Health Technology Assessment - oriented Approach to Hepatology

GF Gensini

Florence, March 10, 2011

Saturday 24 May 1997
BMJ

The future of healthcare systems

Information technology and consumerism will transform health care worldwide

Richard Smith *Editor*
BMJ, London WC1H 9JR

Some tools of managed care

- Managing demand
  - Capitation
  - Gatekeepers
  - Advice lines to patients
  - User fees
  - Consumer education
- Medical management
  - Review of use
  - Preadmission certification
  - Disease management
  - Greater use of guidelines
- Care delivery
  - Telemedicine
  - Greater use of non-doctors

BMJ VOLUME 314 24 MAY 1997

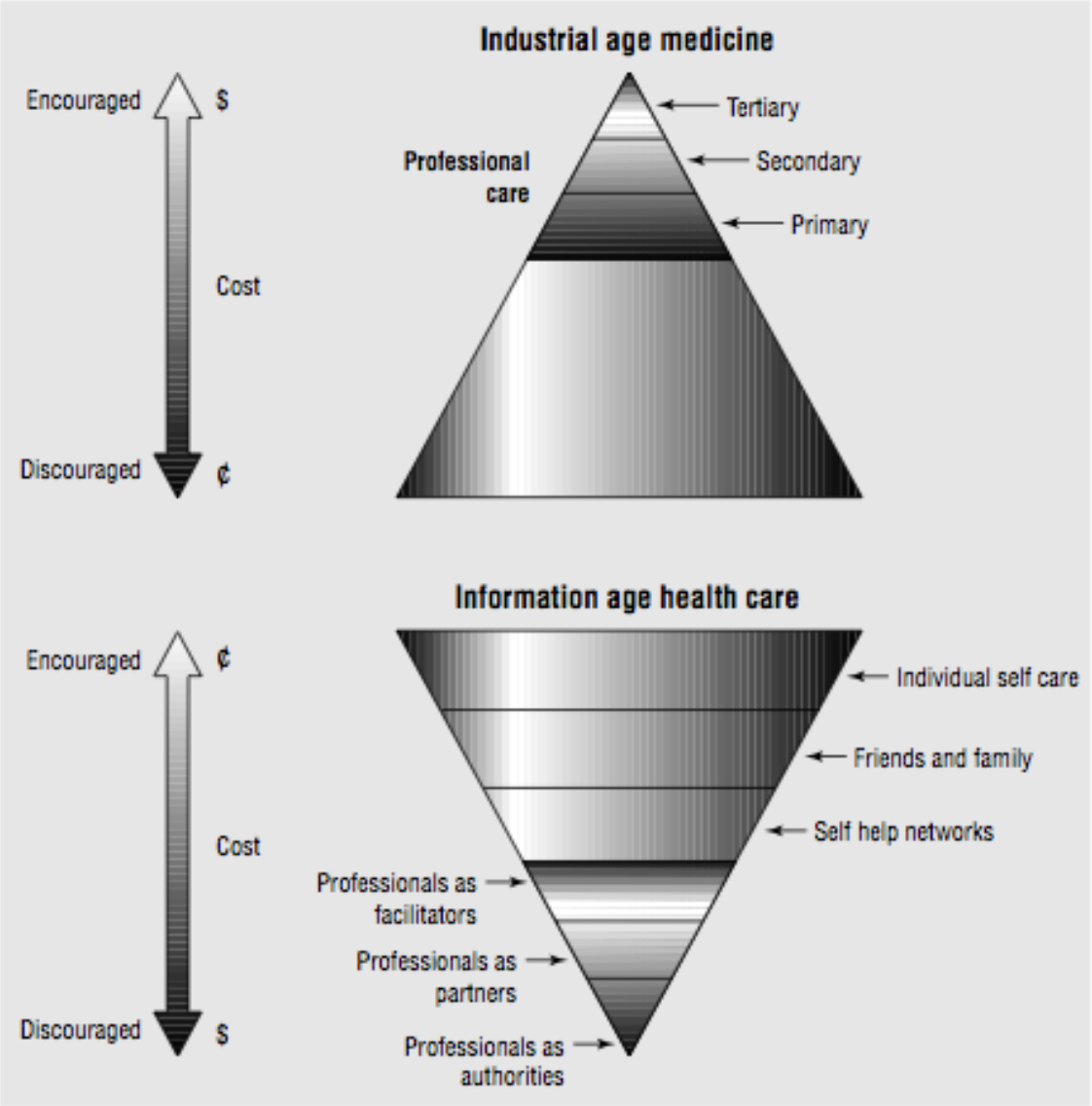


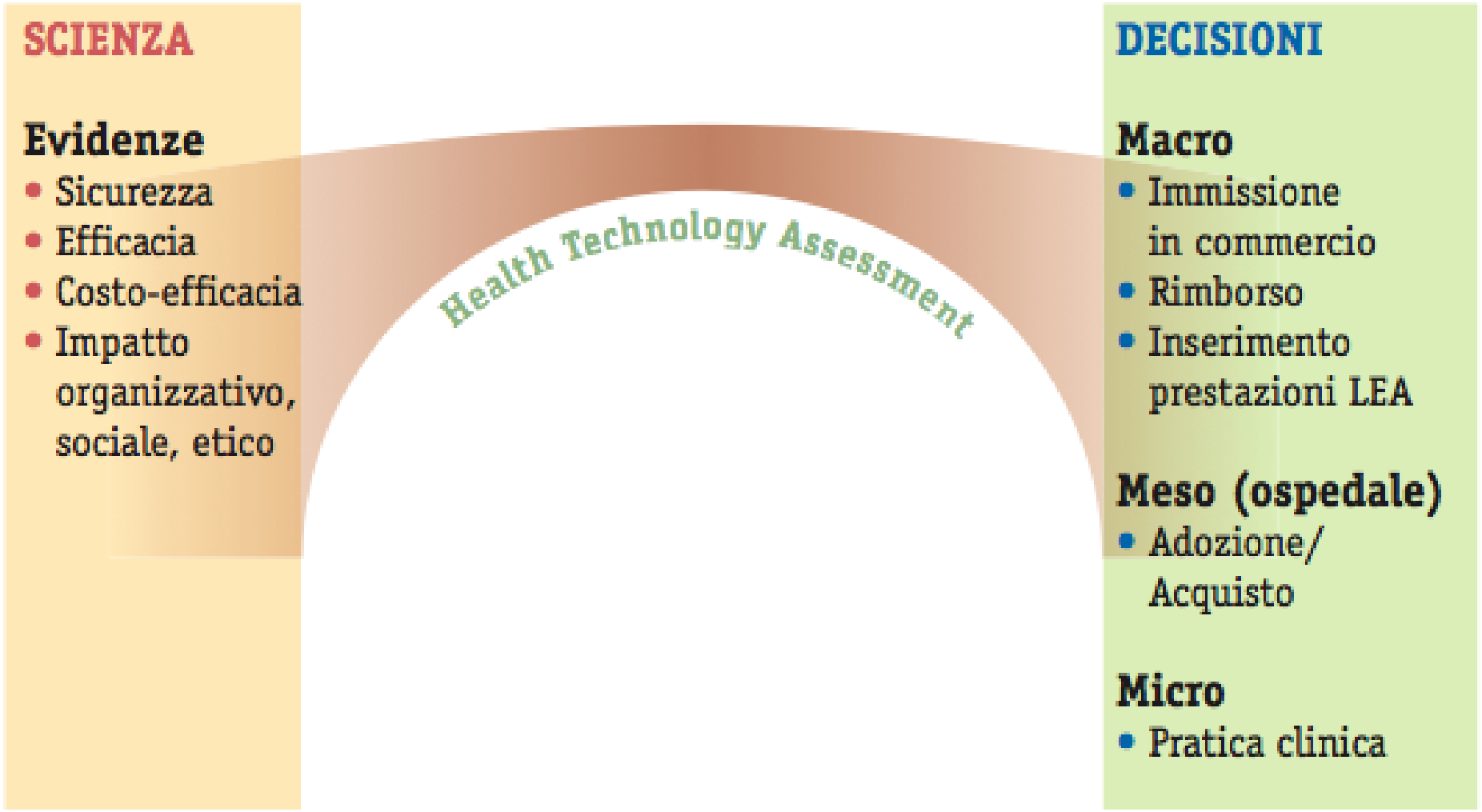
Fig 1 How "industrial age medicine" will invert to become "information age healthcare" (reproduced with permission from Jennings, Miller, and Materna)[1]

What evidence-based medicine is:

The practice of EBM requires the integration of

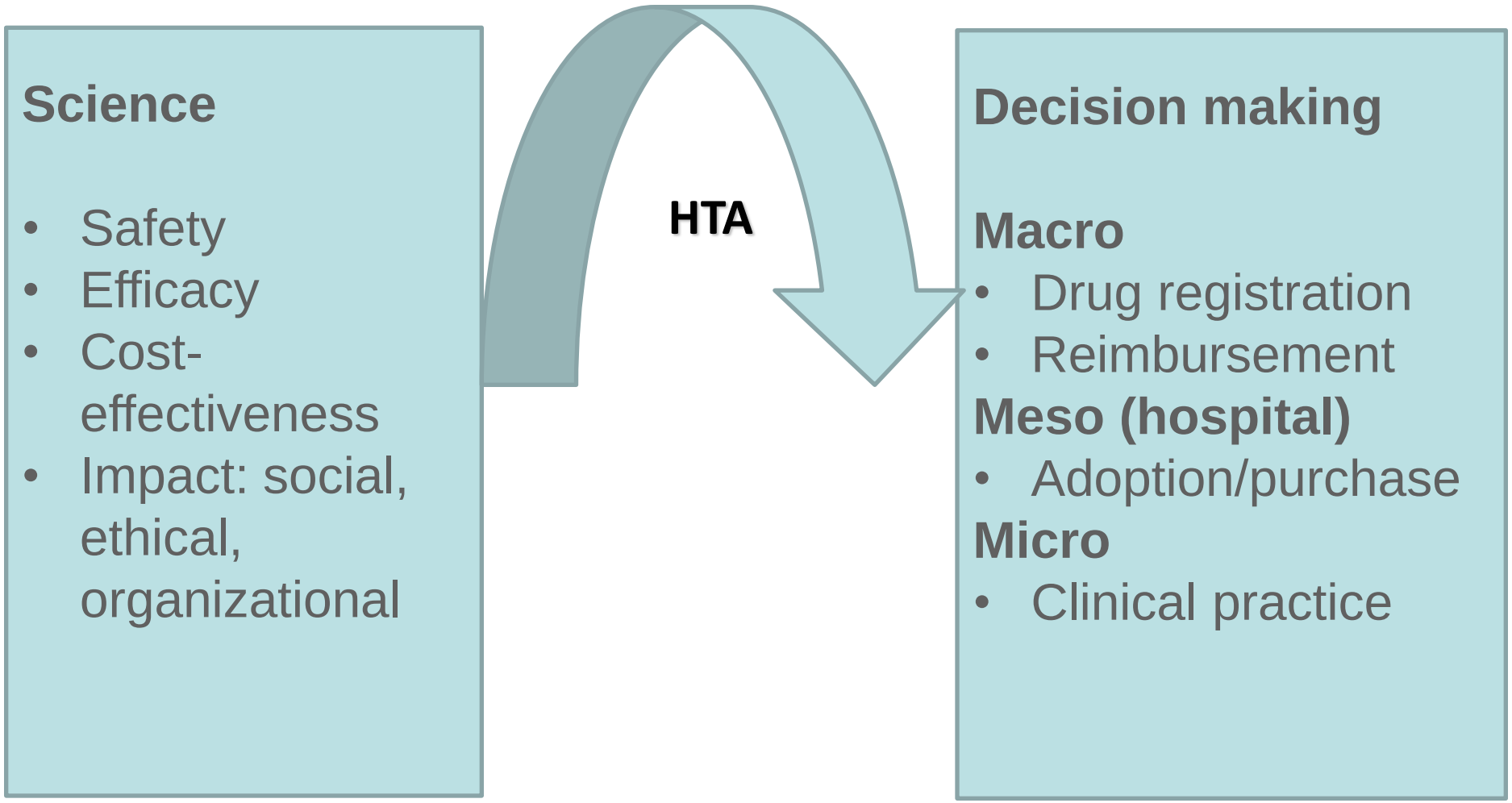
- **individual clinical expertise with the**
- **best available external clinical evidence from systematic research**
- **patient values**

L'Health technology assessment: il ponte tra scienza e decisione



Renaldo Battista, 1997

HTA: bridge between science and decision making



HEALTH TECHNOLOGY ASSESSMENT

Complex and systematic multidisciplinary assessment of *health care, economical, social and ethical consequences* determined, *directly and indirectly, in short term or long term, by new health technologies compared to* the existing ones

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Health technology

- medical equipment
- medical devices
- drugs
- diagnostic tests
- medical and surgical procedures
- health care processes
- structural and organizational patterns of environments deliverinh health care

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HTA: assessment to inform decisions making

Health Technology Assessment is a multidisciplinary assessment tool developed in response to the **gap** between limited resources and expanding health care demand and technological innovation

Battista RN, Hodge Mj, 1999

Battista RN, 1996

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Features of HTA

- **Multidisciplinary/Multidimensional**: because the impact of a technology has to be viewed from different perspectives

- **Structured**: because of the need for sistematic collection and analysis of data and evidence regarding the use of the technology to be evaluated

- **Politically oriented**: because it acts as a «**bridge**» between the world of science and that of decision makers, thus being essentially **policy - driven**.

Banta D, Behney CJ, Andrulis DP, 1978.
Velasco Garrido M, Busse R, 2007

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What HTA does

- **HTA** includes the analysis and critical assessment of all items on which the adoption or the dismissal of a health technology can impact

- Four areas can be identified:

1) technology,
2) patient,
3) budget,
4) organization.

Ham C, Hunter DJ, 1995

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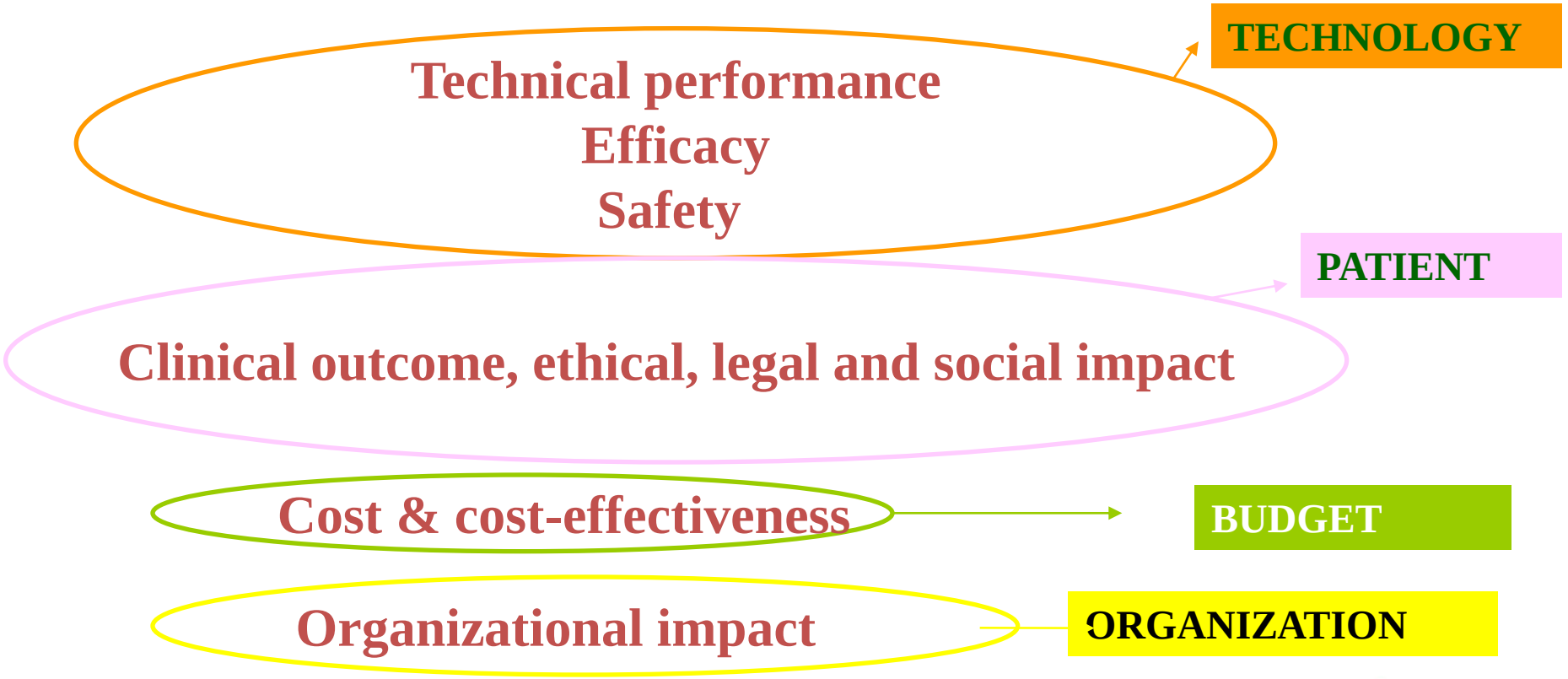
What HTA does

HTA focusses on the following features of a technology :



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HTA: methods

1. **Epidemiological** review of the medical condition;
2. Assessment of **resources used and their cost**;
3. Description adn assessment of current **treatment and management strategies** for the condition;
4. Assessment of **efficacy** and **safety** of th health technology;
5. **Mathematical modelling** of benefits expected by implementing the technology;
6. **Economic assessment**;
7. Assessment of **organizational impact** of the implementation of the technology by the public health care system;
8. Analysis of **ethical, legal** and **social** (acceptability, availability, accessibility, information) issues related to the technology.

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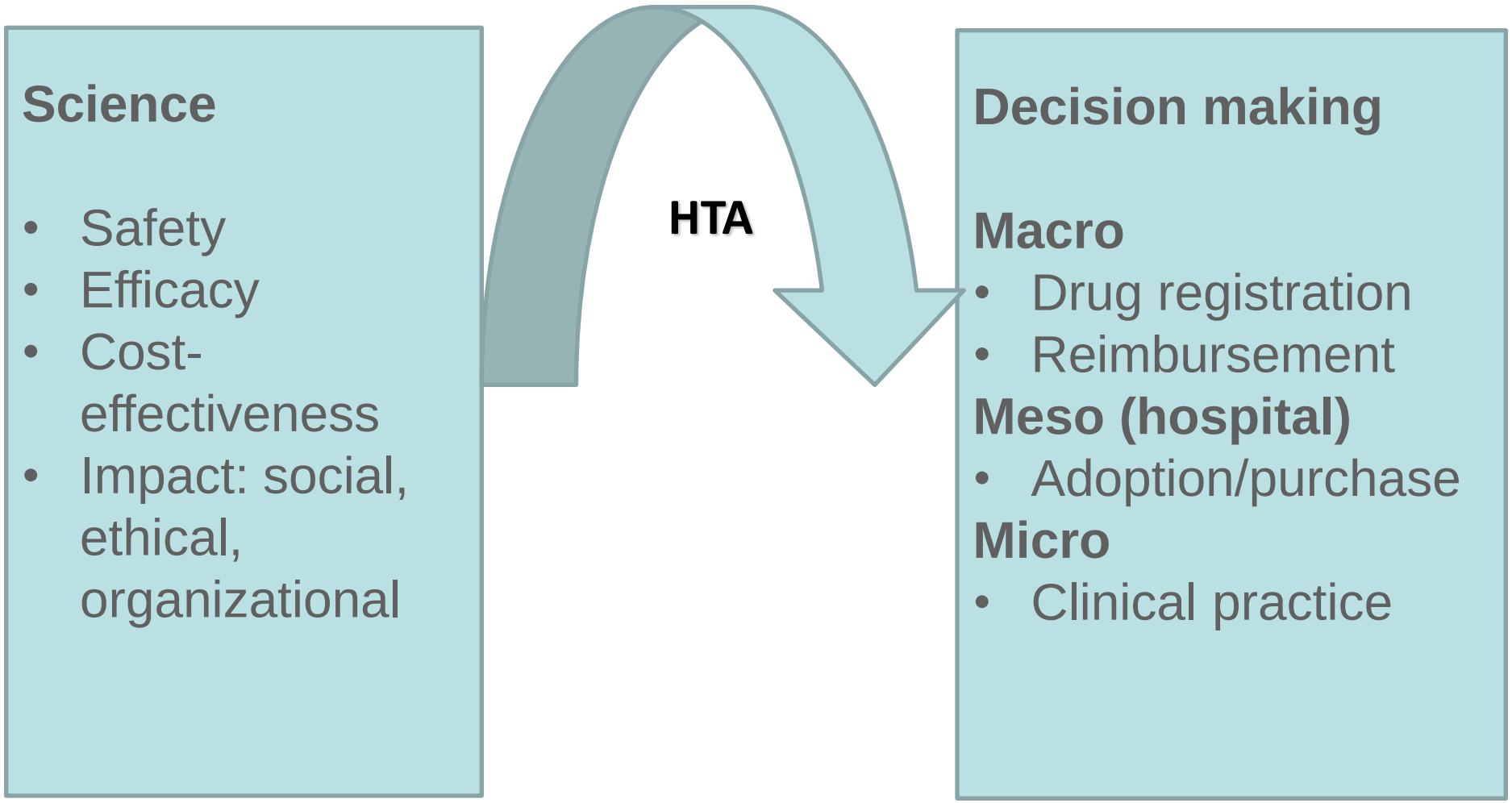
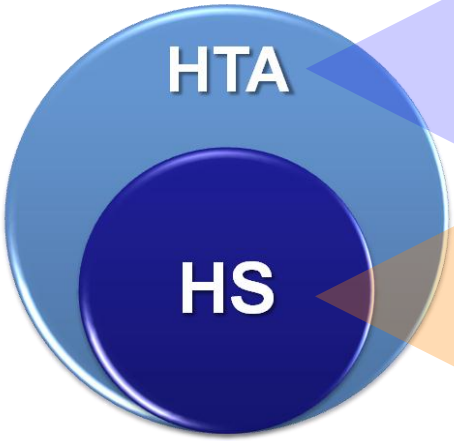
HTA: bridge between science and decision making



