DECIDE

Introduction to Health Interventions, Policy and Services

Health Technology Assessment – HTA

Luís Filipe Azevedo

lazevedo@med.up.pt

Summary

- Technology and Health Technology
- Fundamental characteristics of technology
  - Nature
  - Purpose
  - Stage of diffusion
- Adoption and diffusion of innovation
- Technology Assessment and Health Technology Assessment
- Stakeholders and reference HTA organizations
- Operational Phases in HTA
- Properties, attributes and impacts assessed in HTA
  - Technical properties
  - Safety
  - Efficacy and effectiveness
  - Economic impact and efficiency
  - Psychological, social and ethical impact
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- Methods of assessment in HTA
  - Primary data
  - Evidence synthesis
  - Decision analysis and modelling
  - Consensus methods
  - Ethical analysis
  - Economic evaluation

Technology and health technology

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Health Technology Assessment

- **Technology**

Technology is a practical application of scientific knowledge used to solve a concrete problem

Practical applications of scientific knowledge

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Health Technology Assessment

The development and application of healthcare technologies was the single main factor explaining the fast and accelerating progress of medicine, healthcare and the health sciences in general; and also the main factor explaining the significant improvements in terms of population health and outcomes during the last century, and particularly during the last decades.

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- **Technology**
  - Drugs
  - Medical devices
  - Procedures (surgical, screening, prevention, intervention, etc.)
  - Diagnostic technologies
  - Support and information management systems (information systems, electronic health recods, decision support systems, etc.)
  - Administrative and management systems
  - Organization and structuring models and systems

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- **Why technology is and will be increasingly important? (I)**
  - Advances in science and engineering
  - Intellectual property, especially patent protection
  - Aging populations
  - Increasing prevalence of chronic diseases
  - Emerging pathogens and other disease threats

Health Technology Assessment

- **Why technology is and will be increasingly important? (II)**
  - Changes in payers & providers managerial structures
  - Financial incentives of technology companies, clinicians, hospitals, and others
  - Public demand driven by direct-to-consumer advertising, mass media reports, social media, and consumer awareness and advocacy
  - Off-label use of drugs, biologics, and devices

Health Technology Assessment

- **Why technology is and will be increasingly important? (III)**
  - "Cascade" effects of unnecessary tests, unexpected results, or patient or physician anxiety
  - Clinician specialty training at academic medical centres
  - Provider competition to offer state-of-the-art technology
  - Malpractice avoidance
  - Strong or growing economies

Fundamental characteristics of technology

Nature, Purpose and Stage of diffusion

Health Technology Assessment

- **Technology – Fundamental characteristics**
  - **(Physical) Nature**
  - **Purpose**
  - **Stage of diffusion**

Health Technology Assessment

- **Health technology**
  - **Health technology** is the **practical application of knowledge to improve or maintain individual and population health**
  - Thus, they have **applications in health promotion and in the prevention, early detection, screening, diagnosis, treatment, management and follow up of disease**
  - A large and heterogeneous group of technologies including drugs, medical devices, procedures (surgical, screening, prevention, intervention, etc.), diagnostics, support and information management systems (information systems, electronic health records, decision support systems, etc.), administrative and management systems, organization models and systems

Health Technology Assessment

- **Health technology – (Physical) Nature**
  - *Drugs:* e.g., aspirin, beta-blockers, antibiotics, HMG-CoA reductase inhibitors ("statins")
  - *Biologics:* vaccines, blood products, cellular and gene therapies
  - *Devices, equipment and supplies:* e.g., cardiac pacemakers, CT scanners, surgical gloves, diagnostic test kits
  - *Medical and surgical procedures:* e.g., psychotherapy, nutrition counseling, coronary angiography, gall bladder removal
  - *Support systems:* e.g., electronic patient record systems, telemedicine systems, drug formularies, blood banks, clinical laboratories
  - *Organizational and managerial systems:* e.g., prospective payment using diagnosis-related groups, alternative health care delivery configurations, clinical pathways, total quality management programs

Health Technology Assessment

- **Health technology – Purpose**
  - *Prevention*: protect against disease by preventing it from occurring, reducing the risk of its occurrence, or limiting its extent or sequelae (e.g., immunization, hospital infection control program, fluoridated water supply)
  - *Screening*: detect a disease, abnormality, or associated risk factors in asymptomatic people (e.g., Pap smear, tuberculin test, mammography, serum cholesterol testing)
  - *Diagnosis*: identify the cause and nature or extent of disease in a person with clinical signs or symptoms (e.g., electrocardiogram, serological test for typhoid, x-ray for possible broken bone)
  - *Treatment*: designed to improve or maintain health status, avoid further deterioration, or provide palliation (e.g., antiviral therapy, coronary artery bypass graft surgery, psychotherapy, drugs for cancer pain)
  - *Rehabilitation*: restore, maintain or improve a physically or mentally disabled person's function and well-being (e.g., exercise program for post-stroke patients, assistive device for severe speech impairment, incontinence aid)

Health Technology Assessment

- **Health technology – Stage of Diffusion**
  - *Future:* in a conceptual stage, anticipated, or in the earliest stages of development
  - *Experimental:* undergoing bench or laboratory testing using animals or other models
  - *Investigational:* undergoing initial clinical (i.e., in humans) evaluation for a particular condition or indication
  - *Established:* considered by providers to be a standard approach to a particular condition or indication and diffused into general use
  - *Obsolete/outmoded/abandoned:* superseded by other technologies or demonstrated to be ineffective or harmful

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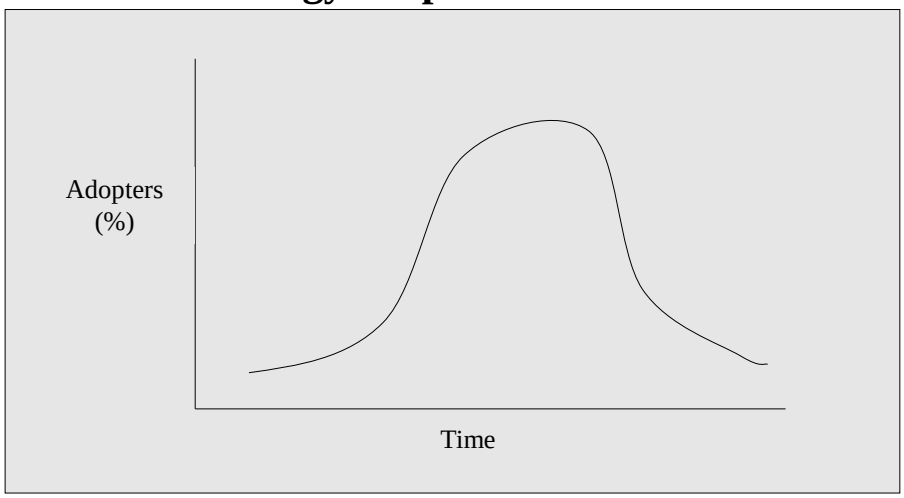
Technology adoption / diffusion curve



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Rogers' model of adoption and difusion of inovation

Rogers, E. M. (1962). *Diffusion of innovations*. New York: Free Press.

