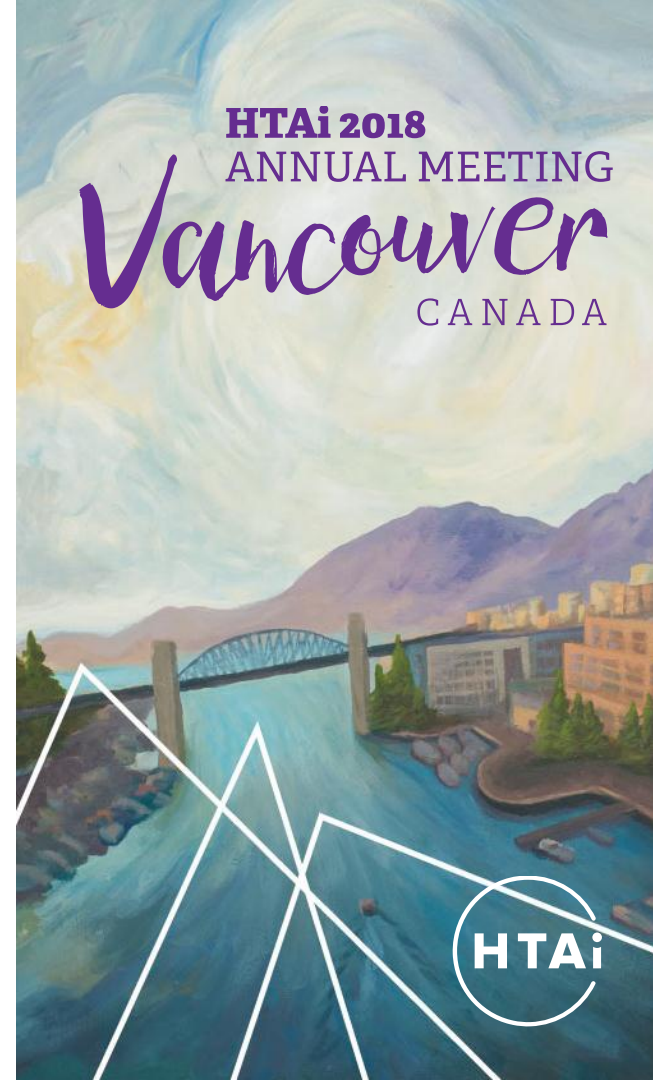


# Early awareness and alert (EAA) of innovation, appropriate use of technologies and disinvestment

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# Aims



- The workshop is aimed at delegates who want to find out about the life cycle concept and the implementation of EAA of innovation and disinvestment systems.
- They may be completely new to EAA and disinvestment activities, in the early stages of developing an EAA or disinvestment system or be working in an EAA or disinvestment system in Low and Middle Income countries (LMIC).

# Panelists



- Hans-Peter Dauben, DAHTA-DIMDI, Germany
- Iñaki Gutiérrez-Ibarluzea, Osteba, Basque Country

