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Early HTA to inform value driven market access and reimbursement planning

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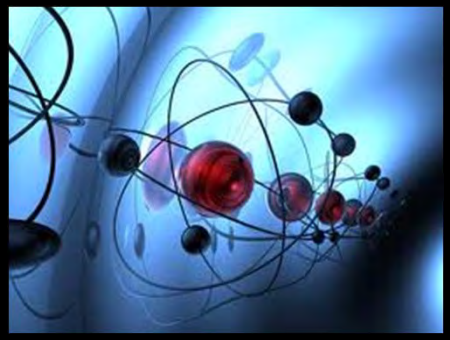

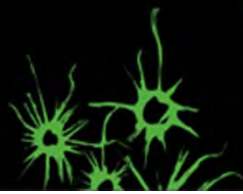

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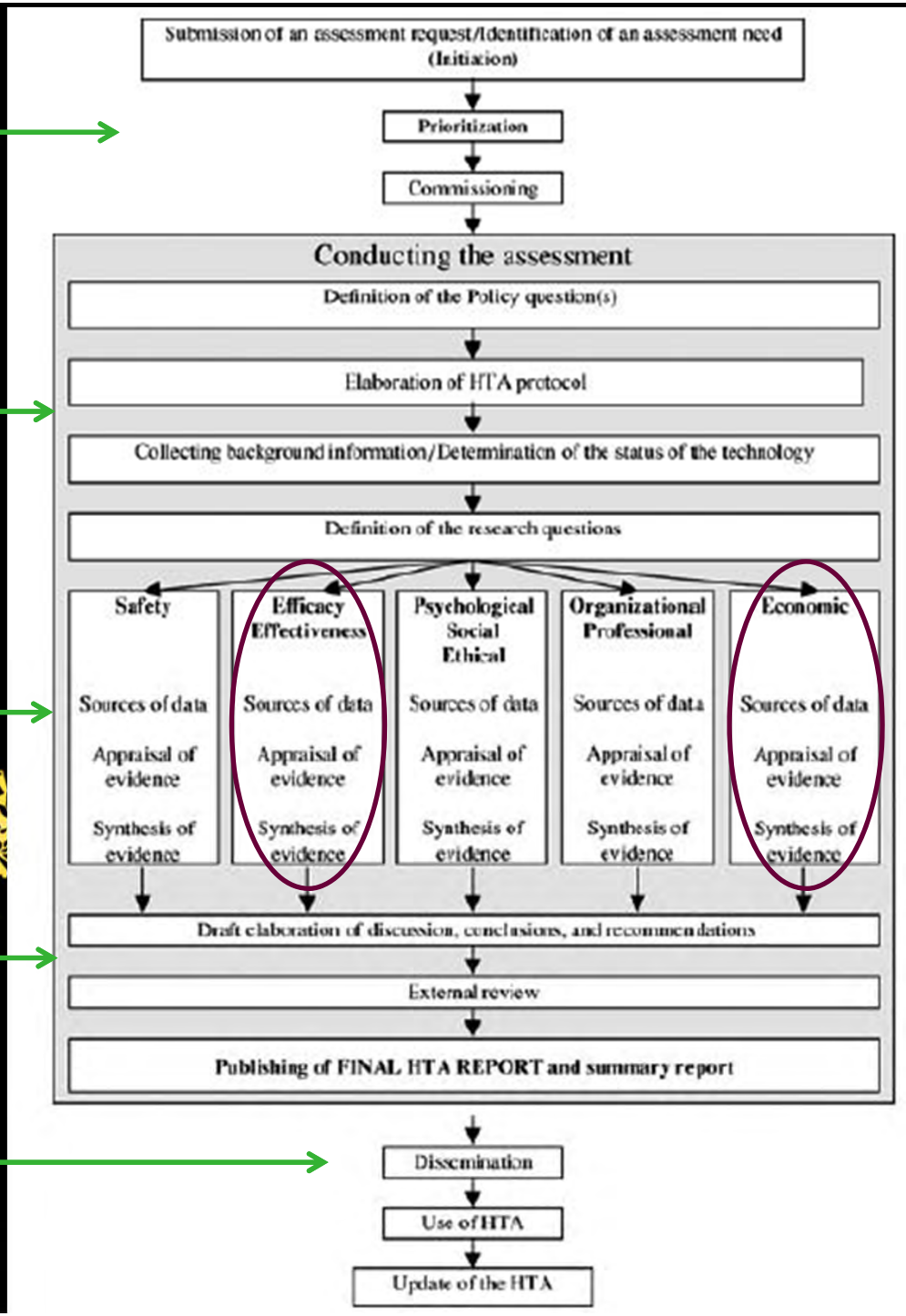
Identification, prioritization, commissioning

Define policy question, develop HTA protocol, background info => Research Question

