Care Innovations Research and Consultancy

# Early to late stage HTA in cooperation with medical device industries

HTAi 2009 - Singapore

# Key-messages

1. Iterative HTA (iHTA) during medical device (MD) development is
   - conceptually and theoretically a “no-brainer”
   - beneficial to society, incl. patients, payers and industry alike
2. Yet, it
   - has rarely been done – if ever – in real-life
   - is unlikely to become widely adopted in its current (academic) form
3. If we want to make iHTA work for real, we need
   - a better common understanding of HTA
   - better tailoring of HTA methods to fit the context & circumstances where “the rubber meets the road”

# Justification for iHTA - theory

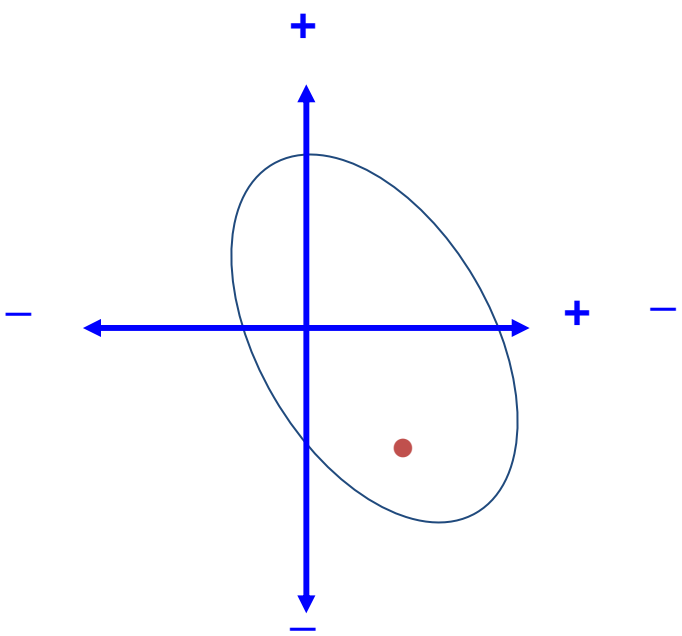
Based on iterative Bayesian approach, which:

1. Allows estimation of CE as part of investment decision process
   - Prevent investment in developing MDs that could never be CE

2. Supports companies to prioritize between several competing MD concepts or prototypes

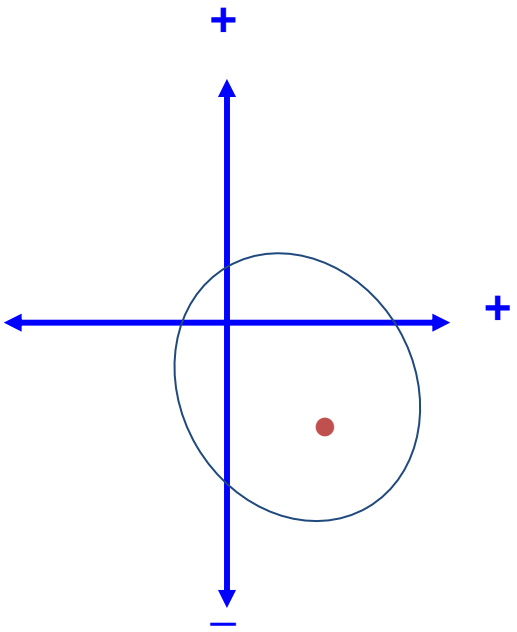
3. Identifies, from early stages, product parameters that have the largest impact on its likely CE
   - Directs efficient R&D spending by Value of Information (VOI) analysis

I believe that…




Stadium 1: Few Data

"Cost Effectiveness Gap - analysis"

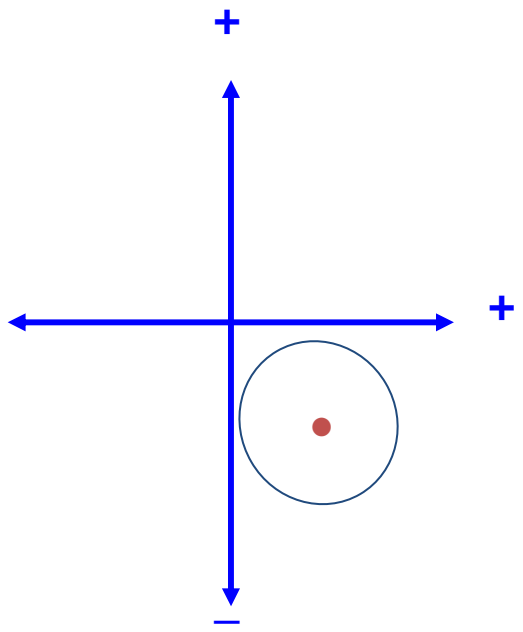



Stadium 2: Some Data

Simple health economic model

Stadium 3: Rich Data

Full health economic model




I can prove that…

Vallejo-Torres L, Steuten LMG, Buxton MJ, et al. IJTAHC 2008;24(4):459-64

# Published MD exemplars by stage

## Early stage:

Headroom analysis: tissue engineered bladder vs. use of bowel in cystoplasty after resection of cancer (Cosh E, et al. J Commer Biotechnol 2007;13:263-71)

