



Addressing ethical issues in the context of an  
HTA.  
HTAi, Adelaide 2006

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HTAi - iHTA

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## Aim

To develop a more systematic approach  
for addressing ethical issues in the  
context of HTA

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## Outline of presentation

Current practice: clinical and cost-effectiveness and ethical issues investigated separately; the former largely ignoring implicit value judgements; the latter largely lacking relevant empirical support.

Alternative: interactive approach, integrating normative and empirical issues.

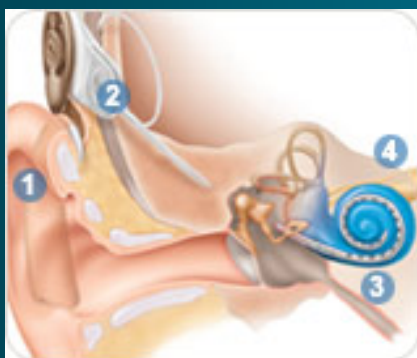
Case study: cochlear implants for prelingually deaf children.

Comparison conventional approach / interactive approach in terms of objectives of assessment, methods used, and responsibility of the researcher.

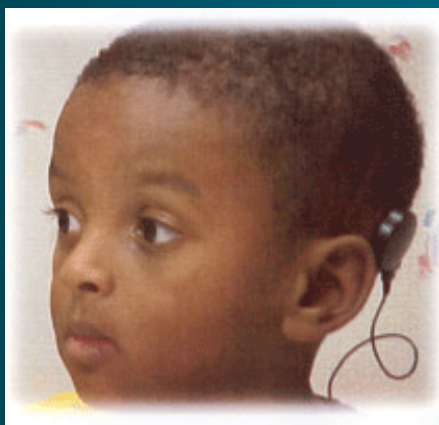
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## Cochlear implant



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## CI: clinical effectiveness

40 consecutive pediatric patients who received a cochlear implant at the Johns Hopkins Hospital  
Hearing parents

Mean pure-tone threshold before and 1 year after implantation: 98 dB vs. 27 dB ( $p < 0.001$ )

Mean Speech Perception Category Score before and 1 year after implantation: 1.6 vs. 4.2 ( $p < 0.001$ )

Developmental Quotient before and 1 year after implantation: 82.4 vs. 90.7 ( $p < 0.001$ )

Pulsifer et al, 2003

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## Quality of life

Time Trade Off measurements:

Utility [health state one year before implantation]: 0.75

Utility [health state one year after implantation]: 0.97

Gain: 0.22

Life expectancy: ca. 73 years


$73 * 0.22 = 16$  Quality Adjusted Life Years gained

Discounting rate of 3%: 6.4 QALYs

$(73 * 0.75 = 57 * 0.97)$

Source: Cheng et al, 2000

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## Costs

- Preoperative costs
- Device costs
- Hospital and surgery charges
- Costs of treatment of complications
- Audiology costs
- Rehabilitation costs
- Device failure costs
- Processor upgrade costs

Lifetime costs at 3% discount rate: US \$60.228

Cheng et al, 2000

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## Cost-utility ratio

$$\text{US \$ 60.228 / 6.4 QALYs} = \text{US \$ 9029 / QALY}$$

Cheng et al, 2000

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## Demonstration at Gallaudet



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## Ethical issues

- [1] The Deaf community represents a cultural minority.
- [2] Cultural minorities are inherently valuable.
- [3] Pediatric cochlear implants will bring about that the Deaf culture will cease to exist.
- [4] Therefore, pediatric CI is wrong.

Source: Lane & Bahan, Otolaryngol Head & Neck Surgery 1998; 119: 297 – 313.

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Clinical and cost-effectiveness analysis:

Normative aspects insufficiently acknowledged and scrutinised

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Trading off quantity for quality of life




*How many years in hell...*

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*...are equivalent to one year in heaven?*

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### Well-known objections to utilitarian theory of justice

Assumption of commensurability

Assumption of aggregation

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## Does CI necessarily imply a negative value judgement of deafness?

Utility [health state one year before implantation]: 0.75  
Utility [health state one year after implantation]: 0.97

$$73 * 0.75 = 57 * 0.97$$

What this means: Willingness to sacrifice 16 years of life in deafness in order to gain the hearing capacity that is offered by CI


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## Corollary: neglect of empirical aspects of ethical analyses

What is the evidence that the use of CI in prelingually deaf children will (or may?) lead to the demise of Deaf culture? Is this a necessary consequence, or is it a possible (contingent) consequence?


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iHTA

A means to address empirical and normative issues in a more systematic and integrative way?