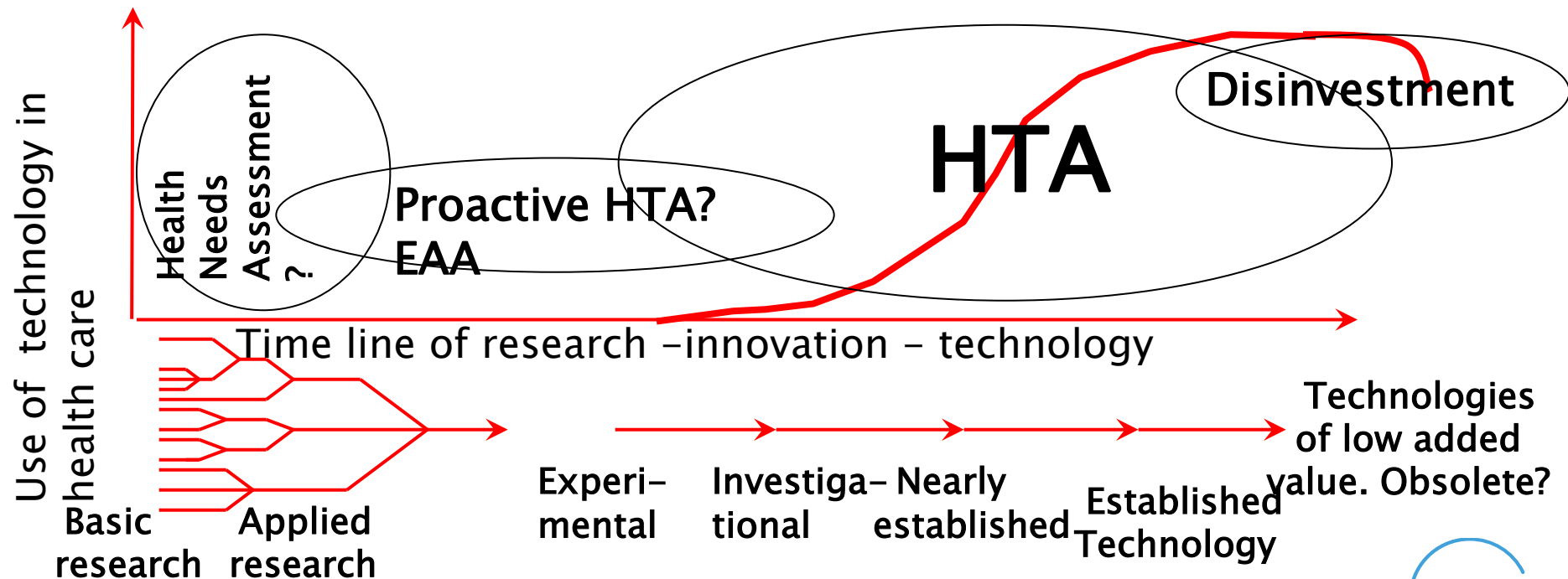
# Outline of first session

- Classical HTA
- Properties and impacts to be assessed
- From regulation to coverage...
- Decisions and overlaps, levels of decision
- Gaps in the continuous of decision making processes
- The life cycle concept

HTA is mainly a *retrospective* assessment approach

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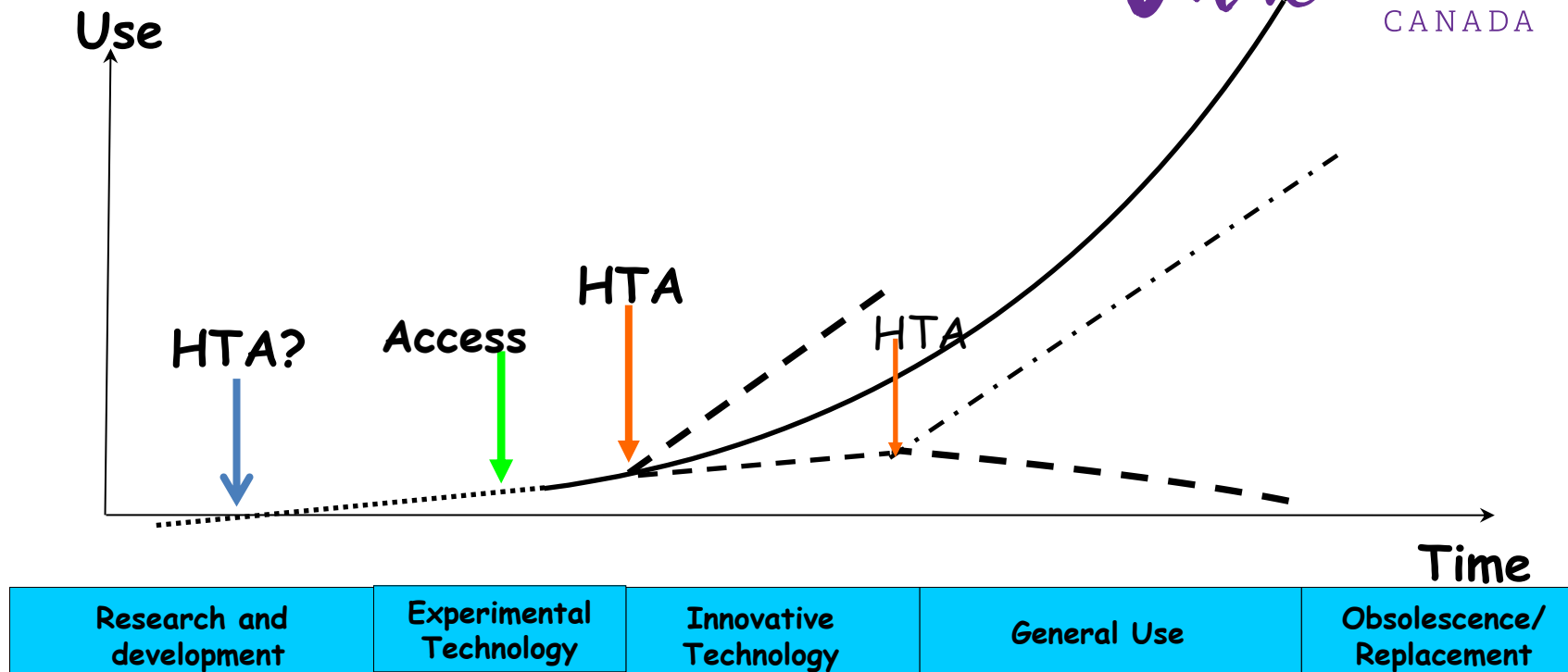


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# Where we go?

