Recent trends and developments in the approach to HTA of medicines

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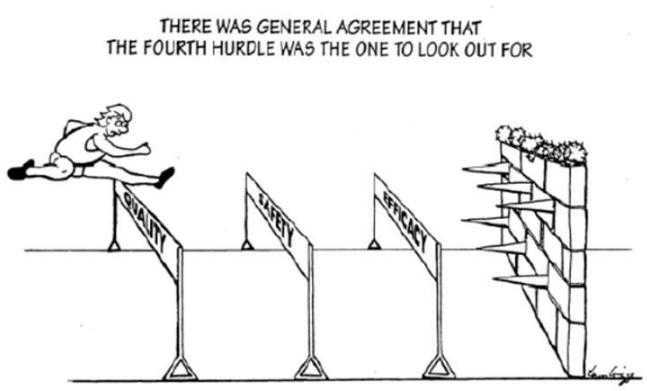
Outline

- What is HTA?
- Current HTA practices
- Methods in HTA
- Future Trends in HTA of medicines / Way forward



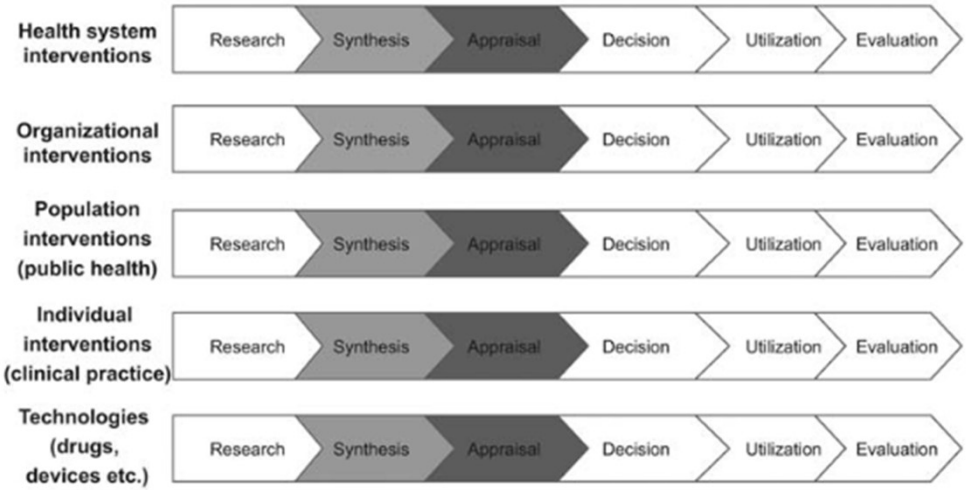
Source: Cai J. Real world Evidence & Market Access Summit 2015

HTA definition (current)

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 in a systematic, transparent, unbiased, robust manner.

Current state of HTA

- Largely based on evidence synthesis of secondary literature
- Existence of evidence gaps: inadequate length of follow-up, few studies, poor study design
- Insufficient evidence
- To inform policy makers, payers, providers and (some extent) patients

