Speech perception is also much improved with two ears as the brain can better process the signal. Because the signal is combined it is also louder, making it easier to process.

The bilateral implant review is summarised below, according to the type of benefits found:

4.1 Hearing in Noise

The evidence gathered in the review supports the view that bilateral cochlear implants provide benefits to hearing in noisy environments. Dunn et al (2010) also concluded this while a number of other studies also support this argument. These studies include:

- Bond M et al (2009) who found that overall the strongest evidence for an advantage from bilateral over unilateral implantation was for understanding speech in noisy conditions.
- Culling, J F et al (2012) who noted that the benefit of bilateral vs unilateral cochlear implantation to be speech perception in noise and the study found that in optimal conditions, the benefit can be much larger than reported in earlier studies.
- Forli F et al's (2011) systematic review of the clinical effectiveness of the cochlear implant procedure in children found that compared to unilateral cochlear implant, bilateral cochlear implants offer advantages in terms of hearing in noise and sound localization.
- Lovett R E et al (2010) found that compared with unilateral cochlear implants, bilateral cochlear implants are associated with better listening skills in severe-profoundly deaf children.

[6] William House was a medical researcher who developed and is widely recognized as inventing the cochlear implant.

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- Vincent C et al (2012) also noted that bilateral performance was significantly better than unilateral cochlear implantation on speech perception in quiet and noise.

- Strom- Roum et al (2012) 'Comparison of bilateral and unilateral cochlear implants in children with sequential surgery' found a small but statistically significant improvement in speech recognition with bilateral cochlear implants compared with a unilateral implant. A major increase in speech recognition occurred with the second cochlear implant during the first year.

- Kim L S et al (2009) investigated the impact of bilateral cochlear implantation use on speech perception in quiet and noise. The participants of the study underwent testing from 4 to 28 months after activation of bilateral hearing. The study found substantial benefits in speech perception in both noise and quiet.

4.2 Localisation

Two cochlear implants can help the user to identify whether a sound is coming from the left or the right. Some studies suggest that true binaural processing does not occur with bilateral cochlear implants wearers and while they can accurately lateralise sound from the left or the right, they remain unable to identify the direction of the sound source as the stimulus is presented closer to front and centre of their head.

According to Lovett R E et al (2010), on average, bilaterally-implanted children performed significantly better than unilaterally implanted children on tests of sound localisation and speech perception in noise. Bilateral implantation was associated with increases in accuracy of sound localisation.

Strom-Roum, H et al (2012) study, showed that sound localisation with two versus one cochlear implant in children with a sequential bilateral cochlear implantation was significantly improved after 24 months (but not 12 months) after the second implantation. The study also noted that a shorter inter-implant interval showed a small but significant beneficial effect on sound localisation.

Vincent C et al (2012) also noted that localisation was significantly better in bilateral cochlear implanted wearers over unilateral cochlear implanted wearers. This study concludes that bilateral cochlear implants are more beneficial than unilateral cochlear implants in children.

4.3 Speech Perception

Speech perception abilities of children with cochlear implants have been studied using various measures in quiet and noise:

- Johnston et al (2009) looked at thirteen studies and eleven of them found significant improvement in children's speech perception in noise. These improvements were due to head shadow effect and to improved ability to concentrate on sound from one ear over another.

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- Lovett et al (2010) found that in speech perception tests children with bilateral implants performed significantly better than children with unilateral cochlear implants.

- Steffans et al (2008) noted that improved speech perception is linked to shorter periods of hearing loss in the second ear, suggesting that the interval between first and second implant should be reduced where possible.

4.4 Communication skills

A second cochlear implant has been shown to improve language acquisition. The combination of directionality, hearing in noise and being able to hear more can lead to children speaking more quickly and more clearly.

Boons, T. et al. (2012) found that the use of bilateral cochlear implants is associated with better spoken language learning and the interval between the first and second implantation correlates negatively with language scores.

Geers and Nicholas (2013) looked at whether the age of implantation is an important factor in spoken language outcomes in later childhood for patients receiving a cochlear implant between 12 and 38 months of age. The study also looked at the advantages of receiving a bilateral cochlear implant after 4.5 years. The study found that age-appropriate spoken language skills were more likely the younger the age of implantation even after an average of 8.6 years of additional cochlear implant use. Receipt of a second device between the ages of 4 and 10 years, and longer duration of device use, did not provide significant added benefit.

Tait M, et al (2010) compared the preverbal communication skills of two groups of young implanted children – those with unilateral cochlear implantation and bilateral cochlear implantation. The groups were measured before and after implantation. Before implantation there was no significant difference between the group's preverbal communication skills. Findings suggest that the profoundly deaf bilateral cochlear implanted children are significantly more likely to use vocalisation to communicate and to use audition when interacting vocally with an adult, compared with the unilaterally implanted children; independent of age at implant and length of deafness.

Boons T et al. (2012) 'Effect of paediatric bilateral cochlear implantation on language development' found that children undergoing bilateral cochlear implants performed significantly better than unilateral cochlear implants in receptive and expressive language tests. This was a case controlled, frequency matched, cross-sectional, multi-centre study with 25 unilateral cochlear implanted children and 25 bilateral cochlear implanted children. The children were retrospectively selected from a sample of 299 children who all underwent cochlear implantation before 5 years old. The groups were matched with great care on 10 auditory, child and environmental factors so the difference can mainly be attributed to the bilateral implantation. The use of bilateral cochlear implantation is associated with better spoken language learning. On expressive language development, there was an advantage for simultaneous implantation compared with sequential implantation. The interval between the first and second implantation correlates negatively with languages scores.

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4.5 Educational attainment

There has been little research conducted which looks specifically at educational attainment of children with bilateral cochlear implants. Older reports do exist on educational outcomes for children with unilateral cochlear implants; however, many of these studies were excluded because they were over 5 years old. Fitting cochlear implants during the early years of a child's life means that school age children enter mainstream education with language skills that are the same, or similar to, their normal hearing classmates.

A study by A Geers (2008) 'Long-term outcomes of cochlear implantation in the preschool years: From elementary grades to high school' suggests that the positive effects of cochlear implants will not necessarily be maintained throughout the child's whole schooling. The study noted that 'early cochlear implantation had a long-term positive impact on auditory and verbal development, but did not result in age-appropriate reading levels in high school for the majority of students.'

The Ministry already provides habitation services and ongoing support services for children who receive unilateral cochlear implants. Bilaterally implanted children are also likely to require ongoing support in an educational setting.

IMPLICATIONS OF IMPLANT

4.6 Impact of early implantation and time between implant

The National Institute for Health and Clinical Excellence (NICE, 2007) recommended simultaneous bilateral cochlear implantation as an option for three particular groups of patients with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids: pre-lingual children, people who are blind and people at risk of cochlear ossification.

Boons, T. et al. (2012) found that the interval between the first and second implantation correlates negatively with language scores. A shorter interval between both implantations was related to higher standard scores. Children undergoing simultaneous cochlear implantations performed better on the *Expressive Word Development Test* than children undergoing two sequential cochlear implantations. On expressive language development, the study found an advantage for simultaneous compared with sequential implantation

Scherf F et al. (2009) looked at 35 children with sequential bilateral cochlear implants after three years of use. Children were assessed before the second implant and at various intervals afterwards. Bilateral cochlear implants offered advantages to all children compared to the first implant even in the children who received the implant after the age of six. The speech recognition outcomes in quiet and noise also improved for all the children after 36 months. However, a linear regression analysis suggested a beneficial effect of younger age at first implantation on the speech-in-noise results. Older children require a longer time horizon to gain similar benefits, however older children still obtained similar results after two years of bilateral use.

Strom-Roum et al (2012) found a shorter interval between the two implantations resulted in better speech recognition with the second implant. The same study also found no definitive point at which the second implant could no longer add positive effect.

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Older children do benefit from bilateral cochlear implants but to a lesser degree than younger children.

4.7 Sequential vs Simultaneous Implants

Speech perception

There is evidence to suggest that the benefits of bilateral cochlear implants are greatest when there is limited time delay between implantation. Gordon and Papsin (2009) found benefits of short inter-implant delays in children receiving bilateral cochlear implants. The study looked at speech perception skills in quiet and noise in children using bilateral cochlear implants to assess what impact the duration of bilateral deafness had and the effects of inter-implant delay. The study found that children who were good cochlear implant candidates were able to achieve better speech perception scores in the bilateral versus unilateral implant conditions when the delay between the first and second implant was less than 12 months and no more the 2 years.

Galvin et al (2008) suggests that if implanting sequentially we can expect better results in speech perception and localisation when there is a shorter time between the two implants.

Sparreboom M et al (2011) looked at sequential bilateral cochlear implants in 29 children. Benefits of bilateral cochlear implant were present after 6 months of use and continued to improve over time. Benefits were recorded for speech perception in quiet and noise and after 24 months of use, speech perception in noise had significantly improved for bilateral cochlear patients. This study suggests that the longer a wearer uses the bilateral cochlear implants the more benefits the wearer gains over time.

Strom-Roum et al (2012) found no definitive point at which the second implant could no longer add positive effect. However, this is not in keeping with all of the evidence reviewed. Some other evidence suggests that children with simultaneously implanted bilateral cochlear implants demonstrated an advantage over children with sequential implants.

Scherf F et al 2009 studied 33 children using the Wurzburg questionnaire for assessing quality of hearing in children and the Categories of Auditory Performance (CAP) test. This found that Children with second implant after 6 years of age had lower Wurzburg and CAP scores than those planted before that age.

Auditory pathways:

A recent study by Gordon KA et al (2013) looked at the impact of unilateral cochlear implants on the bilateral auditory pathways and whether those pathways, once developed, can be reversed by restoring hearing to the contralateral ear. The study found that there was abnormal strengthening of the pathways from the stimulated ear as a result of the loss of contralateral activity including inhibitory processes which are normally involved in bilateral hearing. This occurred within 1.5 years of unilateral hearing and it was not reversed by 3-4 years of bilateral cochlear implant use. This means there is a sensitive period for strong asymmetry in hearing and the brain reorganizes towards the hearing ear and that puts the deaf ear into a disadvantage

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in the long term. Therefore the bilateral auditory input should be provided with as limited a delay as possible. Smulders et al (2011) provides evidence that implantation before the critical age of 3.5 years of both implants is important for binaural pathway development.

Gordon K A et al (2011) looked at the optimal timing for bilateral cochlear implantation for children and found that bilateral deafness should be limited to avoid the auditory pathways reorganising. After a long period of unilateral cochlear implant use this study suggests an asymmetry in the bilateral auditory pathways results that is significantly more pronounced than in those children who receive bilateral implants simultaneously. Behavioural responses to level and timing differences between implants suggest that binaural cues are not being processed normally by children who receive a second implant after a long period of unilateral cochlear implant use and at older ages.

Spatial cues:

A study by Chadha N K et al (2011) showed that children with simultaneous implants were able to use spatial cues to improve speech detection in noise and this was significantly better than in the sequential group. Also Dowell R C et al (2011) found that outcomes for children using bilateral cochlear implants are far more favourable and the benefits may be maximised if the child receives both devices before the ages of between 3.5 to 4 years.

Pre-verbal communication:

Montino et al (2011) looked at pre-verbal communication skills in children, and found that children with simultaneous bilateral cochlear implants had better auditory awareness than children with a unilateral implant. Smulders, et al (2011) undertook a systematic review of evidence looking at the effect of time between sequential cochlear implantation on hearing. The evidence from that study suggests that a second implant can still be beneficial even where there is a substantial interval between sequential implantations but results are not as positive as simultaneous. Seven of the studies looked specifically at pre-lingual deafened children. None of the seven studies mentioned a negative impact on sound localisation, but two studies reported poorer results after an extended implant delay on speech intelligibility in noise and one study reported poorer results after an extended implant delay on speech intelligibility in quiet. That study noted that more research was needed to be conclusive.

A concern with sequential implantation is that not all children who receive their second implant will become full time users. Some children who have had their initial implant for a long time may reject their second implant. According to Galvin and Hughes (2012) 95 percent of those implanted simultaneously used both their implants full-time after 2 months compared to 70 percent of those implanted sequentially. The study recommends that pre-operative counselling needs to include potential adaptation difficulties and issues such as negative influence of age and time between implants.

4.8 Risks

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There is significant risk that the surgical procedure of implanting the electrodes in to the cochlear will destroy any residual hearing in the implanted ear. This means that in the future it will not be possible for the child to revert to using a hearing aid or any other future technologies in that ear. Medical advancements, future technologies and developments are yet unknown, but parents should be aware that cochlear implant surgical procedures have will prevent uptake of future technologies if they become available.

Children and adults can still benefit from advances in cochlear implant technology through new electrode designs and processors upgrades.

A recent study by Anagiotos, A and Beutner, D (2013) 'The impact of blood loss during cochlear implantation in very young children' looked at the intraoperative bleeding during cochlear implantation of very young children. The study reviewed 14 implantations of children under 16 months retrospectively. It concluded that 'intraoperative bleeding should be taken into account during the decision for a simultaneous bilateral implantation'. However, *simultaneous bilateral implant surgery is conducted in the same amount of time as unilateral surgery and reduces the risk of a child requiring two anaesthetics.*

Complications from surgery can be wide ranging; however, according to Loundon, N (2010) major complication rates appear to be relatively low at around 24 patients out of 434 (5.5%) experiencing major complications. These were recorded as:

- severe cutaneous infections (15 patients)
- magnet displacement (3)
- meningitis (2)
- cholesteatoma (a destructive and expanding growth in the middle ear) (2)
- cerebrospinal fluid leak (1) and
- electrode misplacement (1).

In the same study 19 (4.4%) minor complications were recorded. These were recorded as:

- vertigo (9 patients)
- soft-tissue infection (5)
- persistent otitis media (4) and
- facial palsy (1).

Complications led to re-implantation in 13 of the 43 patients (30.2% of patients who had a minor or major complication). The overall re-implantation rate was about 3%.