Assess technology on the HTA elements

Draft, review and write up final report

Dissemination and use of HTA in decision making



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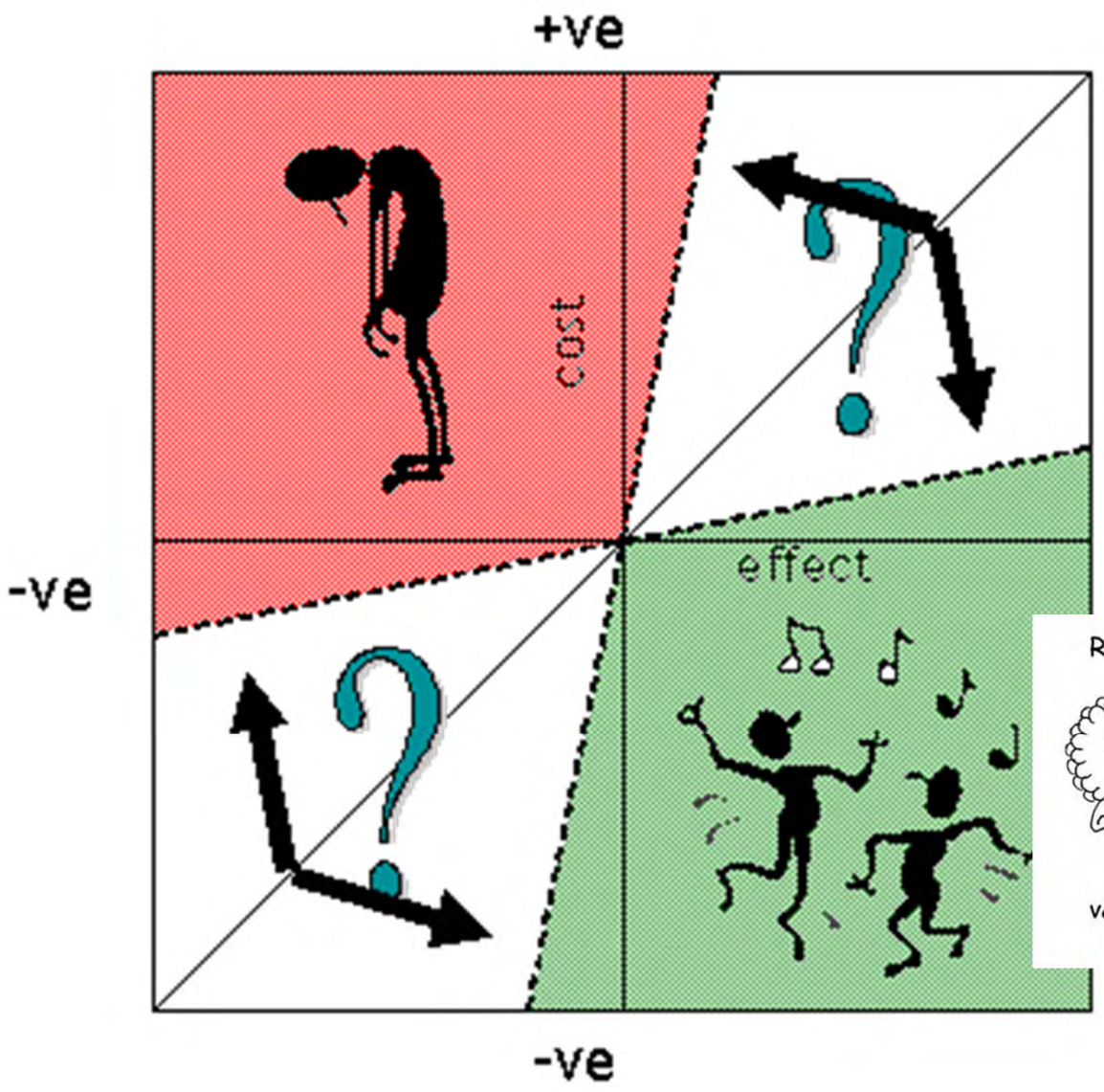

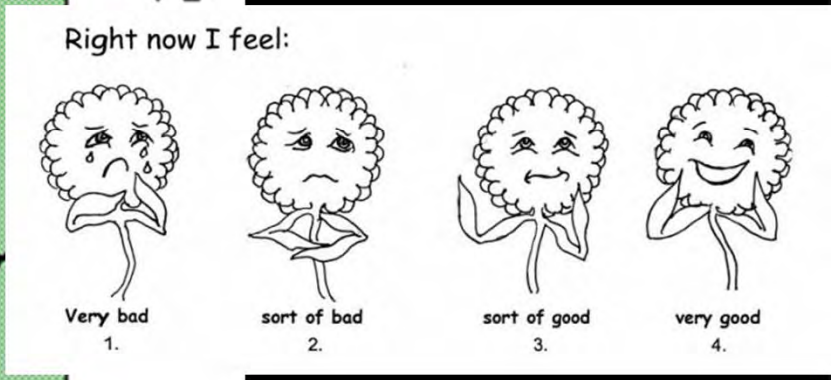

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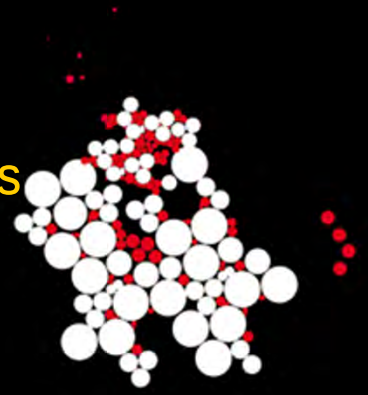
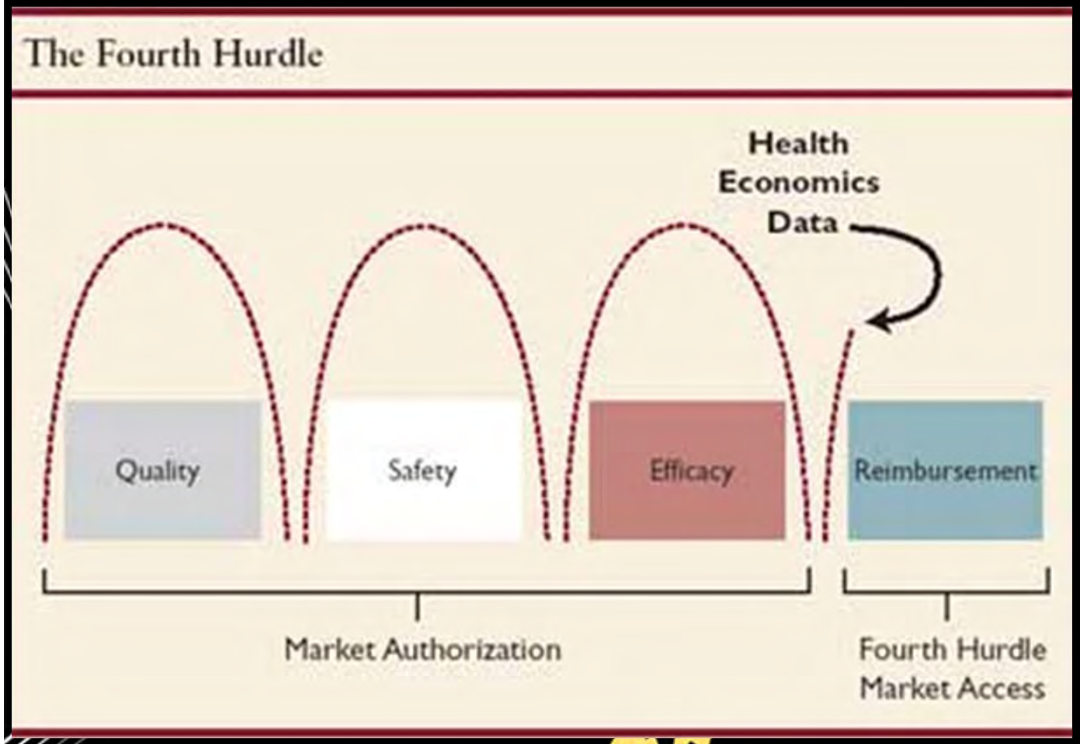
MOH 2012 Committee of Supply Speech Healthcare 2020: Improving Accessibility, Quality and Affordability for Tomorrow's Challenges (Part 2 of 2)