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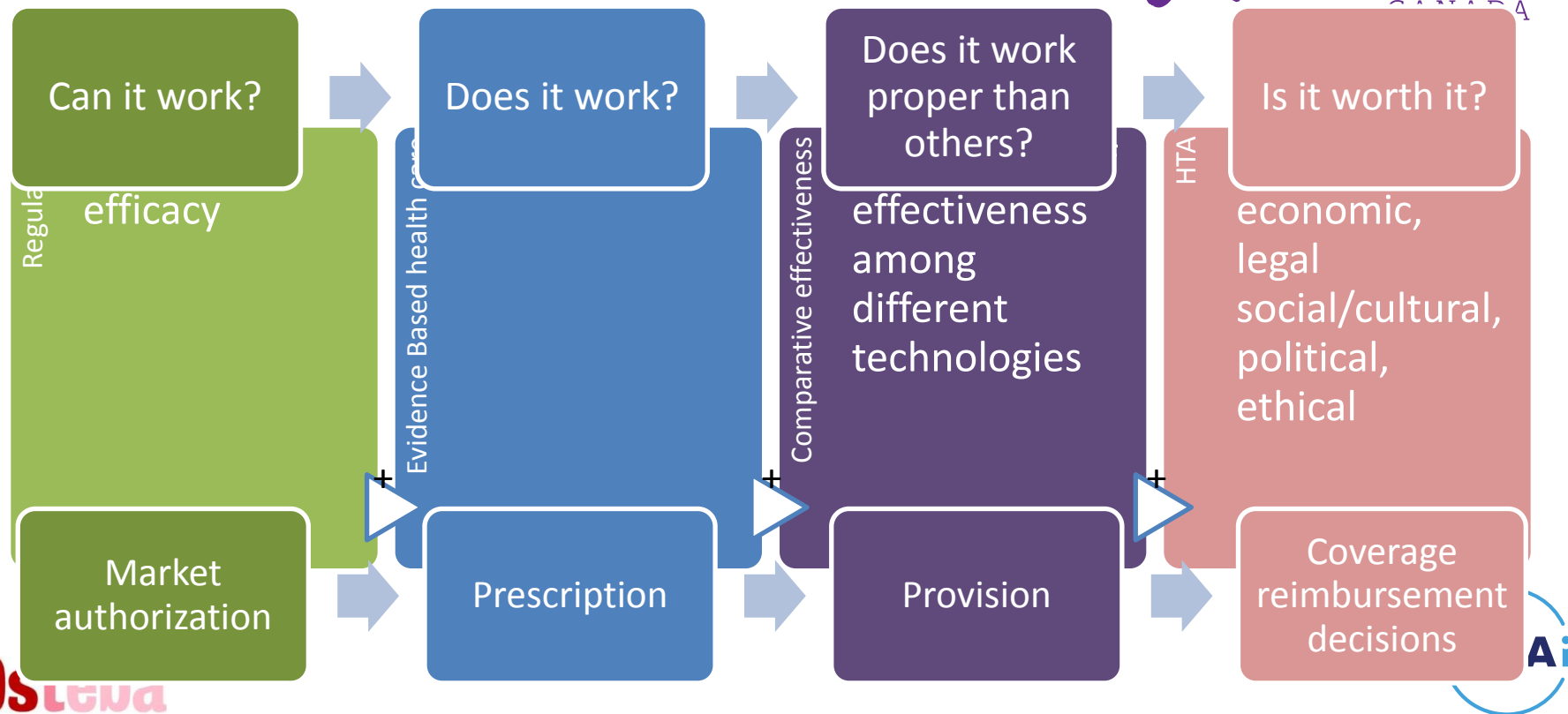


# Properties and Impacts of health technologies to be Assessed

Main categories:

- Technical properties
- Safety
- Efficacy and effectiveness
- Cost and other economic attributes
- Social/cultural, legal, ethical, organizational or political impacts

# From regulation to coverage



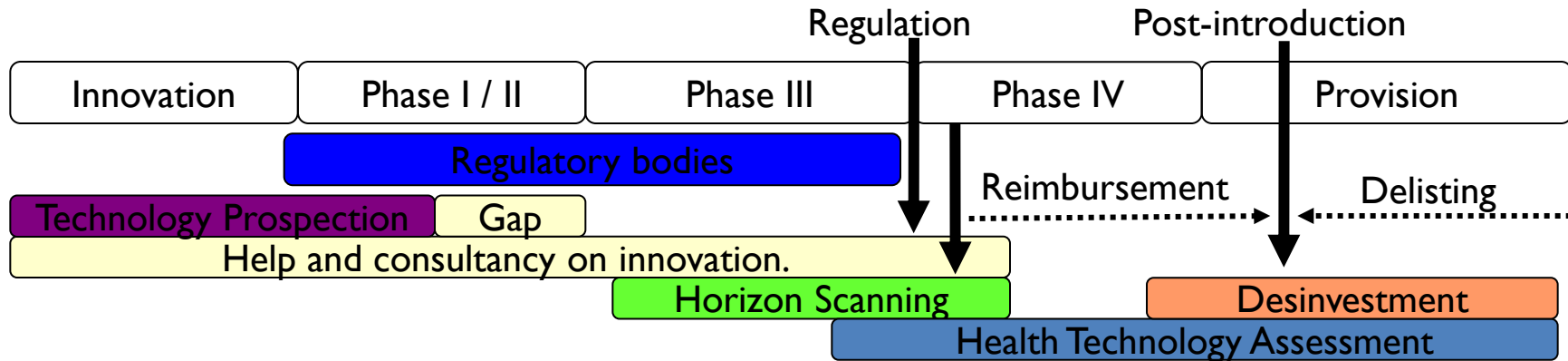
# Decisions and overlaps

- Decisions could be taken on the basis of existing information in each step
- Decisions better informed and more efficient when all the properties and impacts are considered.
- Overlaps exist in reality.