A recent audit was carried out on bilateral paediatric cochlear implantation in the UK, using data from 14 surgical centres including simultaneous and sequential implantations. The study reported on age at implantation, aetiology of deafness, implant type, duration of surgery, use of electrophysiological testing and the use of pre and post-operative imaging.

Details of major and immediate minor complications were also recorded. Over 400 bilateral simultaneous, 394 bilateral sequential and 131 unilateral cochlear implants were carried out across the 13 surgical centres.

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Gordon K A and B C Papsin (2009) observed that sequential implantation caused children and families additional concerns as compared with simultaneous bilateral implantation. Parents of children bilaterally implanted sequentially found the decision to have the second implant more difficult than the first particularly when the child was functioning well with the first device. Some families of children found that having two surgeries within 1 year in combination along with necessary appointments for activation of each implant represented a considerable additional burden of time, anxiety and expense. To compound the problem, many of the children in this group received their first implant as infants and their second as toddlers. Families were surprised with how much more difficult it was to prepare their child for the second surgery and care for them in the recovery period, compared to the first.

4.9 Identity

There has been some concern raised from within the Deaf Community regarding the concept of deafness being something which needs to be 'cured' through the use of cochlear implants and the issue of bilateral cochlear implants in children has been raised as a particular worry[7]. Concerns have been raised about the very young age at which deaf children are undergoing cochlear implant surgery and the fact that parents and guardians do not have access to full and accurate information about the implication of deafness for their children's lives. It should be noted that this is not a concern unique to bilateral cochlear implants; it has been raised as an issue for many years regarding unilateral implants.

There is a sense that the history, culture and language (sign) of deaf people and what deaf people can achieve in society is not being considered and may be eroded. There is also concern that the majority of deaf children are born to hearing parents. These parents need sufficient information available to ensure they are able to make informed choices that recognise Deaf culture. From this perspective being deaf is not a disability and it is possible to lead a happy and productive life without hearing or spoken language[8]. In terms of preserving identity and choice, the child can chose to turn off the implant if they want to be deaf, but they wouldn't be able to get the same benefits of the implant later in life if they were not implanted as a child.

A study by Rich S et al (2013) looked at 12 teenagers with cochlear implants and asked how they coped in school, society and with their self-identity. At school, some reported better achievements than others, but they all expressed some difficulty functioning in class mainly in situations involving several speakers. From a social point of view, some reported a preference for association with normal hearing peers, whereas others favoured hard-of-hearing friends, and one had no preference. On the topic of self-identity, one participant referred to herself as deaf, eight defined themselves as hard-of-hearing, and two considered themselves hearing.

The study suggests that some cochlear implant recipients have both hearing and deaf identities, which will be activated and expressed in different situations. A one-on-one conversation in a quiet setting is more likely to evoke the hearing identity, while doing an activity where the processor may need to be removed (such as

[7] http://www.deafau.org.au/info/policy_cochlear.php
[8] http://www.theatlantic.com/health/archive/2013/08/understanding-deafness-not-everyone-wants-to-be-fixed/278527/

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swimming) will evoke the deaf identity. In some cases, such as going out with friends in the evening, cochlear implant recipients might feel both hearing and hard of hearing at the same time.

Wheeler et al (2009) also reported ambiguity in responses of their adolescent participants as to whether they saw themselves as deaf or hearing due to mixed experiences, according to the situation. It is possible that the cochlear implant intensifies the experience of incongruous identities. A deaf person is deaf in all communicative situations, but an early implantation allows youngsters close to normal functioning in many, but not all, situations. Therefore, two incongruent identities may develop in parallel and come in to play in their respective appropriate situations.

Bilateral cochlear implants may result in children feeling like they do not truly belong in either deaf or hearing culture. If they have not been given the opportunity to learn sign language, this may further exacerbate their difficulties in feeling they are a part of the deaf community.

5. CONCLUSION

The evidence suggests that there are some benefits over unilateral cochlear implantation that can be derived by providing bilateral cochlear implants to children. From the evidence reviewed, the benefits of bilateral cochlear implants are:

- Hearing in noise
- Ability to locate direction of sound
- Better spoken language

It is also important to consider the functional benefits of bilateral cochlear implants. Reduced listening effort with two versus one cochlear implant (Hughes et al 2013) and the positive impact of binaural hearing for bilateral cochlear implant users (Schafer EC, et al 2011 & Mok et al 2010) are some of those benefits. The wearer also has the positive impact of hearing more clearly due to increased volume.

Not all evidence around educational attainment and quality of life is conclusive and and/or may be limited.

Age appropriate spoken language outcomes are more likely the younger the age of the implantation; even after long term use. The receipt of a second device after the age of four years did not provide significant added benefit in terms of spoken language outcomes. On expressive language development there is an advantage for simultaneous implantation compared with sequential and the interval between the first and second implants had a negative impact on language scores.

Overall, the benefits of bilateral cochlear implants are increased most with limited time delay between implants and simultaneous implants are linked with better outcomes than sequential. Recent research into how auditory pathways develop in children with unilateral cochlear implants suggests that the strengthening of the pathways from the stimulated ear occurs after one and a half years of unilateral cochlear implant use. It is not reversed after four years of bilateral cochlear implant

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use. This evidence suggests that there is a sensitive period for asymmetry in hearing though individuals with sequential implants may still derive benefits from the second implant. Evidence suggests that sequential implants ought to be implanted earlier to achieve maximum benefits.

6. METHODOLOGY OF EVIDENCE SUMMARY

6.1 Overview

The Ministry of Health Disability Policy Support was asked to summarise the evidence on bilateral cochlear implants of children under the age of 18. A systematic literature search was conducted to find out available evidence on the following:

- As compared with unilateral cochlear implants do bilateral implants for hearing loss improve: detection of sound, perception and/or production of speech, ability to hear and speak in noise and/or to separate background noise, ability to reach educational goals

- Unilateral versus Bilateral Cochlear Implants

- Is the effectiveness of bilateral implant affected by the time interval between implant, duration or degree of deafness, age at implant
t and is there evidence to suggest that simultaneous implantation provides better results than sequential implantation?

The Reference Librarian at the Ministry of Health Library conducted separate searches on each of the 4 areas above on behalf of Disability Support Policy.

A broad search strategy was adopted to find articles in peer-reviewed journals published in the last five years (from 2013) that met the above criteria. Boolean logic was used to search Ovid MEDLINE®, In-Process Citations, Adapted for Cochrane, Embase, Scopus, ERIC, Mosby's Index, Psych Info, Sociological Abstracts and Google Scholar. The searches carried out for the above are attached at **Appendix 3**

A search of relevant grey literature was also carried out and resources published on NGO websites that met the search criteria were also considered. The search focused on:

- higher-grade research, such as randomised controlled trials, where this was available.
- peer-reviewed journals, although not all of the material meets this criterion
- systematic reviews, health technology reports and journal articles
- lessons from these studies, where they are based solidly on the evidence
- evaluations of programmes that are already running internationally.

6.2 Eligible Studies

The following studies were eligible for inclusion in this evidence summary:

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- Studies designed to allow a comparison of outcomes or harms between bilateral cochlear implants and unilateral cochlear implants

- Studies exploring the relationship between unilateral CI, Unilateral CI plus HA and BI and the outcomes as set out in question one

- Studies exploring the safety and effectiveness of BI, looking at criteria set out in question two

- Studies assessing outcomes following implantation of second CI

- Studies assessing impact of gap between first and second implant

- Studies assessing negative impacts of implantation of second device and any adverse effects attributed to bilateral CI plus any predictors of harm attributed to bilateral CI.

6.3 Excluded Studies

The following studies were excluded from this evidence summary:

- Studies over 5 years old (This timeframe gives us access to the studies leading up to and including the NICE review that took place in 2009, evidence from which was included in our study however, following the 2009 NICE review the Ministry recognises that there has been a great deal more evidence produced in this area. The Ministry wanted to be sure to capture most up to date evidence and so opted to focus on evidence post NICE review in 2009.

- Non English language studies

- Studies that only refer to adults

- Non-Human/animal trials

6.4 Internet searches

To find additional reports and papers of interest, a Google search was undertaken to identify the websites of government and non-government agencies, research centres and organisations of interest that contained relevant information.

7. MATERIAL INCULDED IN THE SUMMARY REVIEW:

Study: 1. Asp F et al (2012) 'Bilateral versus unilateral cochlear implants in children'.
Comparator Results
Compare bilateral and unilateral speech recognition in quiet and in multi-source noise and horizontal sound localization of low and high frequency sounds in children with bilateral cochlear implants

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Q1 Sound detection and perception of speech
Study Sample: Sixty-four children aged 5.1-11.9 years who were daily users of bilateral cochlear implants. Thirty normal –hearing children aged 4.8-9.0 years were recruited as controls.
Conclusion of study: Group data showed statistically significantly bilateral speech recognition and sound localisation benefit was small in quiet than in house. The majority of subjects localized high and low frequency sounds significantly better than chance using bilateral implants, while localization accuracy was close to chance using unilateral implants. Binaural normal-hearing performance was better bilateral performance in implanted children across tests, while bilaterally implanted children showed better localization than normal-hearing children under acute monaural conditions.
Summary: Horizontal sound localization accuracy was better with bilateral input, both with the high frequency and low frequency stimuli. The majority of subjects localized both stimuli significantly better than chance using BiCIs.

Study: 2. Bichey, B G and Rt Miyamoto (2008) 'Outcomes in bilateral cochlear implantation'
Comparator Results Compares quality of life measures (hui3) before first CI before second CI and after second CI Study also examines cost utility analysis but this has not been explored here.
Q1 quality of life
Study Sample: Case control study on 23 bilateral cochlear implant patients
Conclusion of study: Study found an improvement in quality of life with bilateral cochlear implant. Using the HUI3 scoring system to grade QoL in participants before first CI, before second CI and after second CI. Average increase in quality of life after bilateral CI was 0.48 units. The Mark III Health Utility index measures changes in quality of life in eight domains: vision, hearing in noise, speech, ambulation, dexterity, emotion, cognition, and pain. Table 4 shows specific changes noted in each individual after bilateral cochlear implantation when compared with unilateral cochlear implant use for each of these domains. In addition to obvious changes in hearing in noise and improvements in quality of life associated with these changes, additional improvements in quality of life were noted in the domains of speech production, emotion, cognition, and pain. Eleven patients had improvement in communication related to improved hearing in noise, while the remainder of patients had improvements in quality of life.
Summary:

Study: 3. Bond M et al (2009) The effectiveness and cost effectiveness of cochlear implants for severe to profound deafness in children and adults: a systemic review and economic model.
Comparator Results To assess the clinical effectiveness of CI for children and adults with severe to profound sensorineural hearing loss by answering the following: For severely to profoundly dead people with a singular CI (either UI or UI plus HA) is it effective to provide a second CI (i.e. Bilateral)

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Q1 Effectiveness of providing second CI
Study Sample: A systematic review of the literature was undertaken according to standard methods. A state-transition (Markov) model of the main care pathways deaf people might follow and the main complications and device failures was developed. The clinical effectiveness review included 33 papers, of which only two were RCTs. They used 62 different outcome measures and overall were of moderate to poor quality
Conclusion of study: All studies in children comparing one cochlear implant with non-technological support or an acoustic hearing aid reported gains on all outcome measures, some demonstrating greater gain from earlier implantation. The strongest evidence for an advantage from bilateral over unilateral implantation was for understanding speech in noisy conditions (mean improvement 13.2%, $p < 0.0001$); those receiving their second implant earlier made greater gains. Comparison of bilateral with unilateral cochlear implants plus an acoustic hearing aid was compromised by small sample sizes and poor reporting, but benefits were seen with bilateral implants. Cochlear implants improved children's quality of life, and those who were implanted before attending school were more likely to do well academically and attend mainstream education than those implanted later.
Summary:

Study: 4. Caselli M. C. et al (2012) Cochlear implant in the second year of life: Lexical and grammatical outcomes
Comparator Results The authors studies the effect of CI on language comprehension and production in deaf children who had received a CI in their second year of life. However, more pertinent to this study, the authors also compared children with unilateral CI to children with bilateral CI
Q1 Educational outcomes
Study Sample: The authors evaluated lexical and morphosyntactic skills in comprehension and production in 17 Italian children who are deaf (M = 54 months of age) with a CI and in 2 control groups of children with normal hearing (NH; 1 matched for chronological age and the other whose chronological age corresponded to the duration of CI activation).
Conclusion of study: Children with CI appeared to keep pace with NH children matched for time since CI activation in terms of language acquisition, and they were similar to same-age NH children in lexical production. However, children with CI showed difficulties in lexical comprehension when a task required phonological discrimination as well as in grammar comprehension and production. Children with bilateral CI showed better comprehension than did children with unilateral CI; the 2 groups were similar for production. Conclusions: Activation of CI in the 2nd year of life may provide children who are deaf with a good opportunity to develop language skills, although some limitations in phonological and morphological skills are still present 3 years after auditory deafferentation.
Summary:

Study: 5. Chadha NK et al. (2009) Tinnitus is prevalent in children with cochlear implants
Comparator Results To explore the prevalence and the perceived impact of tinnitus in children using CI
Q1 Quality of Life
Study Sample: 40 children (age range 3-15 mean 7 years) and their families were

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interviewed. Unilateral (21) and bilateral (19 – whose procedures were: simultaneous = 6 within 6-12 months=3 or >2 years apart 10. Tinnitus was reported by 38%
Conclusion of study: Tinnitus was most frequent in children aged 6-8 years (8/17 47%) and bilateral impantees with in inter-procedural delay of at least 2 years (6/10 60%) Tinnitus was least reported by those had bilateral implants and were implanted simultaneously or in those 5 years or younger. No obvious relationship was identified between the prevalence of tinnitus and the etiology of deafness, age of implantation or time elapsed since implantation.
Summary: This is the first study to report prevalence of tinnitus in children with CIs. Other studies suggest that CI reduced tinnitus. Further work would need to be done to look at this area further before it would be able to be considered fully.