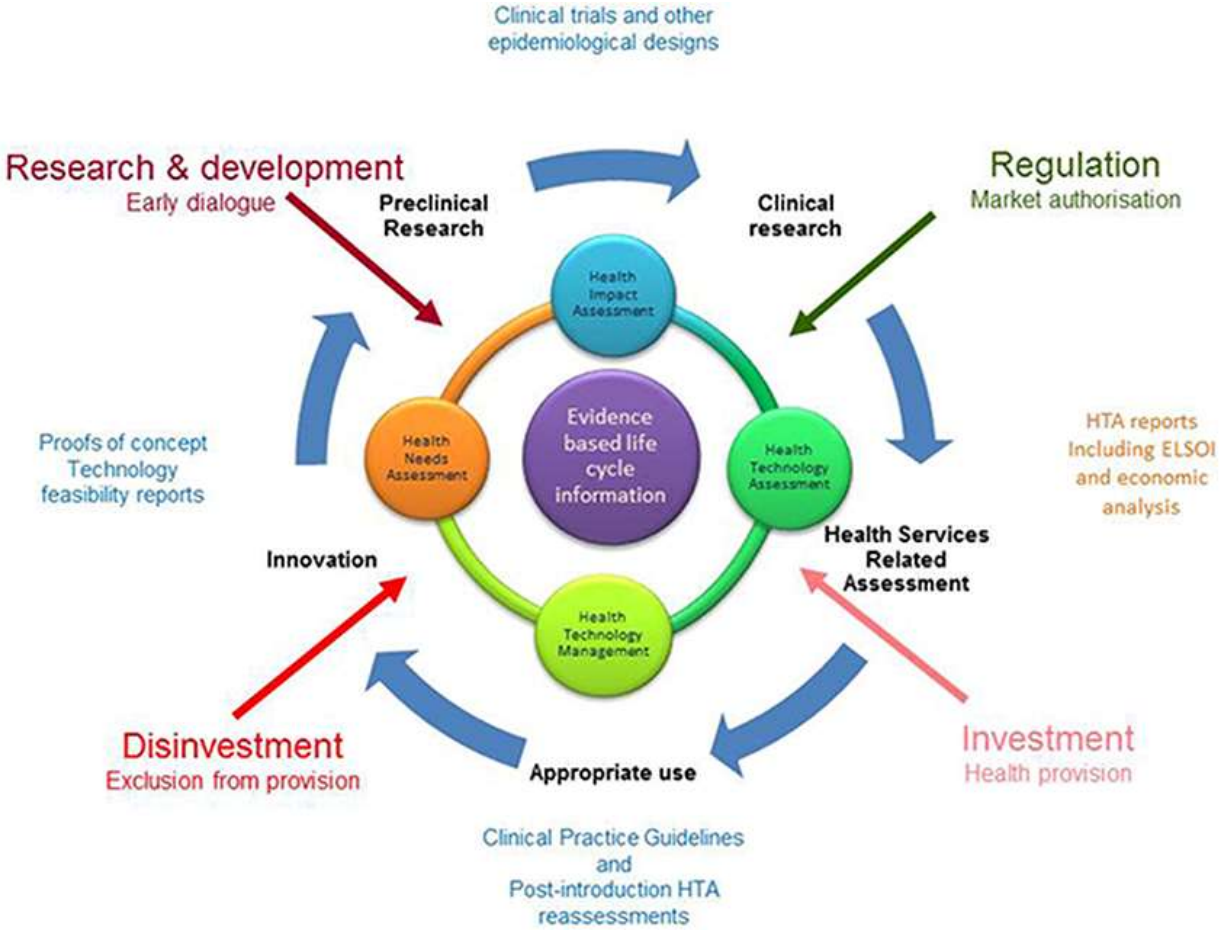


Source: 2008. Garrido et al HTA and health policy-making in Europe. Chap. 8

HTA (new) definition (draft)

