Workshop on practical aspects of HTA – Understanding HTA information.

Ethical aspects

Fundació Doctor Robert
UAB

Dr. Iñaki Gutiérrez-Ibarluzea
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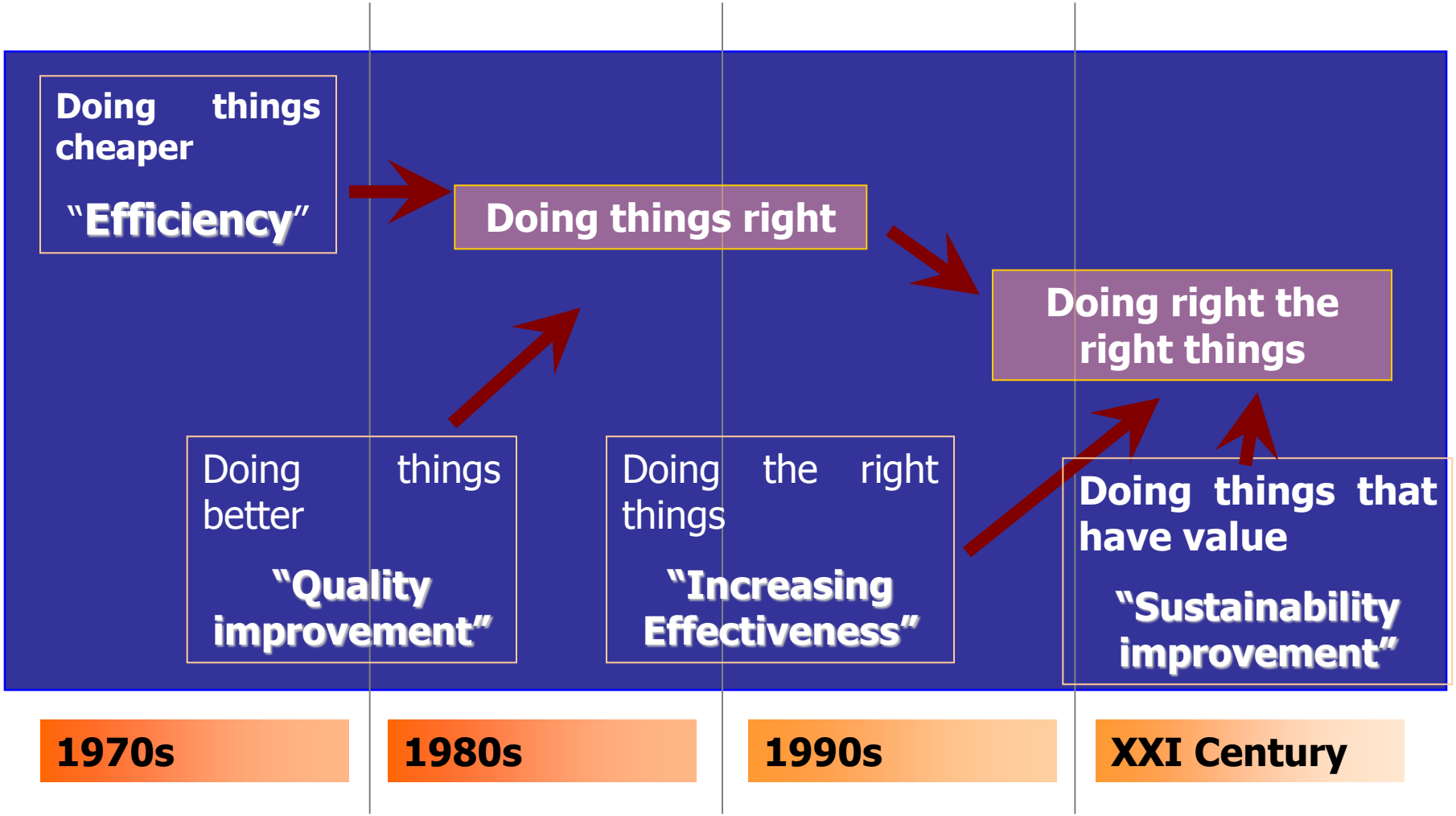
Ministry of Health and Consumer Affairs
Basque Country

Health care systems …

- **When a doctor makes a mistake, it is better to throw land on the issue.**
- **My father sold the pharmacy because there was no other remedy.**
- **Fix the economic problems is easy, all you need is money.**

Wody Allen. Movie Director and Clarinetist.

The evolution of evidence based health care. (Source : Muir Gray JA. modified)



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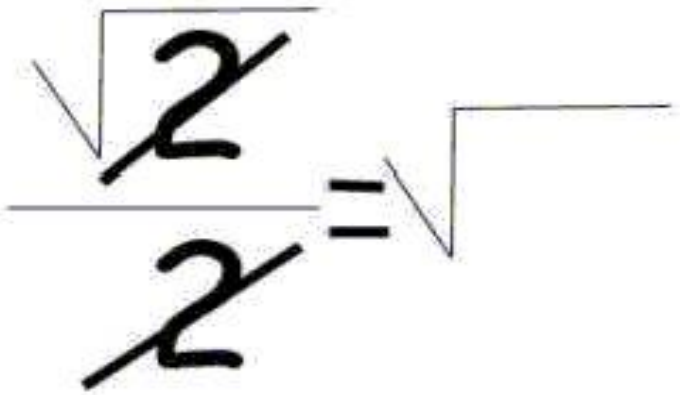
How to capture the value of what?



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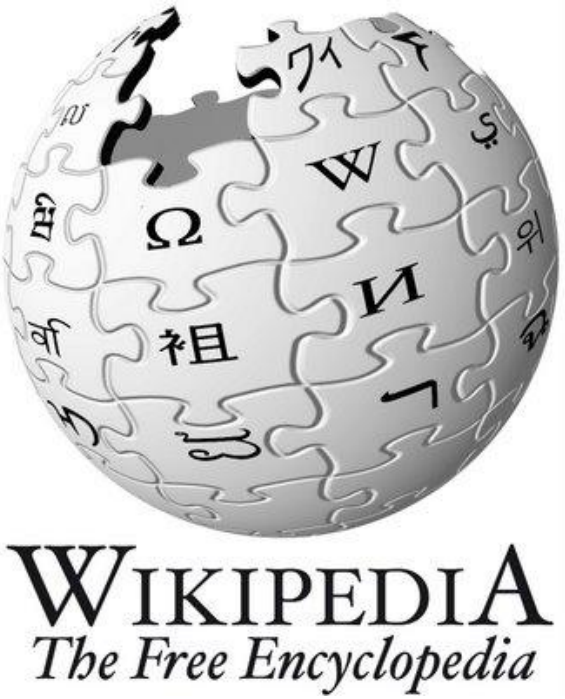
What is value?