Sustainable Healthcare Spending

…"A key driver for the increase in healthcare costs is improvements in medical care – new and improved drugs, better treatments, breakthroughs in surgical techniques – that improve quality of life and extend life. This is good for patients and their families.
However, as a society, we cannot afford to support and subsidise all new treatments "at all costs". New does not necessarily mean better. We need to consider what appropriate and cost-effective treatment is."

http://www.moh.gov.sg/content/moh_web/home/pressRoom/speeches_d/2012/MOH_2012_COS_Healthcare_2020_improving_accessibility_quality_affordability_for_tomorrows_challenges_part_2_of_2.html



Unsatisfactory for most stakeholders:

- Too little room for innovation
- Transparency / public accountability
- Multi criteria vs cost-effectiveness: “value”
- etc...

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Value

Benefit

Price

NPCF NEDERLANDSE PATIËNTEN CONSUMENTEN FEDERATIE

Ministerie van Economische Zaken, Landbouw en Innovatie

Ministerie van Volksgezondheid, Welzijn en Sport

FBTO UNIVÉ achmea delta lloyd DE FRIESLAND ZORGVERZEKERAAR VGZ menzis OHRA ZilverenKruis AGIS ZORGVERZEKERINGEN

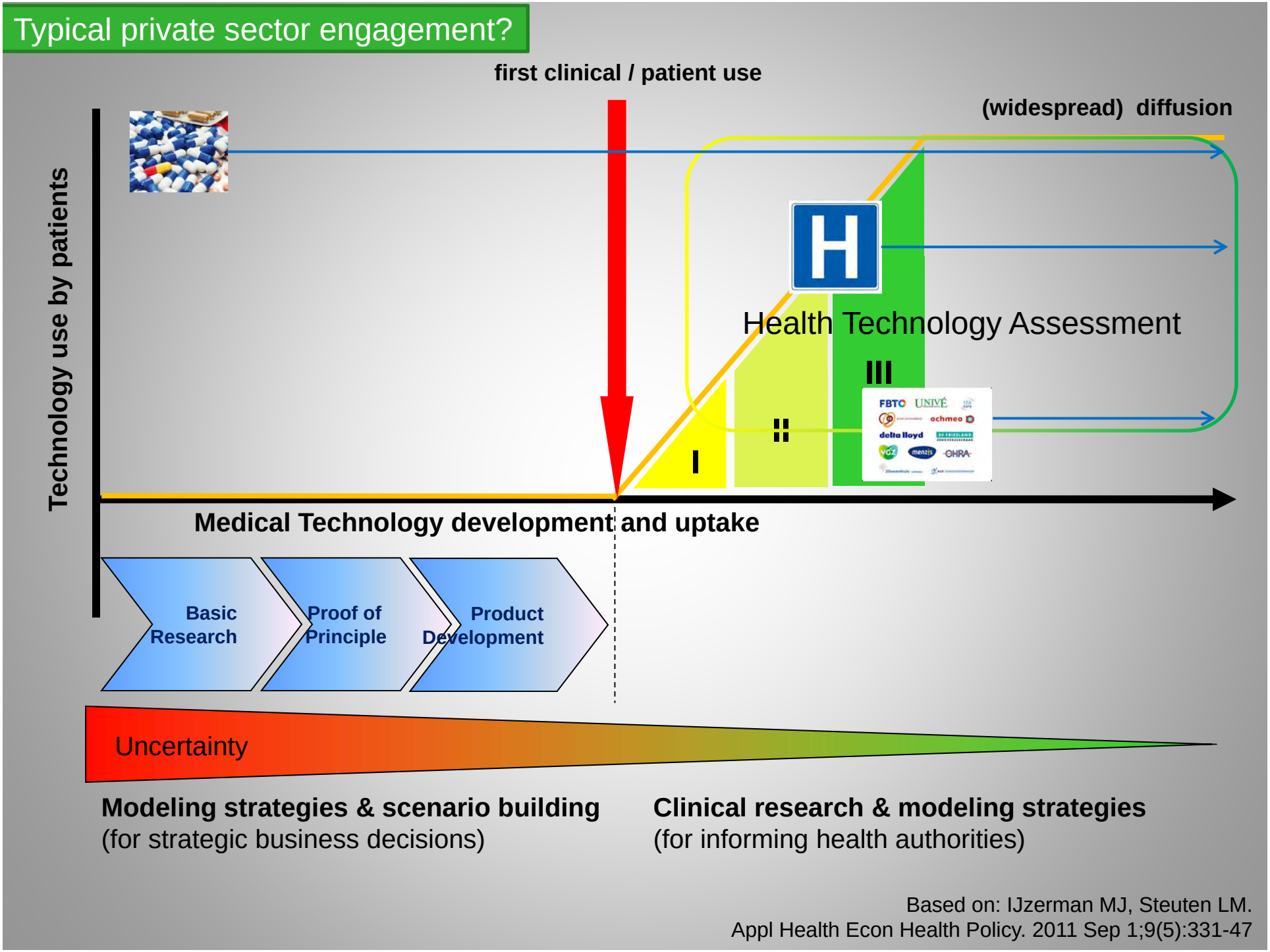
knmg voor verantwoorde medische zorg

Nederlandse Zorgautoriteit

CVZ College voor zorgverzekeringen

Largely private sector; highly regulated

Typical private sector engagement?