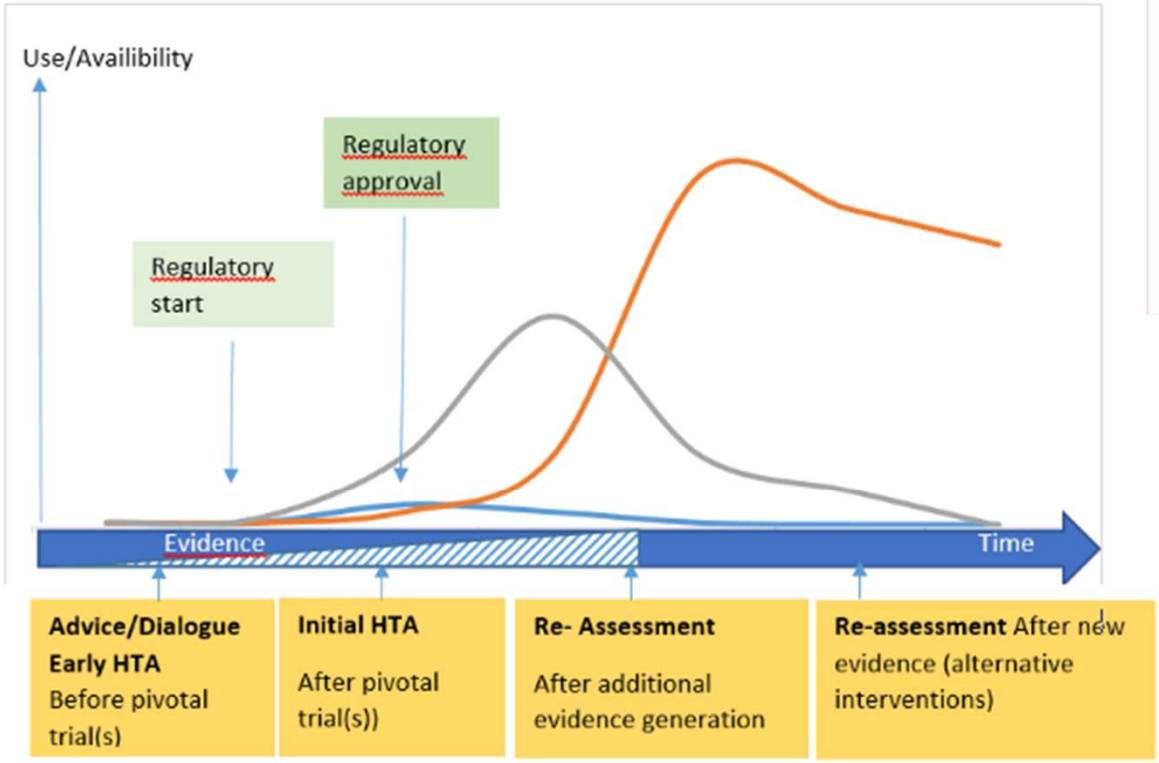
A **multidisciplinary** process that uses explicit and scientifically robust methods to assess the **value** of using a health technology at **different points in its lifecycle**. The process is **comparative, systematic, transparent and involves multiple stakeholders**. The purpose is to inform health policy and decision-making to promote an efficient, sustainable, equitable and high-quality health system.