Study: 6. Culling, J. F., et al. (2012). "The benefit of bilateral versus unilateral cochlear implantation to speech intelligibility in noise."
Q1 Sound detection in noise
Study Sample: The model initially assumed that bilateral cochlear implantees had equally effective implants on each side, with which they could perform optimal better-ear listening. Predictions were compared with measurements of SRM, using one and two implants with up to three interfering noises. The effect of relaxing the assumption of equally effective implants was explored. Novel measurements of SRM for eight unilateral implantees were collected, including measurements using speech and noise at azimuths of ± 60 degrees, and compared with prediction. A spatial map of bilateral implant benefit was generated for a situation with one interfering noise in anechoic conditions, and predictions of benefit were generated from binaural room impulse responses in a variety of real rooms.
Conclusion of study: The model accurately predicted data from a previous study for multiple interfering noises in a variety of spatial configurations, even when implants were assumed to be equally effective (r = 0.97). It predicted that the maximum benefit of bilateral implantation was 18 dB. Predictions were little affected if the implants were not assumed to be equally effective. The new measurements supported the 18 dB advantage prediction. The spatial map of predicted benefit showed that, for a listener facing the target voice, bilateral implantees could enjoy an advantage of about 10 dB over unilateral implantees in a wide range of situations. Predictions based on real-room measurements with speech and noise at 1 m showed that large benefits can occur even in reverberant spaces.
Summary: In optimal conditions, the benefit of bilateral implantation to speech intelligibility in noise can be much larger than has previously been reported. This benefit is thus considerably larger than reported benefits of summation or squelch and is robust in reverberation when the interfering source is close.

Study: 7. Dunn C.C et al. (2010) Bilateral and unilateral cochlear implant users compared on speech perception in noise.
Q1 speech perception in noise Compare speech performance in noise with matched bilateral cochlear implant and unilateral cochlear implant only users
Study Sample: Thirty bilateral CI subjects and 30 CI-only subjects were tested on a battery of speech perception tests in noise that use an eight-loudspeaker array.
Conclusion of study: On average, BCI subject's performance with speech in noise was significantly better than the CI-only subjects. The BCI group showed significantly better performance on speech perception in noise compared with the CI-only subjects, supporting the hypothesis that BCI is more beneficial than CI only.

Summary:

Study: 8. Forli F et al (2011) Systematic Review of the literature on the clinical effectiveness of the cochlear implant procedure in paediatric patients

Q1 systematic review covering simultaneous and sequential

Study Sample: The following aspects were evaluated: post-CI outcomes linked to precocity of CI; bilateral (simultaneous/ sequential) CI vs. unilateral CI and vs. bimodal stimulation; benefits derived from CI in deaf children with associated disabilities. With regard to the outcomes after implantation linked to precocity of intervention, there are few studies comparing post-CI outcomes in children implanted within the first year of life with those of children implanted in the second year.

Conclusion of study: The selected studies suggest that children implanted within the first year of life present hearing and communicative outcomes that are better than those of children implanted after 12 months of age. Concerning children implanted after the first year of life, all studies confirm an advantage with respect to implant precocity, and many document an advantage in children who received cochlear implants under 18 months of age compared to those implanted at a later stage. With regard to bilateral CI, the studies demonstrate that compared to unilateral CI, bilateral CI offers advantages in terms of hearing in noise, sound localization and during hearing in a silent environment. There is, however, a wide range of variability. The studies also document the advantages after sequential bilateral CI. In these cases, a short interval between interventions, precocity of the first CI and precocity of the second CI are considered positive prognostic factors. In deaf children with associated disabilities, the studies analysed evidence that the CI procedure is also suitable for children with disabilities associated with deafness, and that even these children may benefit from the procedure, even if these may be slower and inferior to those in children with isolated deafness, especially in terms of high communicative and perceptive skills.

Summary: The studies demonstrate that compared to unilateral CI, bilateral CI offers advantages in terms of hearing in noise, sound localization and during hearing in a silent environment. The studies also document the advantages after sequential bilateral CI. In these cases, a short interval between interventions, precocity of the first CI and precocity of the second CI are considered positive prognostic factors.

Study: 9. Godar S P and Litovsky (2010) Experience with bilateral cochlear implants improves sound localisation acuity in children.

Experience with bilateral cochlear implants improves sound localisation acuity in children. A growing number of children who are deaf are receiving bilateral cochlear implants (CIs), in an attempt to provide them with acoustic cues known to be important for spatial hearing. A feasible and reliable task for children is the right-left discrimination task, which enables measurement of the smallest angle from midline that can be reliably discriminated.

Q1 Sound localisation

Study Sample: Ten children (5-10 yr of age) were followed longitudinally during their transition from 1 to 2 CIs, with testing before bilateral activation, as well as 3 and 12 months after bilateral activation. Testing at 3 and 12 months after bilateral activation was conducted under bilateral and first CI listening modes. During testing, stimuli were presented from an array of loudspeakers. On each trial, the child reported whether the sound was to the right or

left, with feedback. Percent correct was measured in blocks of trials for numerous angle values.
Conclusion of study: At baseline, some children were unable to perform the right-versus-left task, but group mean MAA was 44.8 degrees. MAA in the bilateral listening mode improved to 20.4 degrees at 3 months and 16.8 degrees at 12 months after bilateral activation. No improvement was seen in the unilateral listening mode. Bilateral performance was better than unilateral.
Summary: Spatial hearing skills in sequentially implanted children develop in an experience-dependent manner, perhaps because of the ability of the auditory system to use newly acquired electrical stimulation presented to the 2 ears.

Study: 10. Grieco-CalubTM and Litovsky (2012) Spatial acuity in 2-to-3year-old children with normal acoustic hearing, unilateral cochlear implants, and bilateral cochlear implants.
Q1 spatial-hearing skills in UCI and BiCI children
Study Sample: To measure spatial acuity on a right-left discrimination task in 2-to-3-year-old children who use a unilateral cochlear implant (UCI) or bilateral cochlear implants (BICIs); to test the hypothesis that BICI users perform significantly better when they use two CIs than when using a single CI, and that they perform better than the children in the UCI group; to determine how well children with CIs perform compared with children who have normal acoustic hearing (NH); to determine the effect of intensity roving on spatial acuity. Three groups of children between 26 and 36 months of age participated in this study: 8 children with NH (mean age: 30.9 months), 12 children who use a UCI (mean age: 31.9 months), and 27 children who use BICIs (mean age: 30.7 months). Testing was conducted in a large sound-treated booth with loudspeakers positioned in a horizontal arc with a radius of 1.2 m. The observer-based psychophysical procedure was used to measure the children's ability to identify the hemifield containing the sound source (right versus left). Two methods were used for quantifying spatial acuity, an adaptive-tracking method and a fixed-angle method. In Experiment 1 an adaptive tracking algorithm was used to vary source angle, and the minimum audible angle (MAA), the smallest angle at which right-left discrimination performance is better than chance, was estimated. All three groups participated in Experiment 1. In Experiment 2 source angles were fixed at +/-50 degrees, and performance was evaluated by computing the number of SDs above chance. Children in the UCI and BICI groups participated in Experiment 2.
Conclusion of study: This report is consistent with a growing body of evidence that spatial-hearing skills can emerge in young children who use BICIs. The observation that these skills are not concomitantly emerging in age- and experience-matched children who use UCIs suggests that BICIs provide cues that are necessary for these spatial-hearing skills that UCIs do not provide
Summary:

Study: 11. Henkin Y, et al (2009) Cortical binaural interaction in bilateral cochlear implants recipients
Comparator Results The objective of the present study was to investigate cortical manifestations of binaural versus monaural processing of speech stimuli in bilateral CI recipients and in normal hearing (NH) subjects by means of auditory event-related potentials (AERPs). AERPs were recorded from a group of pre-lingually deaf children who were implanted simultaneously or sequentially (first CI before age 3 years).

Q1 processing of speech stimui in BiCI recipients

Study Sample: Recordings were obtained while subjects performed oddball discrimination tasks that consisted of the syllables /ka/(target) vs /ta/, in three listening conditions: unilateral right, unilateral left, and bilateral stimulation.

Conclusion of study: Results provided first-time evidence for a cortical inhibitory binaural interaction component (BIC) in the P3 latency range in NH adults and children. In addition, simultaneously implanted children with long CI use exhibited a robust BIC. In sequentially implanted children with long delay and short or long CI use, BIC was absent. However, processing efficacy was enhanced in the bilateral, relative to unilateral condition. Taken together, these preliminary results suggest that BIC holds promise as an objective measure of cortical binaural processing in CI recipients.

Summary:

Study: 12. Hughes K C and K L Gavin (2013) Measuring listening effort expended by adolescents and young adults with unilateral or bilateral cochlear implants or normal hearing. .

Q1 Listening effort To compare the listening effort expended by adolescents and young adults using implants versus their peers with normal hearing when these two groups are achieving similar speech perception scores. The study also aimed to compare listening effort expended by adolescents and young adults with bilateral cochlear implants when using two implants versus one

Study Sample: Eight participants with bilateral cochlear implants and eight with normal hearing aged 10-22 years were included. Using a dual-task paradigm, participants repeated consonant-nucleus-consonant (CNC) words presented in noise and performed a visual matching task. Signal-to-noise ratios were set individually to ensure the word perception task was challenging but manageable for all. Reduced performance on the visual task in the dual-task condition relative to the single-task condition was indicative of the effort expended on the listening task

Conclusion of study: The cochlear implant group, when using bilateral implants, expended similar levels of listening effort to the normal hearing group when the two groups were achieving similar speech perception scores. For three individuals with cochlear implants, and the group, listening effort was significantly reduced with bilateral compared to unilateral implants. Discussion: The similar amount of listening effort expended by the two groups indicated that a higher signal to-noise ratio overcame limitations in the auditory information received or processed by the participants with implants. This study is the first to objectively compare listening effort using two versus one cochlear implant.

Summary: The results provide objective evidence that reduced listening effort is a benefit that some individuals gain from bilateral cochlear implants

Study: 13. Kerber S and B U Seeber (2012) Sound localisation in noise

Q1 Sound localisation in noise. This study aimed to characterize horizontal plane sound localization in interfering noise at different signal-to-noise ratios (SNRs) and to compare performance across normal-hearing listeners and users of unilateral and bilateral cochlear implants (CIs). CI users report difficulties with listening in noisy environments. Although their difficulties with speech understanding have been investigated in several studies, the ability to localize sounds in background noise has not extensively been examined, despite the benefits of binaural hearing being greatest in noisy situations. Sound localization is a measure of binaural processing and is thus well suited to assessing the benefit of bilateral implantation

Study Sample: Six normal-hearing listeners, four unilateral, and 10 bilateral CI users indicated the perceived location of sound sources using a light pointer method. Target sounds were noise pulses played from one of 11 loudspeakers placed between -80 and +80 degrees in the frontal horizontal plane in the free field. Localization was assessed in quiet and in diffuse background noise at SNRs between +10 and -7 dB. Speech reception thresholds were measured and their relation to the localization results examined.
Conclusion of study: This study is the first to examine sound localization with CIs at various SNRs and to compare it with normal hearing. The results confirm that localization with CIs is strongly disrupted in noisy situations. Bilateral CIs were shown to be clearly superior over unilateral CIs for localization in quiet and in noisy situations. With bilateral CIs, localization declined at moderately high absolute noise levels (>63 dB SPL), suggesting that an extension of the acoustic-dynamic range to higher levels would be beneficial. The absence of a relation between speech reception thresholds and spatial resolution highlights the need for additional clinical tests to assess the binaural benefit of a second implant.
Summary: Bilateral CIs were shown to be clearly superior over unilateral CIs for localization in quiet and in noisy situations. With bilateral CIs, localization declined at moderately high absolute noise levels (>63 dB SPL), suggesting that an extension of the acoustic-dynamic range to higher levels would be beneficial.

Study: 14. Litovsky R Y (2011) Review of recent work on spatial hearing skills in children with bilateral cochlear implants
Comparator Results review of recent studies on
Q1 spatial hearing abilities in children who use bilateral cochlear implants.
Study Sample: Results from recent studies are reviewed in two categories. First, studies measured spatial hearing by using sound localization or identification methods, thereby focusing on localization accuracy. Second, studies that measured the ability of children to discriminate between sound source positions in the horizontal plane, thereby focusing on localization acuity where performance was quantified using the minimum audible angle (MAA).
Conclusion of study: Children with BiCIs have localization errors that vary widely. There is evidence that for many children errors are smaller when using two vs. one implant. In the bilateral condition, some children's performance falls within the range of errors seen in children with normal hearing (less than 30 root mean square), but most children have errors that are significantly greater than those of children with normal hearing. On MAA tasks, performance is generally significantly better (lower MAAs) when children are tested in the bilateral listening mode than in the unilateral listening mode. However, MAAs are generally higher than those measured in children with normal hearing
Summary:

Study: 15. Litovsky, R. Y., et al. (2013). "Reaching for sound measures: An ecologically valid estimate of spatial hearing in 2- to 3-year-old children with bilateral cochlear implants."
Comparator Results: A growing number of children who are deaf are receiving BiCIs at a young age. Their spatial hearing abilities are emerging but highly variable within the population. The reaching for sound method uses an ecologically valid approach that engages children and maintains their motivation. The present work was aimed at using the novel RFS method to evaluate spatial hearing in 2- to 3-year-olds with normal hearing and with BiCIs. Children were reinforced for correct responses.
Q1 Spatial Hearing

Study Sample: Six children with BiCIs and 15 children with NH, ages 2 to 3 years participated. In the BiCI group, testing was performed in bilateral or single CI (unilateral) conditions. Loudspeakers were separated by ±60, ±45, ±30, or ±15 degrees. On each trial, a small toy was hidden behind one of the loudspeakers, and the child's task was to reach through a hole in the curtain above the loudspeaker, to indicate source location. At each angle, the ability of the child to reach criterion of 80% or greater correct was assessed.
Conclusion of study: All BiCI users reached criterion at all angles tested in the bilateral condition; however, performance was poorer when using a single CI. Of the 15 NH children, 13 were able to perform the task accurately and reached criterion at all angles.
Summary: Spatial hearing skills studied with the RFS method revealed novel findings regarding the emergence of sound localization in very young BiCI users.