HTA e Horizon Scanning (HS)



Assessment of efficacy and effectiveness of health technologies regarding their clinical and organizational impact as well as their adoption

Identification of health technologies in their early development phase and assessment of their potential clinical and organizational impact

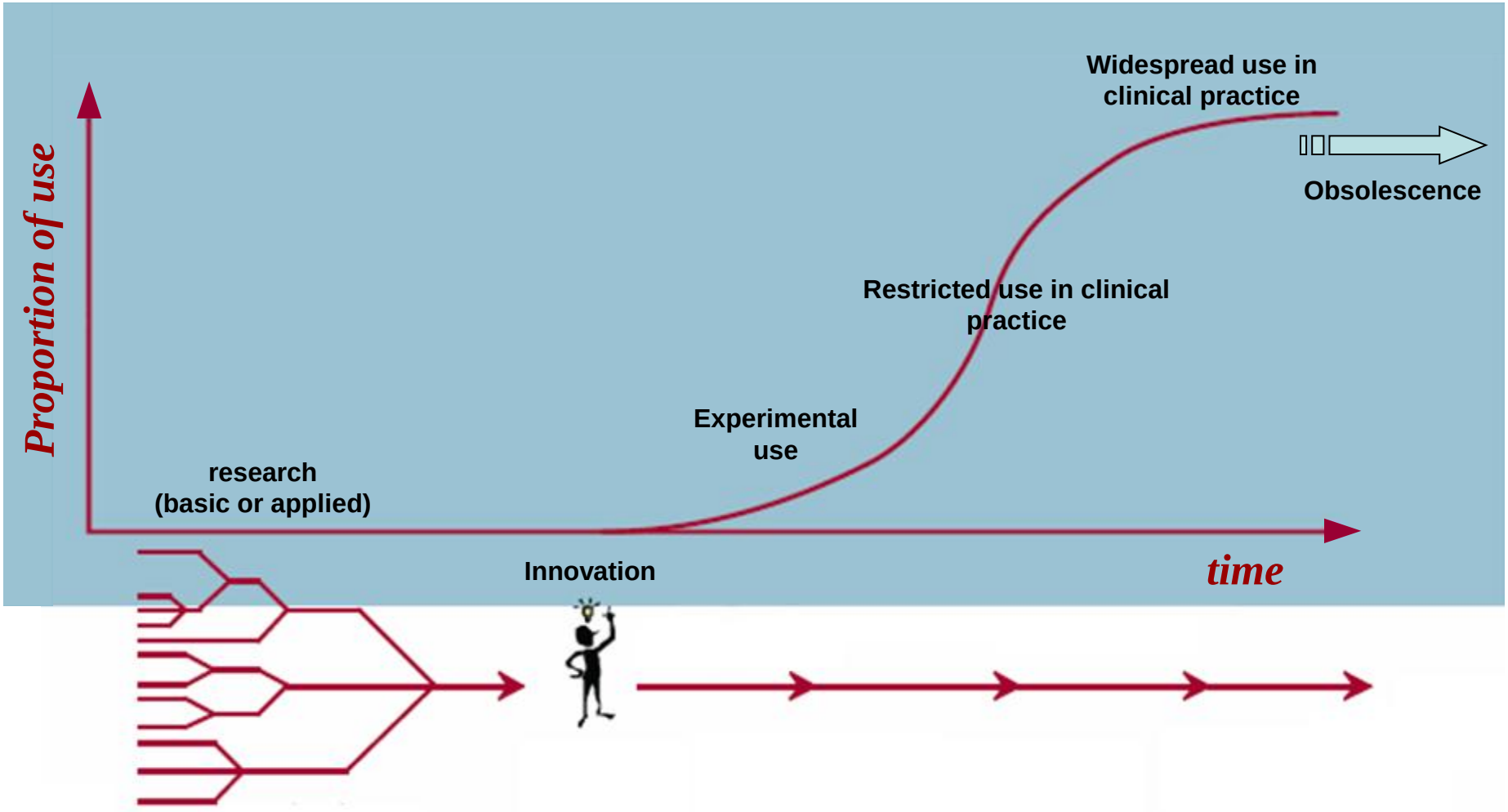
Limits of HTA:

Time needed (at least 12 months) → **Too long for decision makers**

Limits of HS:

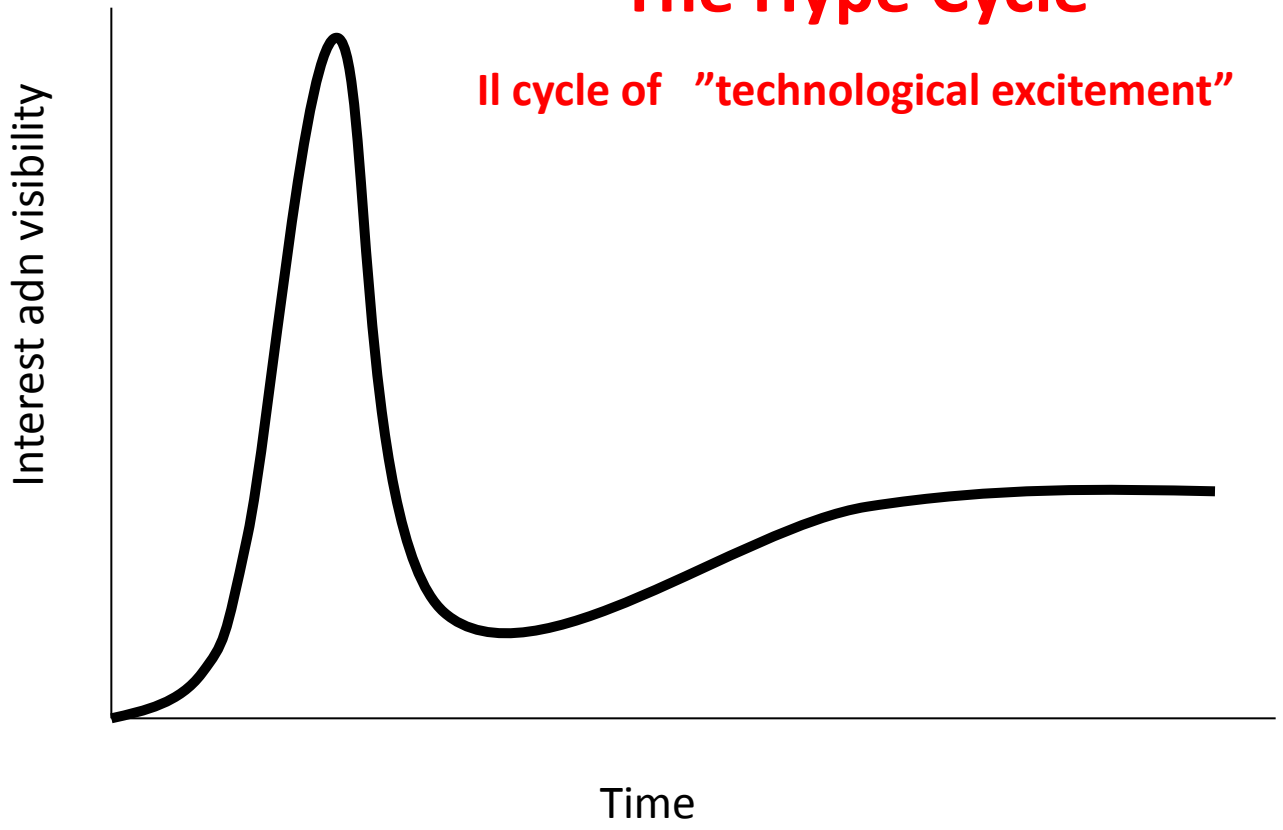
Little available evidence → **Short reports**

Life cycle of a technology



The Hype Cycle

Il cycle of ”technological excitement”