## Mid stage:

Simple health economic model, including VOI: early assessment of 2nd generation LVADs vs. optimal medical care for patients with heart failure (Girling A et al. IJTAHC 2007;23:269-77)

## Late stage:

Full health economic model, including VOI: quite a few

## All stages:

Prospective analysis: none (?)

Retrospective case study: absorbable pins vs. metallic pins in treating hallux valgus (Vallejo-Torres L & Steuten LMG. MDM, under revision)

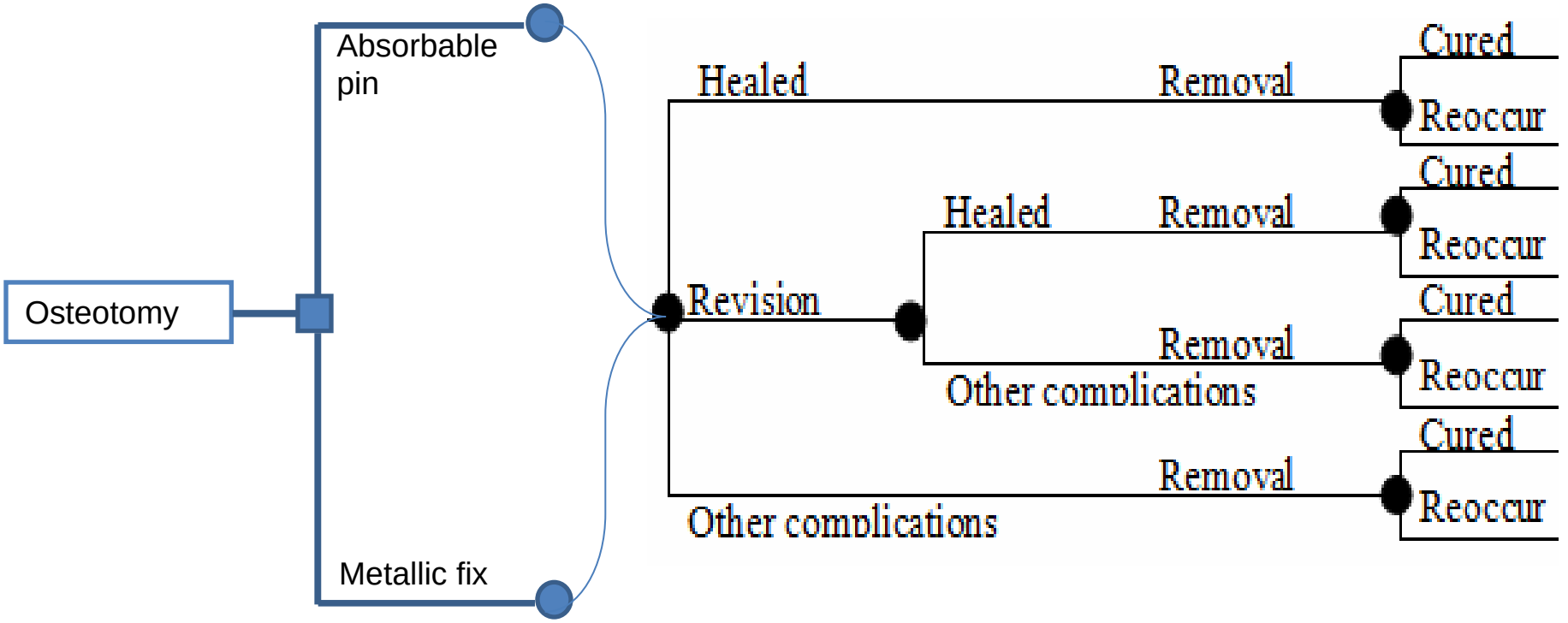
# Retrospective case study iHTA - methods

- Absorbable pin as a substitute for metallic fixation in osteotomies for treating hallux valgus (bunions)