Based on: IJzerman MJ, Steuten LM.
Appl Health Econ Health Policy. 2011 Sep 1;9(5):331-47

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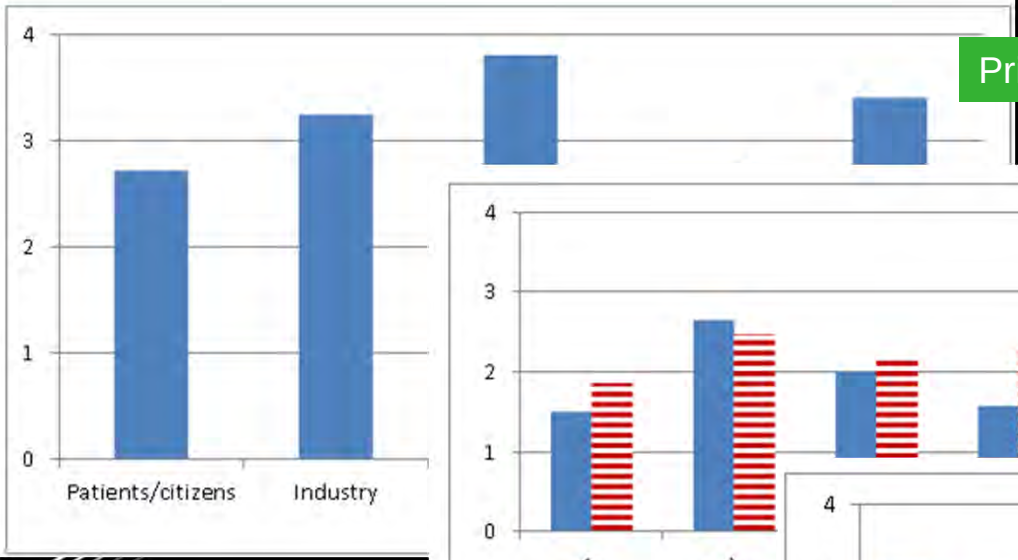
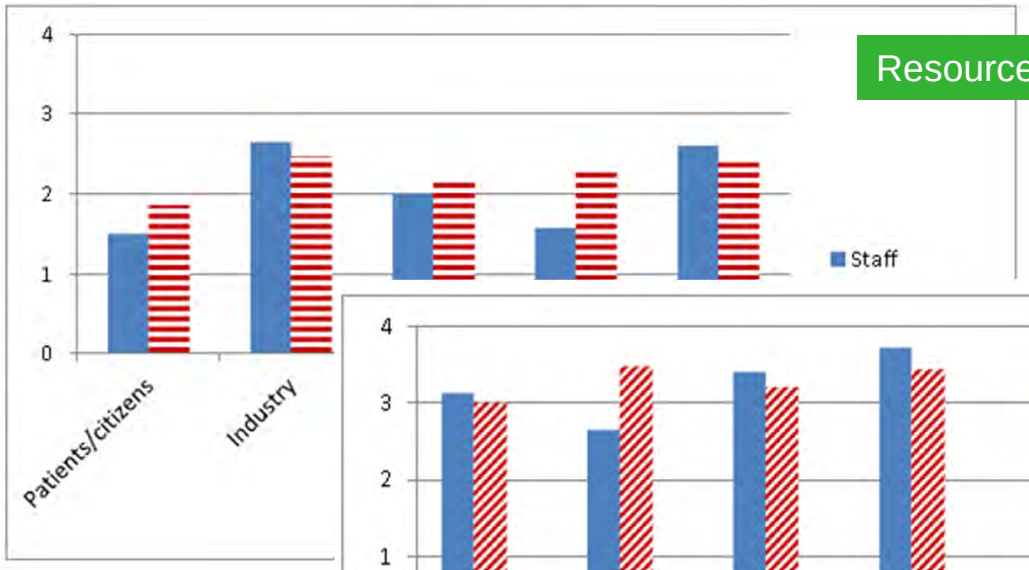
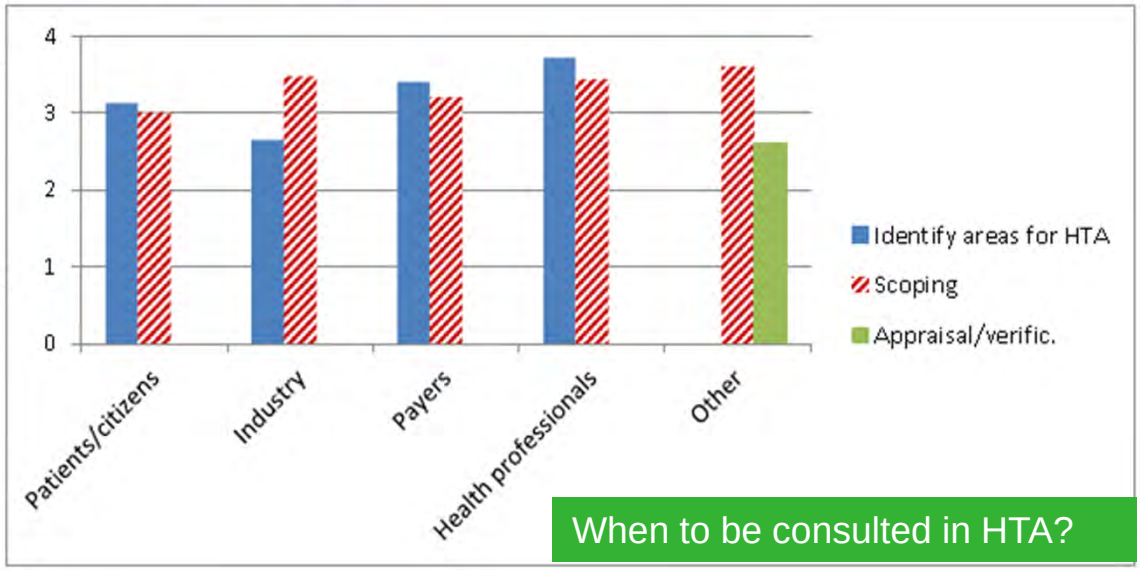
Stakeholder Engagement in HTA:
- Priorities
- Resources
- Timeliness



Priority of HTA?