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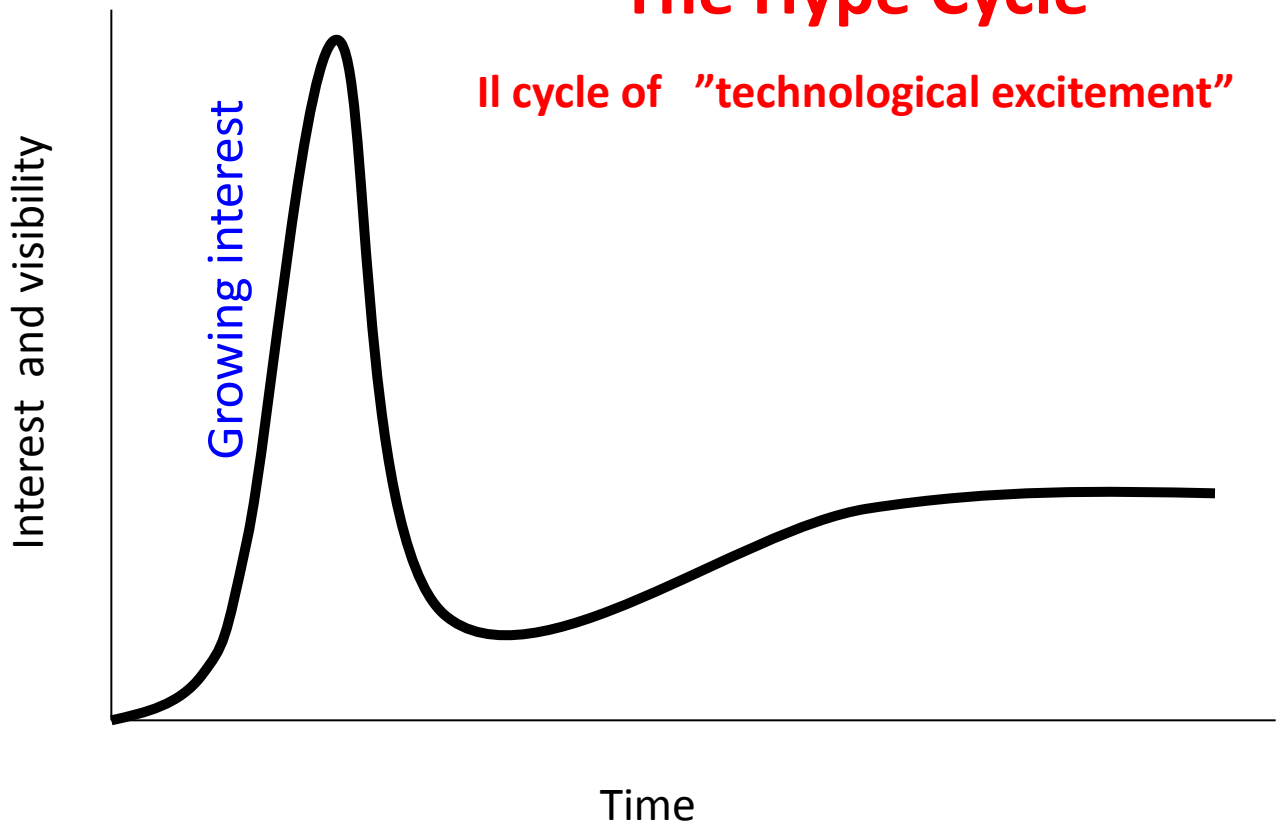
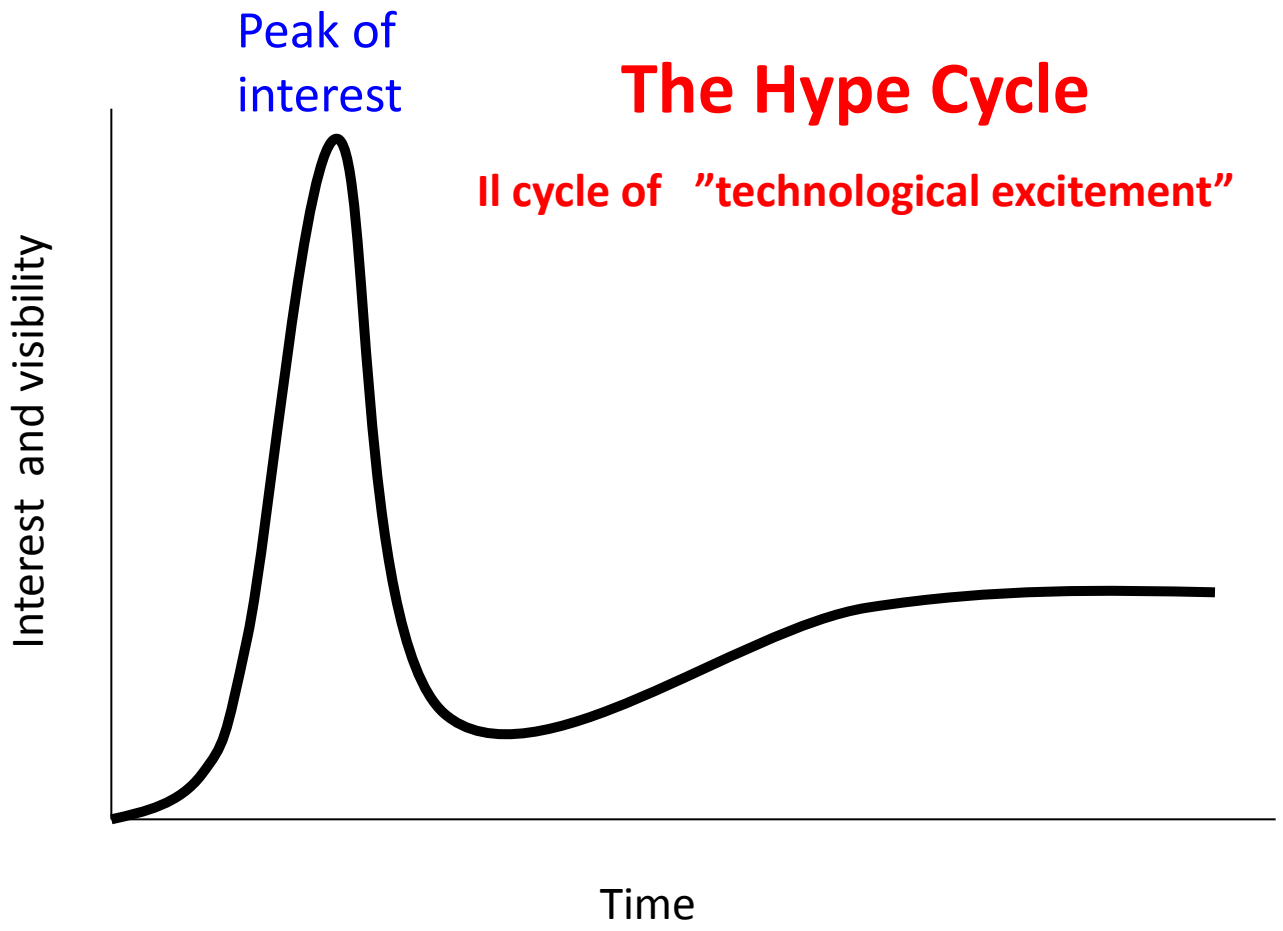
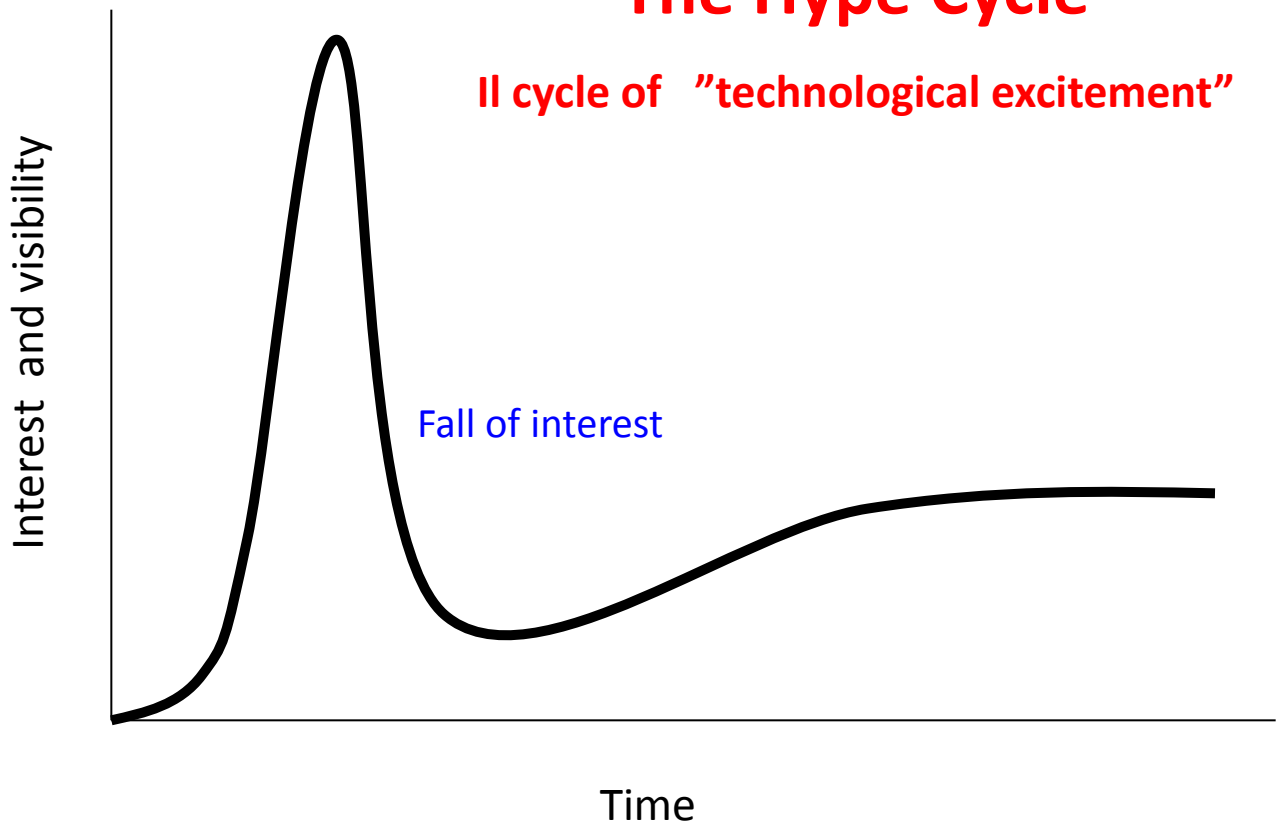



Peak of interest
The Hype Cycle
Il cycle of ”technological excitement”
Interest and visibility
Time

The Hype Cycle

Il cycle of ”technological excitement”