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**Steps taken Interactive HTA**

- Preparation: identification of stakeholders, review of the literature, writing of information leaflet, newspaper advertisements, web page
- First interview round: eliciting claims and concerns
- Second interview round: participants presented with summaries of first interview round, response and comments invited (anonymous)
- Scenario analyses / fact finding
- Third interview round (with input from scenario analyses)
- Drafting of report
- General meeting
- Final report


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 <b>Participants according to function / perspective</b>	
Teachers	5
Social worker	6
Audiologists	4
Psychologist	1
Researcher	4
Technician	1
Speech therapist	2
Representatives of various advocacy groups	9
ENT – physician	5
Deaf persons with / without CI	2
Parents of deaf children with / without CI	7
Policy maker / management	4
Manufacturer of CI	1
<b>TOTAL:</b>	<b>51</b>

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 <b>Route of involvement</b>	
Contacted by the assessor:	39
Became involved through other participants:	10
Newspaper advertisement, web page, flyer:	6


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	Origin of participants by type of organisation
Institute for the Deaf	15
Audiological Centre	1
Rehabilitation centre	3
University Medical Centre	10
Advocacy group	9
Ministry of Education	1
Ministry of Health	1
Manufacturer	1
University	1

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	Interest groups
Organisation for Deaf-blindness (sDG)	
Dutch Association for the Deaf (Dovenschap)	
Federation of Organisations of Parents of Deaf Children (FODOK)	
Dutch Foundation for the Deaf and Hard of Hearing Child (NSDSK)	
Dutch Sign Centre (NGC)	
Dutch Society for the Hard of Hearing (NVVS)	
Dutch Foundation for Auditory Verbal Development (Savon)	
Association of University Hospitals (VAZ)	

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## Procedure

Interviews: reconstruction of interpretative frames  
(elicit claims & concerns)

Confront participants with each others' position /  
view (problem definition, background theory, etc.)

Organise meeting that should result in a number of  
specific statements / recommendations

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## Reconstructing interpretative frames

I: How does this person rate this particular solution? — Can this judgement be explained from the problem definition?

II: How does this person define the problem? — Can the problem definition be explained from the background theory?

III: What is the content of the background theory that this person brings to bear on the situation? — Can the commitment to the background theory be explained from the normative preferences?

IV: What is the content of the normative considerations that this person brings to bear on the situation?

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## Outcome of the iHTA

On the basis of the available evidence and the experience with pediatric cochlear implantation so far, CI was generally regarded as hopeful.

However, it was emphasized that results vary considerably from child to child, and that long-term consequences are as yet unknown.

It was acknowledged that the technology is still rapidly developing.

Pediatric CI is likely to change Deaf culture, though not necessarily bring it to an end.

The selection of end-points in evaluations of pediatric CI has been unduely restrictive.

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## Recommendations (unanimous)

When deaf children are being assessed for eligibility for CI, parents and child should be offered an accompanying programme, including a course of Sign Language and information on Deaf culture.

Methods should be developed to monitor Sign language development.

More research is needed to assess the impact of CI on a child's development of reading skills, and on the long-term consequences for social and emotional well being.

Ultimately, it is up to the parents to decide whether to put forward their child as a candidate for cochlear implantation.

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## Parental experience:

“After the implantation, my child’s proficiency in  
Sign Language improved.”

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## Research questions:

Could acquisition of Sign Language and  
spoken language mutually reinforce each other?

How do acquisition of language and cognitive  
development depend on each other?

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## Relevance of position regarding parental autonomy

2002, Michigan family court

Attorney's desire to force two deaf children in state of custody to get cochlear implantation (Robinson v. Michigan Protection and Advocacy Service 01-0702-00 NA, 2002)

Mother, also deaf, refused consent

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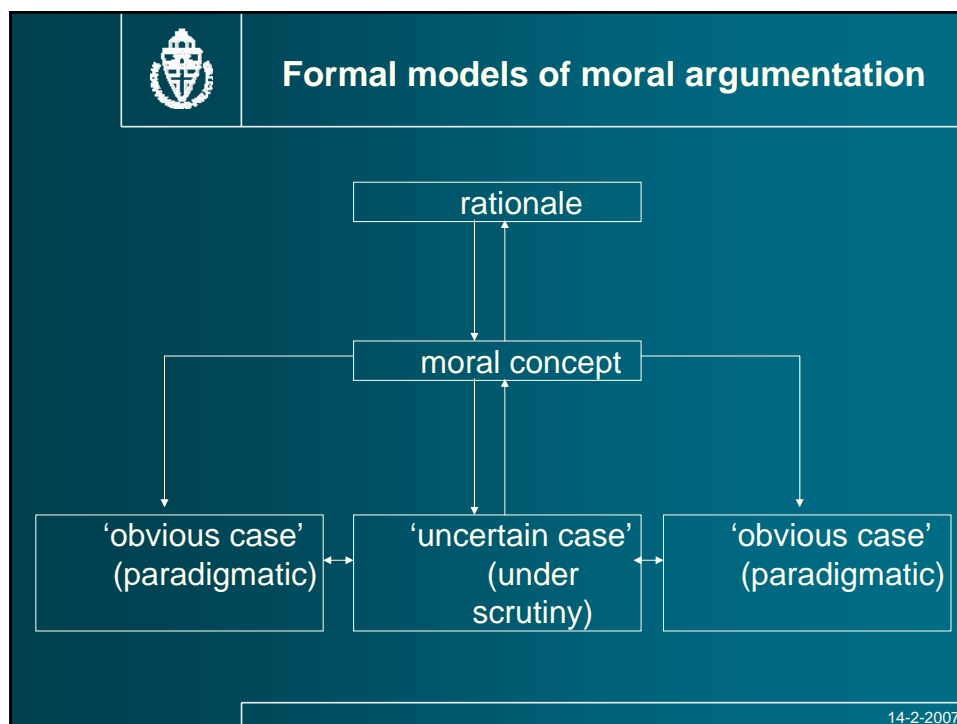