- Value **may refer to:**
  - Value (ethics)
    - Value theory
  - Value (personal and cultural)
  - Value (economics)
    - Theory of value
  - Value investing
  - Value (marketing)
  - Value (computer science)
  - Value (law)
  - Value (semiotics)
  - Value (colorimetry)



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Value economics

- **value is how much a desired object or condition is worth relative to other objects or conditions. Economic values are expressed as "how much" of one desirable condition or commodity will, or would be *given up* in exchange for some other desired condition or commodity**
  - Comparison
  - Exchange

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Value for health

- **Economic imperative (sustainability)**
- **Ethical imperative (quality of care)**
- **Best practice imperative (excellence)**
- **Social imperative (equity)**

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Why are we talking about values?

- **Crisis?**
- **SEC. 2. The Congress hereby finds and declares that:**

  (a) As technology continues to change and expand rapidly, its applications are

  1. large and growing in scale; and

  2. increasingly extensive, pervasive, and critical in their impact, beneficial and adverse, on the natural and social environment.

  (b)Therefore, it is essential that, to the fullest extent possible, the consequences of technological applications be anticipated, understood, and considered in determination of public policy on existing and emerging national problems.

  – (Congress of USA. October 1972)

OTA. Office of Technology Assessment

- **Accordingly, it is necessary for the Congress to:**

1. equip itself with new and effective means for securing competent, unbiased information concerning the **physical, biological, economic, social, and political effects of such applications**; and
2. utilize this information, whenever appropriate, as one factor in the legislative assessment of matters pending before the Congress, particularly in those instances where the Federal Government may be called upon to consider support for, or management or regulation of, technological applications.

Are changes in place?

"So much is expected, by the public and by politicians. But resources are finite and choices have to be made about where and how to invest – and disinvest – to make the most out of the nation's funding for health" ***(NICE, 2006)***

- *Comparison*
- *In exchange*
- *Need for an instrument*

Easiest way?

"The drug itself has no side effects, but the number of health economists needed to prove its value may cause dizziness and nausea"

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Comparison and in exchange?

- **QALY: The quality-adjusted life year (QALY) is a measure of disease burden, including both the quality and the quantity of life lived. It is used in assessing the value for money of a medical intervention. The QALY model requires utility independent, risk neutral, and constant proportional tradeoff behaviour.**
  - Comparison
  - In exchange

What?

- **Disease burden**
- **Quality**
- **Quantity**
- **Value for money**
- **Medical intervention**

- **[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).

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HTA is much more than health economics

"To *infinity and beyond*!"

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Could we use QALY in all cases as sole information?

- **Burden of disease**
  - Deaths caused by ritual circumcision
- **Quality of life**
  - Morbidity related to infection
- **Quantity of life**
  - Reduction in expected life years
- **Value for money**
  - Increase in costs of health system
- **Medical intervention**
  - Improve the method of circumcision

Male circumcision morbidity and mortality statistics
Eastern Cape, South Africa, 2001-5

		Admissions	Mutilations	Deaths
2001	June	124	20	24
2001	December	200	11	12
2002	June	291	14	33
2002	December	156	19	17
2003	June	227	22	21
2003	December	84	7	20
2004	June	118	3	14
2004	December	260	2	13
2005	June	288	9	23
Total		1748	107	177
Average per annum		388	24	39

Source: Department of Health, Eastern Cape

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Could we use QALY in all cases as sole information?

- Physical
- Biological
  - **Better sterilization of procedure**
    - **Reduction of morbidity mortality ratio**
- Economic
  - **Che**
  - **Reus**
- <u>Social</u>
  - **Cultura**
- Political eff

One chief criticised the Department for interfering in the circumcision ritual . He said the ongoing deaths showed that the ancestors did not approve of what health officials were doing in closing down unregistered schools and prosecuting unregistered surgeons.

Daily Dispatch, 11 January 2006

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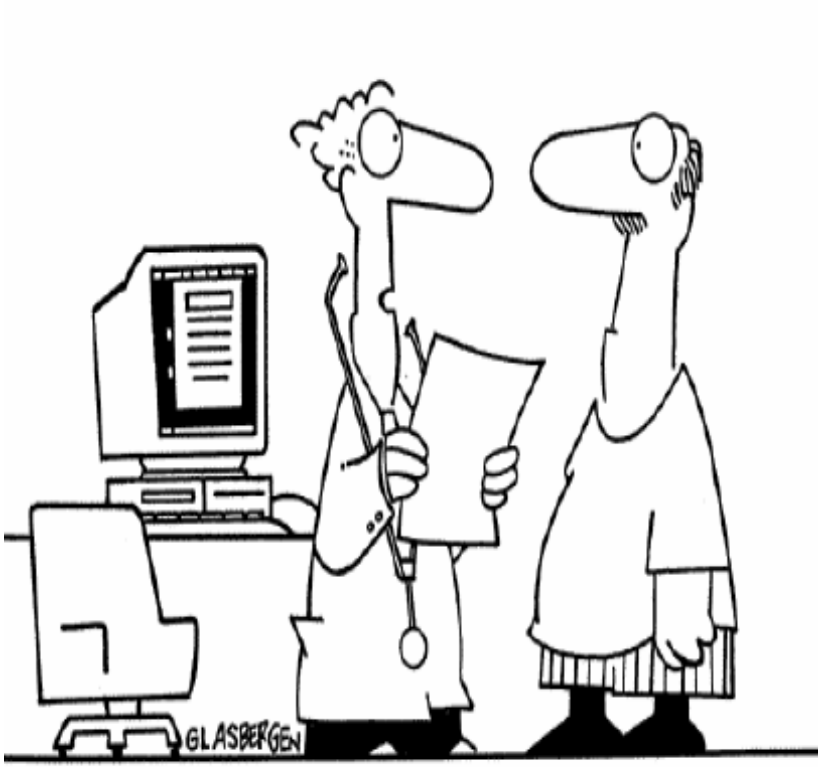
It is not only technology



"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."

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Another example

- **Anticoagulation monitoring**
  - Effectiveness
    - The most accurate test. Lab tests
    - Reasonable accuracy of portable coagulometer
  - Economic
    - Lab tests cheaper than portable coagulometer (direct costs)
    - Indirect costs higher in lab tests
  - Organizational
    - Specialist control Lab test
    - Primary physician control portable coagulometer
  - Social and ethical
    - Lab tests, there is a need for blood sample extraction. Venipuncture
    - Portable coagulometer. Finger-puncture

Value for whom?

