Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé

Agencias de Evaluación de Tecnologías Sanitarias: ¿papel consultivo o vinculante?

« Agencies of Health Technology Assessment: compulsory or advisory role? »

Gert Peeters,
Vice-general director KCE a.i.

Asociación Española de Evaluación de Tecnologías Sanitarias

Zaragoza14/11/2008

Content

1. The Belgian Health Care Knowledge Centre: KCE
2. Challenges
   - Cost driver: medico-technological evolution
   - Health policy: more accountability & transparency
3. HTA in Belgium: KCE in a compulsory or advisory role?
   - Guidelines for pharmaco-economic evaluations
   - Better procedures emerging medical devices
   - Better understanding by policy makers
4. Conclusion
5. Future?

KCE

- The Belgian Health Care Knowledge Centre
  - is a semi-governmental institution
  - operating as an independent agency.
- Most of its activities are commissioned
  - by the Ministry of Public Health and Social Affairs
  - by the National Institute for Health and Disability Insurance (NIHDI).

Mission KCE (1)

- The mission of the KCE is **to advice policy makers** about the possibilities to obtain an efficient allocation of scarce health care resources that optimizes the quality and accessibility of health care.

Mission KCE (2)

- The KCE has four domains of research:
  - Health technology assessment
  - Good clinical practice
  - Health services research
  - Equity and patient behaviour
- The aims of the KCE can be summarized as follows:
  - Production of analyses and studies in the different domains in which decisions must be taken;
  - Collecting and disseminating objective information from registered data, literature and current practice;
  - Developing high level scientific expertise in the four research domains.

KCE Staff

- The KCE has a permanent staff of about 30 experts from different disciplines, including medicine, economics, statistics, sociology, psychology and law.
- By the end of this year, the KCE will have completed a hundred projects, since the start of its activities in 2004.

How the KCE works

- Topic proposals: submitted throughout the year and evaluated once a year.
- Research topics: planned and prioritized with the Board of Directors.
- Research projects performed by internal experts or commissioned to an external partner. All supervised by KCE experts.
- External experts are involved in each project :
  - help to pinpoint the hot issues
  - help to identify the most recent developments in the field
- Final validation - external validators critically review the report:
  - Make comments and request modification
  - reject or approve the report
- Conflicts of interest: disclosed at the start of a project.