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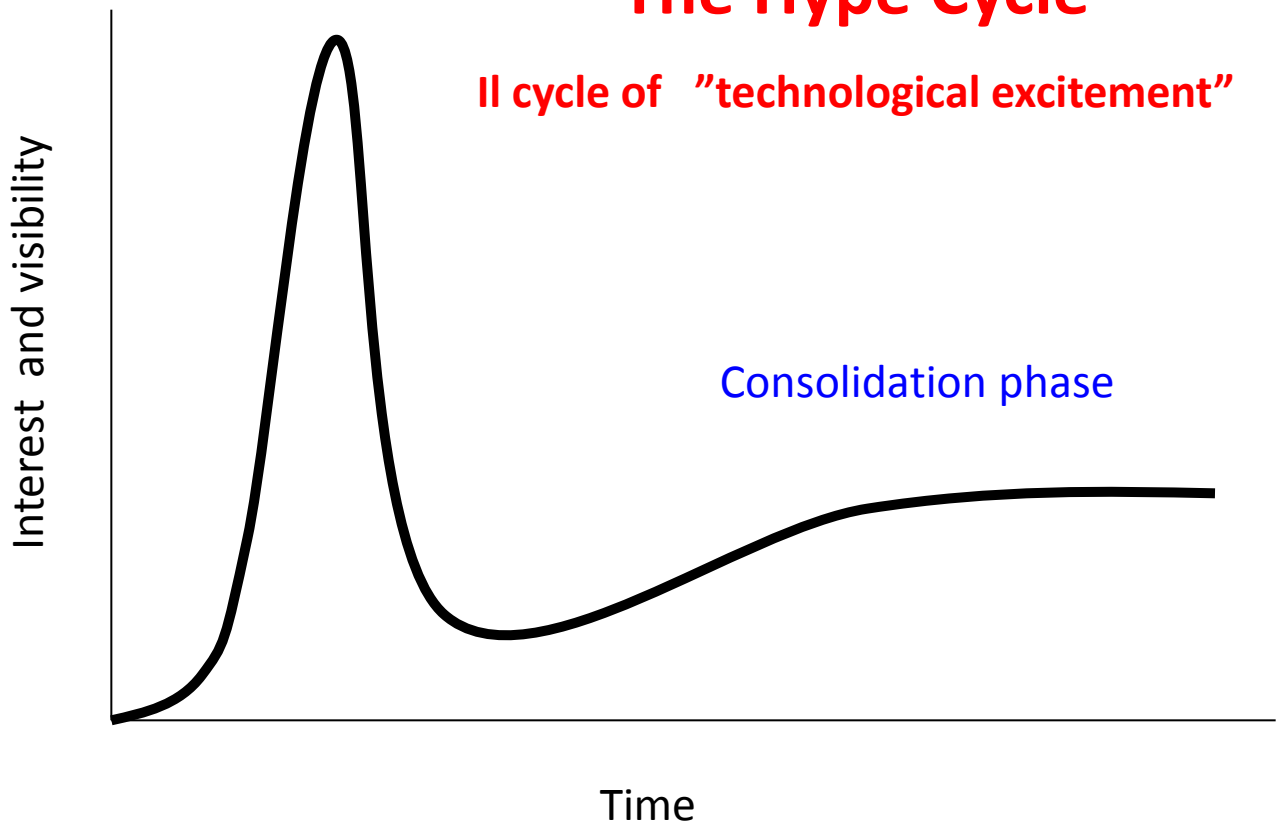
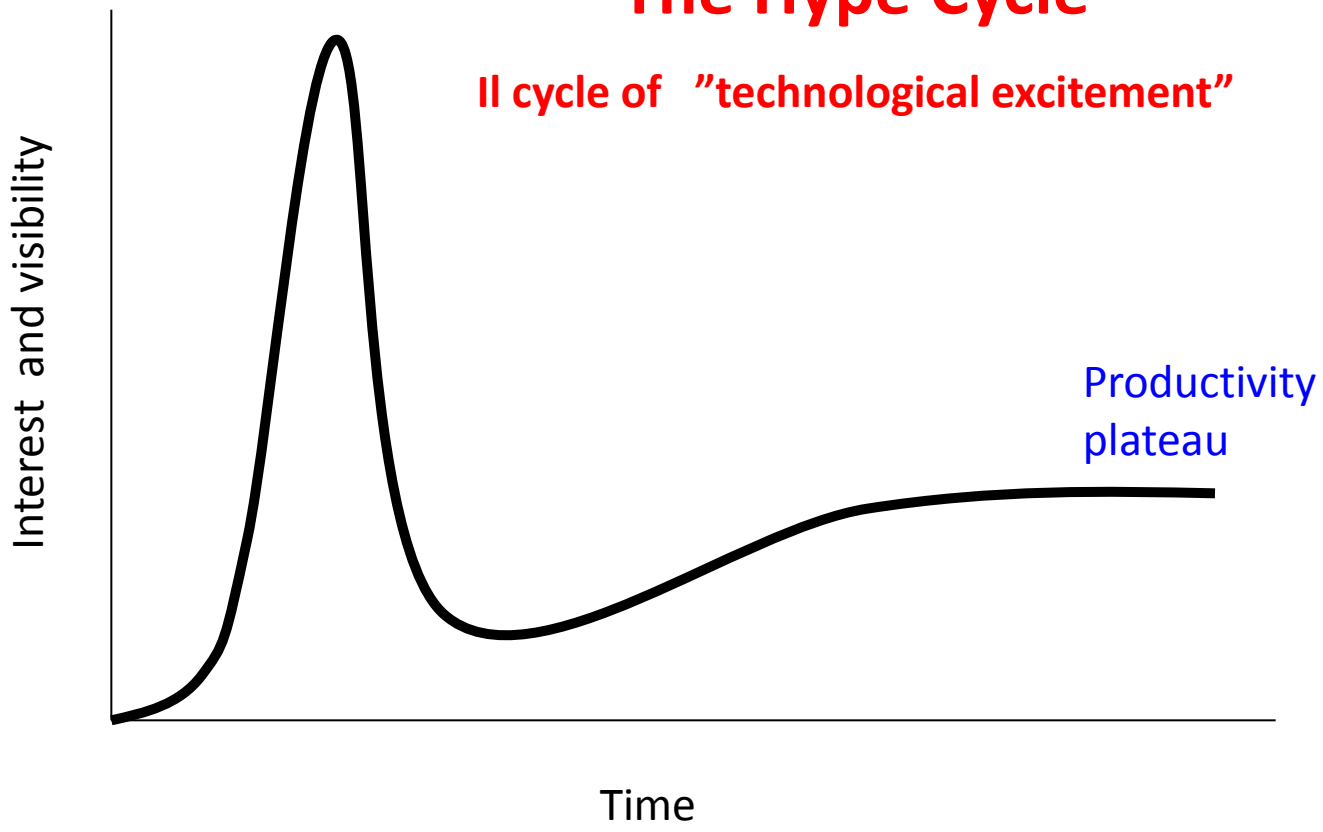
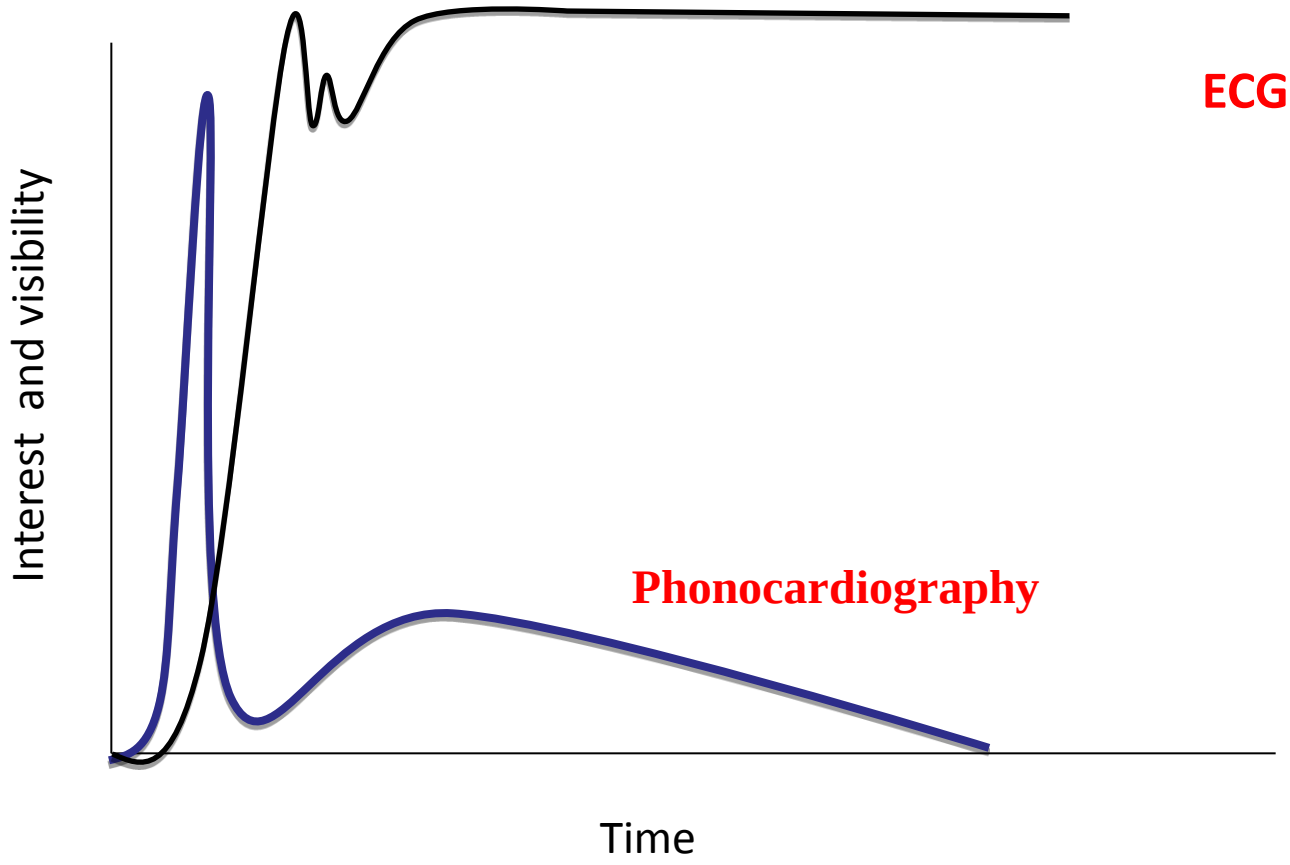


