



Introducing Health Technology Assessment (HTA)

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*Workshop: HTA-what do I need to know as national
patient advocate*

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- Health Technologies (HTs): basic concepts
- What Health Technology Assessment (HTA) is?
- Basis for HTs market approval
- What is assessed in HTA?
- Basic steps of HTA
- Who is who in HTA
- What you can do to get involved

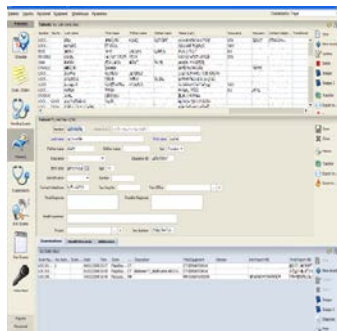


Health Technologies: Material Nature

Medical Devices, equipments & supplies



Support Systems



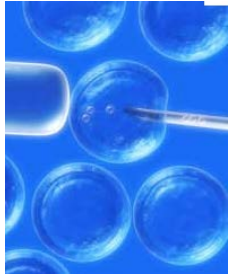
Medical/Surgical Procedures



Drugs



Biologics

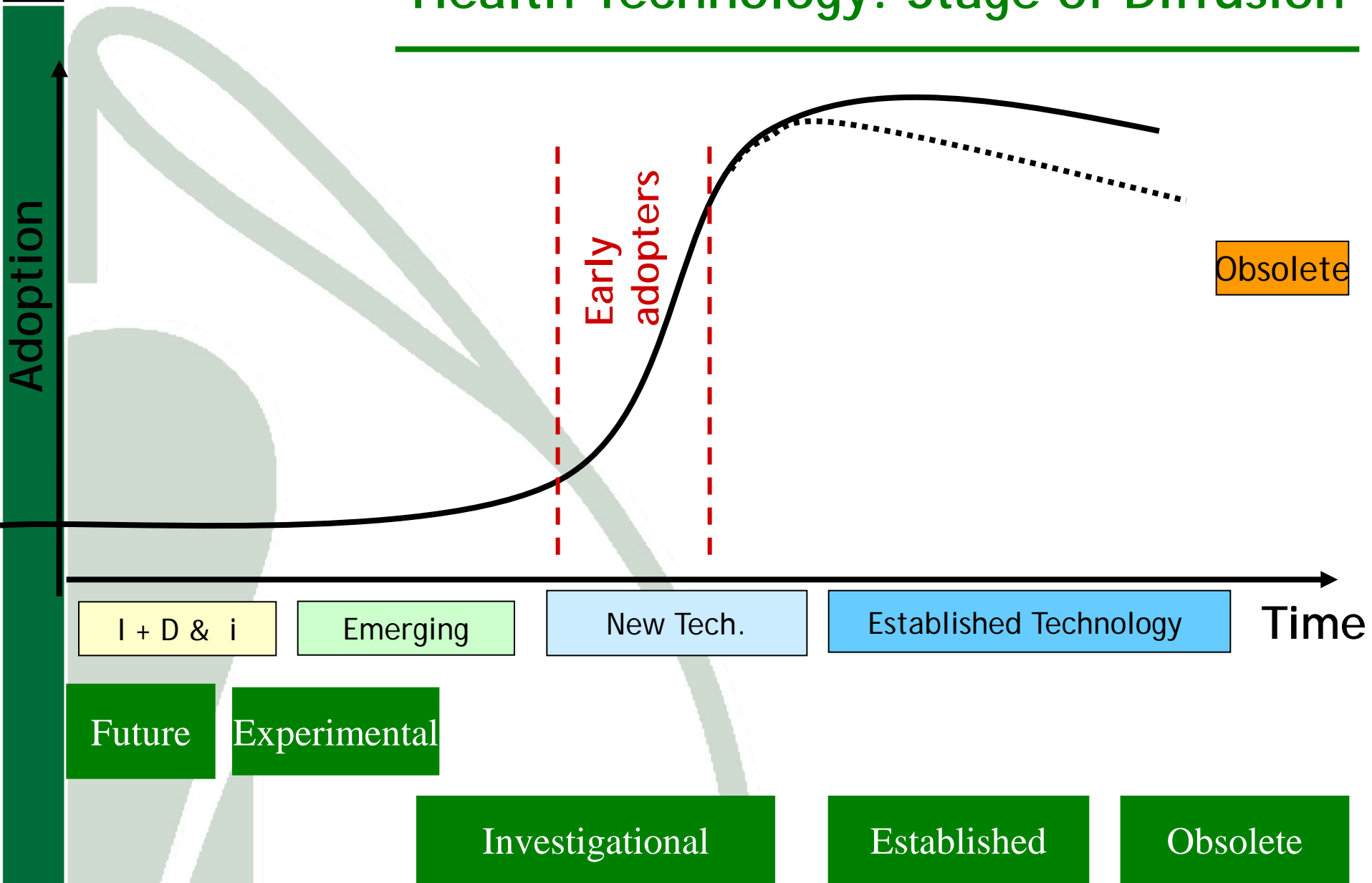


Organizational and managerial Systems

Health Technologies: Purpose or application

- **Prevention:** protect against disease
 - Eg. Immunization, hospital infection control program
- **Screening:** detect abnormality, disease or risk factor
 - Eg. Tuberculin test
- **Diagnosis:** identify the cause of disease
 - Eg. X-ray for possible broken bone
- **Treatment:** improve or maintain health status
 - Eg. Coronary artery by-pass, psychotherapy
- **Rehabilitation:** restore, maintain or improve disable's person function
 - Eg. Exercise program for post-stroke patients

Health Technology: Stage of Diffusion



Obsolete

I + D & i

Emerging

New Tech.

Established Technology

Time

Future

Experimental

Investigational

Established

Obsolete



What Health Technology Assessment (HTA) is?

- It is the **research-based, practice-oriented assessment** of relevant available **knowledge** on the direct and intended **consequences of technologies**, as well as the indirect and unintended consequences
- The **goal** of health technology assessment is to provide **input to decision making in policy and practice**

HTAi Corporate Strategy: <http://www.htai.org/index.php?id=19>

What Health Technology Assessment is?