Dissemination activities

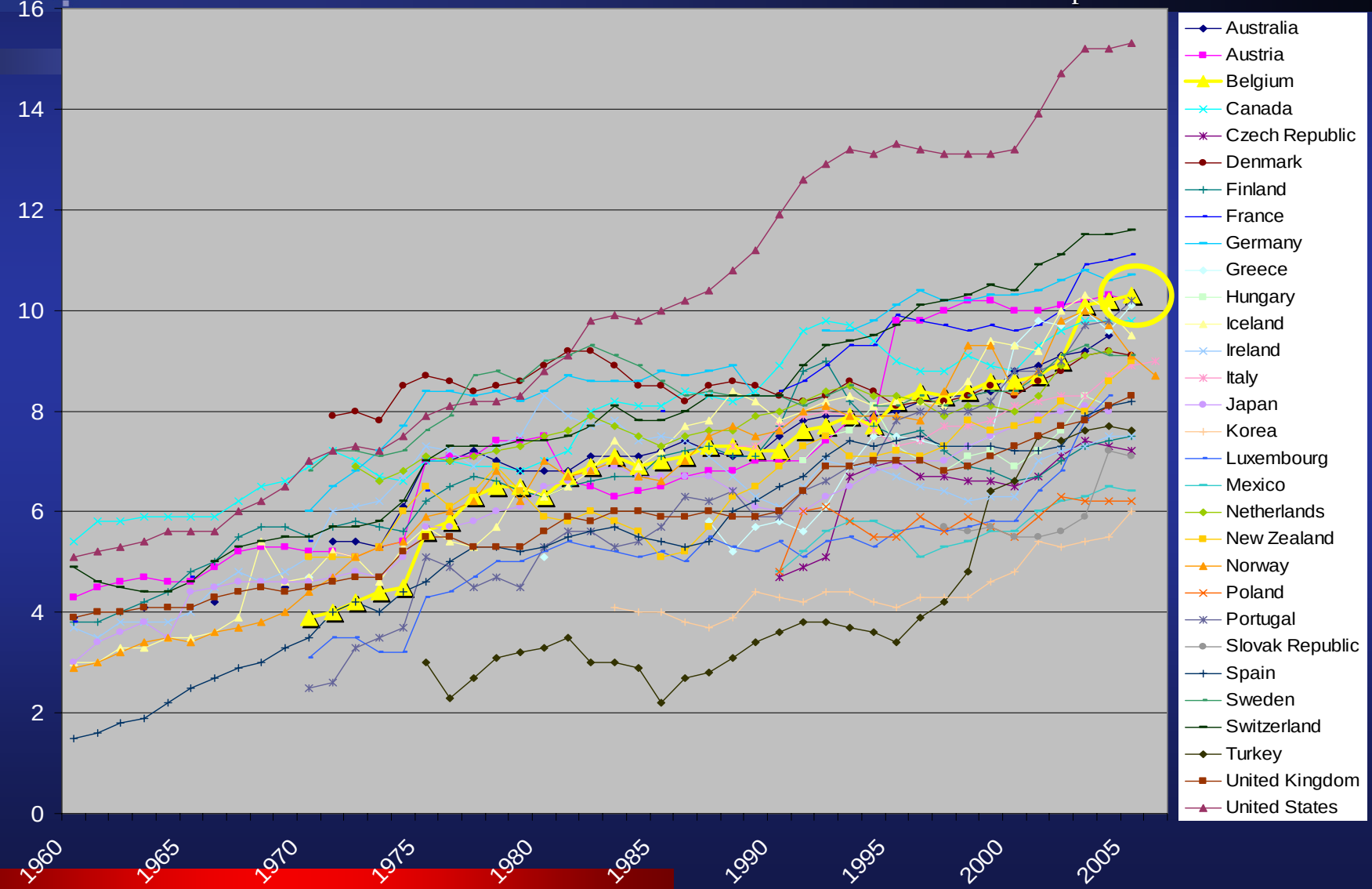
- The KCE has a legal obligation to make every report public. All reports are published on its website at www.kce.fgov.be.
- Reports are often in English, with an executive summary in Dutch and French.
- KCE publishes press releases on its web-site in order to disseminate the message to the general public.
- The KCE organizes seminars on topics within the four research domains of the centre.

Challenges

Health expenditure increases

- Major cost driver: medico-technological evolution
- Health policy: demand for more accountability and greater transparency in costs and quality
  - Therapeutic added value
  - Cost-effectiveness

“Health Systems Must Seek Better Value for Money”



Ensuring Value for Money in Health Care

- As a result of the rapid spread of new technologies, governments have faced unprecedented challenges in providing high quality and innovative care while managing health care budgets and safeguarding the basic principles of equity, access, and choice.
- Governments are increasingly required to manage scarce resources strategically, by investing in services that deliver the best health outcomes: affordable, effective, safe, and patient-centred.
- They must also make sure that innovation is adequately supported, with sufficient access to new treatments.

HTA in Belgium

- HTA: 32 HTAs by KCE

  Examples: new prostate treatments, hadron, hyperbaric O2 therapy, Multislice CT, DES, kyphoplasty, orthopedic material, …
  - Does it work? Is it cost-effective? Budget impact?
  - Price setting! (orthopedic material, stoma,…)
- Compulsory or advisory? – maximasing impact !
  - Guidelines for pharmaco-economic evaluations
  - Better procedures for emerging medical devices
  - Better understanding by policy makers

Guidelines for Pharmacoeconomic Evaluations (1)