The Hype Cycle

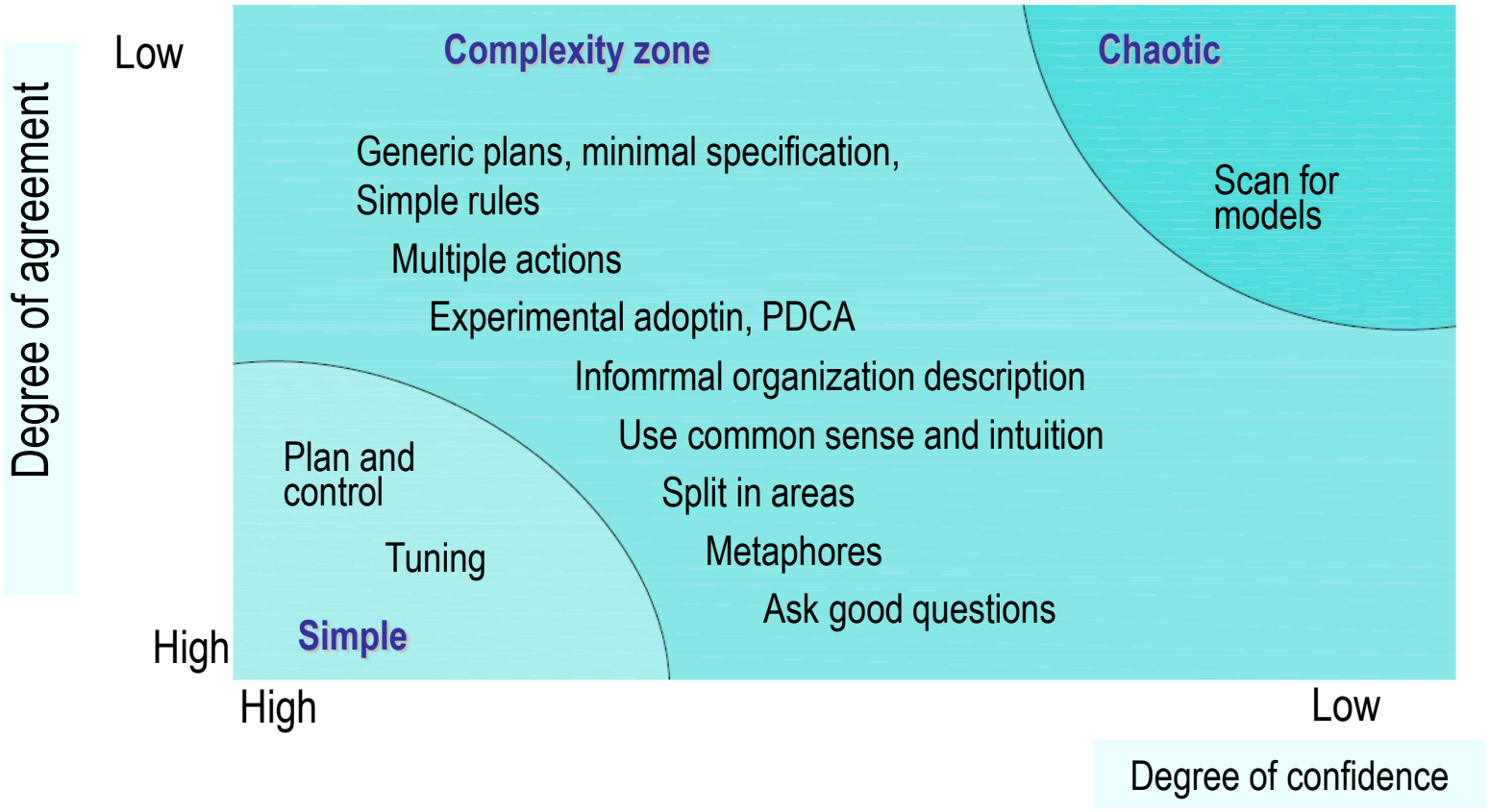
Il cycle of ”technological excitement”



The Hype Cycle in cardiology



COMPLEXITY DIAGRAM

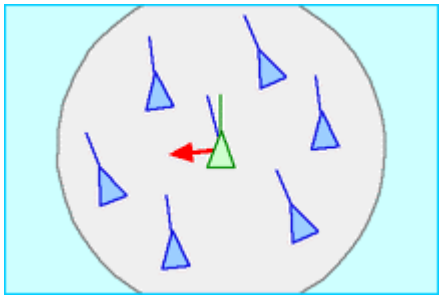


Complex adaptive systems

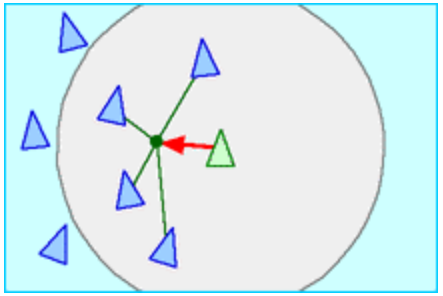
- Rather than trying to reduce the complexity of the system, one should better identify **simple rules** which can determin **complex behaviours**

- The first bird of a **flight** (flock of birds) does not rule other birds who behave following the same three simple rules, based on the position and speed of closer fellows

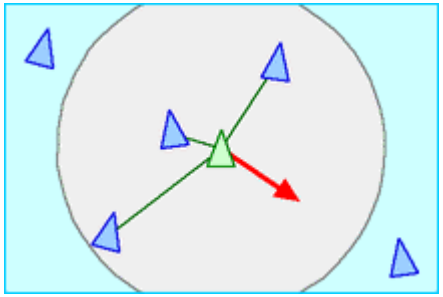
The “rules” of flight



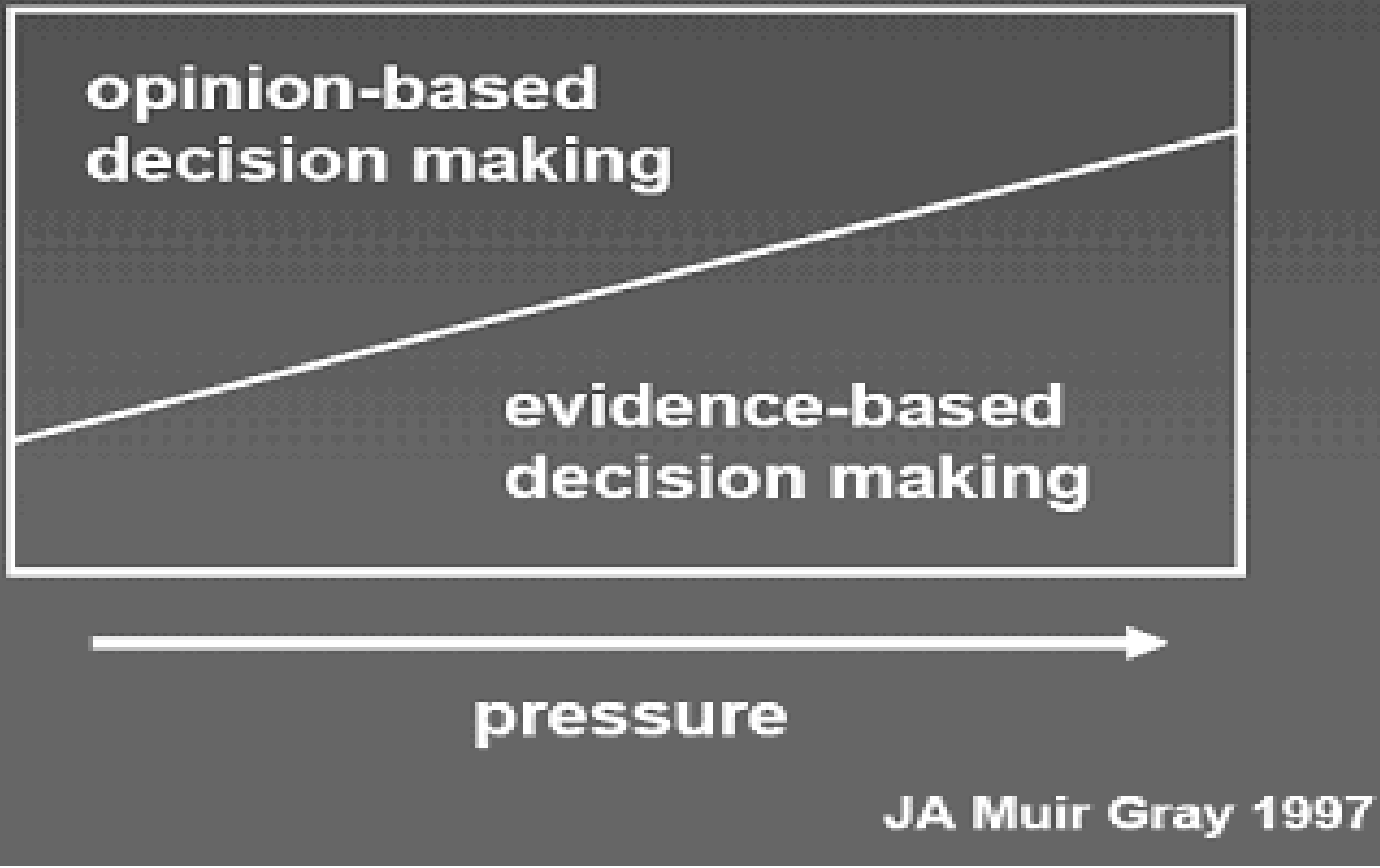
SEPARATION:
Don’t fly too close to your fellows.



UNITY:
Fly in between your fellows.



LINING:
Follow the route of closer fellows



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Sustainability

Sustainability **is a feature of a process or state that can be maintained at the same level indefinitely**

From a social perspective, the term indicates a *balance* between meeting our needs and the chances of future generations to meet their own needs (Brundtland report, 1987).