# Decisions and levels

- Prescription relates to micro decisions
- Provision relates to meso decisions
- Coverage and reimbursement relates to macro decisions.

# Gaps in the decision making process



# It is not only technology

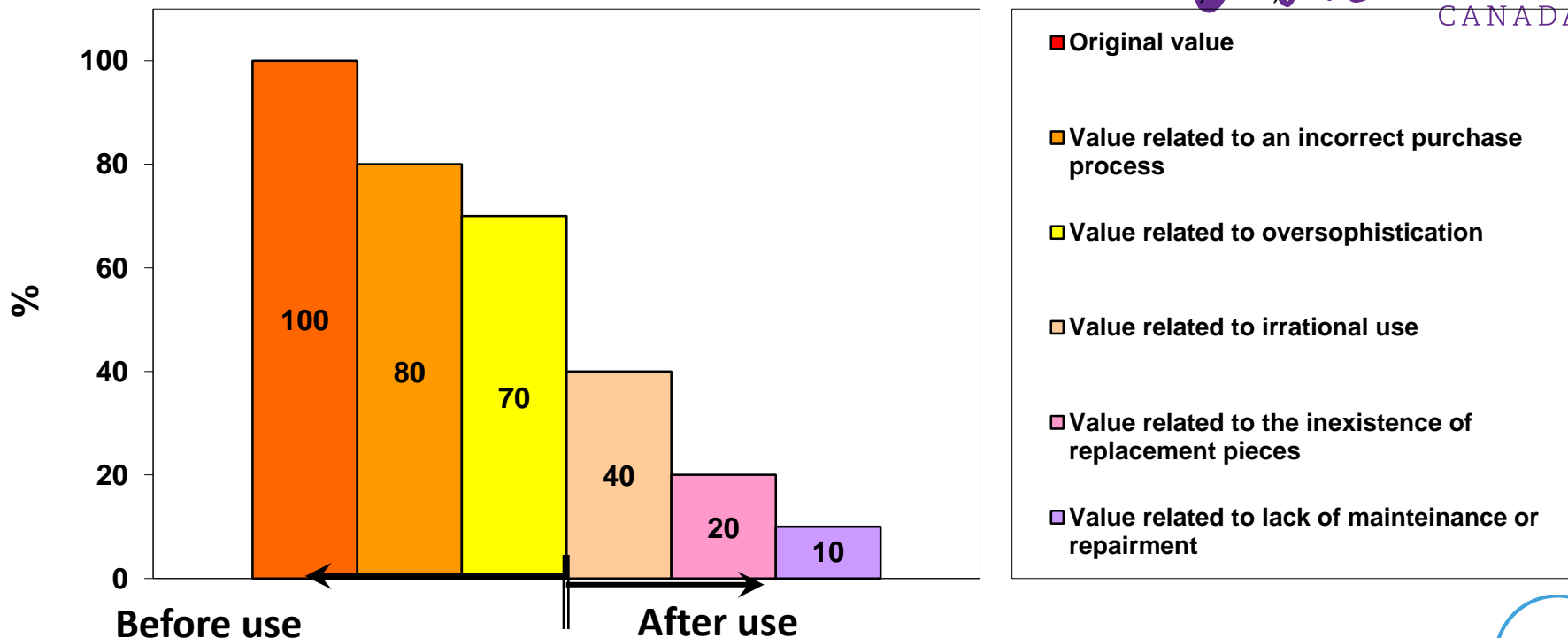
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**“According to my new computerized diagnostic software, you need to upgrade your kidneys, defragment your liver, and make a back-up copy of your spleen.”**

# Value and technology

Fuente: Swiss Center for International Health, Basel, 2005



- **Health technology assessment (HTA) is a multidisciplinary activity** that systematically examines the safety, clinical efficacy and effectiveness, cost, cost-effectiveness, **organisational implications, social consequences, legal** and **ethical** considerations of the application of a health technology – usually a drug, medical device or clinical/surgical procedure or health program