"Be not the first by whom the new is tried, nor the last to lay the old aside"

Alexander Pope

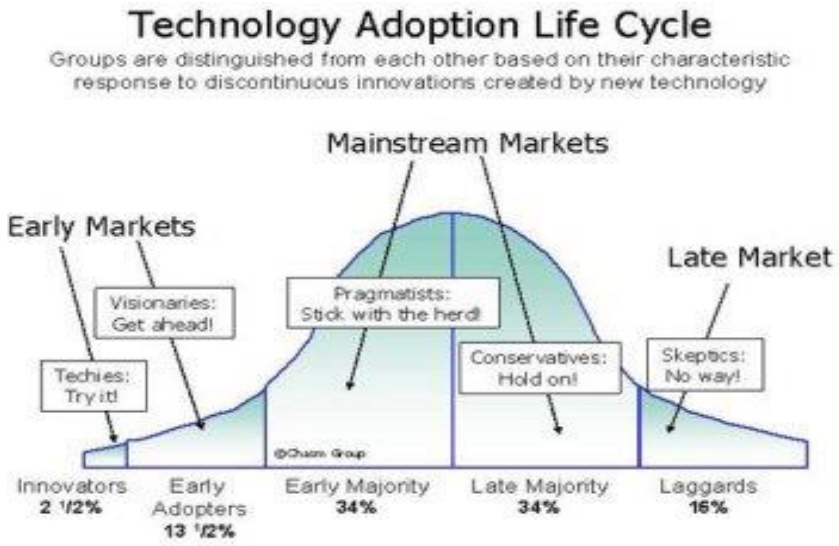
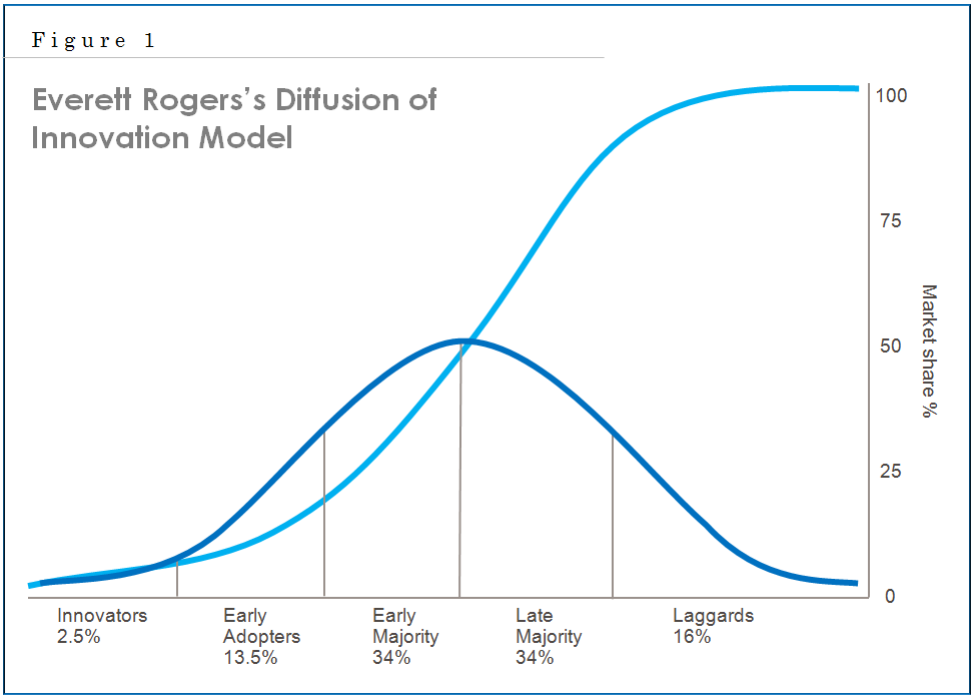
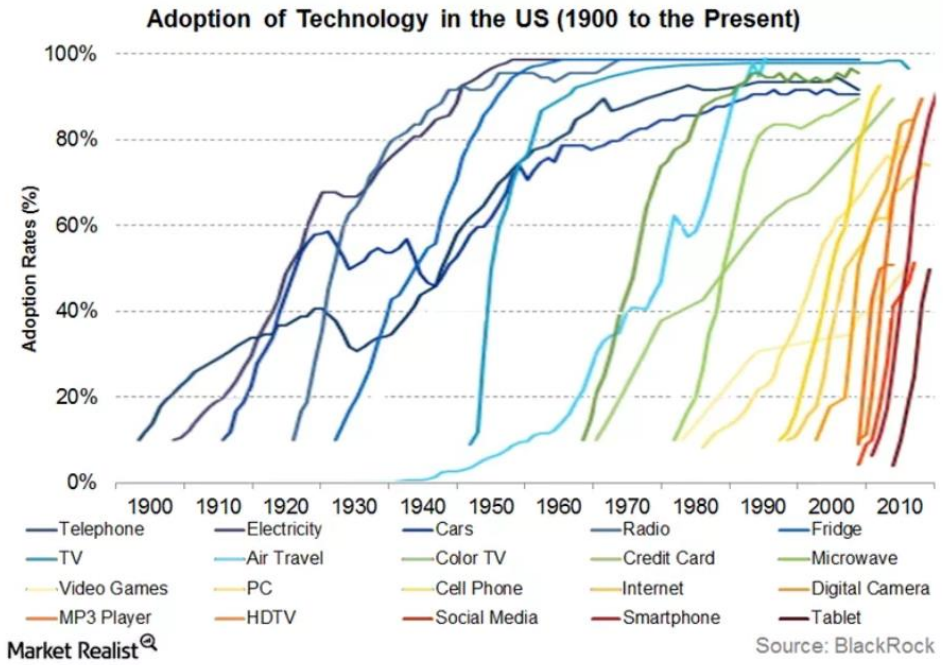


Figure 1





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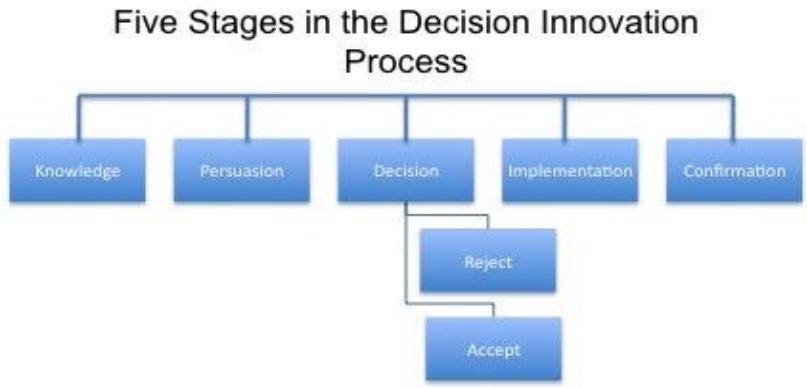

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Technology assessment and health technology assessment

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Health Technology Assessment

The development and application of healthcare technologies was the single main factor explaining the fast and accelerating progress of medicine, healthcare and the health sciences in general; and also the main factor explaining the significant improvements in terms of population health and outcomes during the last century, and particularly during the last decades.