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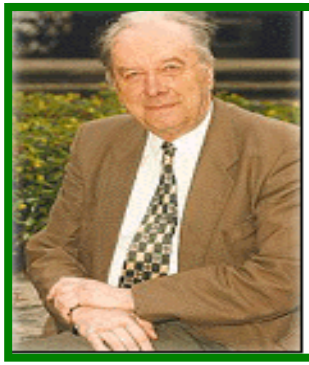
1990 → **2000**

Budgeting for cost containment
('Imperativo economico')

Reforms for cost containment through governance of efficacy, efficiency and appropriate use

"All *effective* treatments should be free"
Archie Cochrane, 1971



"All *cost-effective* treatments should be free"
Alan Williams, 1997

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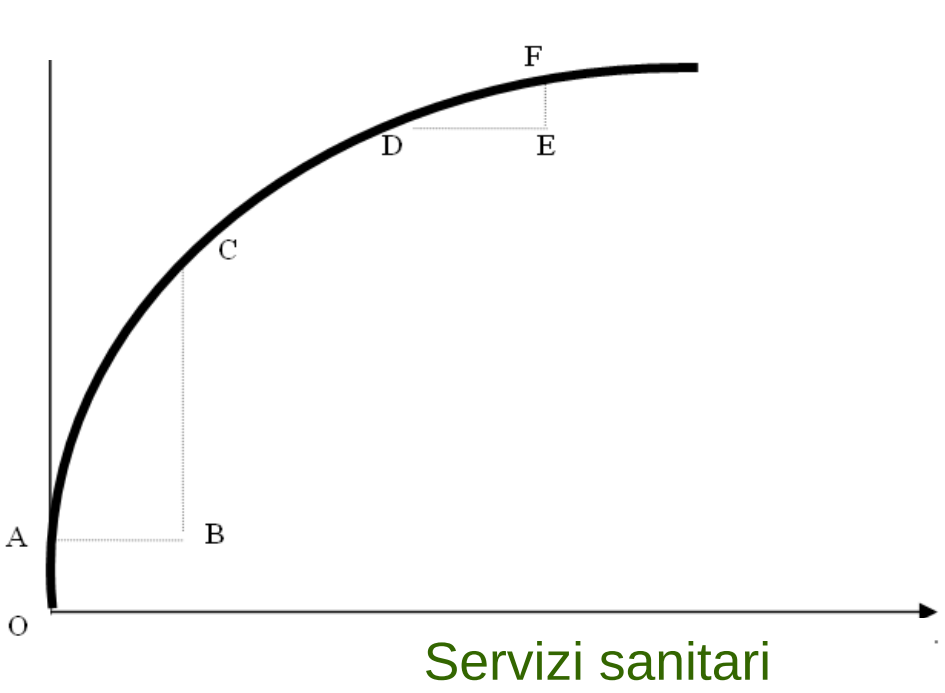
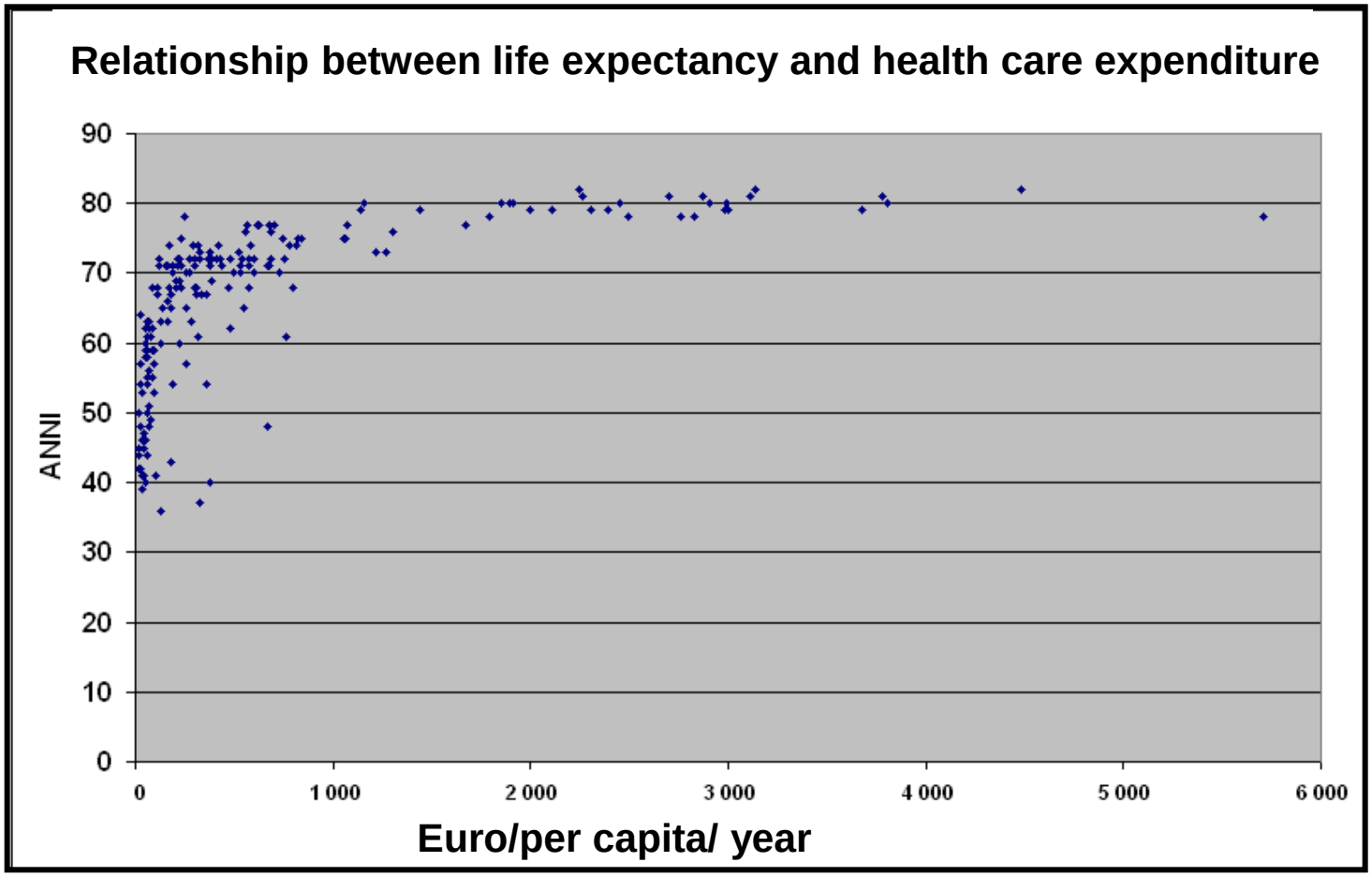
- Nel grafico, OA è il livello di salute posseduto in assenza di servizi sanitari.
- Le prime dosi di servizi sanitari, AB, producono un aumento di livello di salute, BC, di gran lunga più elevato di quello prodotto dalle dosi successive di servizi (DE produce un incremento di salutepari solo a EF).



WHO, 2003



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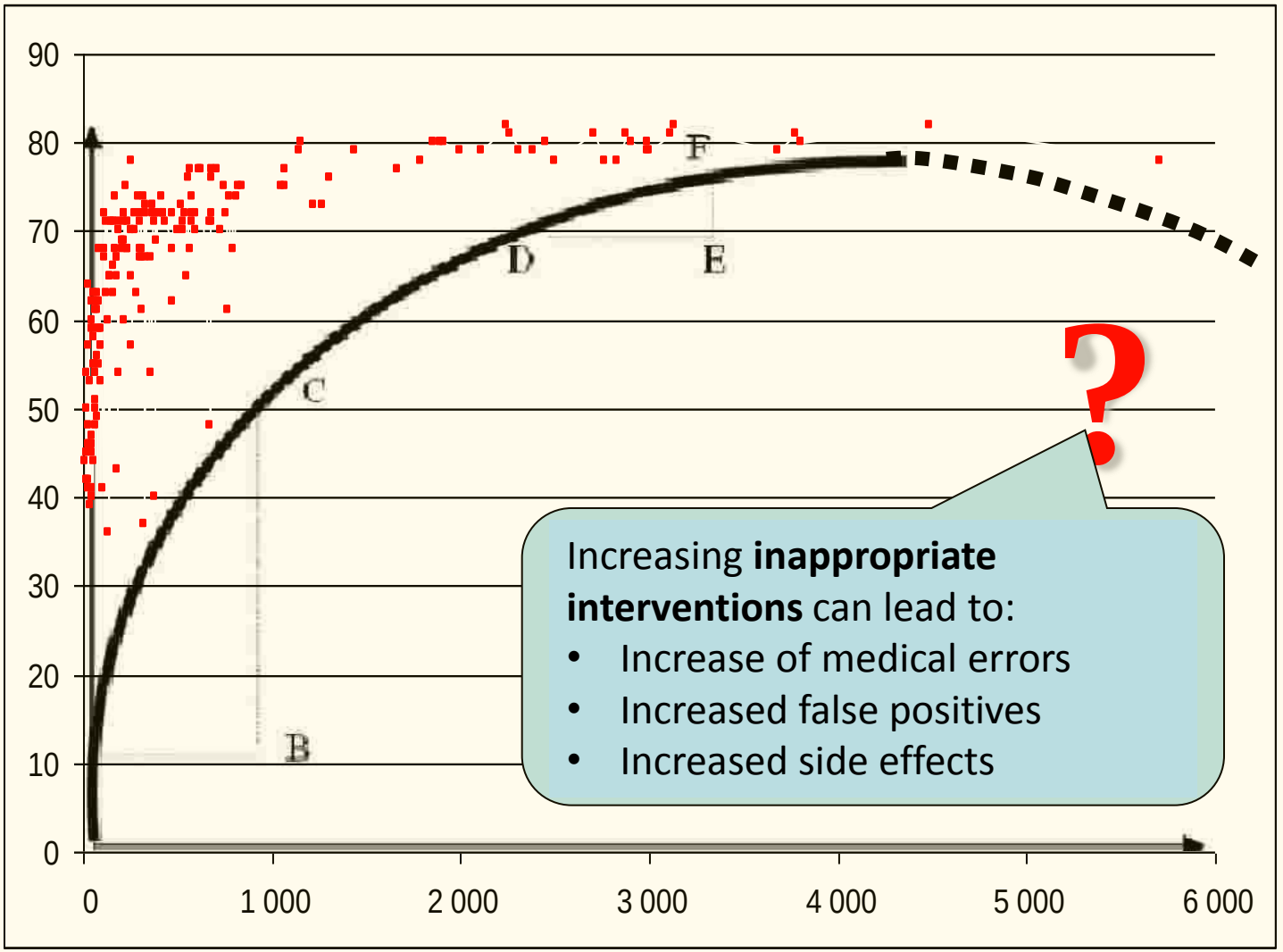