## What is HTA?

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# HTA and LMIC

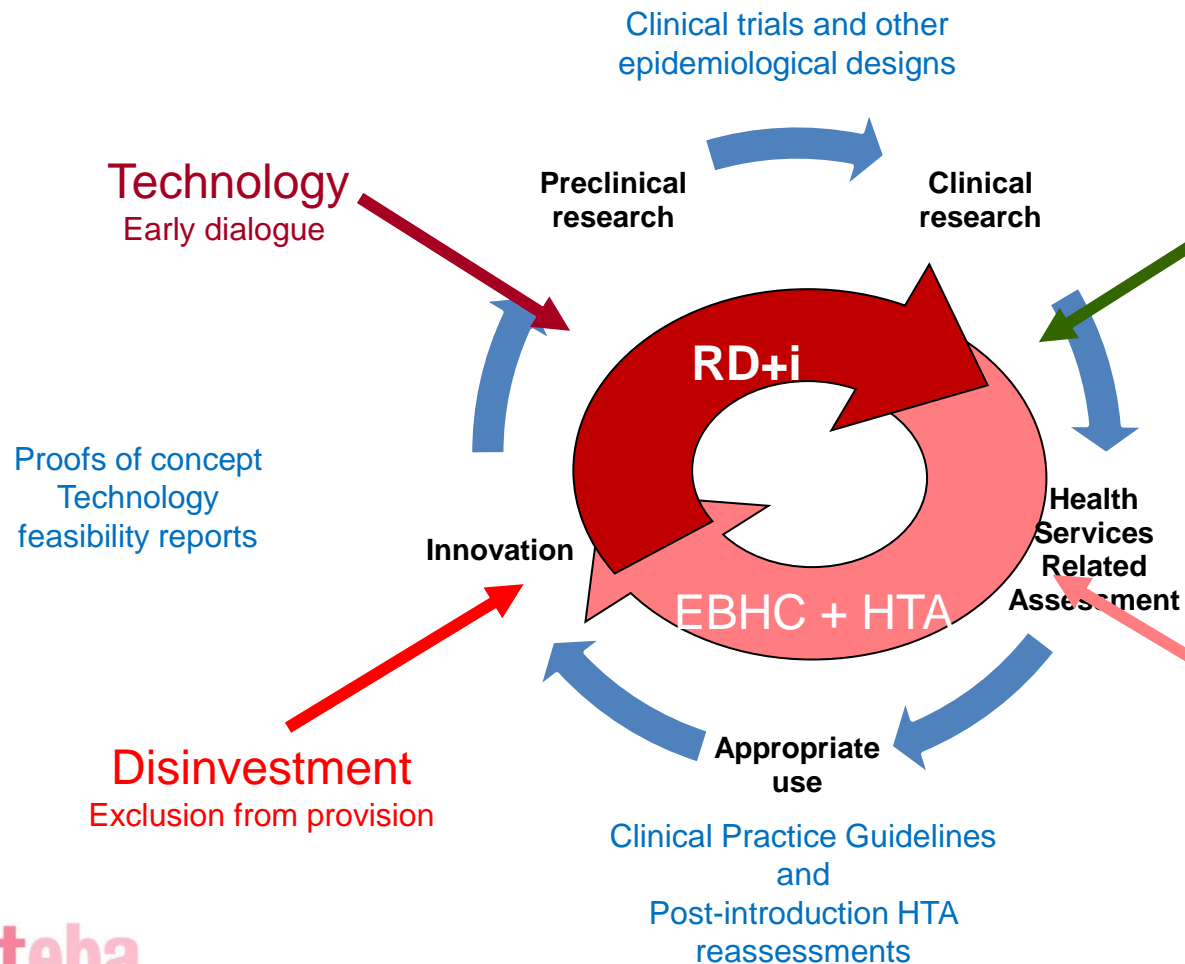
- Mostly centered on reimbursement processes and HTM
- Lack of resources
- Different priorities
- Most of the HTA reports in HIC do not fit with LMIC needs
  - Vaccines
  - Communicable diseases
- Not much experience on analysis of variability in practice and disinvestment