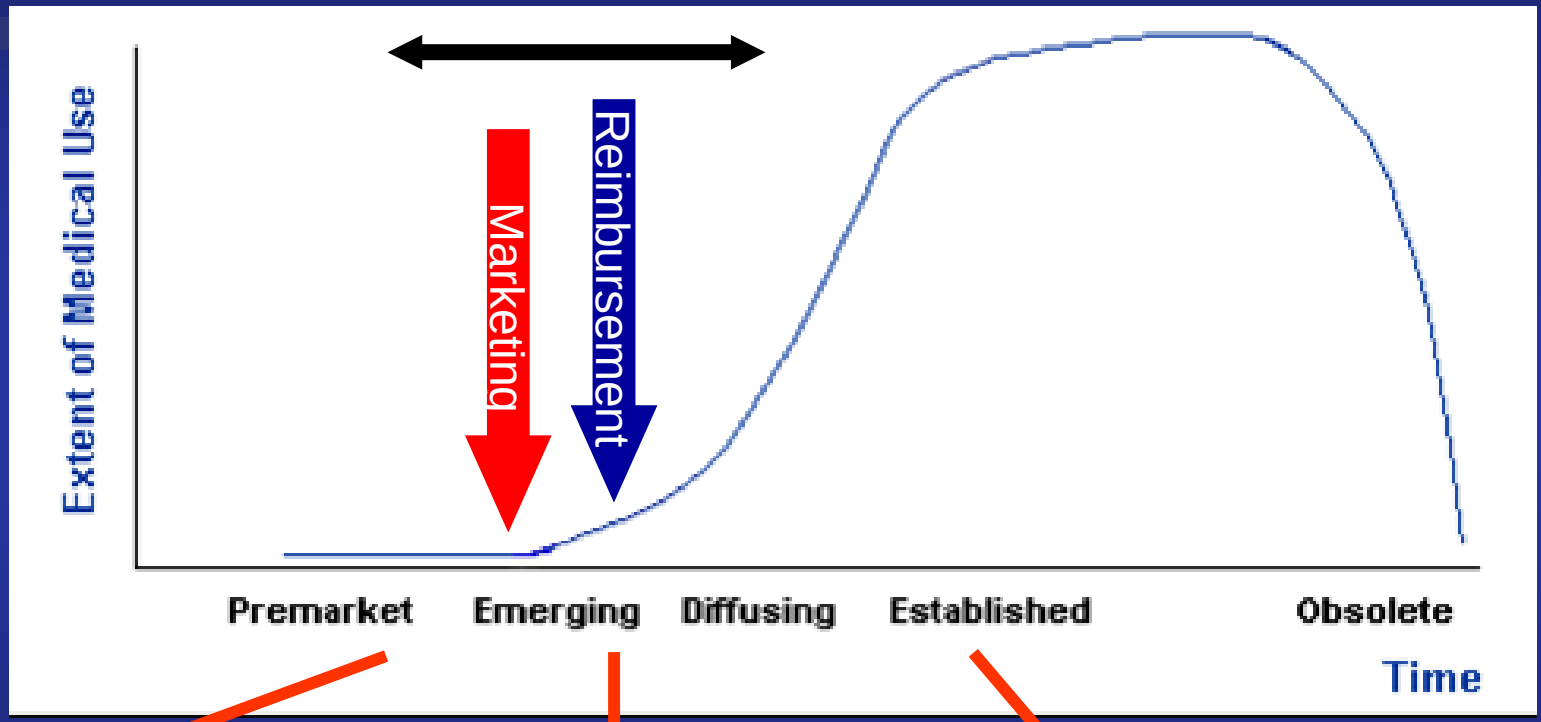
- Guidelines for pharmacoeconomic evaluations submitted
  - in the context of a reimbursement request for pharmaceutical products for which pharmaco-economic assessment is compulsory
  - in the context of a revision file 1.5 to 3 years after the initial reimbursement decision.
- The guidelines are built around a reference case that defines the recommended methodology for each component of the economic evaluation.
- Each pharmaco-economic submission should at least contain a reference case analysis.
- Additional analyses are allowed but cannot replace the reference case.