Research
Basic/Applied



Assessment

Decision

HTA deals with:

- ❖ Global scientific evidence
- ❖ Local evidence and other information

HTA approaches/orientation to HTs:

- ✓ *Technology-oriented*: Focused on specific HTs (STA)
- ✓ *Health Problem oriented*: Solutions for managing a particular problem (MTA)
- ✓ *Project-oriented*: local placement or use of a HT in a particular insitution (mini-HTA, rapid-HTA)

Possibilities of HTA & health systems

MACRO

To Inform Coverage

Distribution and allocation resource

Design of payment systems

Entry Schemes mechanism

To guide **disinvestments** decisions

To guide Scientific and Industrial Policy

Identification of **research gaps**.

Info valorization & transfer

MESO

To Inform Investments (innovation “in”)

Research

To support Valorization & transfer (own innovat)

Assessment “in-time”

To teach Decision makers

MICRO

To Feed **CPG development**

To Support Adequate use oh Health Technol

To Teach Professionals & citizens

To disseminate Mas-media, users associati

What is the basis for HTs market approval?

Regulatory Agencies: PMA (FDA), CE Mark

Can it work?

Safety & Efficacy (Absolute)

Performance

Benefits & Risks

- “Ideal” conditions:
- Best centers
- Best doctors
- Selected patients

Drugs:

Pharmacokinetics

Medical Devices:

Quality

Source information:

Clinical evidence
(RCT: Phase I, II, III)

Source information:

Technical tests

What is assessed in HTA?

Health Technology Assessment

Regulation:
CE Mark, FDA-PMA

Benefits & Risks

- “Real” world:
- Our centers
- Our doctors
- Average patients

Comparative Effectiveness

How much better/safer?

Effectiveness

Safety & Efficacy (Absolute)

Performance

Can it work here?

Can it work?

Source information:

Global evidence:
MegaTrials,
non-experimental

Local evidence:

Pragmatic Trials

Country info,
EHR, Registries

..

Quality of evidence

What is assessed in HTA?