Are there any circumstances where parental autonomy to refuse medical treatment for their children may be overruled?

If yes, could this particular case (of who has the power of decision regarding cochlear implantation?) be a specific instance of such circumstances?

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**Conclusion & discussion**

Is a technology (in)effective, merely because someone claims it to be effective? No, surely not.

Is a technology (in)effective, because the persons participating in the iHTA reached agreement on this issue? No, surely not.

iHTA presupposes, and requires, availability of evidence. It can be considered as a procedure to systematically address the validity, relevance and completeness of the available evidence.

What counts as 'admissible evidence'?

The slide has a dark blue background with a white border at the top containing a crest and the title 'Conclusion & discussion'. A date '14-2-2007' is visible in the bottom right corner.



By bringing to bear a multiplicity of perspectives on the technology and the problem that it purports to solve, assumptions can be more readily identified, and scrutinised for their validity.

This holds for substantive issues (e.g., are development of Sign language and spoken language competitive or mutually supportive?) and for normative issues (should resource allocation decision procedures be based on a utilitarian principle? Does Deaf culture deserve broad public respect and support?)

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iHTA: not confined to the collection and interpretation of the available evidence:

Discussion on the nature of additional evidence that is considered relevant and needs to be collected.

Practical suggestions: how is pediatric cochlear implantation currently organised, and what changes are needed to render it fully consistent with the requirements that came out from the iHTA?

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Practical recommendation: the two perspectives, cochlear implantation and Deaf culture, should be presented in a more balanced way to parents who need to make up their minds about whether to put forward their child as a candidate for CI or not.

This recommendation implies the full recognition of Deaf culture: it is accepted that Deaf culture is a pre-condition for deaf people to develop a sense of self-respect. It is a society's task to ensure that its citizens are enabled to live a life that serves as a basis for self-respect.

Participants agree that deaf culture is, in a number of ways, different from mainstream culture, but deserves our respect and, when necessary, our support.

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When parties succeed in adjusting the CI programme in this respect (more balanced information about CI and Deaf culture, courses for parents in Sign language), this normative commitment is expressed in our acts.

The same holds when parties succeed in getting further research off the ground, that is considered necessary to obtain a more complete view of the value of pediatric CI.

It is, in other words, a test for society as a whole: does it succeed in expressing in their acts what it considers important / valuable?

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## Emerging issues regarding HTA: 1

Role and responsibility of the researcher:

1. Mobilize knowledge
2. Put knowledge to the test / improve and extend our knowledge
3. Skills / expertise of the assessor: collect and help scrutinise knowledge; identify (implicit) assumptions that seem to be guiding the assessment. (conventional: systematic review; statistical expertise; modelling; cost-effectiveness analysis. iHTA: interview skills; reconstructing interpretative frames; ethical expertise – casuistry, theories of justice, deontology, etc.)
4. Is the person who is conducting the assessment responsible for generating a sufficient extent of diversity in problem definition, range of possible solutions, background theory and normative preferences?

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## Emerging issues regarding HTA: 2

HTA as learning?

Should HTA also be aimed at encouraging learning among the various stakeholders? (and, consequently, be judged by reference to this criterion?)

Can we / should we try to establish whether such a learning process is in fact initiated by the HTA? (in what respect, among whom, how sustainably?)

Can and should the learning process (if any) be extended to other parties who did not participate in the iHTA? (vicarious learning) If so, how?

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### Emerging issues regarding HTA: 3

How does the iHTA and its outcome relate to existing, political decision procedures?

Is this type of evaluation more relevant to the policy-making process?

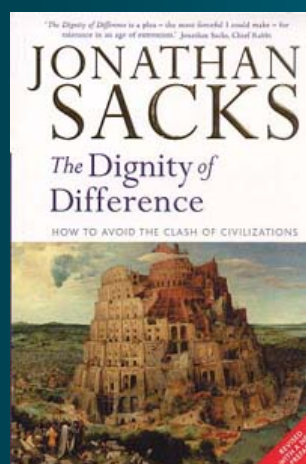
No substitute: trade-offs may, and probably will, have to be made that were not addressed in the iHTA! (allocation of resources)

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### Why take this approach?

#### The dignity of difference



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## Why take this approach?

La condition humain



**Hannah Arendt (1906 – 1975)**

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