Users
Community

Professionals

Managers

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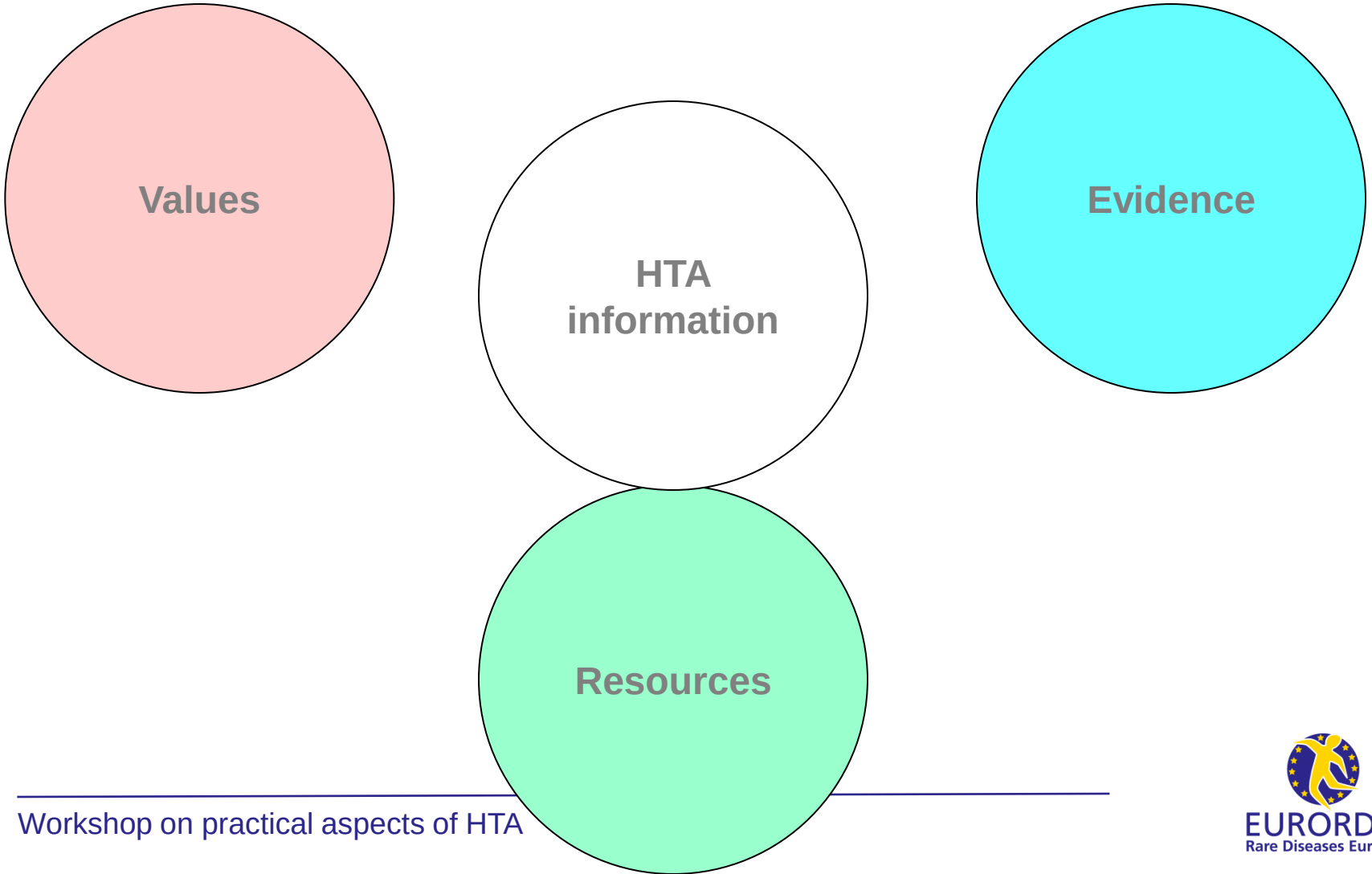
Decision making



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Users and community (values?)

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Users are changing

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Shared decisions

Decisiones compartidas

DEBATE DE SALUD PÚBLICA

RICARD MENEU

- **The 89% of the women with breast cancer wanted to play an active role in the decision on their treatment and only 24% of them were offered by their physician to do so.**

El 89% de las mujeres con cáncer de mama deseaba un papel activo en el tratamiento, pero sólo en el 24% de los casos lo percibía el médico

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Professionals' values

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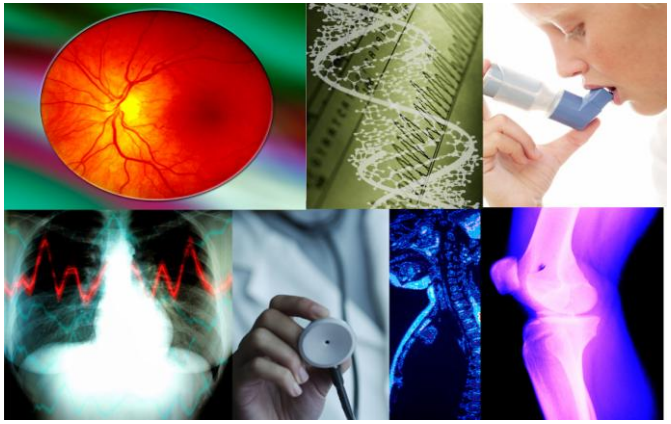
Shared decisions

- **Health care is more technified**
- **Fear to share decisions**
  - To show uncertainty
  - To keep up to date
- **Need for continuous learning**
- **Learning curves and building capacities**

The technologies…

Perfect technologies

- **Effective in all patients**
- **Same doses or cycles!**
- **Without secondary effects or harm!**
- **Costless**



Real technologies

- **Effective in some cases or patients**
- **Different doses**
- **A proportion of patients didn't respond to them or suffer harmful effects**

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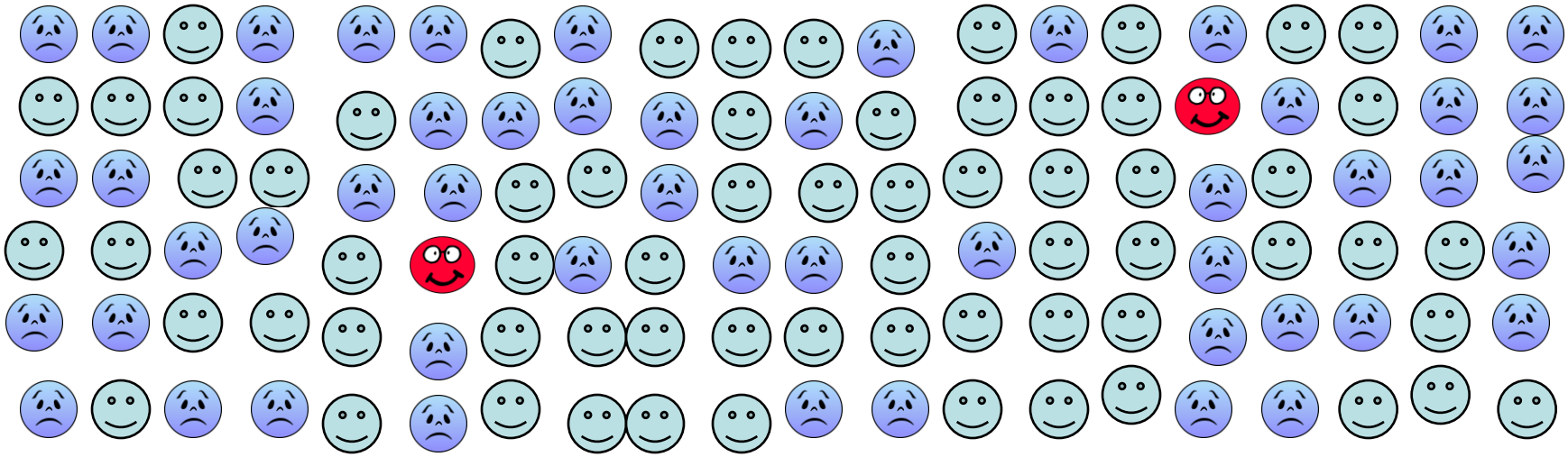
The technologies…