Study: 16. Lovett R E et al (2010) Bilateral or unilateral cochlear implantation for deaf children an observational study
Comparator Results Cochlear implantation in one ear (unilateral implantation) has been the standard treatment for severe-profound childhood deafness. We assessed whether cochlear implantation in both ears (bilateral implantation) is associated with better listening skills, higher health-related quality of life (health utility) and higher general quality of life (QOL) than unilateral implantation.
Q1 (QOL)
Study Sample: Cross-sectional observational study of fifty severely-profoundly deaf and 56 normally-hearing children. Thirty of the deaf children had received bilateral cochlear implants; 20 had unilateral cochlear implants.
Conclusion of study: On average, bilaterally-implanted children performed significantly better than unilaterally implanted children on tests of sound localisation and speech perception in noise. After conservative imputation of missing data and while controlling for confounds, bilateral implantation was associated with increases of 18.5% in accuracy of sound localisation (95% CI 5.9 to 31.1) and of 3.7 dB in speech perception in noise (95% CI 0.9 to 6.5). Bilaterally-implanted children did not perform as well as normally-hearing children, on average. Bilaterally- and unilaterally-implanted children did not differ significantly in parental ratings of health utility (difference in medians 0.05, p>0.05) or QOL (difference in medians 0.01, p>0.05).
Summary: Compared with unilateral cochlear implantation, bilateral implantation is associated with better listening skills in severely-profoundly deaf children.

Study: 17. Sarant, J et al (2011) Bilateral versus unilateral cochlear implants for children; early language findings of a 5 year study of language academic, psychological and other outcomes
Q1 language, social, and academic development
Conclusion of study: The bilateral group scored higher on all language measures. However, the differences in scores between the groups were significant only for the more difficult tasks [Expressive Language and Total Language (PLS-4)]. No significant differences were found between the groups for IQ, parent stress or parental involvement.
Summary: These initial findings must be interpreted with caution, due to the small sample sizes.

Study: 18. Scherf F et al (2009) Three Year post-implantation auditory outcomes in children with sequential bilateral cochlear implantation

Q1 auditory abilities and speech performance in quiet and noise

Study Sample: 35 children with sequential bilateral cochlear implantation after 3 years of bilateral implant use. Testing was done in bilateral and both unilateral listening conditions. The assessments took place before the second implantation and at several time intervals after fitting. As different auditory tests were used, the children were categorized by their age at the second implantation: younger or older than 6 years.

Conclusion of study: The pure tone averages for the bilateral condition were significantly better than those for either unilateral condition after 12 months of bilateral implant use and remained so from that test interval onward. The speech recognition outcomes in quiet and noise also improved significantly for almost all children after 36 months, although a linear regression analysis showed a beneficial effect of younger age at first implantation on the speech-in-noise results.

Summary: Bilateral cochlear implantation offered advantages to all children in comparison with the first implant--even the children who received the second implant after the age of 6 years. Compared to the younger children, the older children needed a longer adjustment period to gain bilateral benefit. However, they obtained similar results after 2 years of bilateral implant use.

Study: 19. Vincent C et al Bilateral cochlear implantation in children: localization and hearing in noise benefits

Comparator Results. The aim of this study was to report speech performance in quiet and in noise, sound localization with cochlear implanted children bilaterally. Their performances were compared also in unilateral conditions. In addition, speech and language evaluation was analysed.

Q1 localization and hearing in noise

Study Sample: Twenty-three children implanted with Neurelec Digisonic SP devices in 3 tertiary centres were tested on a battery of speech perception tests in quiet and in noise. Localization was assessed by lateralization tasks (90 and 30). Progress in speech and language development and subjective assessment of benefit were assessed using several rating scales and questionnaires (categories of auditory perception, speech intelligibility rating, family participating rating scale).

Conclusion of study: Children scored better when tested in bilateral conditions rather than in unilateral conditions. In quiet, the mean scores for the poorer and better side were 52% and 73%, respectively. In the bilateral condition, the mean score increased to 83%. In noise, the mean scores were 39% and 57% respectively, which increased to a mean of 70% in the bilateral condition. Nine children (<9 years) completed the +/-90 lateralization task. For both unilateral conditions performance was not significantly different from chance level. In the bilateral condition, the mean score was 86%. The +/-30 lateralization score was completed by eight of the older children (>9 years). The scores in the unilateral conditions were closed to chance level, but significantly better in the bilateral condition (mean of 86%).

Summary: Performances in bilateral conditions were significantly better than in unilateral conditions on speech perception in quiet and in noise. Localization was significantly better when tested in the bilateral condition for +/-90 lateralization task for the younger children and the +/-30 task for the older children. All these results supported the hypothesis than bilateral cochlear implantation is more beneficial than unilateral implantation in children.

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Study: 20. Strom-Roum H et al (2012) Sound localising ability in children with bilateral sequential cochlear implants.
Q1 Sound localisation
Study Sample: Sixty-three prelingually deaf children (mean age, 11.03; range, 6.5-17 years; SD, 3.09) were tested after 12 and 24 months of using bilateral cochlear implants. Every child was tested with each ear alone and both ears together. Five loudspeakers were placed in a 180 horizontal arch with 45 of separation between each loudspeaker. The child was placed 1.5m from the speakers. For each test run, three stimuli were presented at 65dB (A) from each speaker for a total of 15 stimulus presentations. For each test run, we calculated the mean angular error (MAE) and the proportion of correct speakers identified (CSS: correct speaker score). Performance by chance for the MAE was 72 and for the CSS was 20% (1 of 5 speakers).
Conclusion of study: After 12 months of using bilateral CIs, the added effect of the second CI in the MAE was minor, and there was no significant difference in CSS between listening in the unilateral condition and listening in bilateral condition. After 24 months, however, the added effect of the second CI in the MAE was significant (mean diff=12.2; 95% CI; 4.5-20.0, p=0.003). The mean bilateral CSS increased significantly to 38% (diff=7.7%; 95% CI; 1.4-14.0%; p=0.019) while the mean unilateral CSS remained at a similar level (27%). The influence of age at the time of the first implantation on CSS after 24 months was not significant (p=0.96). However, the inter-implant interval showed a significant decrease in score by 1.4% per year between the two implants (p=0.04).
Summary: Sound localisation with two versus one CI in children with a sequential bilateral cochlear implantation was significantly improved 24 months (but not 12 months) after the second implantation. A shorter inter-implant interval showed a small but significant beneficial effect on sound localisation.

Study: 21. Tait, M et al Bilateral versus unilateral cochlear implantation in young children
Comparator Results To compare the preverbal communication skills of two groups of young implanted children: those with unilateral implantation and those with bilateral implantation.
Q1 preverbal communication skills
Study Sample: The study assessed 69 children: 42 unilaterally and 27 bilaterally implanted with age at implantation less than 3 years. The preverbal skills of these children were measured before and 1 year after implantation, using Tait Video Analysis that has been found able to predict later speech outcomes in young implanted children.
Conclusion of study: Results: Before implantation there was no significant difference between the unilateral group and the bilateral group. There was still no difference at 12 months following implantation where vocal autonomy is concerned, but a strongly significant difference between the groups for vocal turn-taking and non-looking vocal turns, the bilateral group outperforming the unilateral group. Regarding gestural turn-taking and gestural autonomy, there was a strongly significant difference between the two groups at the 12 month interval, and also a difference before implantation for gestural autonomy, the unilateral group having the higher scores. Multiple regression of non-looking vocal turns revealed that 1 year following implantation, bilateral implantation contributed to 51% of the variance ($p < 0.0001$), after controlling for the influence of age at implantation and length of deafness which did not reach statistical significance.
Summary: Profoundly deaf bilaterally implanted children are significantly more likely to use vocalisation to communicate, and to use audition when interacting vocally with an adult,

compared with unilaterally implanted children. These results are independent of age at implantation and length of deafness.

Study: 22. Dunn C C et al (2012 Sequential bilateral cochlear implantation: speech perception and localization pre and post second cochlear implantation
Q1 speech perception and localization in sequentially implanted children In this study, the authors sought to compare speech perception and localization in subjects who wear 1 cochlear implant (unilateral CI) or 1 cochlear implant and hearing aid (CI+HA) and then receive a second cochlear implant (bilateral CI), and to evaluate the importance of the duration between implant surgeries and duration of deafness.
Study Sample: Nine subjects were tested on speech perception in quiet, and 13 subjects were tested on speech perception and localization in noise using an array of 8 loudspeakers. All subjects were tested with unilateral CI prior to bilateral implantation and then again with bilateral CI after at least 3 months of bilateral experience.
Conclusion of study: No significant difference was found between bilateral CI and unilateral CI on averaged speech perception in quiet performance. A significant benefit was found for bilateral CI on averaged speech perception in noise and on localization. Non-significant correlations were found for duration between surgeries, duration of deafness, and duration of bilateral use.
Summary: Improvements for speech perception and localization played in background noise were indicated for most subjects after they received their 2nd implant. The correlations should be reassessed with a larger number of subjects to appropriately evaluate the effects of duration between surgeries, duration of deafness, and duration of bilateral use.

Study: 23. Boons, T., et al. (2012). "Effect of paediatric bilateral cochlear implantation on language development."
Comparator Results
Q1 spoken language outcomes in children undergoing bilateral cochlear implantation compared with matched peers undergoing unilateral implantation.
Study Sample: Case-control, frequency-matched, retrospective cross-sectional multicenter study. Twenty-five children with 1 cochlear implant matched with 25 children wi th 2 cochlear implants selected from a retrospective sample of 288 children who underwent cochlear implantation before 5 years of age.
Conclusion of study: On the receptive language tests (mean difference [95% CI], 9.4 [0.3-18.6]) and expressive language tests (15.7 [5.9-25.4] and 9.7 [1.5-17.9]), children undergoing bilateral implantation performed significantly better than those undergoing unilateral implantation. Because the 2 groups were matched with great care on 10 auditory, child, and environmental factors, the difference in performance can be mainly attributed to the bilateral implantation. A shorter interval between both implantations was related to higher standard scores. Children undergoing 2 simultaneous cochlear implantations performed better on the expressive Word Development Test than did children undergoing 2 sequential cochlear implantations.
Summary: The use of bilateral cochlear implants is associated with better spoken language learning. The interval between the first and second implantation correlates negatively with language scores. On expressive language development, study found an advantage for simultaneous compared with sequential implantation.

Study: 24. Eapen, R. J. and C. A. Buchman (2009). "Bilateral cochlear implantation:

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current concepts."
Q1 speech perception outcomes in quiet and in noise, sound localization
Study Sample: The goal of this review was to examine the most recent literature exploring the indications, outcomes, and long-term benefit of bilateral cochlear implantation in children and adults. The indications for cochlear implantation have expanded, as many unilaterally implanted individuals are able to achieve open-set word recognition.
Conclusion of study: Despite the benefits seen in unilateral implantation, many individuals have difficulty perceiving speech in noisy environments. Bilateral cochlear implantation has made great strides in providing individuals access to sound information from both ears, allowing improved speech perception in quiet and in noise, as well as sound localization. Recently, the House Cochlear Implant study group released a position statement in which the group strongly endorsed bilateral cochlear implantation. Improved speech perception in quiet has also been demonstrated by many groups with bilateral implantation. Improved sound localization abilities have been shown to be dependent on interaural level differences. The binaural benefits of head shadow and summation have been long shown in bilaterally implanted individuals. Recently, a growth in squelch has been seen in these individuals likely as a result of increased experience with both implants. This may indicate neural integration of the inputs over time.
Summary: The literature supports the binaural benefit of bilateral cochlear implantation with demonstrated improved speech perception outcomes in quiet and in noise, sound localization data, and subjective benefits.

Study: 25. Kim L S et al (2009) Bilateral cochlear implants in children
The aim of this study was to investigate the impact of bilateral cochlear implants (CIs) use on speech perception in quiet and noise
Study Sample: The eleven children included in our study were prelingually deaf. With the two-stage technique, the two CIs were performed in all children. They underwent testing from four to 28 months after activation of bilateral hearing.
Conclusion of study: Speech perception tests in quiet and in noise were performed in all children with the first CI alone and bilaterally. In speech-in-noise test, words and noise were presented from the front. Subjects showed varying degrees of improved performance on speech perception tests in quiet and noise according to bilateral auditory experience.
Summary: Bilateral CIs can offer a substantial benefit in speech perception in quiet and noise.

Study: 26. Schafer E C et al (2011) A meta-analysis to compare speech recognition on noise with bilateral cochlear implants
Q1 speech recognition on noise with bilateral cochlear implants
Study Sample: A repeated-measures meta-analytical approach was used to compare effect sizes between binaural CI arrangements for each of the three binaural-listening phenomena and between the two test paradigms. A total of 95 effect sizes were calculated and analysed from 42 peer-reviewed studies published between January 2000 and April 2011
Conclusion of study: Findings revealed significant effect sizes for both CI arrangements for the binaural phenomena of summation and head-shadow effect. A significant effect size for binaural squelch was determined only for bilateral CI users. Further, the two paradigms resulted in similar effect sizes for bilateral and bimodal users, with the exception of binaural squelch. Here, significant effect sizes were significant only in the fixed-testing paradigm.

Summary: The average user of binaural CI arrangements realizes the binaural phenomena of summation and the head-shadow effect, but only the bilateral CI arrangement is afforded the advantage of binaural squelch. Statistically, listeners fit with bilateral CIs have a slight advantage in binaural performance over those using bimodal stimulation.