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- … However, the development and application of technologies is associated with **many issues and areas of discussion, uncertainty and controversy**
  - Weighting **Benefits** vs. **Risks and Harms**
  - Weighting **Benefits** vs. **Costs**
  - **Novelty** vs. **Objective Outcomes**
  - **Market and Commercial Forces** vs. **Objective Assessments**
  - **Technological complexity** vs. **Technological necessity**

Health Technology Assessment

- **Stakeholders**
  - Research, innovation and development centres
  - Technology producers
  - Private and public funding agencies
  - Healthcare funding entities
  - Healthcare systems and healthcare providers
  - Health authorities and regulatory agencies
  - Healthcare professionals
  - Patients
  - Society

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- **Different intertwined stakeholders with…**
  - Different perspectives, aims and objectives
  - Different time horizons
  - Potential conflicts and conflict of interests
  - Need for compromise, balance, equity and rationality

RATIONALITY

EQUITY

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- The origins of **Technology Assessment**

The term "technology assessment" was introduced in 1965 during deliberations of the Committee on Science and Astronautics of the US House of Representatives. Congressman Emilio Daddario emphasized that the purpose of TA was to serve policymaking:

> *[T]echnical information needed by policymakers is frequently not available, or not in the right form. A policymaker cannot judge the merits or consequences of a technological program within a strictly technical context. He has to consider social, economic, and legal implications of any course of action (US Congress, House of Representatives 1967).*

> *Technology assessment would aid the Congress to become more effective in assuring that broad public as well as private interests are fully considered while enabling technology to make the maximum contribution to our society's welfare (National Academy of Engineering 1969).*

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Health Technology Assessment

- Definition of **Technology Assessment**

Technology assessment (TA) is a category of policy studies, intended to provide decision makers with information about the possible impacts and consequences of a new technology or a significant change in an old technology. It is concerned with both direct and indirect or secondary consequences, both benefits and disbenefits, and with mapping the uncertainties involved in any government or private use or transfer of a technology. TA provides decision makers with an ordered set of analyzed policy options, and an understanding of their implications for the economy, the environment, and the social, political, and legal processes and institutions of society (Coates 1992).

Technology assessment is a form of policy research that examines short- and long-term social consequences (for example, societal, economic, ethical, legal) of the application of technology. The goal of technology assessment is to provide policy-makers with information on policy alternatives (Banta 1993).

Health Technology Assessment

- Definition of **Health Technology Assessment**

We shall use the term assessment of a medical technology to denote any process of examining and reporting properties of a medical technology used in health care, such as safety, efficacy, feasibility, and indications for use, cost, and cost-effectiveness, as well as social, economic, and ethical consequences, whether intended or unintended (Institute of Medicine 1985).

[HTA] is a multidisciplinary field of policy analysis. It studies the medical, social, ethical, and economic implications of development, diffusion, and use of health technology (International Network of Agencies for Health Technology Assessment 2002).

Health Technology Assessment

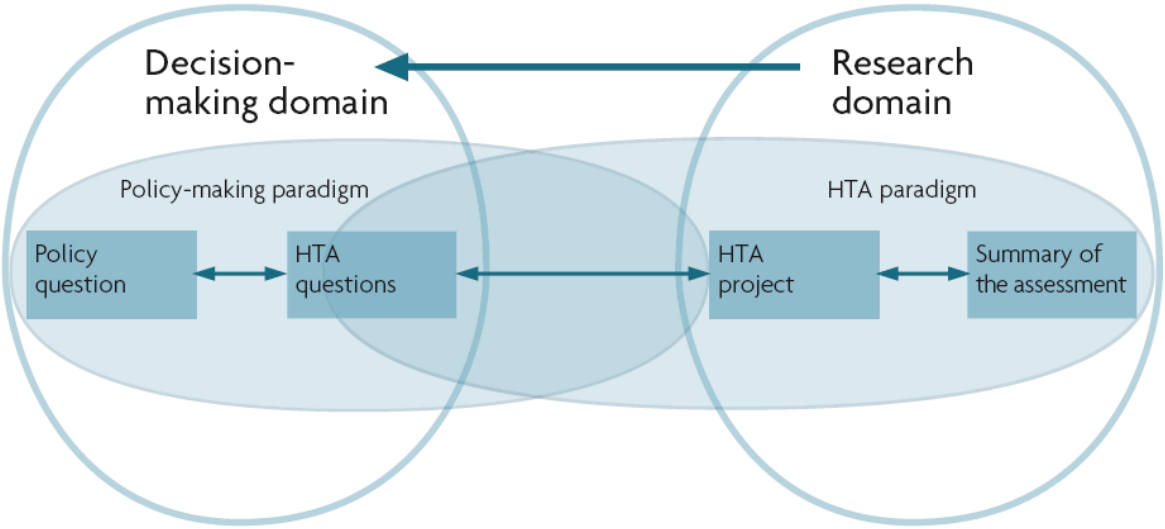
Definition

- Is a **multidisciplinary and transdisciplinary** field of **scientific research assessing, exploring and reporting** the **properties, characteristics, consequences and impacts** of health technologies, aiming to **support and inform decision-making processes in health and medicine** at all levels, **from patients to national health policy**.

Health Technology Assessment

Aims

- Adequately **analyse, synthesise and report** on the best available **scientific knowledge and experience** regarding the **properties and impacts (medical, social, economic, ethical, regulatory and legal) of health technologies** using **systematic, transparent, robust and unbiased** methods and approaches.
- Ultimately, it aims to **support and inform decision making processes and health policy** regarding the **safe, effective, efficient and patient-centred use of technology to maximize value and health gains**.



Based on Kristensen FB et al. 2002 (3).