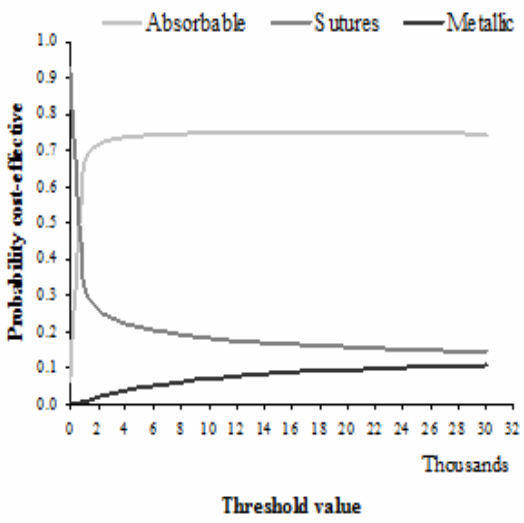
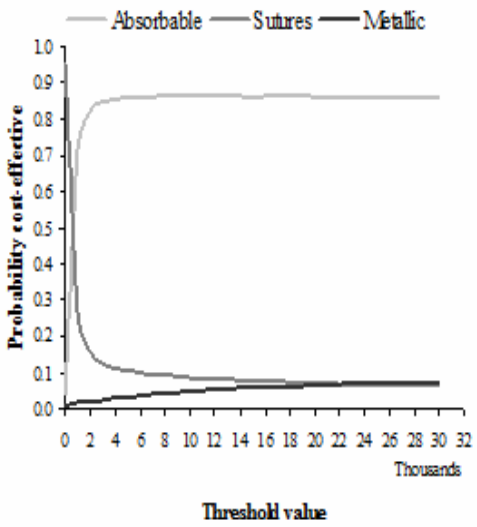
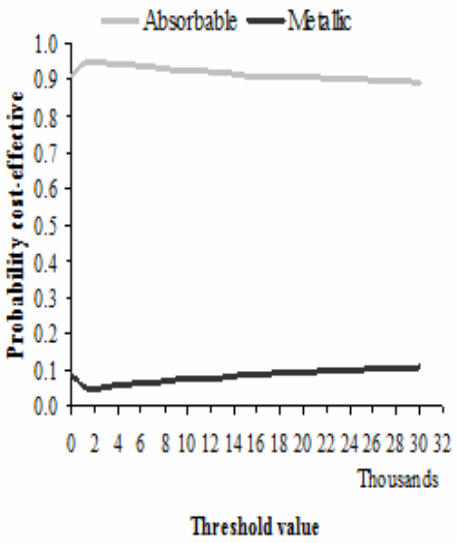
- 4 decision-gates were considered:
  - Gate 1: company received approval to conduct clinical trials
  - Gate 2: a competitor product entered the market
  - Gate 3: company product received CE-Mark approval
  - Gate 4: evaluation of post-marketing studies

- At each gate evaluations were carried out using only the published information that was available by that date
  - Stage 1: cost-effectiveness gap analysis, 1-way sensitivity analyses
  - Stages 2 and 3: decision-analytic model, probabilistic sens. analysis (PSA)
  - Stage 4: decision analytic model, PSA and VOI