Study: 27. Mok M et al (2010) "Speech perception benefit for children with a cochlear implant and a hearing aid in opposite ears and children with bilateral cochlear implants."
Q1 Speech perception
Study Sample: The aims of the present study are to investigate: (1) the effect of using a hearing aid (HA) or a second cochlear implant (2nd CI) on speech recognition in noise for children; (2) the ability to perceive phoneme groups of different frequencies when using a CI and an HA in opposite ears (bimodal fitting) and when using a CI in each ear (bilateral implant fitting), and (3) the relationship between aided thresholds in the HA ear and bimodal advantage. Thirteen school-age children who consistently used a bimodal or bilateral implant fitting participated.
Conclusion of study: Perception was evaluated using consonant-nucleus-consonant words presented from in front with noise from either side. Significant bimodal or bilateral CI advantage in speech perception was demonstrated by most subjects in at least 1 noise condition. Comparisons indicated that the bimodal advantage obtained by the bimodal subjects was greater than the bilateral CI advantage obtained by the bilateral-implant subjects in the noise front condition, but also suggested that the 2nd CI may provide more functional advantage in real life. The mechanisms underlying the advantage provided by the second device appear to be different in the bimodal and bilateral groups. Information transmission analysis did not show a clear difference between the groups in the pattern of advantage across phoneme groups. For the bimodal subjects, those with better aided thresholds at low frequencies and poorer aided thresholds at 4 kHz demonstrated greater bimodal advantage.
Summary: Overall, these findings encourage the use of bimodal and bilateral implant fittings for children, provide insight into the individual variability in bimodal outcome, and enhance understanding of the differences between an HA and a 2nd CI when used together with an implant in the opposite ear.

Study: 28. Van Deun, L, et al. (2010). "Spatial speech perception benefits in young children with normal hearing and cochlear implants."
Q1 Speech perception Several studies have demonstrated better speech perception performance in children using two rather than one cochlear implant (CI). The extent to which bilaterally implanted children benefit from binaural cues to segregate speech and noise in a spatial configuration is less clear. Although better-ear effects are expected to be similar to adults, it is unknown whether electrical stimulation allows true binaural processing of speech signals in noise. Moreover, little data are available on the binaural hearing abilities of normal-hearing children.
Study Sample: This study aimed at (1) developing and evaluating a speech test based on numbers to determine speech reception thresholds (SRTs) fast and accurately in young children, (2) evaluating a setup for measuring benefits of speech perception in a spatial configuration in young children and determining normative values of normal-hearing children, and (3) measuring spatial speech benefits in cochlear-implanted children with good sound localization abilities. The speech test was conducted using the Leuven Intelligibility Number Test (LINT) data

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base. The test was limited to the numbers 1 to 10 spoken by one female speaker ("LittleLINT"). The LINT speech-weighted noise was used as a masker. Perception of this speech material was evaluated at fixed signal-to-noise ratios (SNRs) through monaural presentation via headphones in 34 normal-hearing children of 4 and 5 yrs of age and 20 normal-hearing adults. Subsequently, spatial speech perception benefits were measured in 50 normal-hearing children between 4 and 8 yrs of age, 15 normal-hearing adults, and eight children with bilateral CIs. An adaptive procedure was used for estimating unilateral and bilateral SRTs for different spatial configurations of speech and noise. Speech was always presented at 0 degrees azimuth (the front) and noise at the front, 90 degrees to the right, or 90 degrees to the left.
Conclusion of study: Unilateral headphone SRTs for the LittleLINT were higher for children (-9 dB SNR) than for adults (-13 dB SNR) and were lower than those for the LINT (-10 dB SNR for adults). Slopes (12 to 14%/dB) were comparable with that of the LINT (15%/dB), suggesting equal efficiency for the limited set of numbers. Normal-hearing subjects demonstrated several benefits of two-ear listening in spatial configurations (spatial release from masking [SRM], head shadow, summation, and squelch). Only SRM was influenced by age. Implanted children clearly benefited from bilateral implantation, as shown by SRM (3 dB) and head shadow effects (4 to 6 dB) comparable with normal-hearing children, but no summation or binaural squelch was established. The first CI seemed to contribute most to spatial speech perception. The steep slope, the familiarity to children, and the repeatability of lists make the LittleLINT suitable for fast and accurate SRT estimation in children. Spatial speech perception benefits were observed in normal-hearing subjects from the age of 4 yrs. Cochlear-implanted children showed better-ear effects but there was no evidence of true binaural processing.
Summary:

Study: 29. Anagiotos, A. and D. Beutner (2013). "The impact of blood loss during cochlear implantation in very young children.".
Safety of proceedure The aim of this study was to investigate if the intraoperative bleeding during cochlear implantation in very young children had any clinical importance and if it should influence the clinical management of such cases
Study Sample: A retrospective chart review of the pre- and postoperative hemoglobin concentration was performed on 14 implantations in children aged 16 months or younger at the time of surgery (11 males and 3 females). A postoperative decrease of the hemoglobin value was noted in 13 cases (93 %), with a mean difference between pre- and postoperative measurement of -1.9 g/dl.
Conclusion of study: The most remarkable case was that of a 2-month-old newborn with a bilateral profound hearing loss caused by bacterial meningitis. In the course of the asynchronous bilateral cochlear implantation and due to a remarkable bleeding, a transfusion of packed red blood cells was performed. The increased loss of blood was reported at the time of detaching and lifting up the muscle-periosteal-flap from the mastoid bone as well as at the time of the mastoidectomy. The special physiological properties of this age can contribute to a rapid cardiovascular decompensation in the case of increased blood loss. The consideration of these aspects is of great importance in the stage of planning the cochlear implantation, which in this group of patients should include the requirement of banked human blood. In addition, the intraoperative bleeding should be taken into account during the decision for a simultaneous bilateral implantation.
Summary:

Study: 30. Geers A et al. (2008) Long-term outcomes of cochlear implantation in the preschool years: from elementary grades to high school
Q1 Educational outcomes The objective of this study was to document the development of speech, language, and reading skills between primary and secondary school ages in children who received cochlear implants during preschool years.
Study Sample: Subjects were a sample of 85 North American adolescents recruited from a larger sample of 181 participants from a previous investigation.
Conclusion of study:. Students were first tested in early elementary school (ages eight to nine years) and were re-evaluated in high school (ages 15-18 years) for this study. The methods used were: performance on a battery of speech perception, language, and reading tests. These were compared at both test ages and significant predictors of outcome level identified through multiple regression analysis. Speech perception scores improved significantly with long-term cochlear implant use. Average language scores improved at a faster than normal rate, but reading scores did not quite keep pace with normal development. Performance in high school was most highly correlated with scores obtained in elementary grades.
Summary: In addition, better outcomes were associated with lower PTA cochlear implant threshold, younger age at implantation and higher nonverbal IQ. In conclusion, early cochlear implantation had a long-term positive impact on auditory and verbal development, but did not result in age-appropriate reading levels in high school for the majority of students.

Study: 31. Mok M et al (2010) "Speech perception benefit for children with a cochlear implant and a hearing aid in opposite ears and children with bilateral cochlear implants."
Comparator Results
Q1 Speech perception
Study Sample: The aims of the present study are to investigate: (1) the effect of using a hearing aid (HA) or a second cochlear implant (2nd CI) on speech recognition in noise for children; (2) the ability to perceive phoneme groups of different frequencies when using a CI and an HA in opposite ears (bimodal fitting) and when using a CI in each ear (bilateral implant fitting), and (3) the relationship between aided thresholds in the HA ear and bimodal advantage. Thirteen school-age children who consistently used a bimodal or bilateral implant fitting participated.
Conclusion of study: Perception was evaluated using consonant-nucleus-consonant words presented from in front with noise from either side. Significant bimodal or bilateral CI advantage in speech perception was demonstrated by most subjects in at least 1 noise condition. Comparisons indicated that the bimodal advantage obtained by the bimodal subjects was greater than the bilateral CI advantage obtained by the bilateral-implant subjects in the noise front condition, but also suggested that the 2nd CI may provide more functional advantage in real life. The mechanisms underlying the advantage provided by the second device appear to be different in the bimodal and bilateral groups. Information transmission analysis did not show a clear difference between the groups in the pattern of advantage across phoneme groups. For the bimodal subjects, those with better aided thresholds at low frequencies and poorer aided thresholds at 4 kHz demonstrated greater bimodal advantage.
Summary: Overall, these findings encourage the use of bimodal and bilateral implant

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fittings for children, provide insight into the individual variability in bimodal outcome, and enhance understanding of the differences between an HA and a 2nd CI when used together with an implant in the opposite ear.

Study: 32. Van Deun, L. et al. (2009). "Bilateral cochlear implants in children: Binaural unmasking."
Comparator Results
Q1 Bilateral cochlear implants (CIs) may offer deaf children a range of advantages compared to unilateral CIs (dichotic) between two ears than when it was in phase (diotic), with a mean difference (BMLD) of 6.4 dB.
Conclusion of study: In this paper, we present results on binaural hearing in children with bilateral CIs. Binaural masking level differences (BMLDs) were measured for a 180-degree phase shift in a 125-Hz sinusoid, presented in a 50-Hz-wide noise band and modulating a 1000-pps carrier pulse train. Stimuli were presented to a single electrode in the middle of the electrode array at both ears.
Summary: The present results show that children with bilateral CIs are sensitive to binaural cues in electrical stimuli, similar to adults, even when implants are provided at a later age and with a longer delay between implantations.

Study: 33. Broomfield, S. J., et al. (2013). "Results of a prospective surgical audit of bilateral paediatric cochlear implantation in the UK."
Comparator Results Following the approval of bilateral paediatric cochlear implantation in 2009, the prospective multi-centre UK National Paediatric Cochlear Implant Audit was established to collect a large dataset of paediatric implantations.
surgical practice, outcomes and complications.
Study Sample: Data from 14 surgical centres was collected prospectively, including simultaneous and sequential bilateral as well as unilateral implantations. Data collected included age at implantation, aetiology of deafness, implant type, duration of surgery, the use of electrophysiological testing, and the use of preand post-operative imaging. Details of major and immediate minor complications were also recorded.
Conclusion of study: 1397 CI procedures in 961 CI recipients were included; 436 bilateral simultaneous, 394 bilateral sequential, 131 unilateral. The overall major complication rate was 1.6% (0.9% excluding device failure) and was similar following bilateral CI compared to sequential and unilateral CI.
Summary: This prospective multi-centre audit provides evidence that bilateral paediatric CI is a safe procedure in the UK, thus endorsing its role as a major therapeutic intervention in childhood deafness.

Study: 34.Murphy J, et al. (2011). Spatial hearing of normally hearing children and cochlear implanted children
Comparator Results
Q1 Spatial hearing
Study Sample: Study tested two methods of spatial hearing to provide norms for NH and UCI using children and preliminary data for BCI users. NH children (n=40) were age

matched (6-15 years) to UCI (n=12) and BCI (n=6) listeners. Testing used a horizontal ring of loudspeakers within a booth in a hospital outpatient clinic. In a 'lateral release' task, single nouns were presented frontally, and masking noises were presented frontally, or 90 left or right. In a 'localization' task, allowing head movements, nouns were presented from loudspeakers separated by 30, 60 or 120 about the midline.
Conclusion of study: Normally hearing children improved with age in speech detection in noise, but not in quiet or in lateral release. Implant users performed more poorly on all tasks. For frontal signals and noise, UCI and BCI listeners did not differ. For lateral noise, BCI listeners performed better on both sides (within ~2 dB of NH), whereas UCI listeners benefited only when the noise was opposite the unimplanted ear. Both the BCI and, surprisingly, the UCI listeners performed better than chance at all loudspeaker separations on the ecologically valid, localization task.
Summary: Children using either UCI or BCI have useful spatial hearing. BCI listeners gain benefits on both sides, and localize better, but not as well as NH listeners. However, the BCI listeners performed about twice as well and, in two cases, approached the performance of NH children.

Study: 35 Cullington, H. E. and F. G. Zeng (2010). "Comparison of bimodal and bilateral cochlear implant users." Cochlear Implants International
Comparator Results Many cochlear implant users have difficulty with speech perception in noise, music appreciation, tone of voice recognition, and talker identification. These tasks rely on pitch perception, which is generally poor in cochlear implant users because of the speech-processing algorithm. Benefit may also be obtained by using a hearing aid on the contralateral ear to the implant: bimodal hearing. Amplitude envelope information is extracted from the incoming sound; the temporal fine structure, which is important for pitch perception, is mostly discarded. Bilateral cochlear implantation provides benefit in terms of localization and speech recognition in noise, but does not solve problems related to poor pitch discrimination.
Q1 Speech perception/tone of voice recognition
Study Sample: Thirteen bimodal and thirteen bilateral cochlear implant users were compared on speech recognition with a competing talker, music perception, tone of voice recognition, and talker identification. In order to categorize the extent of residual hearing required for bimodal benefit, a unique cochlear implant subject with normal hearing in the contralateral ear was evaluated on speech recognition with a competing talker.
Conclusion of study: Although there was no significant difference in group mean scores between the bimodal and bilateral cochlear implant users, a slight advantage was seen for the bimodal users. Evaluation of the subject with normal hearing in the contralateral ear showed that the addition of low-frequency sound, even when unintelligible and limited to below 150 Hz, significantly improved cochlear implant speech recognition with a competing talker. This research suggests that bimodal stimulation offers equal performance to bilateral cochlear implantation on these four tasks in adults. Bimodal stimulation should be attempted before considering bilateral implantation.
Summary:

Study: 36. Ching T.Y et al. (2009) Bimodal fitting or bilateral implantation

Q1
Study Sample: Summarises findings from studies that evaluated the benefits of bimodal fitting (combining a hearing aid and a cochlear implant in opposite ears) or a bilateral cochlear implant, relative to unilateral implantation for children.
Conclusion of study: Some children with bilateral cochlear implants were able to use spatial separation between speech and noise to improve speech perception in noise. This is possibly a combined effect of the directional microphones in their implant systems and their ability to use spatial cues. The evidence to date supports the provision of hearing in two ears as the standard of care.
Summary:

Study: 37. Scherf F (2009) Functional outcome of sequential bilateral cochlear implantation in young children: 36 months postoperative results
Q2To examine the effects of sequential bilateral cochlear implantation (CI) on the life of young children after 36 months of bilateral implant use.
Study Sample: Thirty-five children were assessed prior to and 3 until 36 months after activation of the second CI. Main outcome measures were: the Categories of Auditory Performance (CAP), Speech Intelligibility Rating (SIR), communication mode, classroom placement, parent reports and the Würzburg questionnaire. Results were analysed separately for children younger and older than 6 years at the time of the second implantation.
Conclusion of study: At the 3-year test interval, 80% of the younger children attended mainstream schools and were comprehensible for all listeners. They all used oral communication and almost 70% of them could have a conversation over the telephone. After 3 years of bilateral implant use less than 50% of the older children obtained the highest score on the SIR and CAP. Approximately 70% of them was integrated in mainstream schools and used oral communication. All parents reported a more natural communication and an improved quality of life.
Summary: Sequential bilateral implantation seems to offer a wide range of participation benefits to all children and facilitates the social intercourse with their hearing environment. Children with second implant after 6 years of age had lower Wurzburg and CAP scores than those planted before that age

Study: 38. Cullington, H., et al. (2013). "United Kingdom national paediatric bilateral cochlear implant audit: Preliminary results."
Comparator Results Prior to 2009, United Kingdom (UK) public funding was mainly only available for children to receive unilateral cochlear implants. In 2009, the National Institute for Health and Care Excellence published guidance for cochlear implantation following their review. According to these guidelines, all suitable children are eligible to have simultaneous bilateral cochlear implants or a sequential bilateral cochlear implant if they had received the first before the guidelines were published. The measures include localization, speech recognition in quiet and background noise, speech production, listening, vocabulary, parental perception, quality of life, and surgical data including complications..
Q1
Study Sample: Fifteen UK cochlear implant centres formed a consortium to carry out a

multi-centre audit. The audit involves collecting data from simultaneously and sequentially implanted children at four intervals: before bilateral cochlear implants or before the sequential implant, 1, 2, and 3 years after bilateral implants.