In a non selected population, there are no respondent patients or those that suffered harmful effects

“Safe respondents”

No response

Adverse effects

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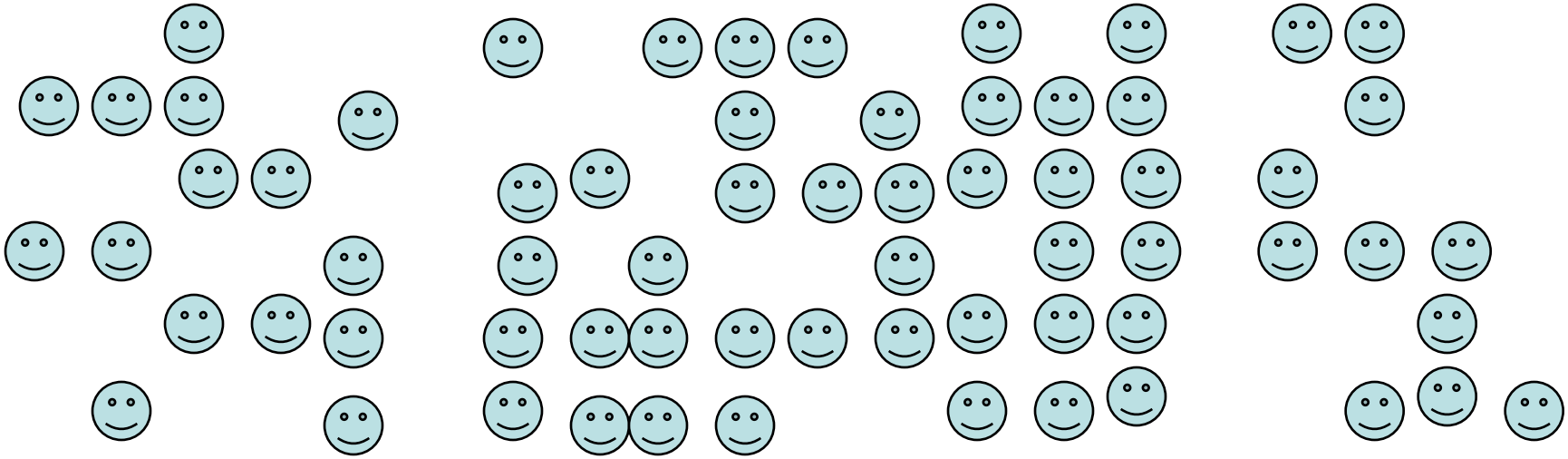
The technologies…



The concept of adapted health systems is that those technologies which procured adverse effects or no effects are not applied to patients.

Safe respondents

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Role of HTA…

- Proactive**: where a range of sources are searched for information on new and emerging health technologies. There is a link with innovators and producers.**

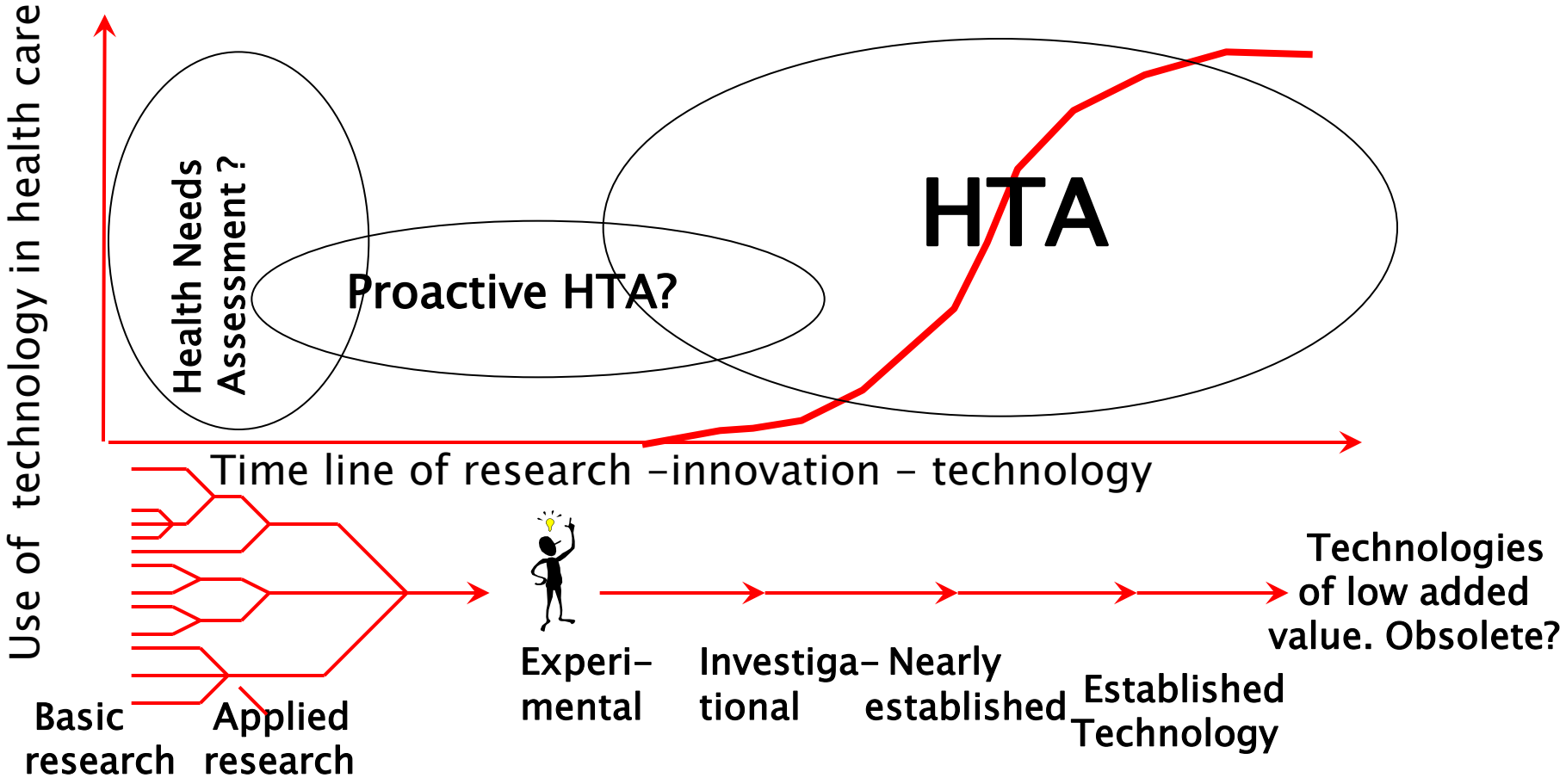
- Reactive: **where systems are in place that allow stakeholders, health professionals, consumers to inform the EAAS of new and emerging health technologies.**

What has been HTA position till now

- **Reactive**
- **Proactive in certain cases:**
  - Horizon scanning an early warning systems or Early Awareness and Alert Systems
  - Observation of technologies post-introduction
  - Monitoring systems
  - Establishing game rules
- **Cautious in the relation with health technology enterprises**

What has been HTA position till now

HTA is mainly a *retrospective* assessment approach



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Proactive systems

- **Identify needs of the health systems**
- **Identify technologies that are in development or to be implemented in the systems**
- **Identify innovative ideas that could cover identified needs**
- **Establish a bridge between health systems and innovation providers or put in touch innovators and producers**
- **Introduce innovation in a rational way (provide adapted technologies) with supportive information tools post-introduction**
- **Nearer to patients' and professionals' preferences**

Innovation?