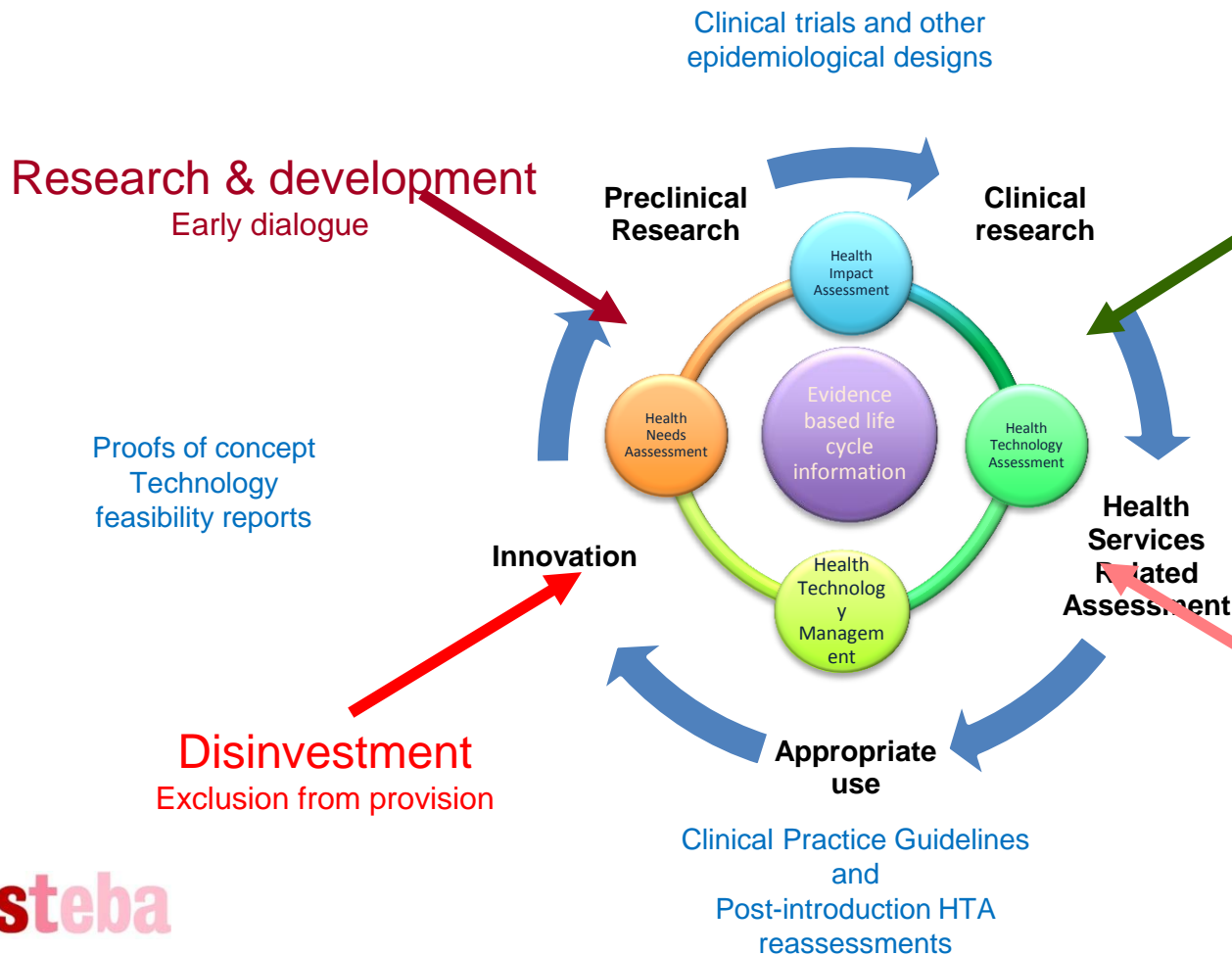
# Gaps in the decision making process (I)

- Before regulation
  - Technology Prospection (what could be applicable to the health care system?)
  - Requirements of the systems
  - Health Needs Assessment
  - Horizon Scanning
  - Early dialogue with manufacturers
- From regulation to reimbursement
  - Early dialogue among regulators and HTA

# Gaps in the decision making process (II)

- Reimbursement and Investment
  - Health Technology Assessment
  - Health Technology Management
  - Post-introduction observation
  - Analysis of variability in practice
- Disinvestment and Innovation
  - Health Impact Assessment
  - Efficiency





# Who is the customer?



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# Who is the customer?

- Public or private?
- Provider or purchaser?
- Professionals or managers?

# Factors to consider:

1. When does your customer want or need to know about technologies?
2. When is the technology likely to enter your healthcare system?

# Buxton's law

*"It's always too early until,  
unfortunately, it's suddenly too late!"*

Martin Buxton,

1



- Too early and there may not be enough information for decision makers
- Too late and the decision may have already been made

# Buxton's law

*"It's always too early until, unfortunately, it's suddenly too late!"*

Martin Buxton, 1987

- Too early and there may not be enough information for decision makers
- Too late and the decision may have already been made

# When does your customer want to know?

It depends:

- when (before?) health authorities, hospitals, doctors, or patients start demanding a new technology (**near horizon**)
- when (before?) doctors ask to purchase a new type of diagnostic or surgical equipment, or when companies start marketing it (**near horizon**)
- when (after?) a new treatment appears promising in early research & development (**distant horizon**)

# Typical time horizons

- Many EAA system use a 0 to 3 year time horizon (**near horizon**)
- Some look ahead up to 5 years (**distant horizon**) – particularly for larger trends (e.g., 3D printing, precision medicine....)
- May mean looking for technologies several years before they are commercially available
- Most technologies of interest will likely be on the near horizon (i.e., within a year of being marketed, or newly licensed & in early stage of diffusion)