Conclusion of study:

Summary: The audit has now passed the 2-year point, and data have been received on 850 children. This article provides a first view of some data received up until March 2012

Study: 39. Galvin, K. L., et al. (2008). "Speech detection and localization results and clinical outcomes for children receiving sequential bilateral cochlear implants before four years of age."

Q1 detection and localization

Study Sample: The aim of this study was to describe the adaptation to bilateral cochlear implant use and the perceptual benefits demonstrated by 10 children who were successful users of a first implant when a second was received before four years of age.

Conclusion of study: Although one subject rejected the second implant at switch-on, the nine subjects who accepted the device adapted easily to bilateral implant use and developed useful listening skills with the second implant. Tests of localization (left versus right) and speech detection in noise were administered in the unilateral and bilateral conditions, usually after six months experience. All subjects demonstrated some bilateral benefit on speech detection testing (mostly due to a head shadow effect), and the majority localized left versus right.

Summary: Results suggested that outcomes may be negatively impacted by increased age at the time of second implant switch-on. The majority of the subjects adapted well to bilateral implant use within six months and demonstrated some perceptual benefit and, according to subjective parent reports, improved daily functioning; however, device rejection must be discussed pre-operatively as a possibility.

Study: 40. Litovsky R Y et al (2012) Studies on bilateral cochlear implants at the University of Wisconsin's binaural hearing and speech laboratory

Q1 Spatial hearing and speech understanding in noise This report highlights research projects relevant to binaural and spatial hearing in adults and children

Study Sample: In the past decade progress has been made in understanding the impact of bilateral cochlear implants (BiCIs) on performance in adults and children. However, BiCI users typically do not perform as well as normal hearing (NH) listeners. This article describes the benefits from BiCIs compared with a single cochlear implant (CI), focusing on measures of spatial hearing and speech understanding in noise. It highlights the fact that in BiCI listening the devices in the two ears are not coordinated; thus binaural spatial cues that are available to NH listeners are not available to BiCI users. Through the use of research processors that carefully control the stimulus delivered to each electrode in each ear, we are able to preserve binaural cues and deliver them with fidelity to BiCI users.

Conclusion of study:

Results from those studies are discussed with a focus on the effect of age at onset of deafness and plasticity of binaural sensitivity. The work with children has expanded both in number of subjects tested and age range included. Research has now tested dozens of children ranging in age from 2 to 14 yr. Findings suggest that spatial hearing abilities emerge with bilateral experience. While the research originally focused on studying performance in free field, where real world listening experiments are conducted, more recently studies have begun under carefully controlled binaural stimulation conditions with children as well. The researchers have also studied language acquisition and speech perception and production in young CI users. Finally, a running theme of this research

program is the systematic investigation of the numerous factors that contribute to spatial and binaural hearing in BiCI users. By using CI simulations (with vocoders) and studying NH listeners under degraded listening conditions, we are able to tease apart limitations due to the hardware/software of the CI systems from limitations due to neural pathology.
Summary: In BiCI listening the devices in the two ears are not coordinated; thus binaural spatial cues that are available to NH listeners are not available to BiCI users

Study: 41. Basura, G. J., et al. (2009). "Bilateral cochlear implantation: current concepts, indications, and results."
Q1
Study Sample: The optimal treatment for bilateral hearing loss continues to evolve as cochlear implant (CI) and hearing aid technologies advance, as does our understanding of the central auditory system. Ongoing discussions continue on the validity and feasibility of bilateral CI in terms of performance, justification of need, medical/surgical safety concerns, and economics. The purpose of this review article is to provide an update on the advantages and disadvantages of bilateral CI and to provide a discussion on timing (simultaneous vs. sequential), technology (bimodal vs. binaural) and feasibility.
Conclusion of study: Binaural advantages are found in both adult and pediatric bilateral CI recipients, the greatest being the head shadow effect and improvements in localization and loudness summation. This theoretically offers an advantage over their unilateral implanted counterparts in terms of improved sound localization and enhanced speech perception under noisy conditions. Most investigators agree that bilateral stimulation during critical periods of development is paramount for optimizing auditory functioning in children. Currently, bilateral CI is widely accepted as a safe and effective means of bilateral auditory stimulation.
Summary:

Study: 42. Thomas Balkany, et al.(2008) William House Cochlear Implant Study Group Position Statement on Bilateral Cochlear Implantation
Pico Outcome:
Study Sample:
Conclusion of study:

Study: 43 Johnston, J. C., et al. (2009). "Bilateral paediatric cochlear implants: a critical review."
Q1
Study Sample: A review of available research on bilateral CIs was conducted to determine the support for this trend. A replicable review was undertaken to evaluate published research studies that examined the effectiveness of bilateral paediatric cochlear

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implantation. Databases, reference lists, and journals were searched for relevant documents using a pre-determined search protocol. Twenty-nine articles met the review's inclusion criteria and were retrieved and reviewed.
Conclusion of study: A recent trend has been the implantation of bilateral cochlear implants (CIs) for children with severe to profound hearing loss. This review adds to the previously published reviews on the topic by identifying additional paediatric studies. Sound localization and speech recognition in noise appear to be improved with bilateral compared to unilateral cochlear implants. Similarly, evoked potential measures suggest improved morphology when the second CI is implanted early.
Summary: Well-designed and controlled studies that explore a variety of outcomes including cost-effectiveness, quality of life, speech, language, and psycho-educational measures should be further explored in order to provide additional support for parents and clinicians confronted with the bilateral cochlear implant decision.

Study: 44 Wheeler et al (2009) Children with cochlear implants: The communication journey
Q1 Communication Cochlear implantation is now a well-established procedure for profoundly deaf children providing access to speech through hearing for many of them.
Study Sample: This study, following on from two earlier studies, looked in depth at the experiences of 12 families
Conclusion of study: Much attention has focused on which communication mode to adopt with this group of children but very little work has looked at the choices that parents make before and after cochlear implantation..
Summary: It finds that parents choose the most effective way of communicating with their child but retain as their goal, the development of oral communication skills. For many this is a journey in which different approaches are utilised at various stages in the child's development.

Study: 45. Key A P F et al (2010) Auditory processing following sequential bilateral cochlear implantation: A paediatric case study using event related potentials
Comparator Results Better behavioural performance with bilateral implants is expected when bilateral cochlear implantation is performed simultaneously or when a second implant is provided after a short interval of auditory deprivation at a younger age (Murphy and O'Donoghue, 2007; Wolfe et al, 2007; Steffens et al, 2008).
Q2 - to examine changes in various levels of auditory processing using single syllable and word-level stimuli in a child who received bilateral cochlear implants sequentially.
Study Sample: The participant was a 6-yr-old female with the diagnosis of bilateral profound sensor-ineural hearing loss. She received her first cochlear implant in her right ear (2 yr, 4 mo of age), underwent revision surgery (3 yr, 6 mo of age), and later received a bilateral cochlear implant (6 yr, 8 mo of age).
Conclusion of study: The results suggest that sequential bilateral cochlear implantation contributes to improved auditory processing beyond the benefits of the single implant even

in users with an extended period of deafness in the later-implanted ear.
Summary:

Study: 46. Montino et al (2011) Preverbal communication skills in children with early bilateral and monolateral cochlear implant.
Comparator Results The aim of the study was to compare preverbal communicative characteristics of children who were early implanted with a monolateral or simultaneous bilateral cochlear implant.
Q2 monolateral vs simultaneous bilateral cochlear implant
Study Sample: Material and Methods: Video analysis results are reported in 4 children affected by congenital profound sensorineural hearing loss of genetic origin (biallelic mutation of GJB2 gene). Two children received a monolateral cochlear implantation, while the other two were implanted bilaterally. Surgery was performed at 12 months in all cases
Conclusion of study: We discovered that children with simultaneous bilateral cochlear implant presented a better auditory awareness compared to children with monolateral one. There were no significat differences between the two groups in the other parameters of the video analysis.
Summary: As regards to preverbal skills mono or bilateral cochlear implantation did not differently influence communication efficacy, which was on the contrary more affected by the mother's communicative style.

Study: 47. Smulders, Y E et al (2011) What is the effect of time between sequential cochlear implantation on hearing in adults and children - systematic review of cohort studies
Q2 Effect of time between sequential cochlear implantations on hearing results in both adults and children
Study Sample: Eleven studies evaluating the effect of time between sequential cochlear implantations on hearing performance were included. Although the quality of studies was poor because of a significant risk of bias, all studies reported that auditory performance is better in a bilateral listening situation than with either one cochlear implant activated unilaterally. Five studies discussed post lingual deafened adults. In four, bilateral hearing was not affected by the amount of time between implantations. One study did report a negative effect of delay on speech intelligibility in silence. Seven studies discussed pre lingual deafened children. None reported a negative effect of inter implantation delay on sound localization performance. One study reported poorer results after extended intervals on speech intelligibility in silence and two in noise.
Conclusion of study: Current evidence suggests that a second implant can be beneficial even after a substantial interval between sequential implantations. The quality of the evidence is, however, rather poor; to confirm this postulation, high-quality trials assessing the effectiveness of a second cochlear implant after a time delay should be initiated.

Study: 48. Sparreboom M et al (2012) Sequential bilateral cochlear implantation in children: development of the primary auditory abilities of bilateral stimulation

Q2 The advantages of sequential bilateral cochlear implantation
Study Sample: The advantages of sequential bilateral cochlear implantation were assessed in 29 children with a severe to profound hearing loss. The effect of age at second implantation and the effect of duration of bilateral implant use on the outcomes in speech perception and directional hearing were investigated. The children received their second cochlear implant at an age ranging from 2.8 to 8.5 years. Measurements were carried out preoperatively and postoperatively after 6, 12 and 24 months of bilateral implant use. A matched control group of 9 children with a unilateral implant were also measured over time and were compared with the study group after 12 and 24 months. Speech reception in both quiet and in noise and lateralization were measured. After 24 months, a minimum audible angle task was carried out.
Conclusion of study: Bilateral advantages with regard to speech reception in quiet and in noise were already present after 6 months of bilateral implant use and improved thereafter. After 24 months, speech reception in noise had significantly improved with bilateral implants compared to that of children with a unilateral implant. The percentage of children that could accurately lateralize increased from 57% after 6 months to 83% after 24 months. With regard to the minimum audible angle task, loudspeakers were placed on average at +/-42. Age at second implantation did not have an influence on all outcomes.
Summary: From the results it can be concluded that the advantages of bilateral hearing occur after sequential bilateral implantation and that age at second implantation does not influence the amount of bilateral advantage. Furthermore, it can be concluded that longer periods of bilateral implant use lead to greater bilateral advantages.

Study: 49. Strom Roum H et al (2012) Comparison of bilateral and unilateral cochlear implants in children with sequential surgery
Q2 Speech recognition in quiet assessed in sequential and simultaneously implanted children
Study Sample: Seventy-three pre-lingually deaf children received sequential bilateral cochlear implants. Speech recognition in quiet with the first, second and with both implants simultaneously was evaluated at the time of the second implantation and after 12 and 24 months.
Conclusion of study: Mean bilateral speech recognition 12 and 24 months after the second implantation was significantly higher than that obtained with either the first or the second implant. The addition of a second implant was demonstrated to have a beneficial effect after both 12 and 24 months. Speech recognition with the second implant increased significantly during the first year. A small, non-significant improvement was observed during the second year. The inter-implant interval significantly influenced speech recognition with the second cochlear implant both at 12 and 24 months, and bilateral speech recognition at 12 months, but not at 24 months. A small, but statistically significant improvement in speech recognition was found with bilateral cochlear implants compared with a unilateral implant. A major increase in speech recognition occurred with the second cochlear implant during the first year.
Summary: A shorter time interval between the two implantations resulted in better speech recognition with the second implant. However, no definitive time-point was found for when the second implant could no longer add a positive effect.