Health Technology Assessment

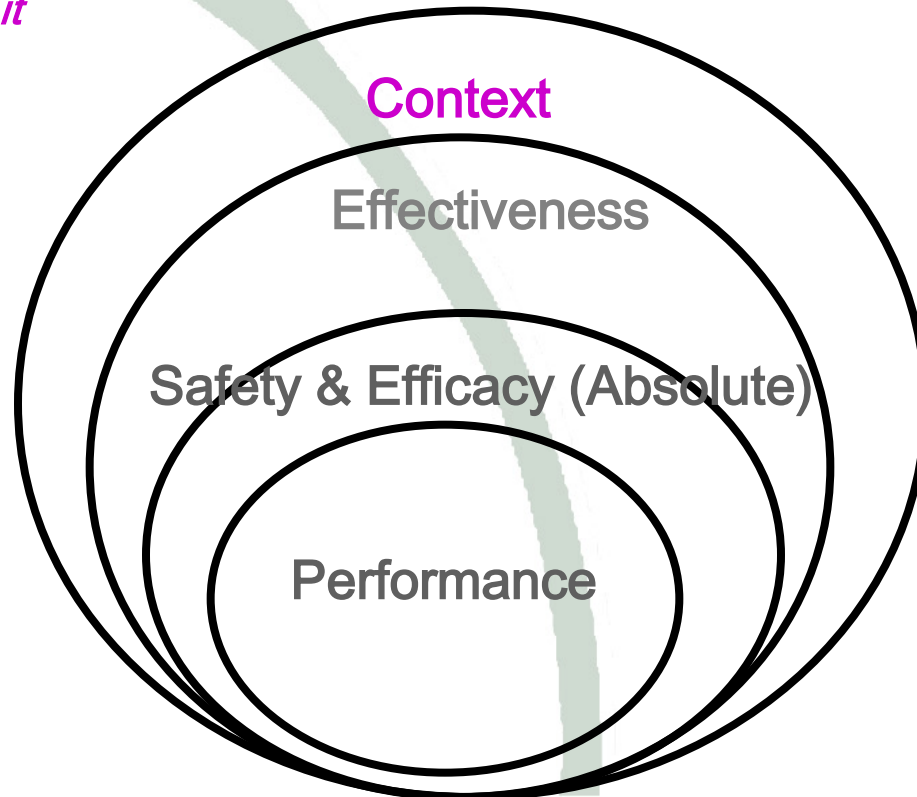
Regulation:
CE Mark, FDA-PMA



Should we do it here?

Can it work here?