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Health Technology Assessment

Orientation

- It is not necessarily centred on a particular technology
- It may have different orientations
  - **Centred around one or several technologies**
  - **Centred around a clinical problem, disease or clinical indication**
  - **Centred around a project**

Health Technology Assessment

Orientation

- **Technology-oriented assessments**
  - Intended to determine the characteristics or impacts of particular technologies. For example, a government agency may want to determine the clinical, economic, social, professional, or other impacts of cochlear implants, cervical cancer screening, PET scanners, or widespread adoption of electronic health record systems.
- **Problem-oriented assessments**
  - Focus on solutions or strategies for managing a particular disease, condition, or other problem for which alternative or complementary technologies might be used. For example, clinicians and other providers concerned with the problem of diagnosis of dementia may call for HTA to inform the development of clinical practice guidelines involving some combination or sequence of clinical history, neurological examination, and diagnostic imaging using various modalities.
- **Project-oriented assessments**
  - Focus on a local placement or use of a technology in a particular institution, program, or other designated project. For example, this may arise when a hospital must decide whether or not to purchase a PET scanner, considering the facilities, personnel, and other resources needed to install and operate a PET scanner; the hospital's financial status; local market potential for PET services; competitive factors; etc.

Health Technology Assessment

Timing

- What is the right time to perform an HTA?
- Early on the process or later on the process?
- "It is always too early until, unfortunately, it is suddenly too late!" (Buxton, 1987)
- The problem of the "moving target"
- Partial and rapid HTAs

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Health Technology Assessment

Properties, attributes and impacts to be assessed

- Technical properties
- Safety
- Efficacy and/or Effectiveness
- Economic attributes or impacts
- Organizational and professional impact
- Ethical, social, legal and/or political impact

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Agencies and organizations conducting HTA

- Regulatory agencies
- Government and private sector payers
- Managed care organizations
- Health professions organizations
- Standards setting organizations
- Hospitals and health care networks
- Group purchasing organizations
- Patient and consumer organizations
- Government policy research agencies
- Private sector assessment/policy research organizations
- Academic health centers
- Biomedical research agencies
- Health product companies
- Venture capital groups and other investors

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Reference agencies and organizations of HTA

- HTA International
  [www.htai.org]
- International Network of Agencies for Health Technology Assessment (INAHTA)
  [www.inahta.org]
- European network for Health Technology Assessment – EUnetHTA
  [www.eunethta.net]

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Reference agencies and organizations of HTA

- National Institute for Clinical Excellence (NICE) [www.nice.org.uk] and [www.hta.nhsweb.nhs.uk]
- Agency for Healthcare Research and Quality (AHRQ) [www.ahrq.gov]
- Centre for Applied Health Services Research and Technology Assessment (CAST) [www.sdu.dk/Om_SDU/Institutter_centre/CAST.aspx?sc_lang=en]

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Reference agencies and organizations of HTA

- AcademyHealth [www.academyhealth.org]
- Cochrane Collaboration [www.cochrane.org]
- International Health Economics Association [www.health economics.org]
- International Society for Pharmacoeconomics and Outcomes Research [www.ispor.org]
- Society for Medical Decision Making [www.smdm.org]

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Operational phases in HTA

1. Identify assessment topics
2. Specify the assessment problem
3. Determine locus of assessment
4. Retrieve evidence
5. Collect new primary data (as appropriate)
6. Appraise/interpret evidence
7. Integrate/synthesize evidence
8. Formulate findings and recommendations
9. Disseminate findings and recommendations
10. Monitor impact

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Health Technology Assessment – Operational Phases

- Submission of an assessment request/identification of an assessment need
- Prioritization
- Commissioning
- Conducting the assessment
  - Definition of policy question(s)
  - Elaboration of HTA protocol
  - Collecting background information/determination of the status of the technology
  - Definition of the research questions
  - Sources of data, appraisal of evidence, and synthesis of evidence for each of:
    - Safety
    - Efficacy/effectiveness
    - Psychological, social, ethical
    - Organizational, professional
    - Economic
  - Draft elaboration of discussion, conclusions, and recommendations
  - External review
  - Publishing of final HTA report and summary report
- Dissemination
- Use of HTA
- Update of the HTA

Properties, attributes and impacts assessed in HTA

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Properties, attributes and impacts to be assessed

- Technical properties
- Safety
- Efficacy and/or Effectiveness
- Economic attributes or impacts
- Organizational and professional impact
- Ethical, social, legal and/or political impact

Health Technology Assessment

- **Technical properties**
  - Nature, purpose and stage of diffusion
  - Description and technical characteristics of technology
  - Presentation and instructions for use
  - Clinical indications

Health Technology Assessment

- **Safety**
  - Unintended current or future risks
  - Adverse reactions and adverse events
  - Morbidity and disability associated with the technology
  - Mortality associated with the technology

Health Technology Assessment

- **Safety**

HMA Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

Guideline on good pharmacovigilance practices (GVP)

Annex I - Definitions (Rev 4)

9 October 2017
EMA/876333/2011 Rev 4*

Adverse event (AE)

Any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment [Dir 2001/20/EC Art 2(m)].

An adverse event can therefore be any unfavourable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product (see GVP Annex IV, ICH-E2D Guideline).

Health Technology Assessment

- **Safety**

Guideline on good pharmacovigilance practices (GVP)
Annex I - Definitions (Rev 4)

Adverse reaction; synonyms: Adverse drug reaction (ADR), Suspected adverse (drug) reaction, Adverse effect, Undesirable effect

A response to a medicinal product which is noxious and unintended [DIR 2001/83/EC Art 1(11)][1].

Response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility (see GVP Annex IV, ICH-E2A Guideline). An adverse reaction, in contrast to an adverse event, is characterised by the fact that a causal relationship between a medicinal product and an occurrence is suspected. For regulatory reporting purposes, if an event is spontaneously reported, even if the relationship is unknown or unstated by the by healthcare professional or consumer as primary source, it meets the definition of an adverse reaction (see GVP Annex IV, ICH-E2D). Therefore all spontaneous reports notified by healthcare professionals or consumers are considered suspected adverse reactions, since they convey the suspicions of the primary sources, unless the primary source specifically state that they believe the event to be unrelated or that a causal relationship can be excluded.

Adverse reactions may arise from use of the product within or outside the terms of the marketing authorisation or from occupational exposure [DIR 2001/83/EC Art 101(1)]. Use outside the marketing authorisation includes off-label use, overdose, misuse, abuse and medication errors.

Health Technology Assessment

- **Safety**

Guideline on good pharmacovigilance practices (GVP)
Annex I - Definitions (Rev 4)

Unexpected adverse reaction

An adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics [DIR 2001/83/EC Art 1(13)][17].