Study: 50. Papsin, B. C. and K. A. Gordon (2008). "Bilateral cochlear implants should be the standard for children with bilateral sensorineural deafness."
Q2 interval between implant
Study Sample: Bilateral cochlear implants are provided to children in an attempt to establish binaural processing and allow hearing with greater ease. Arguments against implantation, which prevailed for many years, are countered by some of the findings reported over the past 1-2 years
Conclusion of study: Behavioural and electrophysiological outcomes in children receiving cochlear implants suggest that two issues are most important when considering bilateral cochlear implants for any child: the duration of deafness prior to the first implantation affecting development of oral speech and language skills and the inter-stage interval (between implantation of the first and second ears) likely affecting development of binaural processing.
Summary: Based on the data reported to date, both the interval between onset of deafness and cochlear implantation and the interval between implantation of the first and second ears should be narrow in children. We recommend that simultaneous bilateral implantation be provided when possible and, if not, the inter-stage interval should be limited. We further recommend continued exploration of outcomes in children with longer inter-stage intervals with a view to defining a point at which bilateral cochlear implantation provides so little benefit that it is not cost-effective.

Study: 51. Wie, O. B. (2010). "Language development in children after receiving bilateral cochlear implants between 5 and 18 months."
Q2 language development in children who received simultaneous bilateral cochlear implants (CIs) between 5 and 18 months of age and to compare the results with language development in chronologically age-matched children with normal hearing.
Study Sample: Data were collected in a clinical setting at postoperative cochlear implant check-ups after 3, 6, 9, 12, 18, 24, 36, and 48 months of implant use. The sample included 42 children: 21 cochlear implant users and 21 with normal hearing, matched pairwise according to gender and chronological age. Communication assessments included the LittlEARS questionnaire, the Mullen Scale of Early Learning, and the Minnesota Child Development Inventory
Conclusion of study: The cochlear implant users' hearing function according to LittlEARS was comparable to that of normal-hearing children within 9 months post-implantation. The mean scores after 9 and 12 months were 31 and 33, respectively in the pre-lingually deaf versus 31 and 34 in the normal-hearing children. The children's receptive and expressive language scores showed that after 12–48 months with cochlear implants, 81% had receptive language skills within the normative range and 57% had expressive language skills within the normative range. The number of children who scored within the normal range increased with increasing CI experience.
Summary: The present study showed that pre-lingually deaf children's ability to develop complex expressive and receptive spoken language after early bilateral implantation appears promising. The majority of the children developed language skills at a faster pace than their hearing ages would suggest and over time achieved expressive and receptive language skills within the normative range.

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Study: 52. Chadha, N. K., et al. (2011). "Speech detection in noise and spatial unmasking in children with simultaneous versus sequential bilateral cochlear implants."
Q2 compare performance (speech detection in noise) **of sequential versus simultaneous implanted children** speech detection in noise performance for children with bilateral cochlear implants (BiCI), to compare performance in children with simultaneous implant versus those with sequential implant, and to compare performance to normal-hearing children.
Study Sample: Children with early-onset bilateral deafness and 2-year BiCI experience, comprising the "sequential" group (>2 yr interimplantation delay, n = 12) and "simultaneous group" (no interimplantation delay, n = 10) and normal-hearing controls (n = 8).
Conclusion of study: Speech detection in noise was significantly poorer than controls for both BiCI groups (p < 0.0001). However, the SU in the simultaneous group approached levels found in normal controls (7.2 +/- 0.6 versus 8.6 +/- 0.6 dB, p > 0.05) and was significantly better than that in the sequential group (3.9 +/- 0.4 dB, p < 0.05). Spatial unmasking was unaffected by the side of noise presentation in the simultaneous group but, in the sequential group, was significantly better when noise was moved to the second rather than the first implanted ear (4.8 +/- 0.5 versus 3.0 +/- 0.4 dB, p < 0.05). This was consistent with a larger BSA from the sequential group's second rather than first CI.
Summary: Children with simultaneously implanted BiCI demonstrated an advantage over children with sequential implant by using spatial cues to improve speech detection in noise.

Study: 53. Galvin, K. L. and K. C. Hughes (2012). "Adapting to bilateral cochlear implants: early post-operative device use by children receiving sequential or simultaneous implants at or before 3.5 years."
Q2 time between implant and age at implant To classify adaptation difficulties, or lack thereof, experienced by a clinical population of young bilateral cochlear implant recipients.
Study Sample: Forty-six of the first 48 children sequentially or simultaneously implanted at <=3.5 years at the Melbourne Clinic participated. Classification into categories was based on daily use of both implants at 2 months post-switch-on, with follow-up information obtained at 12 months.
Conclusion of study: : The 37 Category 1 children wore both implants full time at 2 months, and 35 still did so at 12 months. The two Category 2 children used both implants 4 hours daily at 2 months, but achieved full-time use within 12 months. The five Category 3 children used both implants for <=1 hour, with only three achieving full-time use within 12 months. The two Category 4 children did not use two implants at 2 months, and one still did not wear both implants at 12 months. There were weak/modest but significant relationships between category and each of time between implants and age at bilateral implantation.
Summary: Ninety-five percent of simultaneously and 70% of sequentially implanted children demonstrated full-time use within 2 months, and nearly all continued to do so at 12 months. Full-time use maximizes opportunities to develop listening skills. Monitoring device use is

necessary for all children, especially when significant change occurs. For those experiencing difficulty in adapting, bilateral implant use usually increased over 12 months. Pre-operative counselling must include discussion of possible adaptation difficulties and raise the potential negative influence of age at bilateral implantation and time between implants.

Study: 54. Geers, A. E. and J. G. Nicholas (2013). "Enduring advantages of early cochlear implantation for spoken language development."

Q2 spoken language development – implications of age of implant In this article, the authors sought to determine whether the precise age of implantation (AOI) remains an important predictor of spoken language outcomes in later childhood for those who received a cochlear implant (CI) between 12 and 38 months of age. Relative advantages of receiving a bilateral CI after age 4.5 years, better pre-CI-aided hearing, and longer CI experience were also examined.

Study Sample: Sixty children participated in a prospective longitudinal study of outcomes at 4.5 and 10.5 years of age. Twenty-nine children received a sequential second CI. Test scores were compared with normative samples of hearing age mates, and predictors of outcomes were identified.

Conclusion of study: Standard scores on language tests at 10.5 years of age remained significantly correlated with age of first cochlear implantation. Scores were not associated with receipt of a second, sequentially acquired CI. Significantly higher scores were achieved for vocabulary as compared with overall language, a finding not evident when the children were tested at younger ages.

Summary: Age-appropriate spoken language skills continued to be more likely with younger AOI, even after an average of 8.6 years of additional CI use. Receipt of a second implant between ages 4 and 10 years and longer duration of device use did not provide significant added benefit

Study: 55. Gordon, K. A., et al. (2010). "Cortical function in children receiving bilateral cochlear implants simultaneously or after a period of inter-implant delay." Children using bilateral cochlear implants (CIs) develop normal patterns of cortical activity when inter-implant delays are minimized.

Comparator Results

It is not clear whether bilateral CIs can promote normally functioning bilateral auditory pathways in children.

Q2 inter implant delays

Study Sample: Cortical responses were recorded from 64 cephalic sites in 2 normal hearing participants and 8 children with 3 to 4 years of bilateral CI experience (age at first CI, 0.9-4.1 yr; age at second CI, 1.1-9.7 yr; inter-implant delay, 0-5.8 yr).

Conclusion of study: Beamformer analyses on the dominant positive peak in CI users and P1 in normal hearers revealed that stimuli delivered from the left side evoked responses lateralized to right auditory cortex in the 2 participants with normal hearing and the 3 children receiving bilateral CIs with minimal interimplant delay at young ages. These 5 participants showed a shift in cortical lateralization away from the right cortical hemisphere when stimuli were moved to the right. In contrast, 4 of 5 children receiving bilateral CIs after longer delays and at older ages showed abnormal ipsilateral parietal activity in response to

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left stimuli and lateralization to the left cortical hemisphere in response to both right and left stimuli. The fifth child in this group showed abnormal lateralization to the ipsilateral cortex in response to both right and left stimuli.
Summary: The data suggest that, after 3 to 4 years of bilateral CI use, normal-like patterns of bilateral cortical activity are promoted in children receiving bilateral CI with minimal interimplant delays and young ages but are not present in older children who had longer interimplant delays.

Study: 56. Gordon K A and B C Papsin (2009) Benefits of short interimplant delays in children receiving bilateral cochlear implants
Comparator Results
Q2 Speech perception skills in quiet and noise in children using bilateral cochlear implants and to assess the influence of duration of bilateral deafness and interimplant delay.
Study Sample: Speech perception was assessed in 58 children with early-onset deafness; 51 received their first implant after less than 3 years of bilateral deafness and their second implant simultaneously or after a long (>2 yr) or short (6-12 mo) interimplant delay. Another seven children had longer periods of bilateral deafness (>3 yr) before the first implant and received their second after a long (>2 yr) interimplant delay. Mean (standard deviation) of bilateral implant use was 12.5 (7.9) months ranging from 6 to 36 months. Repeated measures in quiet were completed in three quiet and two noise (no spatial separation) conditions. In quiet, children listened with their right implant alone, left implant alone, and with both implants. In noise, children wore one implant in the experienced (or right for simultaneous group) ear and both implants.
Conclusion of study: Speech perception scores were poorer in noise than in quiet, but significant improvements were found when bilateral rather than unilateral implants were worn. Improvements were greatest for children who were implanted with a short duration of bilateral deafness and a limited inter implant interval. Sequential implantation, whether after a short or long delay, was observed to cause children and families additional concerns as compared with simultaneous bilateral implantation. Parents of children bilaterally implanted sequentially often commented that the decision to proceed with a second CI surgery was much more difficult than the first particularly when the child was functioning well with the first device. Some families of children in short delay group also ex[pressed that having two surgeries within 1 year in combination along with necessary appointments for activation of each implant represented a considerable additional burden of time, anxiety and expense. To compound the problem, many of the children in this group received their first implant as infants and their second as toddlers. It was surprising to families how much more difficult it was to prepare their child for the second surgery and care for their child during the surgical recovery period and initial stages of bilateral implant use compared with the first.
Summary: Benefits of bilateral implantation in the short term are clearest in children with limited delays between implantation. Children who were goof CI users or appropriate CI candidates were more consistently able to achieve better speech perception scores in the bilateral versus unilateral implant conditions when the delay between the first and second implant was less than 12 months that then more the 2 years.

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Study: 57. Gordon, K. A., et al. (2013). "Bilateral input protects the cortex from unilaterally-driven reorganization in children who are deaf."
Comparator Results. Unilateral hearing in childhood restricts input along the bilateral auditory pathways, possibly causing permanent reorganization. In this study we asked: (i) do the auditory pathways develop abnormally in children who are bilaterally deaf and hear with a unilateral cochlear implant? and (ii) can such differences be reversed by restoring input to the deprived ear?
Q2 simultaneous implantation
Study Sample: We measured multichannel electroencephalography in 34 children using cochlear implants and seven normal hearing peers. Dipole moments of activity became abnormally high in the auditory cortex contralateral to the first implant as unilateral cochlear implant use exceeded 1.5 years. This resulted in increased lateralization of activity to the auditory cortex contralateral to the stimulated ear and a decline in normal contralateral activity in response to stimulation from the newly implanted ear, corresponding to poorer speech perception.
Conclusion of study: These results reflect an abnormal strengthening of pathways from the stimulated ear in consequence to the loss of contralateral activity including inhibitory processes normally involved in bilateral hearing. Although this reorganization occurred within a fairly short period (~1.5 years of unilateral hearing), it was not reversed by long-term (3-4 years) bilateral cochlear implant stimulation. In bilateral listeners, effects of side of stimulation were assessed; children with long periods of unilateral cochlear implant use prior to bilateral implantation showed a reduction in normal dominance of contralateral input in the auditory cortex ipsilateral to the stimulated ear, further confirming an abnormal strengthening of pathways from the stimulated ear. By contrast, cortical activity in children using bilateral cochlear implants after limited or no unilateral cochlear implant exposure normally lateralized to the hemisphere contralateral to side of stimulation and retained normal contralateral dominance of auditory input in both hemispheres.
Summary: Results demonstrate that the immature human auditory cortex reorganizes, potentially permanently, with unilateral stimulation and that bilateral auditory input provided with limited delay can protect the brain from such changes. These results indicate for the first time that there is a sensitive period for bilateral auditory input in human development with implications for functional hearing.

Study: 58. Vischer, M., et al. (2011). "Predictive factors for the performance of the second cochlear implant in sequentially bilateral implanted children, adolescent and adults."
Comparator Results
Q2
Study Sample:
Conclusion of study: Presents a study which examined the predictive factors for the performance of the second cochlear implantation in sequentially bilateral implanted children, adolescent and adults. Forty-six cochlear implants (CI) listeners included in the study enjoyed good or excellent benefit from their second CI. The seven adolescent individuals receiving very little benefit from their second CI are late implanted subjects with their first CI or low performers on their first CI or they were not successful to accomplish appropriate training with the second CI. They have the common disadvantage of sensory deprivation of

the second ear, a well-known unfavourable condition for cochlear implantation.
Summary: Individuals with moderate benefit of their first CI will generally not gain improvement in speech understanding from a second CI. Eighty-seven percent of sequentially implanted bilateral CI listeners enjoy good or excellent benefit from their second CI, additional 10% receive fair benefit.