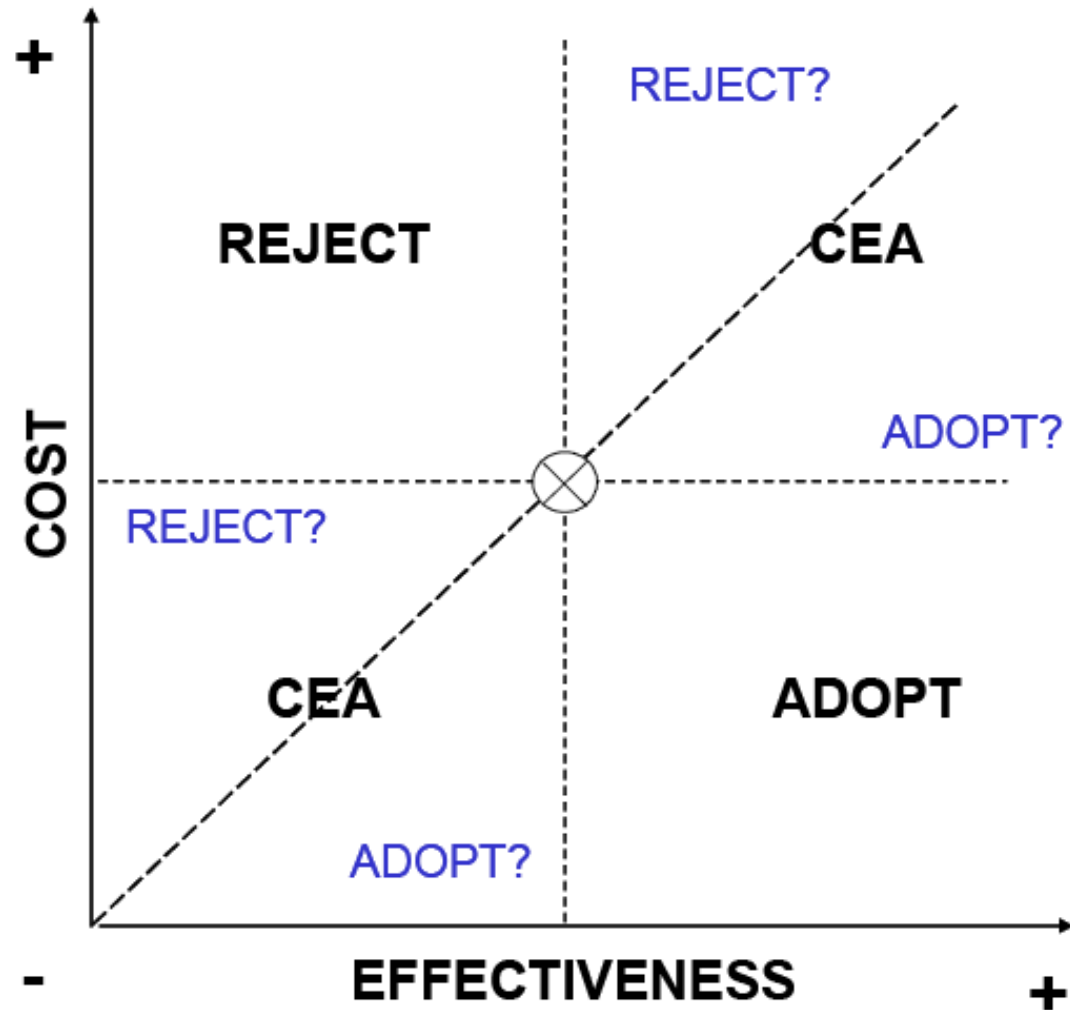
Can it work?



Source information:

**Economic
evaluation studies**

What is assessed in HTA?



C_0
C_0

(s)

What is assessed in HTA?