Resources for HTA?



When to be consulted in HTA?

European Commission: Health and Consumer DG report on modalities of stakeholder consultation in future HTA (2012)

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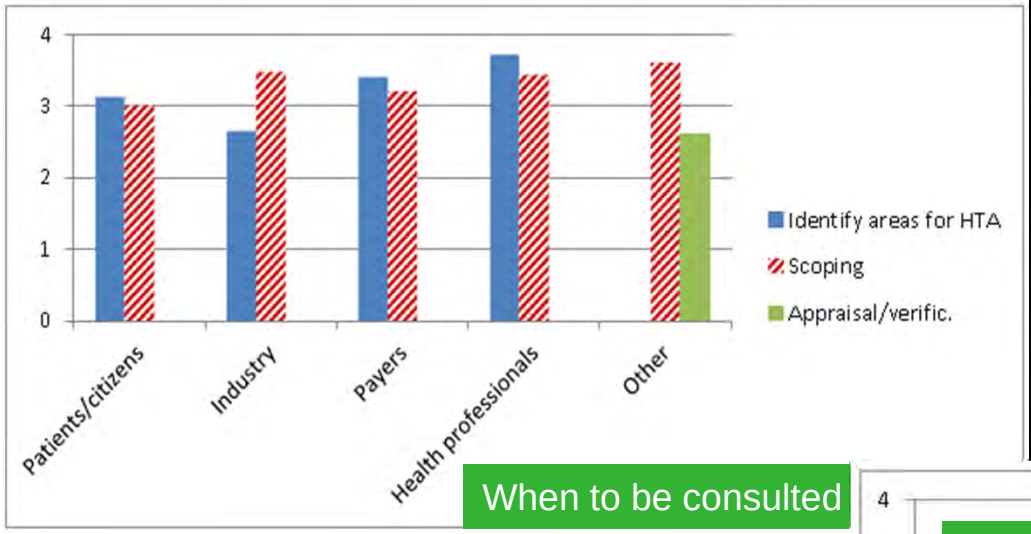
Stakeholder Consultation in HTA: mismatch regarding timeliness



When to be consulted

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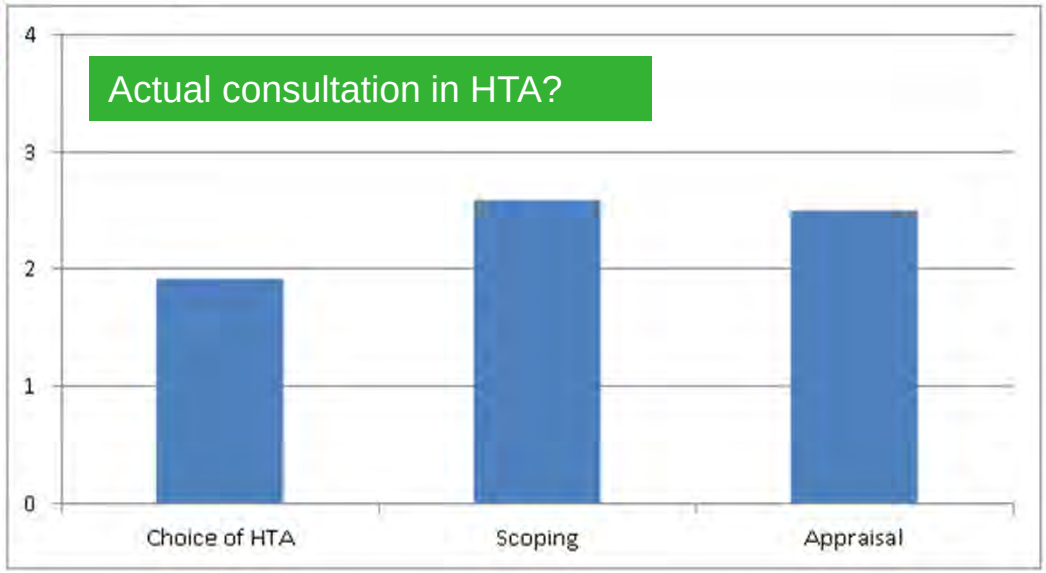
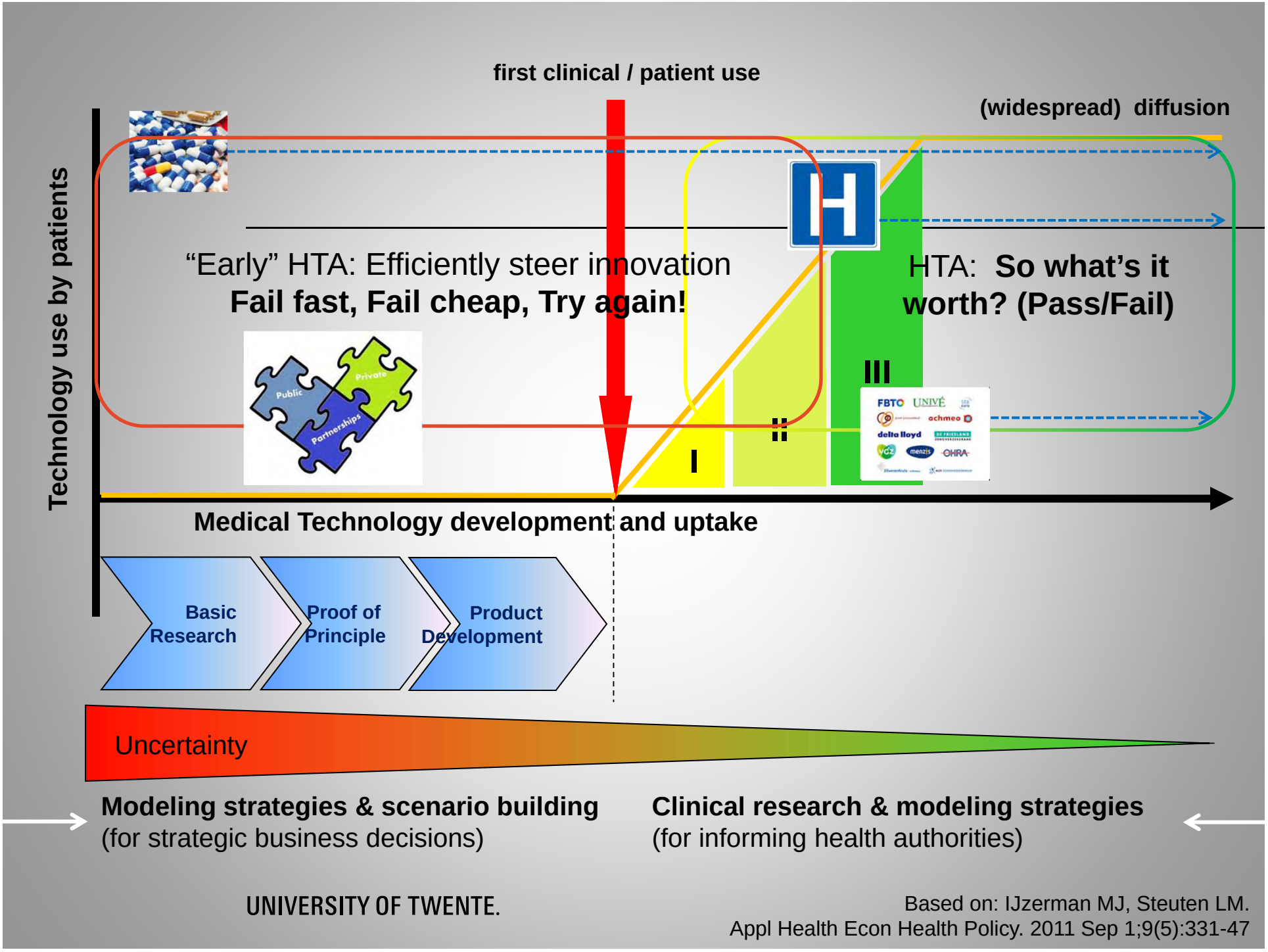