# When is the technology likely to enter the healthcare system?

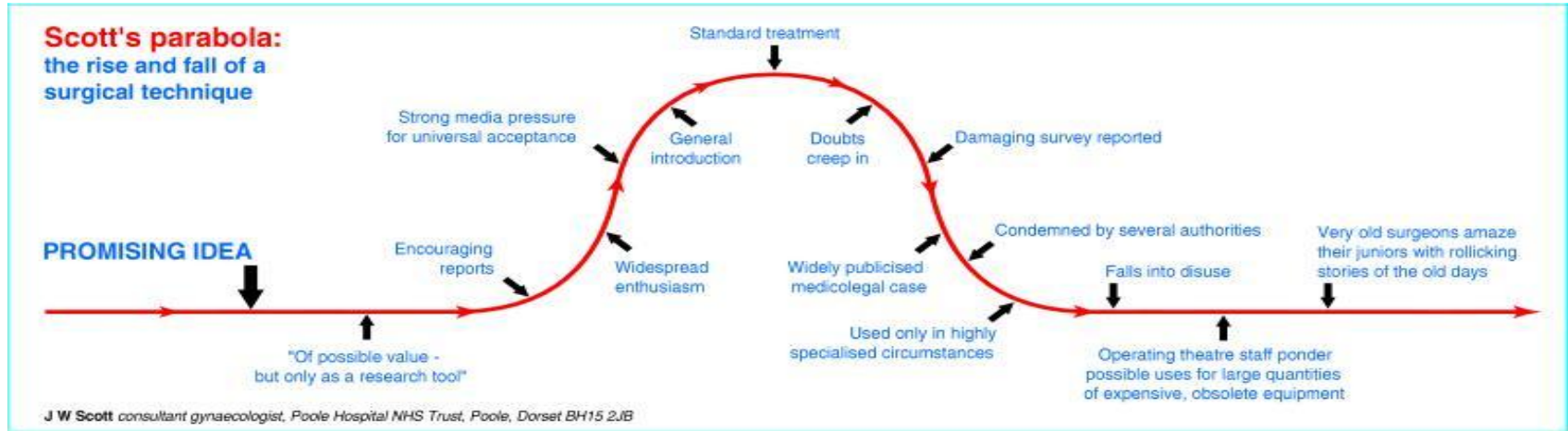
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- Different types of technologies take more or less time to reach the market
- For drug technologies, the stages of development & timelines to marketing are easier to track (e.g., phase I, II, or III trials, & sometimes post-market trials)
- Devices & other non-drug technologies don't necessarily follow this process

# ...When is the technology likely to enter the healthcare system?

- In new areas (e.g., companion diagnostics, stem cell therapies) technologies may follow a more complex & longer development timeline
- Some technologies (e.g., public health interventions or surgical procedures) may enter healthcare without requiring regulatory approval
- Regulatory approval times vary worldwide - what is new or emerging in one country or region may have been available for several years elsewhere

# Technology lifecycle



- Tongue in cheek, but true!
- Most technologies follow something of this S diffusion curve over their lifecycle

# Technology lifecycle

- Information may be needed at various points over the technology's lifecycle, from early alerts and awareness to obsolescence (for possible disinvestment)
- Many technologies that appear promising never make it to the market
- The further from marketing or widespread use the less “good” evidence may be available