- **The best innovation in biomedical research is to produce effective and safe drugs.**
  - Luis Truan. Minister of Health of Cantabria (Spain)

LO + LEÍDO

- El Gobierno aprueba los datos mínimos que deben contener los informes clínicos para que éstos puedan ser utilizados por todos los centros y dispositivos asistenciales del SNS
- Un nuevo test permite el diagnóstico rápido de la tuberculosis
- "Están transformando una profesión vocacional y humana en un trabajo burocrático, frío y funcionarial, para salir del paso", dice CSI.F
- Un verano marcado por la candidatura de Trinidad Jiménez a la Presidencia de la Comunidad de Madrid

NACIONAL

Luis Truan dice que la mejor innovación en investigación biomédica es el desarrollo de fármacos eficaces y seguros

E.P.

El consejero de Sanidad de Cantabria ha participado junto al del País Vasco, Rafael Bengoa, en el 'X Encuentro de la industria farmacéutica: presente y futuro de la investigación', en la UIMP

Santander (14-9-10).- El consejero de Sanidad de Cantabria, Luis Truan, ha afirmado que la mejor innovación en investigación biomédica es el desarrollo de fármacos "eficaces, seguros y con la mayor rapidez posible", y ha destacado que Cantabria vive actualmente un proceso de "impulso" de esta investigación, tanto en su vertiente básica como clínica, a través del Instituto de Formación e Investigación Marqués de Valdecilla (IFIMAV).

Truan participó el pasado viernes, junto al consejero de Sanidad del País Vasco, Rafael Bengoa, en la mesa redonda sobre 'Innovación y transformaciones del SNS. Visiones desde las Comunidades Autónomas', dentro del 'X Encuentro de la industria farmacéutica: Presente y futuro de la investigación', que se celebra en la Universidad Internacional Menéndez Pelayo (UIMP).

En su intervención, el consejero cántabro ha dado a conocer la situación de la investigación clínica de medicamentos en Cantabria, actividad que lleva a cabo el IFIMAV mediante un equipo de más de 450 profesionales

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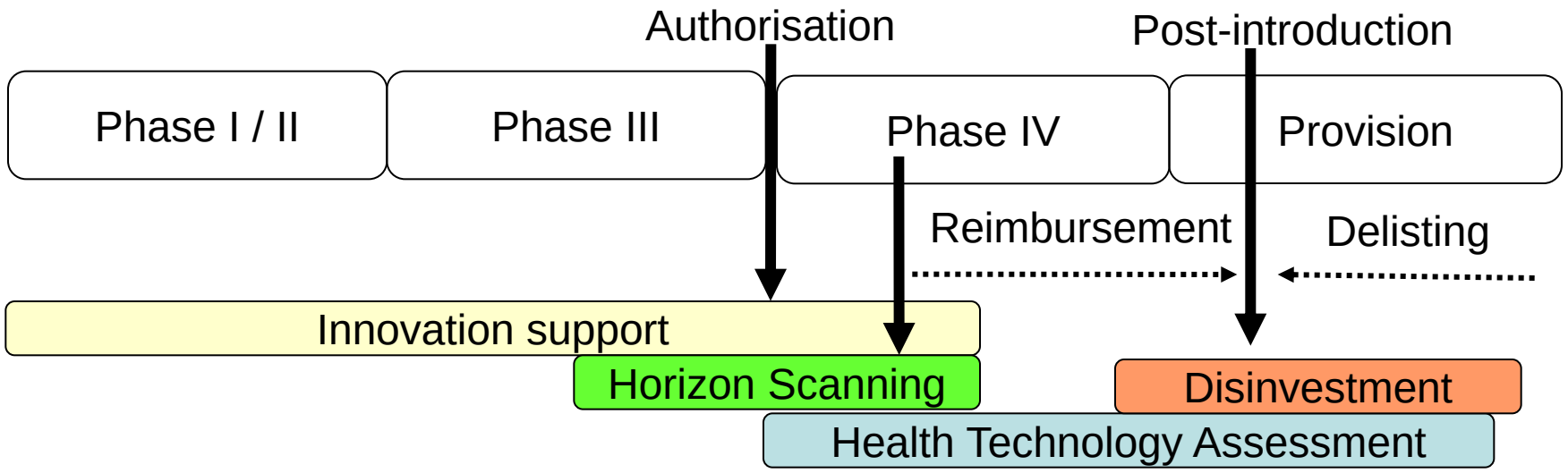
HTA new paradigm



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Which parameters should we use?

- **Evidence**
  - Physical
  - Economic
  - Biological
- **Values**
  - Ethics
  - Law
- **Organization**
  - Social
  - Cultural
  - Health system