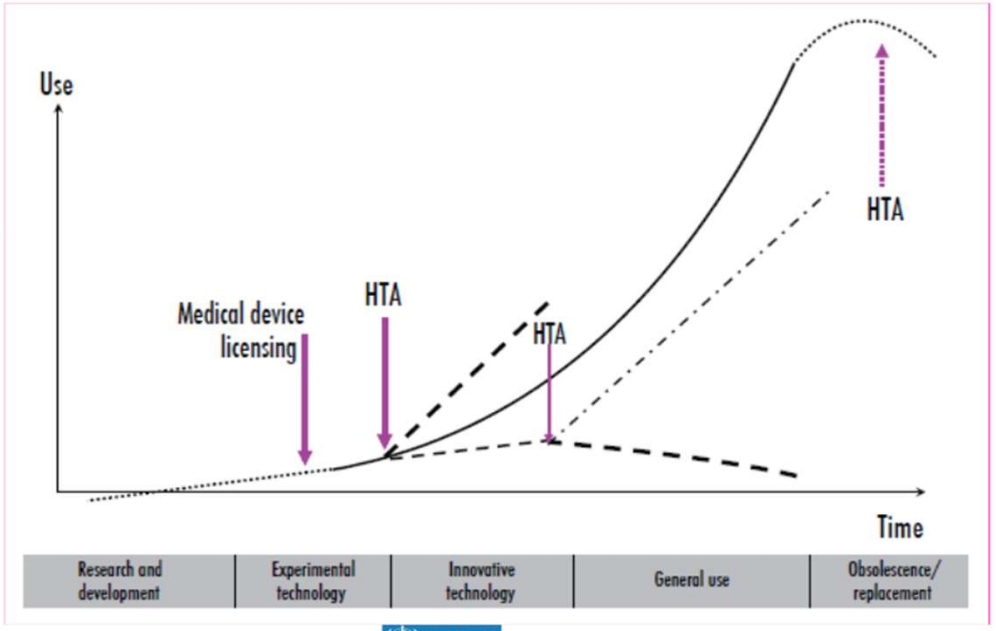
Health Technology Assessment

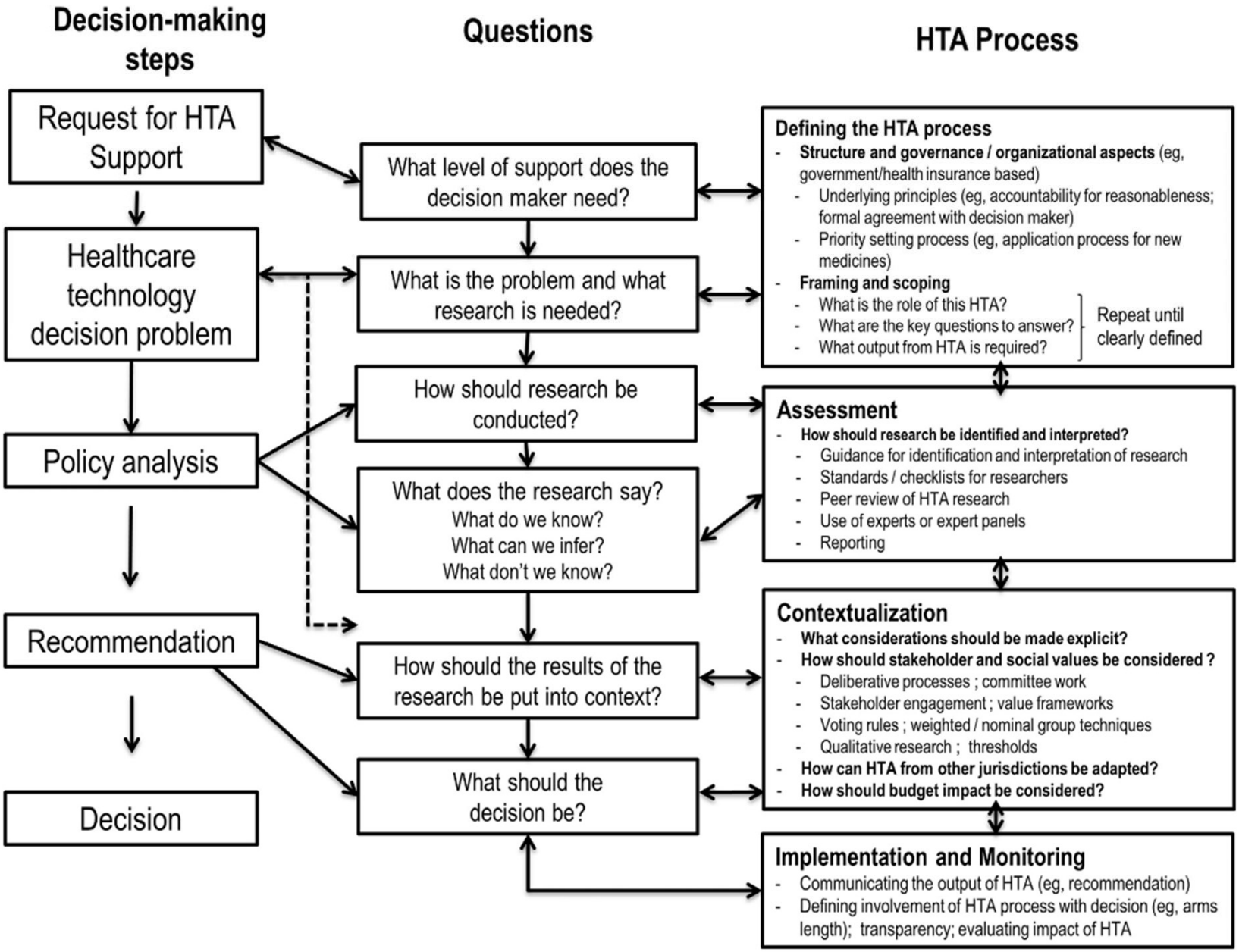


Source: Gutiérrez-Ibarluzea I, Chiumente M and Dauben H-P (2017) The Life Cycle of Health Technologies. Challenges and Ways Forward. *Front. Pharmacol.* 8:14. doi: 10.3389/fphar.2017.00014