Serious adverse reaction

An adverse reaction which results in death, is life-threatening, requires in-patient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect [DIR 2001/83/EC Art 1(12)].

Life-threatening in this context refers to a reaction in which the patient was at risk of death at the time of the reaction; it does not refer to a reaction that hypothetically might have caused death if more severe (see GVP Annex IV, ICH-E2D Guideline).

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- **Efficacy and Effectiveness**
  - Mortality and Survival
  - Morbidity
  - Disability
  - Quality of life
  - Quality adjusted life years (QALYs)
  - Other patient reported outcome measures (PROMs)

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Efficacy	Effectiveness	Source
The ability of a particular medical action in altering the natural history of a particular disease for the better under ideal conditions.	The ability of a particular medical action in altering the natural history of a particular disease for the better under actual conditions of practice and use	Cochrane (9)
The probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under ideal circumstances of use.	The benefit of a technology under average conditions of use	U.S. Congress (59)
Maximum achievable benefit	Achieved benefit	Williamson (61)
Can it work? Does the maneuver, procedure, or service do more good than harm to people who fully comply with the associated recommendations or treatment?	Does it work? Does the maneuver, procedure, or service do more good than harm to those people to whom it is offered?	Sackett (54)
What works under carefully controlled conditions, such as RCTs	What works in day-to-day clinical practice	Rettig (51)

Table 9. Evaluation of Efficacy and Effectiveness for Diagnostic Interventions

Level	Typical measures
Technical efficacy	• Physical parameters describing technical performance of the test (e.g., image quality)
Diagnostic accuracy efficacy	• Sensitivity (% of positives among ill) • Specificity (% of negatives among healthy) • Accuracy (% of correct diagnoses) • Likelihood ratio (likelihood for a given test result in a patient with the target disorder compared to the likelihood of the same result in a patient without the target disorder; details at http://cebm.jr2.ox.ac.uk/docs/likerats.html)
Diagnostic thinking efficacy/effectiveness	• Post-test odds/probability compared to pre-test odds/probability in target population • % of cases in which test is judged "helpful" to making diagnosis
Therapeutic effectiveness	• % of cases in which test is judged "helpful" in planning therapy • % of therapeutic procedures avoided due to test information
Health-related effectiveness (patient outcomes)	• Mortality/morbidity avoided with test • Changes in quality of life through use of test

Source: Adapted from Flynn and Adams (20) and Fryback and Thornbury (21).

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- **Economic impact**
  - Costs and changes in costs
  - Economic Evaluation
    - Partial Economic Evaluations – Cost analysis
    - Full Economic Evaluations
      - Cost-minimization analysis
      - Cost-Benefit analysis
      - Cost-Effectiveness analysis
      - Cost-Utility analysis
  - Prioritization, equity and distributive justice

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- **Psychological, social and ethical impact**
  - Acceptance and adherence
  - Satisfaction
  - Demand and supply
  - Preferences
  - Information needs
  - Guidance and counselling

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- **Organizational and professional impact**
  - Health services utilization
  - Changes in settings and location of treatment and follow up
  - Changes in length of stay
  - Changes in human an material resources
  - Organizational changes
  - Education, training and updating needs

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- **Legal and political impact**
  - Legal framework
  - Regulatory marketing authorisation process
  - Regulatory reimbursement process
  - Social and media impact
  - Prioritization of investment, health policy and health equity

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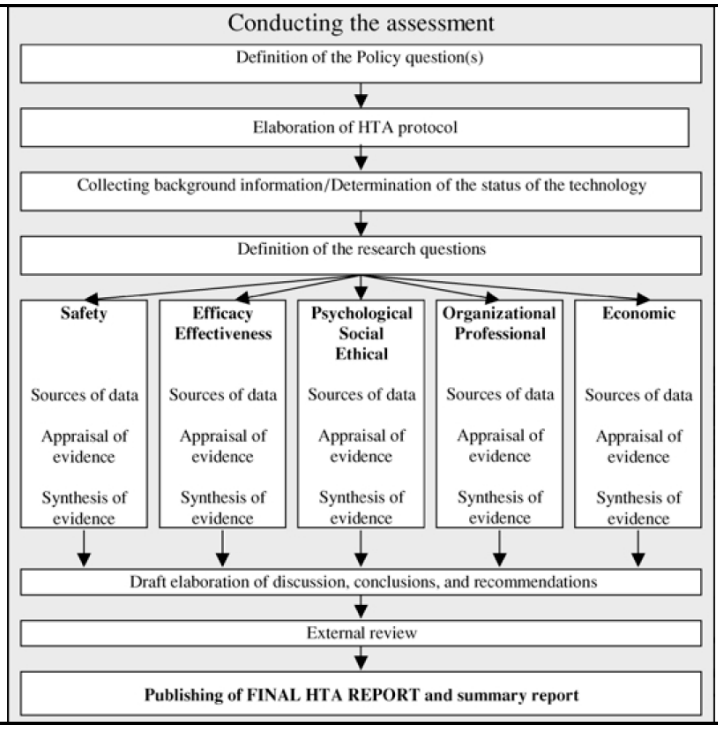

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- **Example I: Questions in an HTA on HPV vaccination**
  - *What are the effects and side effects of HPV vaccination?*
  - *Are there any interactions with other vaccines in the childhood immunization program?*
  - *What influence has choice of vaccination age on acceptance of the vaccination?*
  - *Are there any ethical problems in relation to the HPV vaccination?*
  - *What organizational consequences will different vaccination strategies have?*
  - *What are the benefits compared with the costs for different models of the vaccination program?*

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- **Example II: Questions in an HTA on colorectal cancer screening**
  - *What is the status of current screening methods and strategies?*
  - *Are there any alternative methods and strategies?*
  - *What are the organizational consequences of alternative strategies?*
  - *What are the patient-related aspects of the problem?*
  - *What are the consequences in terms of resources?*
  - *How will a possible screening influence organization and economy?*