Context

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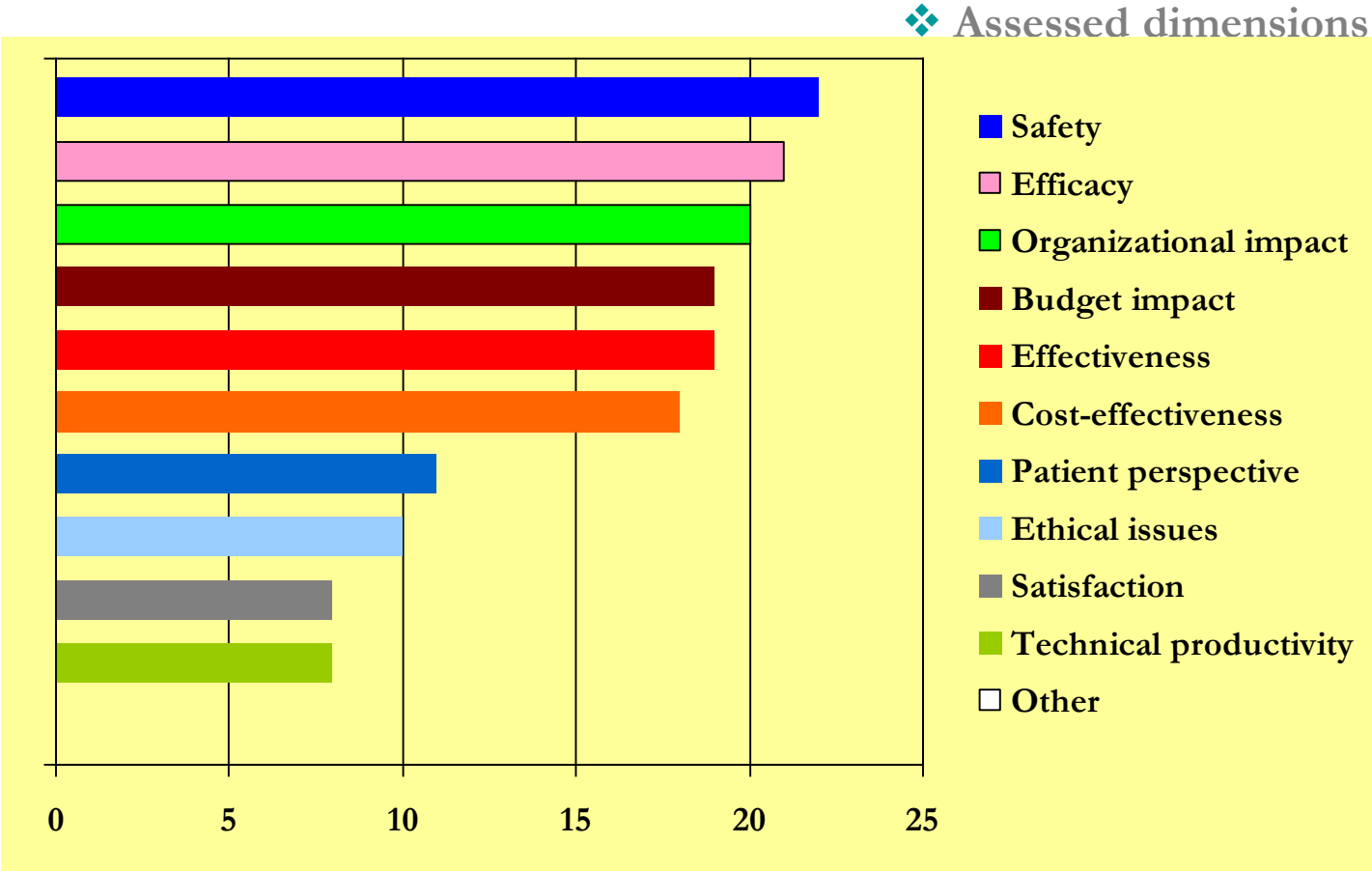
Which parameters are commonly used?

- Hta assessment is mainly focused on safety, efficacy and organizational dimensions.
- Unlike technical productivity and satisfaction are rarely assessed

SPIG: Hospital based HTA World Survey



SPIG on Hospital-HTA, 2007

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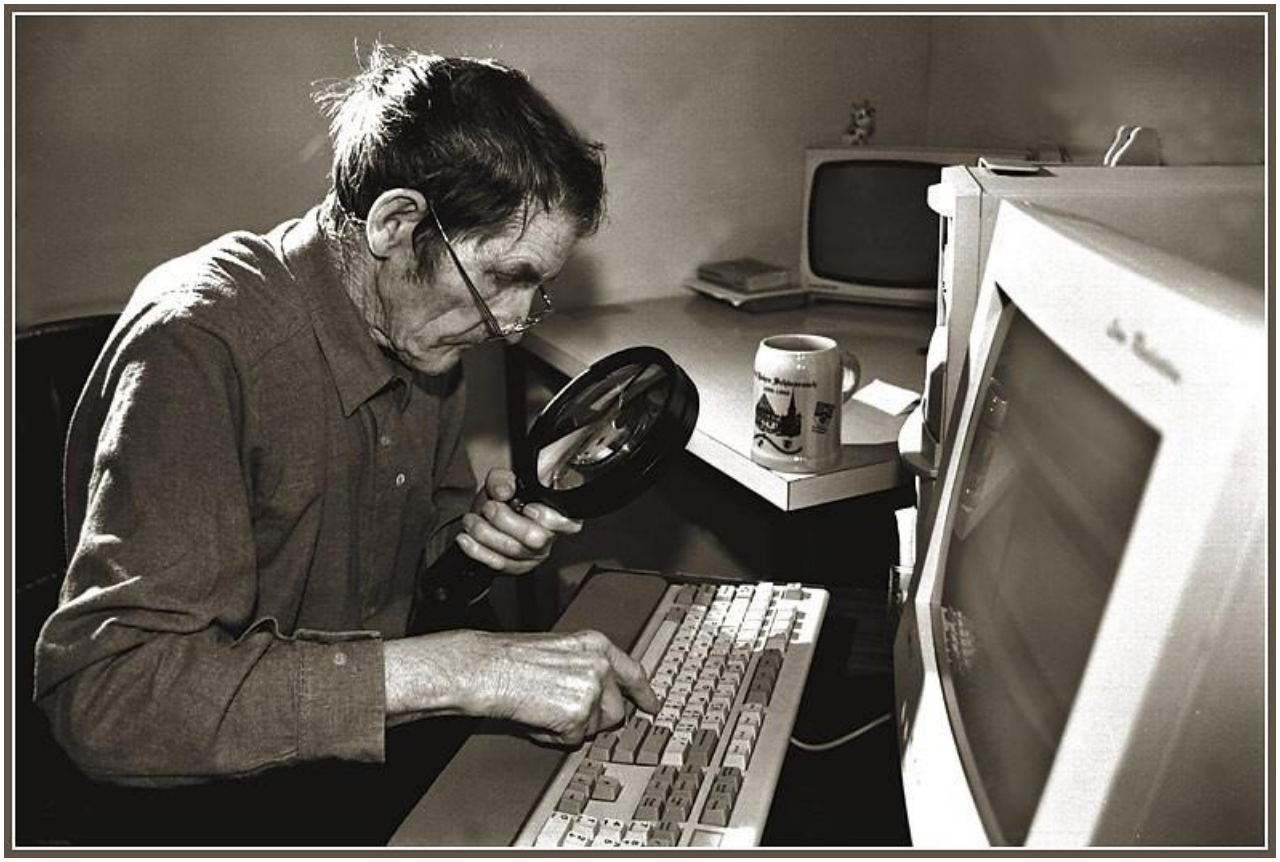
We have the tools…but perhaps



We don’t have the skills

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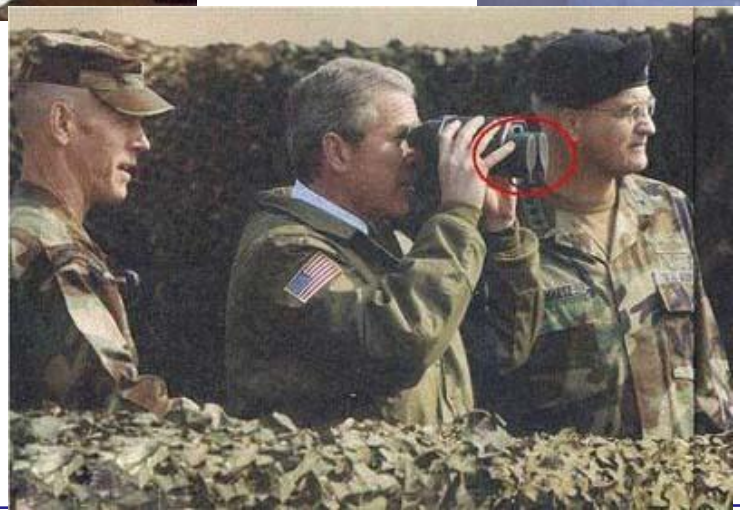
We have the tools…but perhaps

Perhaps we don't have the attitudes



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Ethics an society

Who are we supposed to love?