Study: 59. Dowell, R. C., et al. (2011). "Bilateral cochlear implants in children."
Comparator Results This article provides a brief overview of the advantages of two-ear hearing in children and discusses the limitations, from a psychophysical and a technical perspective, which may constrain the ability of cochlear implant users to gain these benefits. The latest outcomes for children using bilateral cochlear implants are discussed, which suggest that results are more favourable for children who receive both devices before the age of 3.5 to 4 years. The available studies that have investigated electrophysiological responses for children receiving bilateral implants are discussed. These also support the notion that optimum development of binaural auditory skills may be more difficult after the age of 3.5 to 4 years. Studies that investigate the alternative for some children of using a hearing aid on the opposite ear to the cochlear implant are briefly discussed. These indicate that advantages for speech perception in noise and localization can be obtained consistently for children with significant residual hearing in the nonimplanted ear. The article concludes with an attempt to bring the available scientific evidence into the practical clinical context with suggestions that may assist clinicians in making recommendations for families considering bilateral cochlear implantation. Although the evidence remains limited at this time, it is reasonable to suggest that bilateral cochlear implantation can provide improved auditory skills over a single implant for children with severe and profound bilateral hearing loss.
Q2 impact of delay on bilateral implant
Study Sample:
Conclusion of study:
Summary: The available data suggest that the benefit may be maximized by introducing both implants as early as possible, at least before 3.5 to 4 years of age

Study: 60. Gordon K A et al (2011) What is the optimal timing for bilateral cochlear implantation for children
Q2 optimal timing for bilateral cochlear
Study Sample: This research aims to determine whether binaural auditory processing is affected by these variables in an effort to determine the optimal timing for bilateral cochlear implantation in children. **Results** Bilateral cochlear implants (CIs) have been provided to children who are deaf in both ears with intent to promote binaural hearing. If it is possible to establish binaural hearing with two CIs, these children would be able to make use of interaural level and timing differences to localize sound and to distinguish between sounds separated in space. These skills are central to the ability to attend to one particular sound amidst a number of sound sources. This may be particularly important for children because they are typically learning and interacting in groups. However, the development of binaural processing could be disrupted by effects of bilateral deafness, effects of unilateral CI use, or issues related to the child's age at onset of deafness and age at the time of the first and

second cochlear implantation.

Conclusion of study: It is now clear that the duration of bilateral deafness should be limited in children to restrict reorganization in the auditory thalamo-cortical pathways. It has also been shown that unilateral CI use can halt such reorganization to some extent and promote auditory development. At the same time, however, unilateral input might compromise the development of binaural processing if CIs are provided sequentially. Mismatches in responses from the auditory brainstem and cortex evoked by the first and second CI after a long period of unilateral CI use suggest asymmetry in the bilateral auditory pathways which is significantly more pronounced than in children receiving bilateral implants simultaneously. Moreover, behavioural responses to level and timing differences between implants suggest that these important binaural cues are not being processed normally by children who received a second CI after a long period of unilateral CI use and at older ages.

Summary: In sum, there may be multiple sensitive periods in the developing auditory system, which must be considered when determining the optimal timing for bilateral cochlear implantation.

Study: 61. Pallares N et al Bilateral sequential cochlear implants in children: Outcomes in auditory abilities

Q2

Study Sample: 1. To compare time to reach the maximum speech perception score, between first and second ear implanted 2. To compare word recognition using bilateral and unilateral CI 3. To assess the incidence of age at first and second CI 4. To consider the impact of the time interval between first and second CI in speech perception

Conclusion of study: All subjects use both devices properly. Progress of the second implanted ear varies and is determined by performance with first CI, length of auditory deprivation, gap between 1st and 2nd CI and age at 1st and 2nd CI.

Summary: Bilateral cochlear implant in children promotes the best condition to receive auditory information. It could improve language, communication and academicals capabilities

Study: 62. Galvin, K. L., et al. (2010). "Can adolescents and young adults with prelingual hearing loss benefit from a second, sequential cochlear implant?"

Q2 This study aimed to determine if adolescents/young adults gained additional perceptual benefit from sequential bilateral cochlear implants within 12 months, and to document adaptation to the second implant.

Study Sample: Assessments comprised a pediatric version of The Speech, Spatial and Qualities of Hearing Scale (SSQ), anecdotal reports of device use and daily listening, and the Adaptive Spondee Discrimination Test (AdSpon). All nine participants achieved full-time use of, a preference for, and superior daily listening with, bilateral implants. Eight participants were comfortable using the second implant alone, and two achieved similar daily listening with either implant alone.

Conclusion of study: SSQ ratings were higher post-operatively for the majority of participants. AdSpon performance was superior bilaterally for five participants with noise ipsilateral to the first implant, but not contralateral. Unilateral performance with either implant was similar for one participant. A second implant may provide additional benefit up to 19 years of age, even with congenital hearing loss and >16 years between implants. Families and clinicians should understand the aspects of second-implant candidacy and post-operative use that are unique to adolescents/young adults.

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Study: 63 Karen A. Gordon, Salima Jiwani, and Blake C. Papsin (2013) "Benefits and detriments of unilateral cochlear implant use on bilateral auditory development in children who are deaf"
Q2 development of auditory pathways in unilateral implants
Study Sample:
Conclusion of study: We have reviewed evidence showing that access to sound within limited durations of bilateral deafness in early life promotes normal-like development of activity along the auditory pathways in children who have many years of hearing experience with a unilateral cochlear implant. At the same time, however, the unilaterally driven stimulation leaves the opposite pathways deprived of input and susceptible to reorganization. We find that providing bilateral cochlear implants to children after a period of unilateral deafness of longer than 1.5 years drives abnormal mismatches in activity at the level of the brainstem and cortex. This is characterized by abnormal strengthening of activity to both the contralateral and ipsilateral auditory cortices from the first implanted ear. These abnormalities in auditory development are associated with more asymmetric speech perception, poorer hearing in noise, abnormal sound localization, and an inability to identify inter-aural timing cues. These skills are important for normal integration and processing of auditory input. Our current studies are now examining how much residual hearing is needed in the un-implanted ear to provide a potential protective effect against unilaterally driven reorganization and whether bimodal hearing (acoustic and electrical input) can be used to restore binaural hearing. Further, we are asking whether the sensitive period for bilateral input can be "reopened" by attempting to strengthen pathways from the second implanted ear to restore symmetric bilateral pathways and binaural hearing. Our findings suggest that both bilateral and unilateral deprivation should be limited to promote optimal binaural hearing in children who use cochlear implants, and enable them to function better and more naturally in challenging listening situations such as the playground or classroom environments
Summary: We therefore suggest that binaural hearing is compromised in children who receive bilateral cochlear implants after a period of unilateral implant use exceeding 1.5 years. With that in mind, cochlear implants should be provided to children early as well as bilaterally within very limited or no delays between implants (i.e., simultaneously).

Study: 64 Van Deun et al (2010) Earlier intervention leads to better sound localization in children with bilateral cochlear implants.
Q2 early intervention
Study Sample: We present sound localization results from 30 children with bilateral cochlear implants. All children received their implants sequentially, at ages from 6 months to 9 years for the first implant and 1.5-12 years for the second implant, with delays of 10 months to 9 years.
Conclusion of study:. Localization was measured in the sound field, with a broadband bell-ring presented from 1 of 9 loudspeakers positioned in the frontal horizontal plane. The

majority of the children (63%) were able to localize this signal significantly better than chance level. Mean absolute error scores varied from 9 to 51 degrees (root mean square error scores from 13 to 63 degrees). The best scores were obtained by children who received their first implant before the age of 2 years and by children who used hearing aids prior to implantation for a period of 18 months or longer. Age at second implantation was important in the group of children who did not use a contralateral hearing aid during the unilateral implant period. Additionally, children who attended a mainstream school had significantly better localization scores than children who attended a school for the deaf. No other child or implantation variables were related to localization performance. Data of parent questionnaires derived from the Speech, Spatial and Qualities of Hearing Scale were significantly correlated with localization performance..
Summary: This study shows that the sound localization ability of children with bilateral cochlear implants varies across subjects, from near-normal to chance performance, and that stimulation early in life, acoustically or electrically, is important for the development of this capacity

Study: 65 Chisholm, K., et al. (2011). "Simultaneous vs sequential vs unilateral cochlear implantation in children under 18 months."
Q2 This paper aims to identify the impact of receiving just one or two cochlear implants, and if two, the impact of simultaneous or sequential.
Study Sample:. Data analysed for 3 groups of 10 children who received their first CI under 12 months 1. bilateral simultaneous CI's 2. bilateral sequential CI's (second CI before 2 yrs) 3. unilateral CI (bimodal)
Conclusion of study: Outcome on speech, language, perceptual and functional measures at 6 and 12 months post cochlear implantation were measured. There was no significant difference between groups. Individual differences within groups were evident. Parental support influenced on outcome.
Summary: These findings are demonstrate good outcomes can be attained if the child is implanted within the first 12 months of life, albeit bilateral or unilateral. The importance of parents involvement in defining the outcome of their child will be discussed.

Study: 66 S Rich et al (2013) "Being an adolescent with a cochlear implant in the world of hearing people: Coping in school, in society and with self-identity."
Q2: A deaf child implanted at an early age with good habilitation may have good language abilities and function well in daily life. As the implanted child grows up, managing in the world of hearing people may become more complex. During adolescence, the teenager copes with many issues, including identity, socialization with the peer group, and managing in the school setting. These issues may be even more challenging for the adolescents using a cochlear implant.
Study Sample: This study was designed to shed light on how adolescents with cochlear implants experience coping with the issues mentioned. Twelve teenagers (14-18 years old), fairly similar to the entire adolescent implanted population at the center at which the study was conducted, participated in the study. They had been unilaterally or bilaterally implanted at differing ages. The participants filled out a questionnaire dealing with their functioning in the educational setting, their social preferences and functioning, and their identity as hearing

or deaf. The results were analyzed using the principles of thematic analysis.

Conclusion of study: At school, some reported better achievements than others but they all expressed some difficulty functioning in class mainly in situations involving several speakers. From a social point of view, some reported a preference for association with normal hearing peers, whereas others favored hard-of-hearing friends, and one had no preference. Of those who touched on the topic of self-identity, one referred to herself as deaf, eight defined themselves as hard-of-hearing, and two consider themselves hearing.

Summary: From the responses of these teenagers, it is clear that adolescents with cochlear implants are a heterogeneous group. Parents and teachers should be aware that adolescents with implants, even when successful academically, may experience difficulties in the classroom setting. Most of the participants in this study learning in a mainstream setting, preferred social relationships with hearing peers (to hard of hearing/deaf). The responses of these adolescents with cochlear implants support the conjecture that they have both a hearing identity and a deaf identity, which may be expressed at varying intensities depending on the situation at the time.

Study: 67 Peters, R. et al (2010) "Worldwide trends in bilateral cochlear implantation"

Practice elsewhere: The goal of this study was to ascertain worldwide experience with bilateral cochlear implantation (BCI) with regard to patient demographics, trends in provision of BCI to adult and child patient populations, differences and similarities in BCI candidacy criteria, diagnostic requirements, and treatment approaches.

Study sample: An electronic survey consisting of 59 mainly multiple-choice questions was developed for online completion. It examined the implant experience and clinical opinion of expert cochlear implant (CI) centres worldwide on the indications, motivations, and contraindications for adult and paediatric, simultaneous and sequential BCI candidacy. Seventy-one percent (25/35) of the CI clinics approached completed the survey. Collectively, these 25 clinics represent experience with approximately 23,200 CI users globally, representing 15% of the total estimated CI population worldwide. The total number of BCI surgeries reflected in their experience (2,880) represents 36% of the estimated number worldwide as of December 2007.

Conclusion of study: Cumulatively to the end of 2007, 70% of all BCI surgeries have occurred in children, with the 3- to 10-year-old age group having the highest representation (33% of all BCIs), followed in order by adults (30%), children under 3 years of age (26%), and children between 11 and 18 years of age (11%). Seventy-two percent of all BCI surgeries were performed sequentially (70% of children, 76% of adults). Children <3 years of age represent the only age group of all patients in which simultaneous surgeries predominate (58% simultaneous).

For all other age groups, sequential surgeries far outnumber simultaneous (3–10 years, 84% sequential; 11–18 years, 94% sequential; adults, 76% sequential).

Prior to January 2007, 68% of BCIs were performed in children. This increased to 79% for the year 2007 ($P < .001$). With regard to children only, a change is apparent over time in terms of the age group making up the majority of paediatric BCI surgeries performed. Prior to 2007, children 3 to 10 years of age made up 50% of the children undergoing BCI, whereas those <3 years made up only 33%. In 2007 this shifted more toward the younger age group (47% for those <3 years and 40% for 3–10-year olds; $P < .001$).

United States clinics had a higher proportion of adult BCI patients (59% children, 41% adults) than the non-United States clinics (78% children, 22% adults; $P < .001$). The majority of responders do not hold to a minimum or maximum age by which they limit BCI.

APPENDIX 1: GLOSSARY

Binauaral: Having the perception of sound with both ears

Bimodal stimulation: The use of one cochlear implant and one hearing aid)

Head Shadow: Head shadow causes particular difficulty in sound localisation in people with unilateral hearing

Contralateral ear: opposite side of a point of reference

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APPENDIX 2: REFERENCES:

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Cochlear implants for children and adults with severe to profound deafness (2009) – NICE

http://publications.nice.org.uk/cochlear-implants-for-children-and-adults-with-severe-to-profound-deafness-ta166/guidance *(Reviewed in 2011 – comments from review below) - http://www.nice.org.uk/nicemedia/live/12122/55227/55227.pdf*

Review of Cochlear Implantation in Scotland National Services (2006 – a bit old, but though you may like to see it anyway)

http://www.nsd.scot.nhs.uk/publications/servicereviews/Review%20of%20Cochlear%20Implantation%20Services%202006.pdf

Evidence-based practice for cochlear implant referrals for infants

http://www.nal.gov.au/pdf/Evidence-based-practice-for-cochlear-implant-referrals-for-i.pdf

Clinical Guidelines for Paediatric Cochlear Implantation (2011)

http://www.healthnetworks.health.wa.gov.au/docs/2011_CI_Guideline.pdf

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Appendix 3: Search Strategy

As compared with unilateral cochlear implants do bilateral implants for hearing loss improve: detection of sound, perception and/or production of speech, ability to hear and speak in noise and/or to separate background noise, ability to reach educational goals

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present> (adapted for: Cochrane, Embase, ERIC, Mosby's Index, Psych Info, Sociological Abstracts, Scopus)

Unilateral versus Bilateral Cochlear Implants

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present> (adapted for – Embase, Cochrane, PsychInfo, Scopus, Google Scholar)

Is the effectiveness of bilateral implant affected by the time interval between implant, duration or degree of deafness, age at implant and is there evidence to suggest that simultaneous implantation provides better results than sequential implantation?
Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>(adapted for: Cochrane, Embase, ERIC, Mosby's Index, Psych Info, Sociological Abstracts, Scopus)

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