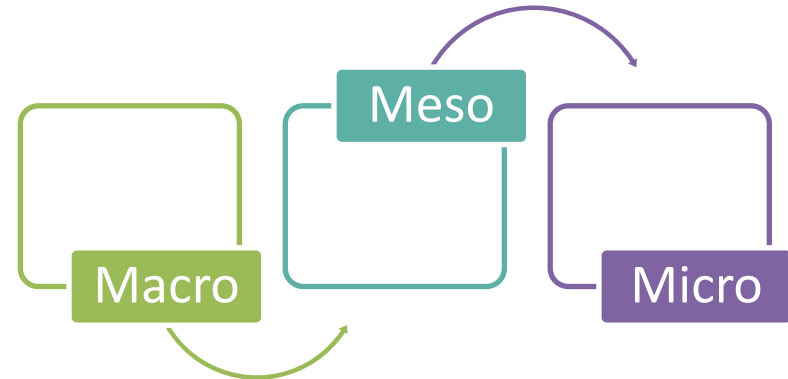
# Current Trends

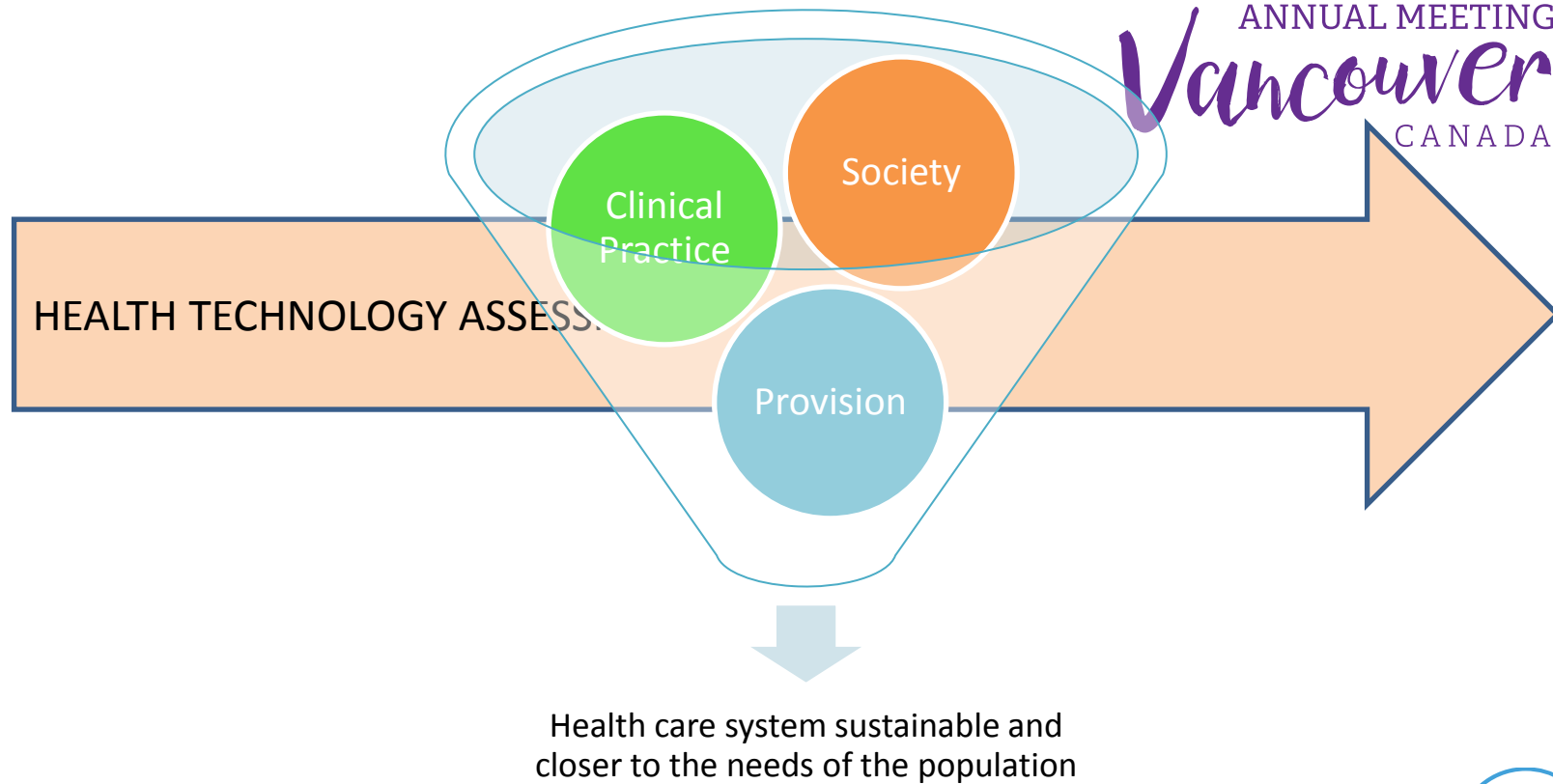
- EUnetHTA
  - Macro decisions
  - Sharing information, actions and methods
  - Low impact on provision
- France:
  - Centralised and regulatory
  - Low impact on provision
- To be closer to provision:
  - HTA in hospitals
    - CEDIT
    - Gemelli
    - Miguel Servet (Zaragoza)
    - Clinic (Barcelona)
    - Txagorritxu hospital
    - INESS
  - Created by the Health provider
    - NICE..
  - Or insurance and providers
    - Kaiser Permanente
    - BlueCross BlueShield



# Trends

- Closer to decision
- Sustainability
- Impact on provision
- Increase stakeholders involvement
- Not just recommendations but involvement in the implementation and the evaluation
- Assessment-Re-assessment
  - Life cycle of technologies





# What we could share...

- Macro level
  - Core elements
  - Implementation low
  - Low impact on provision and prescription
- Meso level
  - Evidence
  - Benchmarking
  - Impact on provision
  - Low impact on prescription
- Micro level
  - Benchmarking
  - High internal validity
  - External validity low
  - High impact on prescription



# Existing HTA units... so similar... so different

- How they are related to the customer
- How they produce information
- How far they involve stakeholders
- Dimensions that they include in the analysis
- Relations with other HTA units or agencies

# Some ideas....

- Health technologies should be considered as a whole
- Life cycle of technologies is a more appropriate concept
- Different processes are comprised
  - Identification of health needs
  - Innovation
  - Effective implementation of technologies
  - Delisting or disinvestment of technologies of low-added or no added value

# Initiatives currently in practice

- Horizon scanning / Early Awareness and Alert Systems
  - EuroScan, HTAi ISG on DEA
- Early Dialogue.
  - JA2 EUnetHTA and Tender DG SanCo;
  - Concept papers and guidances
- Incorporation
  - Innovative purchasing process
    - Coverage with evidence
    - Risk sharing agreements
  - Post-introduction observation
- Disinvestment
  - HTAi ISG on DEA
  - EuroScan
  - Brazil Guideline on Disinvestment
  - Argentinean process on Disinvestment
  - Bahamas analysis of drugs to be reimbursed

# CONCLUSIONS

- Context is important
- Same evidence could lead to different recommendations
- HTA is needed at the three levels
- HTA initiatives that have been focused at the macro level are not successful
- Identify the customer and feed its needs
- Importance of the combination of methods (qualitative and quantitative)