Actual consultation in HTA?



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Based on: IJzerman MJ, Steuten LM.
Appl Health Econ Health Policy. 2011 Sep 1;9(5):331-47

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	"Regular" HTA	"Early" HTA
Aim	Assess **safety, effectiveness and cost-effectiveness** of a new technology.	Assessment of **(future)** safety, effectiveness and cost-effectiveness of a new technology.
Decision support	Decision support for **healthcare policy makers, financers, care providers and patients** regarding market access, **reimbursement and technology use**	Decision support for **developers and investors** regarding **technology design and strategic management** and healthcare policy makers, financers, care providers and patients re market access & reimbursement.
Available evidence	Predominantly based on **clinical and cost-effectiveness studies** of the new technology, but increasingly also with outcomes research in **daily practice** EMPIRICAL RESEARCH + MODELLING	Predominantly based on prototype testing, animal studies, **early clinical experiences and expert opinions a/o extrapolations** from data of previous generation or similar technologies ADVANCED MODELLING
Influence on technology's added value	**Limited impact** on added value of the new technology	Can have **important influence on (future) added value** of the new technology

Adapted from: Pietzsch JB, Paté-Cornell ME. Int J Technol Assess Health Care. 2008 Winter;24(1):36-44.

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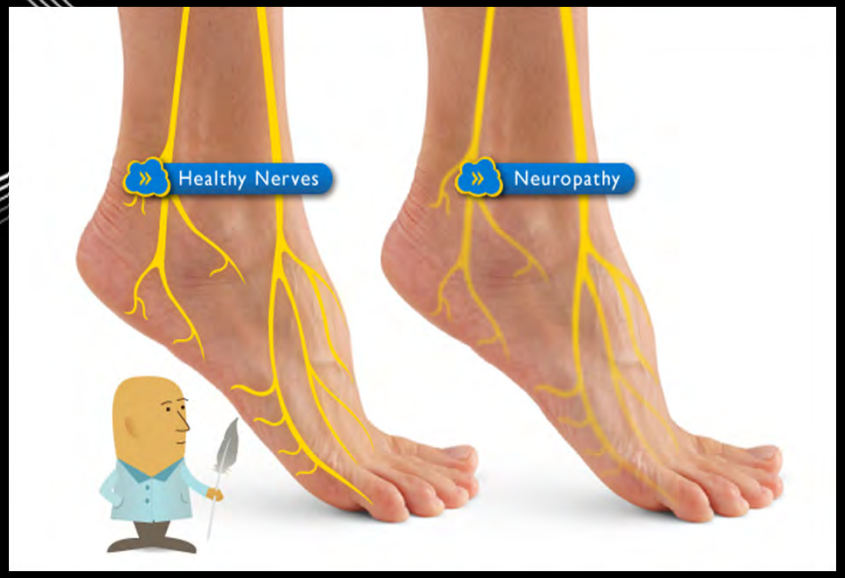
Two examples of early HTA

1. Gap-analysis: Pain and loss of sensation in diabetic neuropathy
2. Early modeling: Lab on a Chip technology



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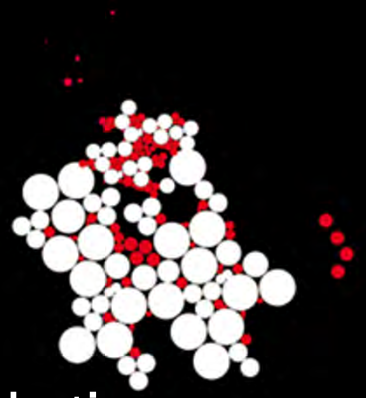
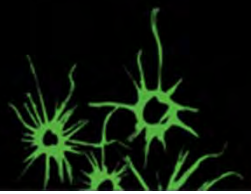
Pain and loss of sensation in diabetic neuropathy



- Product to treat pain and loss of sensation due to diabetic peripheral neuropathy
- By using electrotherapy technology (TENS-like) for patients' feet using a gel bath solution; sensation is restored and pain reduced
- The device will be designed for home use
- Patients can self-administer the 30 minute sessions needed to treat their complaints

No empirical data available yet, so how can early MTA help?