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Methods in HTA

Methods in HTA

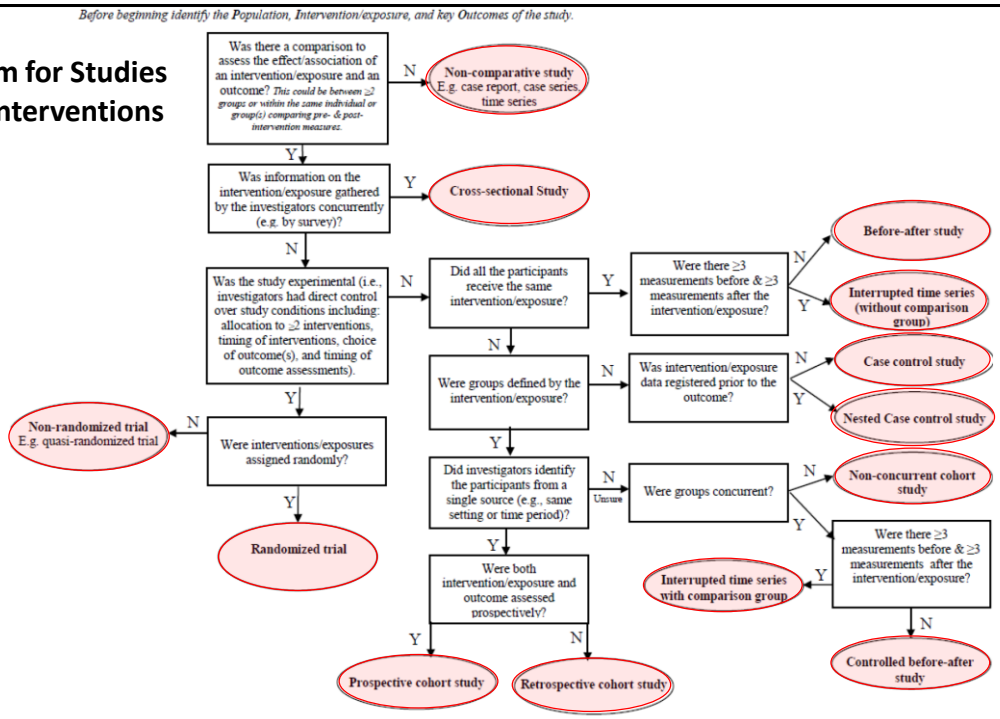
- **Methods based on primary data**
  - Primary data methods involve **collection of original data**, ranging from more scientifically rigorous approaches for determining the causal effect of health technologies, such as randomized controlled trials (RCTs), to less rigorous ones, such as case series. These study designs can be described and categorized based on multiple attributes or dimensions:
    - Experimental studies
    - Quasi-experimental studies
    - Observational studies

Methods in HTA

- **Methods based on primary data**

Experimental Studies	Non-experimental studies
Randomized controlled trial	Prospective cohort
Randomized cross-over trial	Retrospective cohort
N-of-1-trial	Case-control
Group randomized trial	Cross-sectional
Pragmatic trials (randomized)	Interrupted time series with comparison
	Non-concurrent cohort
	Interrupted time series without comparison
	Before-and-after
	Time series
	Case Series
	Case study

Design Algorithm for Studies of Health Care Interventions



Box III-13. Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence

Question	Step 1 (Level 1*)	Step 2 (Level 2*)	Step 3 (Level 3*)	Step 4 (Level 4*)	Step 5 (Level 5)
How common is the problem?	Local and current random sample surveys (or censuses)	Systematic review of surveys that allow matching to local circumstances**	Local non-random sample**	Case-series**	n/a
Is this diagnostic or monitoring test accurate? (Diagnosis)	Systematic review of cross sectional studies with consistently applied reference standard and blinding	Individual cross sectional studies with consistently applied reference standard and blinding	Non-consecutive studies, or studies without consistently applied reference standards**	Case-control studies, or "poor or non-independent reference standard**	Mechanism-based reasoning
What will happen if we do not add a therapy? (Prognosis)	Systematic review of inception cohort studies	Inception cohort studies	Cohort study or control arm of randomized trial*	Case-series or case-control studies, or poor quality prognostic cohort study**	n/a
Does this intervention help? (Treatment Benefits)	Systematic review of randomized trials or *n*-of-1 trials	Randomized trial or observational study with dramatic effect	Non-randomized controlled cohort/follow-up study**	Case-series, case-control studies, or historically controlled studies**	Mechanism-based reasoning
What are the COMMON harms? (Treatment Harms)	Systematic review of randomized trials, systematic review of nested case-control studies, *n*-of-1 trial with the patient you are raising the question about, or observational study with dramatic effect	Individual randomized trial or (exceptionally) observational study with dramatic effect	Non-randomized controlled cohort/follow-up study (post-marketing surveillance) provided there are sufficient numbers to rule out a common harm. (For long-term harms the duration of follow-up must be sufficient.)**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning
What are the RARE harms? (Treatment Harms)	Systematic review of randomized trials or *n*-of-1 trial	Randomized trial or (exceptionally) observational study with dramatic effect			
Is this (early detection) test worthwhile? (Screening)	Systematic review of randomized trials	Randomized trial	Non -randomized controlled cohort/follow-up study**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning

*** Level may be graded down on the basis of study quality, imprecision, indirectness (study PICO does not match questions PICO), because of inconsistency between studies, or because the absolute effect size is very small; Level may be graded up if there is a large or very large effect size.**

**** As always, a systematic review is generally better than an individual study.**

Guidelines for Reporting and Critically Appraising Biomedical Research

HEADS

- **AMSTAR** (Assessment of Multiple Systematic Reviews) (Shea 2009)
- **CHEERS** (Consolidated Health Economic Evaluation Reporting Standards) (Husereau 2013)
- **CONSORT** (Consolidated Standards of Reporting Trials) (Turner 2012)
- **GRACE** (Good ReseArch for Comparative Effectiveness) (Dreyer 2014)
- **MOOSE** (Meta-analysis of Observational Studies in Epidemiology) (Stroup 2000)
- **PRISMA** (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) (Moher 2009)
- **QUOROM** (Quality Of Reporting Of Meta-analyses) (Moher 1999)
- **STARD** (Standards for Reporting of Diagnostic Accuracy) (Bossuyt 2003)
- **STROBE** (Strengthening the Reporting of OBservational Studies in Epidemiology) (von Elm 2008)
- **TREND** (Transparent Reporting of Evaluations with Nonrandomized Designs) (Des Jarlais 2004)

EQUATOR NETWORK (http://www.equator-network.org/reporting-guidelines/)

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Methods in HTA

- **Evidence Synthesis Methods**
  - Evidence synthesis methods involve **combining data or information from existing sources, including from primary data studies**.
  - These can range **from quantitative, structured approaches such as meta-analyses or systematic literature reviews to informal, unstructured literature reviews**. Having considered the merits of individual studies, an assessment group must then **integrate, synthesize, or consolidate the available relevant findings**.
  - For many topics in HTA, t**here is no single definitive primary study, e.g., that settles whether one technology is better** than another for a particular clinical situation. **Even where definitive primary studies exist, findings from them may be combined** or considered in broader social and economic contexts in order to help inform policies.