IDEALS, MORALITY HONESTY

GOD

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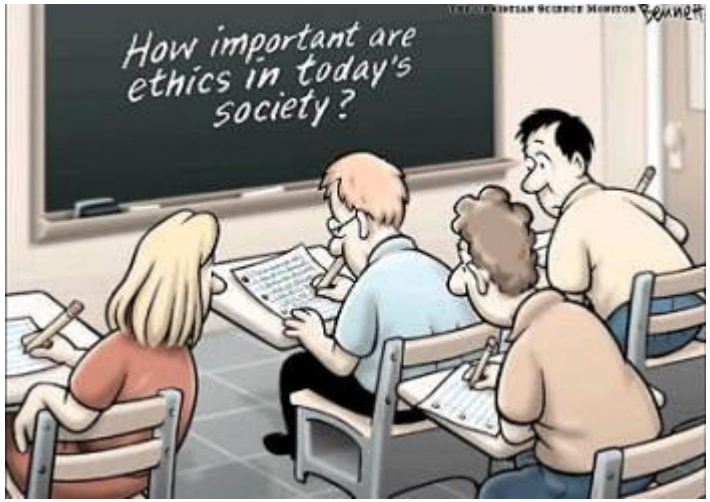
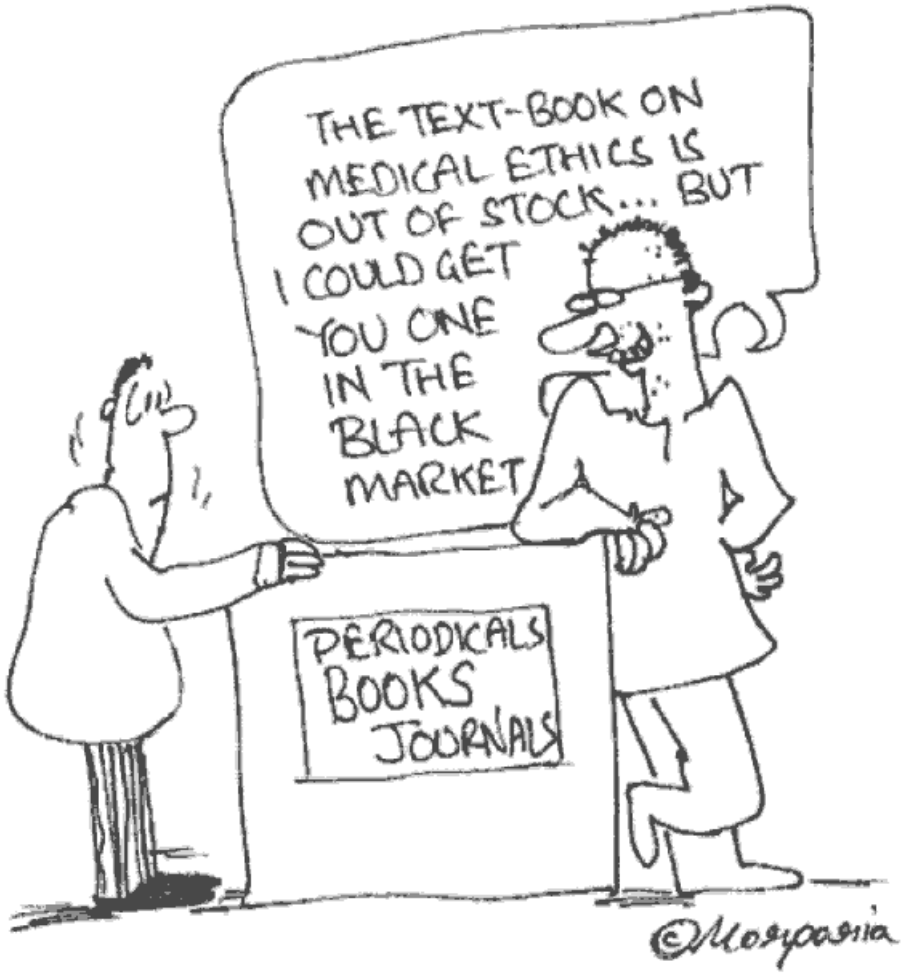
How important are values and ethics in HTA?





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How to deal with ethical issues in HTA?

- Can there be a procedure for handling ethical issues concerning technologies being assessed?
  - **If yes, what would such a procedure look like?**
  - **If no, why not and what else can be done to assure good quality of the assessment of the ethical aspects of a technology?**
- What kind of ethical issues and questions are relevant with respect to a given technology?
  - **Consequences**
  - **Duties**
  - **Relevant law**
  - **Human rights**
  - **Ethical principles (beneficence, non-malfeasance, justice, autonomy)**

How to deal with ethical issues in HTA?

- How far should HTA go in:
  - **a) Displaying values involved in the HTA-process itself?**
  - **b) Highlighting relationships between knowledge and norms?**
  - **c) Making recommendations with respect to ethical issues?**
- What is the relevance of addressing ethical issues with respect to achieving a successful dissemination?
  - **a) With respect to professionals?**
  - **b) With respect to health policy?**
- What kinds of methods might be used to tackle these kinds of issues in an HTA and how might INAHTA help to assist with appropriate methodologies and quality checks?

Ethical approach in HTA

- **Related to the technology to be assessed**
  - Consequences of applying the technology

- **Related to the HTA analysis itself**
  - Starting point (Why this technology?)
  - Potential uses of the HTA report
  - Ethical implications of an HTA appraisal
  - The extension of ethical analysis in the HTA process

Ethical approach in HTA

- To make the implicit ethical standpoint clear, the process has to be *explicit, systematic, and transparent*
  - **(Oortwijn 2000).**
- There could be a risk of distorting priorities if all stakeholders were to be involved at the early stage of prioritization of the topics.

Ethical approaches in HTA

1. Descriptive/reflective analysis in the undertaking of assessments to recognize values involved in the framing of HTA questions,
2. The application of biomedical ethical principles (principlism) for the study of the ethical implications of a particular technology,
3. Historical analysis to detect values underlying the development of a technology, and
4. Stakeholder analysis for the identification of stakeholder values.

When and what should we consider?

- **Pre-assessment**
  - *Are there moral challenges related to **components of a technology** that are relevant to the technology as such?*
  - *What is the **characteristic** of the technology to be assessed?*
  - *Is the **symbolic value of the technology** of any moral relevance?*
  - *At **what time** in the development of the technology is it assessed?*
  - *Are there **related technologies** that have or have not been assessed?*
- **Protocol development**
  - *Are there morally relevant issues related to the **choice of end points** in the assessment?*
  - Are there morally relevant issues related to the **selection of meta-analysis and studies** to be included in the HTA?
  - *Are there moral issues in **research ethics** that are important to HTAs?*

When and what should we consider?