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STAKEHOLDERS

The ties between an organization and its components is *value exchange*:
An organization aiming to being succesfull must generate «value» and share it with all its components according to their own expectations and needs

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Stakeholder in health care systems

CLIENT (sick and healthy)

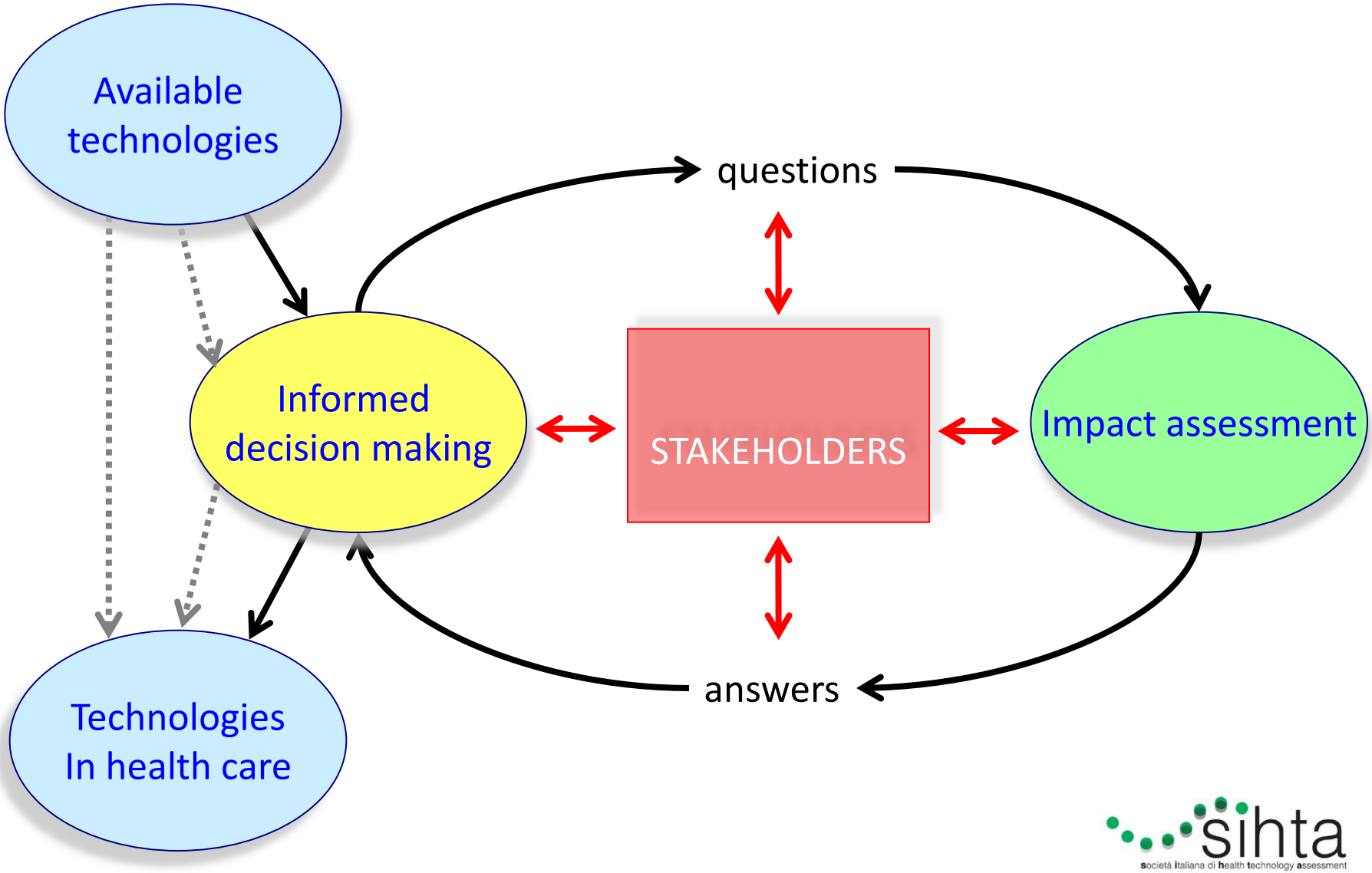
EMPLOYEES (high % of professionals with prolonged training, career expectations, high level of autonomy)

OWNERS (citizens thorugh their political expression in reginal governments)

PARTNER AND PROVIDERS (from general practitioners to service providers)

CITIZENSHIP (local majors representatives or valuntary organizations)

Adoption and implementation of health technolgies: Governance



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Examples of items of interest for citizenship in an HTA

Social: impact on working process, family, leisure time, lifestyle, quality of life

Economical: direct and indirect costs o on each social item and the ability to sustain such costs

Ethical: accessibility, equity, alternatives…

Personal: expectations, hopes, empowerment, beliefs, anxiety, reliance, knowledge, skills….

Relational: involvement in decision making, relationship with personal physician and with health care system, undertsanding technology, understanding knowledge, playing roles

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Functions of HS system

From: Wild and Langer, Health Policy 87 (2008) 160–171

HTA e HS

- **Institutional activity**
- **Strategic value *(decision making)***
- **Objective and balanced *(evidence-based)***
- **Supported by public agencies *(no interest in marketing)***
- **Partnership with private sector *(producers)***

In Italy

- Production of HTA reports
- National Horizon Scanning-COTE
- Platform for sharing products HTA-HR&i Transfer
- Cooperation with reginal systems

In Europe

- EUnetHTA
- Joint action
- EuroScan

Peculiarity of medical devices

agenas AGENZIA NAZIONALE PER I SERVIZI SANITARI REGIONALI

Special problems:

- **heterogeneity**: from simple supplies to complex diagnostic equipment, to implantable devices
- **Technological progress** after marketing phase
- Clinical efficacy influenced by **professionals' learning curve**
- Economic assessment related to **organizational impact**
- **Scarcity of comparative studies**

RIHTA

Progetto RIHTA set in **2009 : *Rete Italiana di HTA delle Regioni***

Collaborative network between regional agencies and Agenas aiming to:

- share knowledge on widespread technology
- prepare shared reports (methodology)
- support regions which have not set an HTA system
- facilitate integration of HTA in decision making
- avoid duplication and increase productivity

Complex task

APPROPRIATE HUMAN RESOURCES

COOPERATION AMONG RESEARCH INSTITUTES

COOPERATION AMONG LEVELS OF HEALTH CARE GOVERNANCE SYSTEM

COOPERATION WITH PROFESSIONALS AND INDUSTRY

RELIABLE METHODOLOGY

- ✓HTA production should follow rules inspired to current epidemiological methodology and public health principles
- ✓Stakeholder involvement should follow transparent rules, which are able to manage the perspectives of different stakeholders
- ✓Health Technology Assessment supports but does nor replace clinical or political/public health decision making
- ✓Italian reegulation is scarce
- ✓Most effective HTA systems are scientifically sound, independent and sustained by policy that grants their incorporation in decision making at any level

The true function of HTA is ethical

Basically

HEALTH TECHNOLOGY ASSESSMENT

GOVERNANCE OF INNNOVATION

SUSTAINABILITY

ACCOUNTABILITY
(be and be seen as responsible for)

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HTA REPORT

Wireless Capsule Endoscopy in the diagnosis of small bowel disease

This report should be cited as "Age.na.s. HTA Report - Wireless Capsule Endoscopy in the diagnosis of small bowel disease, Rome, September 2008"

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Il presente report non contiene il riferimento delle aziende Given Imaging GmbH e MG Lorenzatto S.p.A. come "external reviewers". Tali aziende, pur essendo state contattate durante l'elaborazione del report, hanno comunicato di non riconoscersi nelle conclusioni dello stesso, dal momento che non ritengono essere stati presi in considerazione i commenti e le modifiche dalle stesse proposti.

Executive summary

One-liner

A quick diagnosis for occult bleeding in the gut is necessary. We summarised the evidence of performance and impact of the video capsule developed for this purpose.

Background

The Wireless Capsule Endoscopy (WCE) is a recent technology that allows imaging of the small intestine, an anatomic site that has proved peculiarly difficult to visualise. The patient swallows a small capsule, which whilst moving through the gastrointestinal tract, captures images. The main indication for WCE use is diagnosis of Obscure Gastrointestinal Bleeding in adults, which is defined as bleeding of unknown origin that persists, or recurs, or is visible after a negative colonscopy and/or upper endoscopy result. Obscure Gastrointestinal Bleeding is a syndrome or group of symptoms rather than a single pathology, and as such makes it difficult to make reliable estimates of prevalence. In recent years indications for WCE use are increasing, but this may not be supported by sufficient evidence. Anecdotal evidence and expert opinion about the diffusion of WCEs imply that Italy is the country where its use is most widespread. A systematic assessment of this device for the Italian context has become urgent since new models of the WCE at higher prices are currently becoming available on the International market.

Conclusions

12

Based on evidence from one randomised controlled trial the WCE appears dominant for the diagnosis of Obscure Gastrointestinal Bleeding in the small bowel compared to Push Enteroscopy. However its dominance is based on tolerability, rather than proof of a superior diagnostic accuracy. The WCE procedure has a high failure rate, results in serious harms in 1% of cases, but is more acceptable to patients than its alternatives. Given its tiny evidence base, high cost, and potentially high failure rate, the WCE procedure should be only be reimbursed if used in a valid evidence-generating framework.

Raccomandazione

Sarebbe importante che nel futuro il rimborso della VCE fosse legato alla produzione di evidenze fondate su trial randomizzati ben costruiti, il cui obiettivo sia testare le performance della tecnologia per le sue diverse indicazioni, sotto la supervisione di una commissione scientifica ed etica. Questo tipo di approccio, che a livello internazionale è già in uso (ed è chiamato Coverage with Evidence Development), dovrebbe essere adottato per tutte le tecnologie emergenti prima che queste si diffondano, in modo non governato e spesso senza sufficienti evidenze, in Italia. In particolare, rispetto al contesto italiano alcune nuove indicazioni proposte, come per la diagnosi di celiachia, appaiano inutili in quanto per tale diagnosi è comunque necessaria una biopsia che affermi l'effettiva presenza della patologia.