Guidelines for Pharmacoeconomic Evaluations (2)

- Compulsory
- Fixed structure and content:
  - Standardised framework for discussion
  - Basis for explicit and transparent decisions
- Burden of proof by the industry

- Also compulsory for all emerging technologies ?

'It's always too early until, unfortunately, it's suddenly too late!' (Buxton)



safety and efficacy

Added value?

cost-effectiveness?

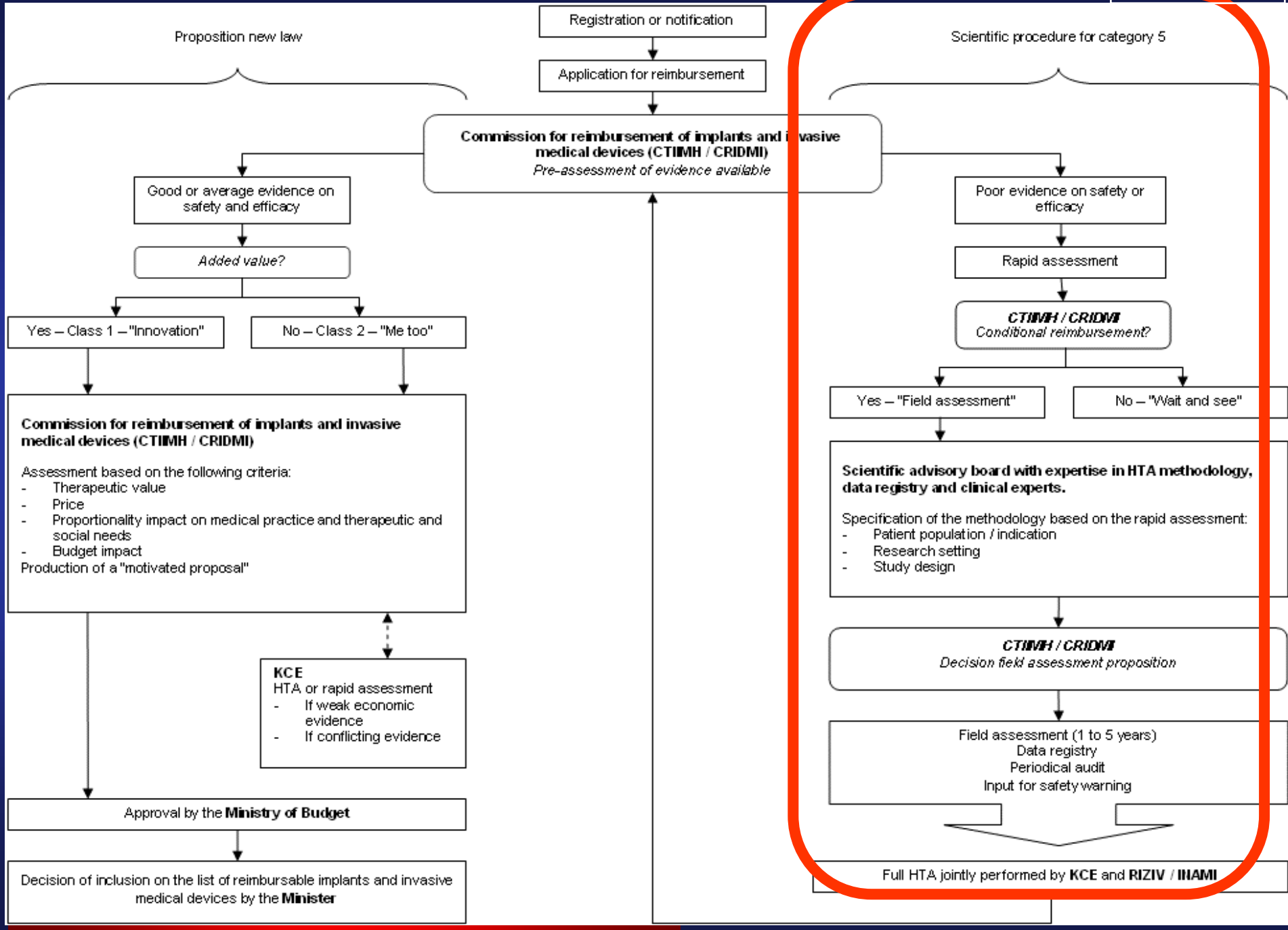
Benefits & harms?