→ Cost-effectiveness GAP-analysis



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Diabetic neuropathy – key characteristics

Epidemiology: describe target population

- **How many people suffer from Diabetic Neuropathy?**
- **Increase in coming years?**

Target population / market (economies of scale)

Health economics:

- **How large is the disease burden? (HR-Quality of Life)**
- **How large is the cost-of-illness to society?**

"Headroom" for quality improvement and cost savings

User preferences:

- **Who should use the technology?**
- **What are the current or next-best alternatives?**
- **Requirements re design / user friendliness?**

Predict user preferences and adoption rates

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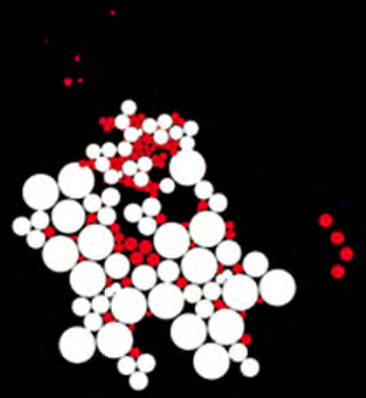
MTA: cost-effectiveness gap analysis



Optimistic assumptions:

Product leads to improvements in Quality of Life of: +10%

Saves 2x / year costs outpatient treatment (2x € 750)

Cost Effectiveness threshold = € 30.000/Quality Adjusted Life Year

C/E gap = € 30.000 * 0.1 + €1500 = € 4500

Can you develop and produce this product for ≤ € 4500?

YES: continue development; NO: reconsider technology/ targetgroup/ price etc…

=> Reimbursement for current generation TENS lies around € 120 - € 150 /year (!)

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Conclusion for new “TENS” system

Crucially important to articulate and proof the added value of this new technology for home use in comparison to usual care

- **Safe and easy to use by patients themselves**
- **At least as effective as current technologies**
- **Save expensive clinic visits**

Only when the evidence for this is accepted by DMs...:

- **Physicians / nurses as prescribers**
- **Patients as users**
- **Health insurers as payors**

...a premium price can be expected above the current market price of €120-150 / year.

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ELSEVIER

Contents lists available at SciVerse ScienceDirect

Technological Forecasting & Social Change

Early Bayesian modeling of a potassium lab-on-a-chip for monitoring of heart failure patients at increased risk of hyperkalaemia

Gijs van de Wetering [a,b], Lotte M.G. Steuten [b,c], Clemens von Birgelen [c,d], Eddy M.M. Adang [a], Maarten J. IJzerman [b,c,*]

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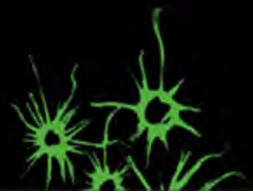
[b] Department of Health Technology and Services Research, University of Twente, Enschede, The Netherlands
[c] MIRA - Institute for Biomedical Technology and Technical Medicine, University of Twente, Enschede, The Netherlands
[d] Thoraxcentrum Twente, Medisch Spectrum Twente, Dept. of Cardiology, Enschede, The Netherlands



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Early HTA to value lab on a chip technology

Several application areas including renal and heart failure

- **Added clinical value is prevention of hyperkalemia**
- **Some data available, but no large patient trials yet**

Which application(s) to pursue?

...investing in initial studies?

...first to market application?

...market size vs uncertainty?

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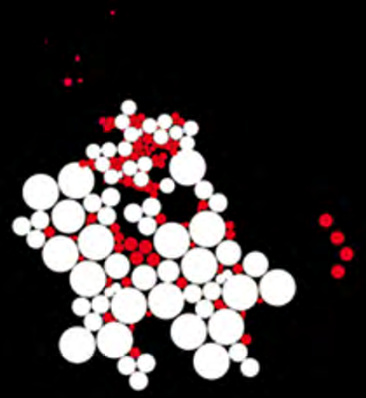
Early HTA: key considerations



Direct medical costs Lab on a chip:

- **Costs lab-on-a-chip: €16.60 per measurement**
- **Costs multi-reader: €130/year**
- **10 measurements per month, 120 per year**

Disease burden: probability to develop hyperkalemia

- **Renal failure: 5-10%**
- **Heart failure: 17%**

Consequences hyperkalemia: **neurologic deficits, cardiac arrest, death**

Current treatment: **drugs and diet (both diseases)**

Optimistic assumptions re clinical impact / Health-Related Quality of Life

- **Probability to develop hyperkalemia becomes zero**
- **All HRQoL disutility and costs associated hyperkalemia prevented**

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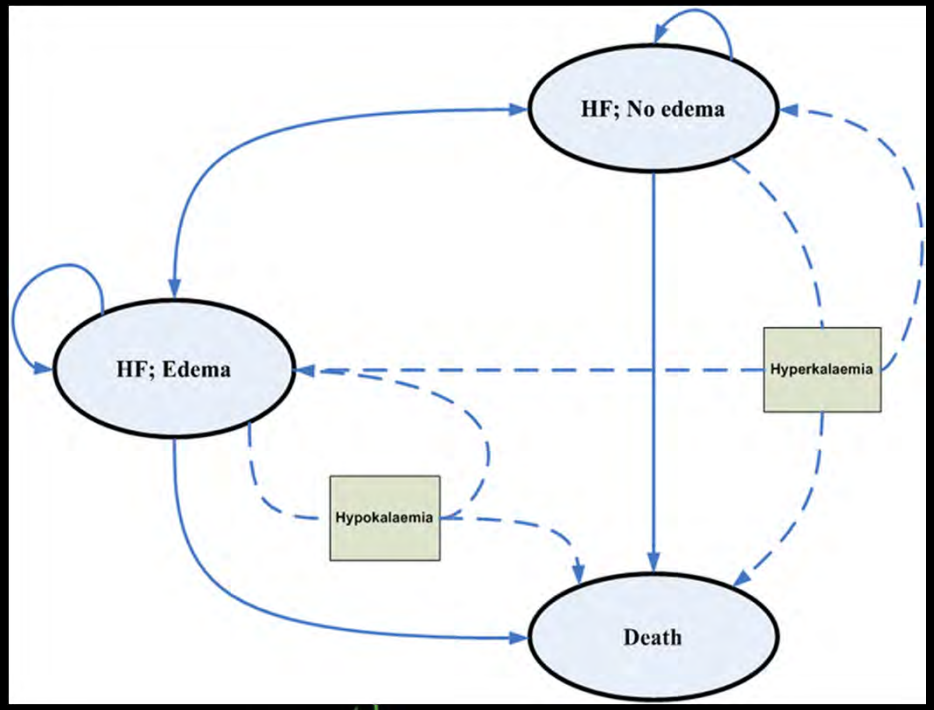
Early HTA: health-economic model

Development of Markov models for heart failure and renal failure to assess the expected 5 year cost-effectiveness vs. usual care.