# Retrospective case study iHTA - model



# Retrospective case study iHTA - results

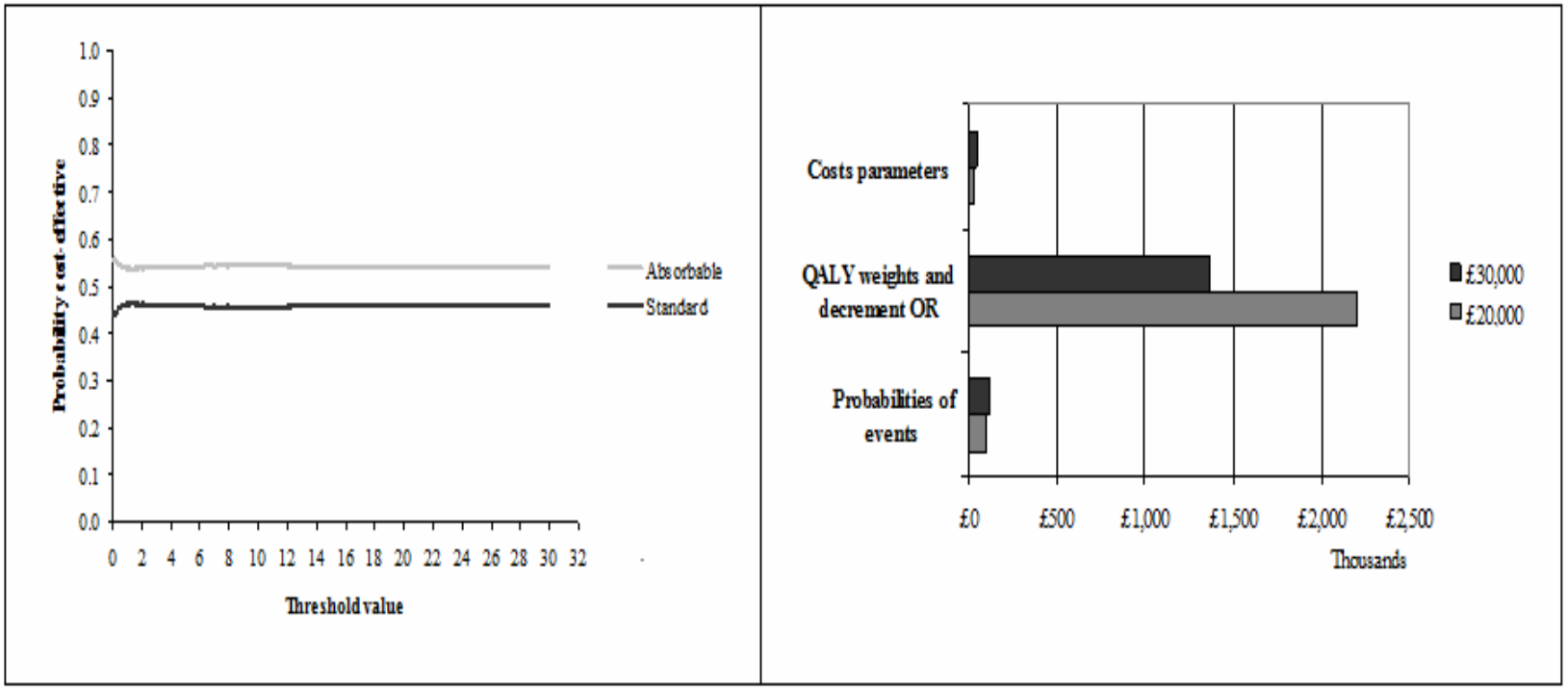
| GATE 1 (… -1987) | GATE 2 (1988-1990) | GATE 3 (1991-1994) |
|---|---|---|
|  |  |  |



Absorbable pins dominate metallic fixation, with a high probability of being cost-effective

# Retrospective case study iHTA - results

Stage 4




- ICER absorbable pins vs. metallic fix: £ 283 /QALY
- But, probability cost-effectiveness much lower

  => uncertainty caused by updated QALY-estimates

# Useful??

Yes, to the extent that it convinced the company of the feasibility and potential usefulness of iHTA to them.

But, an example that did *not* make it to market, or did so but shouldn't have, would have been more informative.

Also, the example showed that decision-uncertainty does not necessarily decrease as more/better data become available.

- especially not since companies tend to overestimate the benefits of their product; should be accounted for in fitting distributions.

# Real world concerns remain - 1

- Which perspective?
  - Societal perspective irrelevant for most important customers of MD industry, i.e. local payers
- Explicit reimbursement-decisions based on cost / QALY are rare
  - Definition of “value” often implicit
  - Meaning / understanding of cost-effectiveness (thresholds) varies between parties involved

# Real world concerns - 2

- Transferability of results and/or flexibility of models to inform specific local decision-making is limited
  - Addressing differences in countries, care settings, customers is a necessity
- Perverse system incentives exist
  - sometimes even the best health economic arguments don't hold because of system issues


WELL, WE'RE GONNA CUT THAT "VIVA VIAGRA" JINGLE IN HALF...
WE CAN CERTAINLY SLOW DOWN RESEARCH ON THE NEW BUNION MRI MACHINE...
...NO MORE OCTOMOMS! FROM NOW ON, IT'S A LIMIT OF SEVEN!
WE CAN USE LUKEWARM WATER IN THE CIALIS HOT TUB...
Voluntary Ideas for Cost-cutting by the Health Care Industry...


“The drug itself has no side effects, but the number of health economists needed to prove its value may cause dizziness and nausea”

# Way forward…

1. Make up our minds as regards appraisal of MDs
   - New MDs vs. 2nd / 3rd generation MDs, risk profile
2. Create a common understanding of what we want from (i)HTA and what we can(not) expect from it
3. Clear understanding of what the decision context is
   - Customers / target patient / change in treatment pathways / where costs and benefits fall / system (dis)incentives
4. Create pragmatic, yet valid and transparent models
   - that can easily be updated as new data become available
   - and be tailored to specific local settings
     - Example: Steuten & Vallejo et al. Health Policy 2008;89(1):46-57

- Acknowledgement:
  - All data and exemplar models referred to were produced will being appointed by MATCH *(Multidisciplinary Assessment of Technology Centre for Healthcare - www.match.ac.uk)*

- Disclaimer:
  - this is just me talking…

# Thank you!

Lotte MG Steuten, PhD MSc
Director Care Innovations Research and Consultancy

info@careinnovationsrc.org