Health Technology Assessment

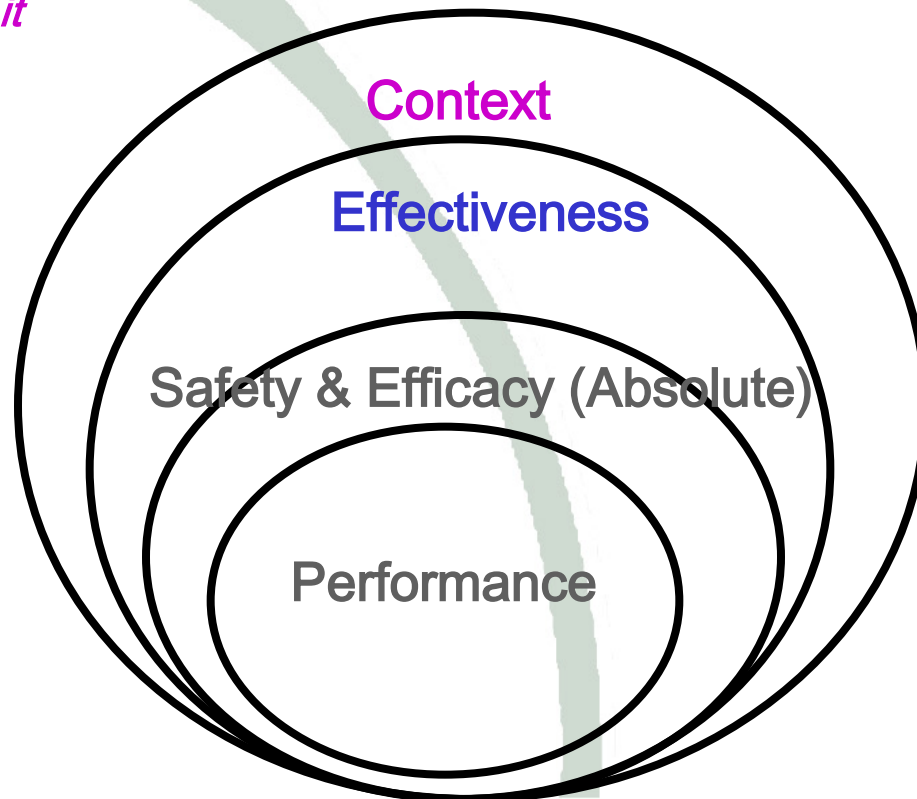
Regulation:
CE Mark, FDA-PMA



Should we do it here?

Can it work here?

Can it work?



Source information:

Economic
evaluation studies

Budget impact

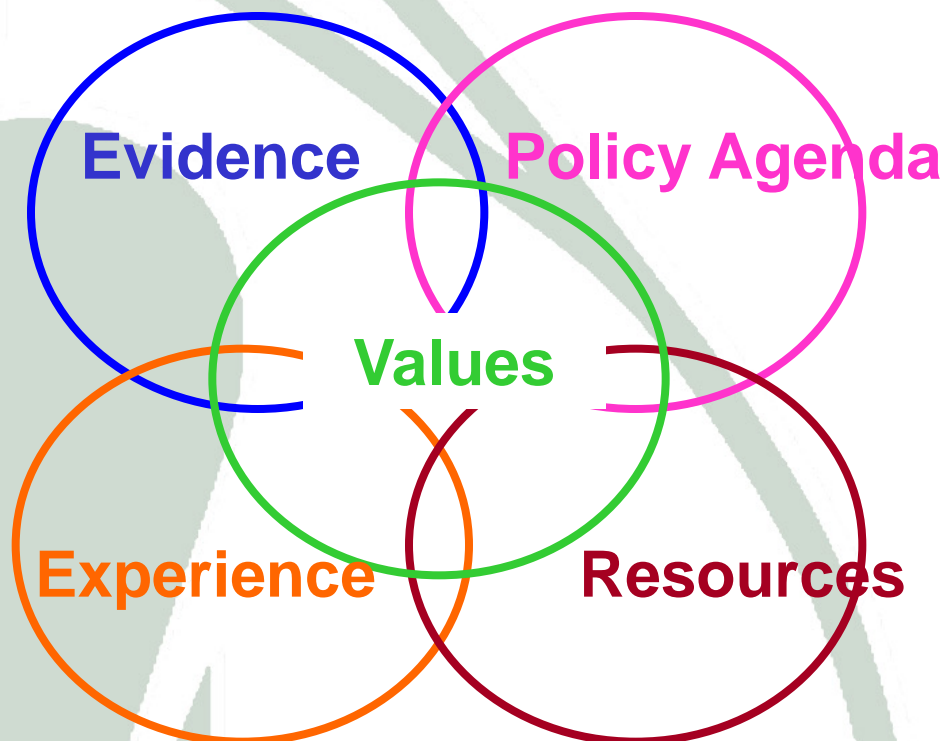
Ethical, Legal
appraisal

Organizational
analysis

1. Identify assessment topics
2. Specify the assessment problem (definition of policy question)
3. Determine the scope of the assessment
4. Search and retrieve evidence
 1. Appraise/interpret evidence (Quality!)
 2. Integrate/synthesize evidence
 3. Collect new primary data (as appropriate)
5. Formulate findings and recommendations
 1. +/- Appraisal
6. Disseminate findings and recommendations
7. Monitor impact

Why are different HTA based-decisions are made in different jurisdictions?

More about Context !!!!!



Other criteria in final decision:

- Need
- Available alternatives
- Innovativeness
- Burden / severity disease
- Relevance for public health
- Equity

Who is who in HTA?



Doers and users HTA
More than 1,200 individuals
Organizational members
48 Non-Profit
16 For-Profit
10 Interest Subgroup:
Patient and Citizens

Only public
HTA
agencies

**INAHTA: Consumer
involvement**



What can you do to get involved?



Listen to: Liuska Sanna !!!



Thank you for your attention!