- **Synthesis and generalization**
  - *Are the **users** of the technology in the studies representative of the users that will apply it in clinical practice?*
  - *Are there morally relevant aspects with respect to the **level of generalization**?*
- **Recommendations**
  - *What are the moral consequences of the **HTA**?*
    - What are the consequences with respect to **rationing**?
    - What is the role of the **economic models** that are applied in the calculations of cost-effectiveness?

Current ethical approach in HTA

- **Pragmatic approach**
  - Utilitarianism
  - Moral approaches
- **Principialism (Beauchamp and Childress, 2001)**
  - Respect for Autonomy
  - Non-Maleficence
  - Beneficence
  - Justice

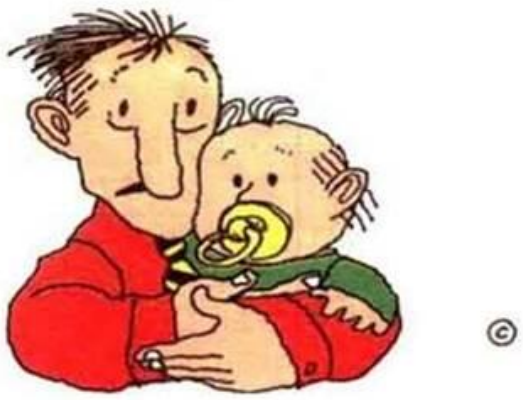
Some doubts

- How to relate an ethical analysis to the economical part of HTA?
  - **It could be claimed that a cost-utility analysis actually deals with an ethical issue transformed into a quantifiable matter**
- The mere concept of cost-utility is **utilitarianism** in a disguise.
- It is not obvious that medical treatment has increased the quality of life or QALYs as its goal.
- Ethical problem that has to do with the very concept of HTA.

Some possible solutions

- Hofmann Bjørn. Towards a procedure for integrating moral issues in HTA. *International Journal of Technology Assessment in Health Care* 2005;21(3).

It is important that we learn from the beginning



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FOCUS

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Ethics and HTA: some lessons and challenges for the future

Published online: 21 January 2004

1 Introduction

What have we learned? Is there in the contribution to this special theme a clue as to what is the best way of integrating ethical inquiry into health technology assessment (HTA)? Particularly, what is the significance of the social shaping perspective in this respect? In this concluding paper, we attempt to collect the lessons we have learnt and to answer these questions. Of course, our answer will not be the final one. It is difficult to find an appropriate and widely endorsed model of integrating ethical implications in HTA studies, if there *is* such a single appropriate model at all. But despite reserves, it is equally fair to claim that it is definitely possible to reach beyond what ethical inquiry in HTA too often concerns, namely to conclude that "the technology raises serious ethical concerns that must be dealt with." This is truly a death sentence, for both HTA and medical ethics, just when their integration is called for. In the remainder of this paper, we address three questions.

First, the main question of this issue is: *How could ethical inquiry be integrated into HTA*? Or in other words: What methods do we have to address moral aspects of technology in a valid and useful way? This question is addressed by discussing the following aspects: How can ethical issues be identified and addressed, and how could the perspective of social shaping of technology add to this?

Second: *Who is to face the challenge of ethical inquiry?* Under this header, we discuss the role of researchers, policy-makers, laypersons, and ethicists. In addition, we address the issue of moral competence.

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Why this technology?

- **Identification process**
  - Proactive
  - Reactive
  - Mixed methods
- **Prioritisation process**
  - Population and users
  - Technology
  - Safety and adverse effects
  - Costs and other implications

AATRM (CATALONIA)	CADTH (CANADA)	OSTEBA (BASQUE COUNTRY)	TNO (THE NETHERLANDS)
Prevalence Costs of technology Variation in the rates of use Burden of disease Change in health Results Change in costs Ethical, legal and social aspects	Burden of disease Clinical impact Alternatives Budget impact Economic impact Available evidence	Variation in the rates of use Importance of the illness Prevalence Change in health results Ethical and legal aspects Costs	Burden of disease Benefits for the patient Prevalence Direct costs to the patient Economic consequences Impact in health policy

Just play a role in prioritisation

- **PriTec tool**
  - Population and users
  - Technology
  - Safety and adverse efects
  - Costs and other consequences

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Prioritisation. Population and users

Population/users

Criteria	Explanation	1	2	3	4	5	6	7	8	9
Frequency of use	When it is known or anticipated that the technology is going to be applied to a large number of patients									
Burden of disease	The condition or indication for which the technology is used carries a high mortality, morbidity, disability or greatly impairs quality of life									
Population/user impact	The technology can produce significant improvements in the health / welfare of the individuals or the population to which it applies (ie mass screening).									
Vulnerable populations	The technology has been designed to be used fundamentally in highly sensitive groups (pregnant women, chronic patients)									

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Prioritisation. Technology

Technology										
Criteria	**Explanation**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Innovative Technology	When the design, materials or operating are completely new and very different to other existing technologies and/or there are no prior alternative technologies for this clinical condition.									
Invasive Technology	Technology that requires aggressive surgery or medical procedures for its application. Also implantable devices or systems designed to be partly or wholly introduced into the human body, with the intention to remain there after the procedure.									
Different expectations of Use	Health technology can be susceptible to different applications in clinical practice and to be used in clinical indications other than those approved.									

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Prioritisation. Safety / adverse effects

Safety / adverse effects										
Criteria	**Explanation**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Safety	there is evidence in the literature of adverse effects or/and they are expected due to the existence of adverse effects with similar technologies or procedures.									
Potential adverse effects not detected	The available evidence is considered insufficient to have information about rare side effects. The studies include a small number of patients in total or for specific subgroups and / or the follow-up period of study is short to properly assess the occurrence of adverse effects in the medium to long term.									
Risks	There is a possibility that health care workers suffer harm resulting from the use of the technology (eg. radiation) or the technology poses an environment hazard.									

Prioritisation. Costs and Other issues

Costs and other										
Criteria	**Explanation**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
learning requirements	technologies that require an intensive period of training and whose outcomes are heavily dependent on the acquired knowledge and personal skills (learning curve).									
Economic Impact	Required investment in infrastructure, equipment and / or cost of consumables, maintenance or human resources.									
Organizational or structural impact	technologies that require a multidisciplinary approach, the creation of specific units.									
Other implications	It is anticipated that the technology has an important impact on ethical, social, cultural and/or legal aspects.									

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Prioritisation exercise

- **Individual reading of technologies' briefings (15 minutes)**
- **Workgroup scoring (20 minutes)**
- **Consensus scoring and PriTec tool guidance (25 minutes)**
- **Discusion. (10 minutes)**
- **Questions and closure (20 minutes)**

Thanks, gracias, moltas gracies, eskerrik asko

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