Methods in HTA

- **Evidence Synthesis Methods**
  - Methods used to combine or integrate data from primary sources include the following:
    - Systematic literature review
    - Meta-analysis
    - Modelling (e.g., decision trees, state-transition models, infectious disease models)
    - Group judgment (“consensus development”)
    - Unstructured literature review
    - Expert opinion

HEADS

Methods in HTA

- **Decision Analysis and Modelling Methods**
  - Quantitative modelling is used to evaluate the clinical and economic effects of health care interventions.
  - Models are used to represent (or simulate) health care processes or decisions and their impacts under conditions of uncertainty.

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Methods in HTA

- **Decision Analysis and Modelling Methods**
  - Decision trees
  - Influence diagrams
  - Bayesian/Belief Networks
  - Markov models
  - Probabilistic sensitivity analysis

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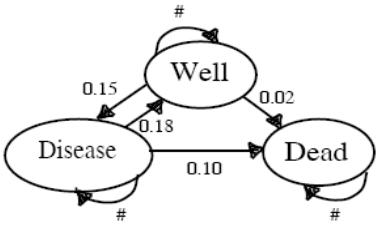


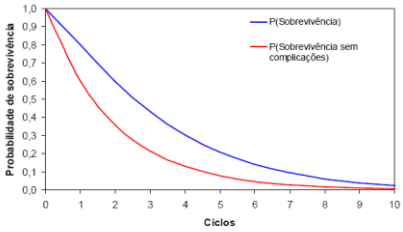
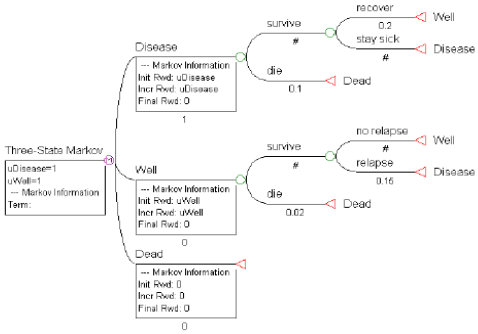
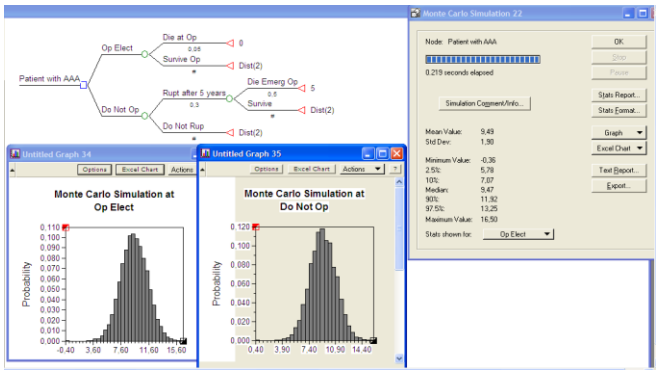


Figura 15: Curvas de sobrevivência global e sem complicações. Simulação de coorte de Markov associada ao problema relativo às complicações do tratamento anticoagulante. Representação das probabilidades de sobrevivência para os primeiros 10 ciclos do processo.





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Methods in HTA

- **Economic Evaluation Methods**
  - Partial Economic Evaluation – Cost analysis
  - Full Economic Evaluations
    - Cost-minimization analysis
    - Cost-Benefit analysis
    - Cost-Effectiveness analysis
    - Cost-Utility analysis

Perspectives	Types of costs	Examples
Healthcare payer		
Hospital	Direct costs	Healthcare staff, medicine, tests, capital costs (equipment and buildings), inpatient stay (hotel), outpatient visits, overhead costs (e.g., food, light, heat), possibly research, and education
Ambulatory care	Direct costs	Visits with general practitioner, ambulatory specialist, physiotherapist, etc., prescription drugs (the share paid by the healthcare payer), screening programs
Societal perspective		
	Direct costs (possibly in other sectors)	Rehabilitation, home care and nursing care at home, social arrangements
	Direct costs (for the patient and family)	User payment (medicine, dentist), cost for traveling, time costs due to patient's time used for the treatment, family or friends' (unpaid) use of time of the patient
	Lost production in society	The patient's temporary absence from work due to illness, reduced working capacity due to illness and disablement, or lost production due to an early death
	Future healthcare costs	Future unrelated healthcare costs caused by curing the patient with the present treatment

Source: Modified from Kristenson et al. (37).

Type of economic analysis	When should the specific type of analysis be chosen?
Cost-minimization analysis	If the compared technologies are equally effective, then it is only necessary to collect data about costs
Cost-effectiveness analysis	If the effectiveness of the compared technologies are different (e.g., the difference in costs have to be weighted against the difference in effectiveness)
	If activities with the same aim and measure of effectiveness are compared
Cost-utility analysis	If health-related quality of life is an important health outcome
	If activities across specialties or departments in the healthcare sector are compared
Cost-benefit analysis	If non-health effects also are of importance (e.g., the treatment process itself, utility of information)
	If only one technology is assessed (net benefit)
	If individual lives are valued in monetary units
	If activities across society are compared

Source: Kristensen et al. (37).

Methods in HTA

- **Consensus Development Methods**
  - In various forms, **group judgment or consensus development** is used to **set standards**, make **regulatory recommendations** and **decisions**, make **payment recommendations** and **policies**, make **technology acquisition decisions**, formulate **practice guidelines**, define the **state-of-the-art**, and other purposes.
  - The term **"consensus development"** can refer to particular group **processes or techniques** that generally are intended to **derive best estimates of parameters or general (or unanimous) agreement on a set of findings or recommendations**.

Methods in HTA

- **Consensus Development Methods**
  - In contrast to the quantitative synthesis methods, consensus development is **generally qualitative in nature**.
  - It may be **unstructured and informal**, or it may involve **formal group methods** such as the **nominal group**, **focus group** and **Delphi techniques** (Fink 1984; Gallagher 1993; Jairath 1994).
  - Although these processes typically involve **face-to-face interaction**, some consensus development efforts combine **remote, iterative interaction of panellists (as in the formal Delphi technique) with face-to-face meetings**; **video and web conferencing and related telecommunications** approaches also are used.