HTA and diffusion of health technologies

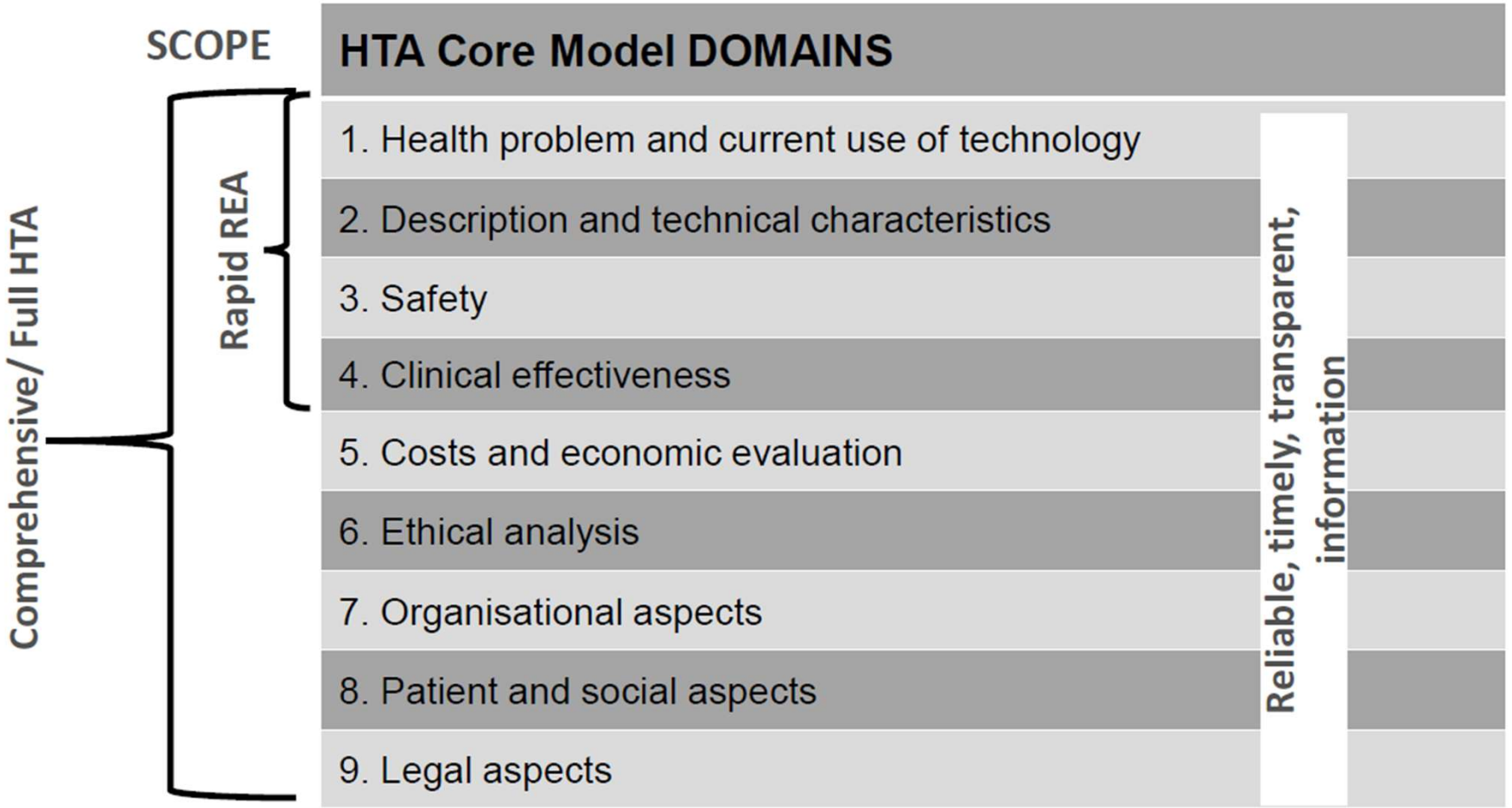






Source: Kristensen. Value in Health, "Identifying the need for good practices in HTA: Summary of the ISPOR HTA Council Working Group Report"

The Domains of the HTA Core Model



Source: EUnetHTA
www.eunethta.eu

Methods in HTA: is it done same way?

❑ Uses a variety of methods?