Findings:

- **Renal failure: €1M / QALY**
- **Heart failure: €35K / QALY**

(threshold €20K-€80K / QALY)



Advise: **continue heart failure;**
reconsider renal failure

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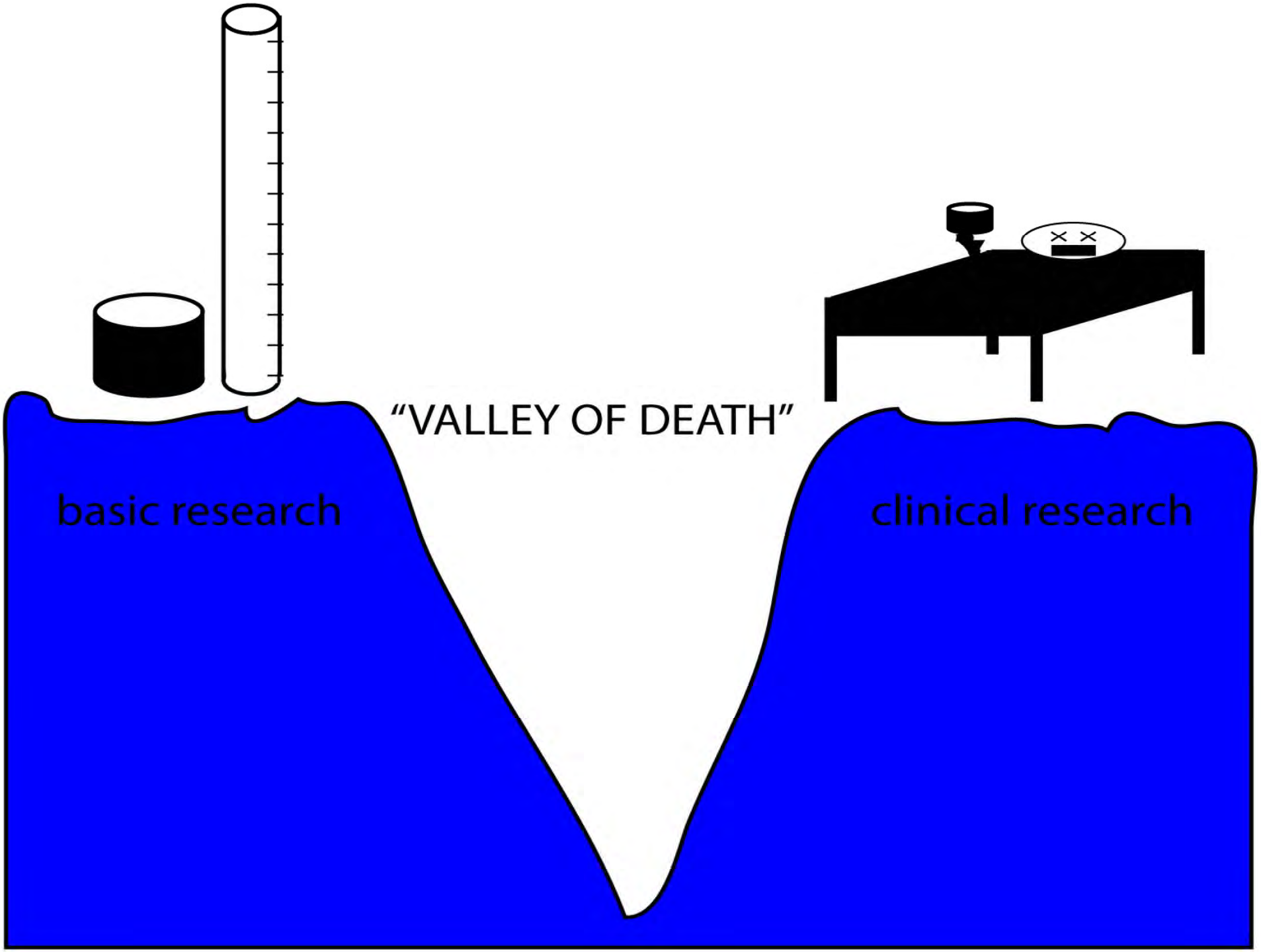
"VALLEY OF DEATH"
basic research
clinical research

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Conclusion

- HTA will and should increasingly be undertaken in earlier stages of technology development
  - to anticipate market access and reimbursement decisions
- Private sector engagement is crucial in modern HTA
- Methods for HTA need to be adapted to allow assessment earlier in the process
- “Value” should be considered in a broader sense than cost-effectiveness


INNOVATION
SUCCESS
EVALUATION
DEVELOPMENT
GROWTH
SOLUTION
PROGRESS
MARKETING
TEAMWORK

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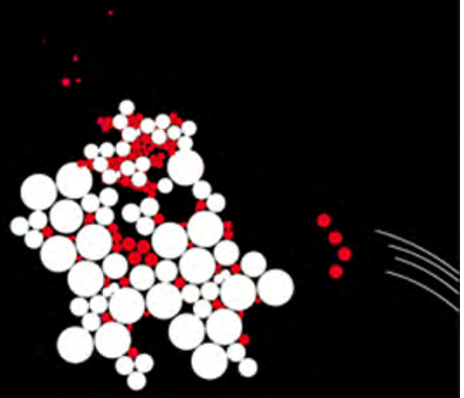

Thank you!

l.m.g.steuten@utwente.nl