Methods in HTA

- **Consensus Development Methods**

Comparison of focus group, nominal group and Delphi technique processes

Dimension	Focus groups	Nominal groups	Delphi technique
Overall orientation/ dynamics	Full group membership and interaction	Individual and group participation in direction/ group-decision outcome (Stewart and Shamdasani, 1990) Socially facilitating (Dalton *et al.*, 1970)	Group in name only – individual interview with sharing of all members' ideas and responses
Overall methodology	Unstructured, face-to-face group meeting Flexible, variable behaviour (Van de Ven and Delbecq, 1974)	Structured/balanced focus on task (Delbecq *et al.*, 1975) Time and opportunity to reflect (Dunnette, 1964)	Task-instrumental focus
Role orientation	Socio-emotional Group maintenance focus (Dunnette, 1964) Self-weighting effect (Kelly and Thibaut, 1954)	Balanced focus on social maintenance and task role (Bales, 1953)	Task-instrumental focus
Relative quality of ideas	Low; focused "rut" effect on train of thought (Dunnette, 1964; Torrance, 1957)	High; independent, tolerant thinking (in writing) and pooled ideas (Van de Ven and Delbecq, 1971) Broad, deep insights (Langford *et al.*, 2002)	High; isolated recording of ideas
Search behaviour	Reactive, short problem focus (Maier and Hoffman, 1960) Task-avoidance	Proactive, extended, focus (Horowitz and Newman, 1964) Task-centred	Proactive, controlled focus High task
Normative behaviour	Status incompatibilities (Vroom *et al.*, 1969) Conformity pressures (Hoffman, 1965) Covert judgements (Collaros and Anderson, 1969)	Tolerance of non-conformity via independent search/ choice activity Overt criticism (Collaros and Anderson, 1969)	Freedom not to conform via isolated anonymity (Dalkey and Hilmer, 1963)
Equality of participation	Member dominance	Member equality (Maier, 1957)	Respondent equality (Dalkey and Hilmer, 1963)
Method of problem solving	Person centred	Problem centred (Green, 1975) Insights into perceptions/ constructs (Hussey and Hussey, 1997)	Problem centred
Closure decision process	High lack of closure (Van de Ven and Delbecq, 1974)	Prevents premature closure (Maier and Hoffman, 1960)	Low lack of closure (Van de Ven and Delbecq, 1974)

Lloyd, S. (2011). Applying the nominal group technique to specify the domain of a construct. Qualitative Market Research: An International Journal.

Methods in HTA

- **Consensus Development Methods**
  - In **HTA**, **consensus development is not used as the sole approach** to deriving findings or recommendations, but rather **as supported by systematic reviews and other analyses and data**.
  - Virtually **all HTA efforts involve some form of consensus development at some juncture**, including one or more of three main steps of HTA: **interpret evidence**, **integrate evidence**, and **formulate findings and recommendations**.
  - **Consensus development also can be used for ranking**, such as to set **assessment priorities**, and for **rating**, such as **drawing on available evidence and expert opinion to develop practice guidelines**.

HEADS

Methods in HTA

- ***Ethical Analysis***
  - **Ethical, legal, and social considerations arise in HTA** in the form of **normative concepts (e.g., valuation of human life)**; **choices about how and when to use technologies**; **research and the advancement of knowledge**; **resource allocation**; and the **integrity of HTA processes** themselves (Heitman 1998).

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Methods in HTA

- ***Ethical Analysis***
  - The **origins of technology assessment** called for the field to **support policymakers' broader considerations of technological impacts**, such as the "**social, economic, and legal implications of any course of action**" (US Congress, House of Representatives, 1967) and the "**short- and long-term social consequences (for example, societal, economic, ethical, legal) of the application of technology**" (Banta 1993).
  - **Methods for assessing ethical, legal, and social implications** of health technology have been **underdeveloped** relative to other methods in HTA, although there has been **increased attention in recent years to developing frameworks and other guidance for these analyses (Duthie 2011; Potter 2008)**.

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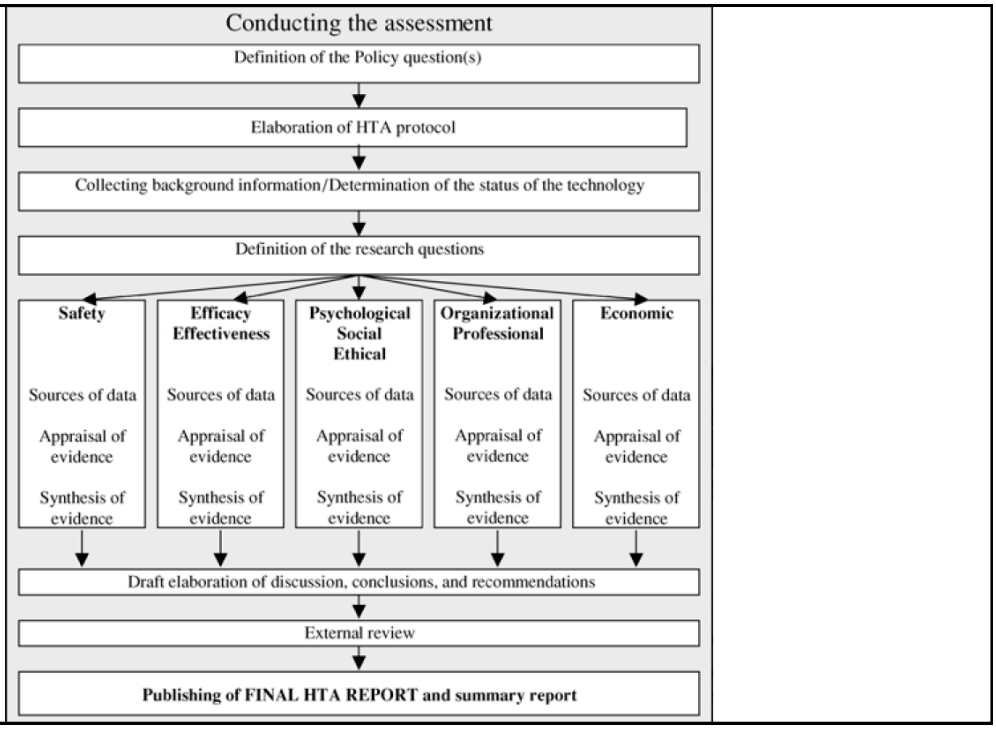
Methods in HTA

Methods Used for Ethical Analysis in HTA

Method	Description
Casuistry	Solves morally challenging situations by comparing them with relevant and similar cases where an undisputed solution exists
Coherence analysis	Tests the consistency of ethical argumentation, values or theories on different levels, with an ideal goal of a logically coherent set of arguments
Principlism	Approaches ethical problems by addressing basic ethical principles, rooted in society's common morality
Interactive, participatory HTA approaches	Involves different stakeholders in a real discourse, to reduce bias and improve the validity and applicability of the HTA
Social shaping of technology	Addresses the interaction between society and technology and emphasizes how to shape technology in the best ways to benefit people
Wide reflective equilibrium	Aims at a coherent conclusion by a process of reflective mutual adjustment among general principles and particular judgements

Source: Saarni et al. 2008.



Questions?