- It ranges from rapid reviews to statistical modelling approaches
- Budget and time constraints
- Availability of literature (new technology)

	Sweden	Netherlands	Denmark	Germany	United Kingdom	France	Italy	Spain	Poland
Clinical Trial	✓	✓	✓	✓	✓	✓	✓	✓	✓
EPI and observational analyses	✓	✓			✓	✓	✓	✓	✓
Cost and economic analyses	✓	✓	✓	✓	✓	✓	✓	✓	✓
Comparative analyses	✓	✓	✓	✓	✓	✓	✓	✓	✓
Post - marketing surveillance	✓	✓				✓	✓	✓	
Modelling	✓	✓	✓	✓					
Expert - opinion	✓	✓			✓	✓	✓	✓	✓
Group judgement		✓			✓	✓	✓	✓	✓
Systematic review	✓		✓	✓	✓	✓	✓	✓	✓
Meta - analyses	✓		✓	✓	✓	✓	✓	✓	

Source:

Future trends in HTA

- Novel approaches toward implementing HTA
- Patient engagement in HTA processes and health outcomes research
- Health-related biotechnologies and rare diseases
- Assessment of companion diagnostics
- Digital technologies (e-health and m-health)
- Personalized medicine
- Big data

Source: INAHTA. INAHTA_Introduction to HTA-2019

Disruptive innovation in health care

Type of innovation that creates new networks and new organisations based on a new set of values, involving newplayers, which makes it possible to health improve outcomes and other valuable goals, such as equity and efficiency. This innovation displaces older systems and ways of doing things.

Source: 2016. EU Expert Panel on effective ways of investing in health

An innovation that improves a product or service in ways that the market does not expect, typically first by designing for a different set of consumers in a new market, and later by lowering prices in the existing market

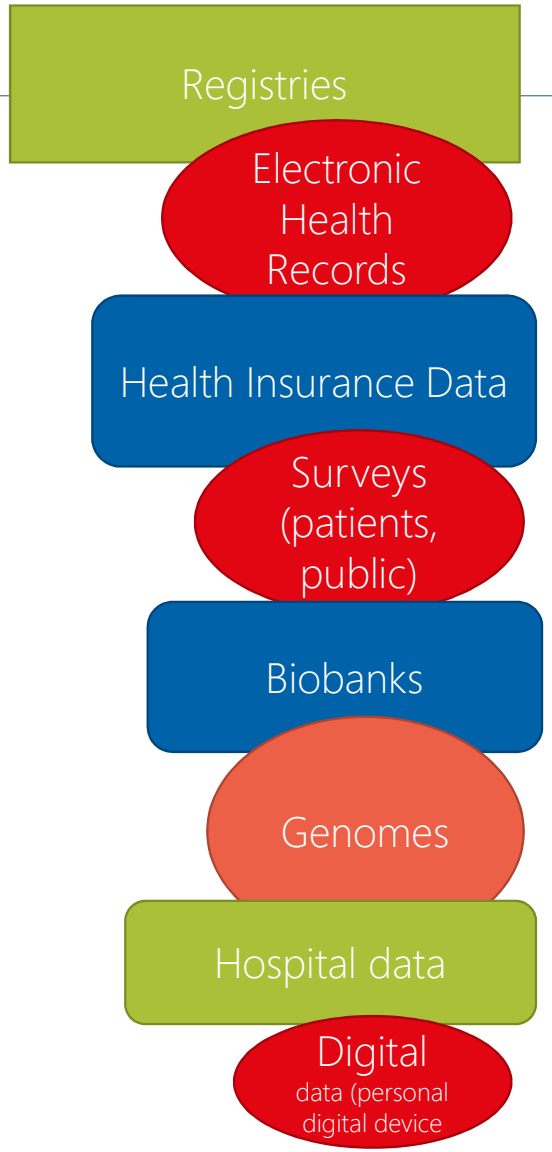
Source: derived from 2018 HTAi Policy Forum background paper

Real World Evidence

Challenges:

- For which information gaps/HTA questions might RWE be acceptable?
- Transferability issues
- Data infrastructure and access to data (quality)
- When to use RWE across the lifecycle?

Source:HTAi GPF 2019 Real-world evidence in context of health technology assessment processes – from theory to action



Big Data: is a large amount of information that is being gathered, aggregated, and analysed by commonly used technological instruments. The presence of Big Data allows population-based health care (improvement) to become routine (Auerswald P, 2015).

HTA of Orphan Medicinal Product (OMPs)

- OMPs usually target life-threatening diseases.
- Clinical benefit/risk ratio may be very positive, while R&D costs are high.
- The amount and type of data needed to conduct useful HTA is usually unavailable at the time of marketing authorisation for OMPs.
- Necessity to broaden the range of criteria considered in assessment of OMPs including qualitative data from PROs and a framework for systematic consideration of ethical and social issues in the appraisal process.

(HTA) Personalized medicine

- Genome/ genetic testing
- Companion diagnostic tests

HTA

- The test must **measure** what is supposed to (analytical validation
- The result (test) must correctly **classify** patients (clinical validation)
- Classification of these patients must then lead to **improved** health outcomes (clinical utility)
- Whole process has to fit into the health care budget of the country (economic evaluation)
- Ethically, socially and legally **accepted**

Source: 2017. CADTH conference. adapted Assessing the value of diagnostic innovation: A growing role for HTA?

(HTA) LDTs

- Evidence requirements are clearly delineated
  - no universal guidance on outcomes to be measured
  - Appropriate study types
  - Performance requirements
  - Comparative effectiveness
- Impact of HTA recommendations varies
- No uniform approach to HTAs of LDTs
- Concern about the quality, safety, effectiveness of tests (genetic tests)
- Tests without clinical utility - > unnecessary burden on society and patients
- When clinical utility is inferred -> payers may tend not to accept the result

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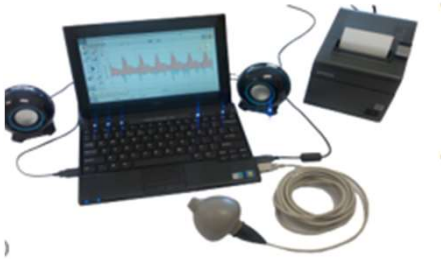
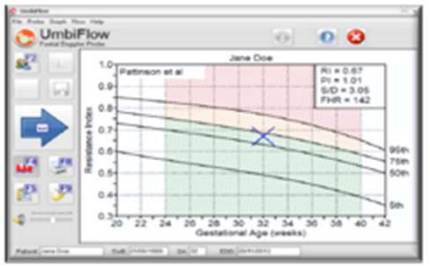
Source: 2017. CADTH conference. adapted Assessing the value of diagnostic innovation: A growing role for HTA?

(HTA) Doppler ultrasound

- Criteria for HTA -> BoD, Clinical impact, level of interest, target population
- Stakeholder engagement throughout the HTA processes
- Not only use of secondary evidence, data used from field study.
- Consultation of experts
- Contextual (equity, access, system capacity, affordability)
- Decision for procurement





Evolution (and challenges) of HTA

- Goal of better reports, better health care, better health
- Continuous development of new technologies -> new methodological approaches
- Research and HTAs on public health interventions (prevention)
- HTA and re-evaluation for potential disinvestment
- HTA in the whole lifecycle of a HT, i.e. shortly before and directly after market launch (currently mainly for drugs)

Source: INAHTA. INAHTA_Introduction to HTA-2019

Evolution (and challenges) of HTA

- Integration of broader considerations (implementation issues, environmental impact of technology)
- Increased stakeholder involvement (patients, industry, decision-makers)
- Merging HTA agencies into a broader institutions
- Growing networks and large agencies versus local capacity
- Moving from project to permanent collaboration in HTA networks

-> CAPACITY BUILDING

Source: INAHTA. INAHTA_Introduction to HTA-2019

HTA in SA

If you want to go somewhere, it is best to find someone who has already been there

Robert Kiyosaki

Collaboration and Cooperation →

SAHTAS
Southern African Health Technology Assessment Society

scientific and professional society for all those who produce, use, or encounter HTA in Southern Africa; neutral forum for collaboration and the sharing of information and expertise.

→ **CAPACITY BUILDING in HTA** at University of Pretoria in cooperation with SAHTAS & CMeRC & Supranational organizations (HTAi, INAHTA, EUnetHTA)

Thank You

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