RCT's unethical?

change practitioner beliefs and practices?

Better procedures (1)

- Ex. new procedure by NIHDI and KCE for introduction of experimental emerging medical devices including hospital HTA to support real innovation
- Poor evidence of safety or efficacy → rapid assessment → CTIMH → conditional reimbursement → field assessment proposition → field assessment (1-5 y) → full HTA


Proposition new law
Registration or notification
Application for reimbursement
Scientific procedure for category 5
Commission for reimbursement of implants and invasive medical devices (CTIMH / CRIDMI)
Pre-assessment of evidence available
Good or average evidence on safety and efficacy
Added value?
Yes – Class 1 – "Innovation"
No – Class 2 – "Me too"
Poor evidence on safety or efficacy
Rapid assessment
CTIMH / CRIDMI
Conditional reimbursement?
Yes – "Field assessment"
No – "Wait and see"
Commission for reimbursement of implants and invasive medical devices (CTIMH / CRIDMI)
Assessment based on the following criteria:
- Therapeutic value
- Price
- Proportionality impact on medical practice and therapeutic and social needs
- Budget impact
Production of a "motivated proposal"
KCE
HTA or rapid assessment
- If weak economic evidence
- If conflicting evidence
Scientific advisory board with expertise in HTA methodology, data registry and clinical experts.
Specification of the methodology based on the rapid assessment:
- Patient population / indication
- Research setting
- Study design
CTIMH / CRIDMI
Decision field assessment proposition
Field assessment (1 to 5 years)
Data registry
Periodical audit
Input for safety warning
Approval by the Ministry of Budget
Decision of inclusion on the list of reimbursable implants and invasive medical devices by the Minister
Full HTA jointly performed by KCE and RIZIV / INAMI

Better procedures (2)

- Compulsory for all emerging technologies !
- Part of the innovation policy: combines
  - better policy for government regulation

  and
  - incentives for the industry towards innovation
- Opportunity to support more professionalism in research governance.
- Offers a framework for transparent partnership between government, researchers and industry.
- Strong framework for explicit and transparent decision making.

Better understanding by policy makers

- HTA is well known amongst health economists; what about the policy makers?
- A KCE report on ICERs and ICER thresholds: inform health care policy makers about the best way to allocate limited resources in health care in order to maximize health gains;
  - introduce the concepts of cost-effectiveness analysis (CEA), ICERs and ICER threshold values
  - explain briefly how they are obtained
  - explain how they are or can be used in real-life decision making contexts.
- Its aim is not to make a full overview of all methodological aspects related to cost-effectiveness analysis and the calculation of an ICER.
- Knowledge of policy makers is a basic condition; otherwise, economic evaluation would fail to provide a guide for making rational resource allocation in most cases.

To conclude: better use by policy makers ?

- Cost-effectiveness analysis has a key role as **a** tool in the provision of a framework for decision-making.
- HTA agencies offer more understanding of the cost effectiveness of just a few new technologies…
- Increasing the use of economic evaluation (in Belgium), to make decision making more explicit and transparent, requires a search for how best to incorporate HTA within existing and competing decision making priorities.
- Little is known about how policy makers and health professionals perceive and value the findings of HTA research and whether such evidence is meaningful to them and relevant to the decisions they take.
- It is important to recognise other important societal values in making health resource allocation decisions.
- Accountability in policy decisions necessitates that the information upon which decisions are based (including cost-effectiveness analysis, CEA) is accessible and publicly available.

Future?

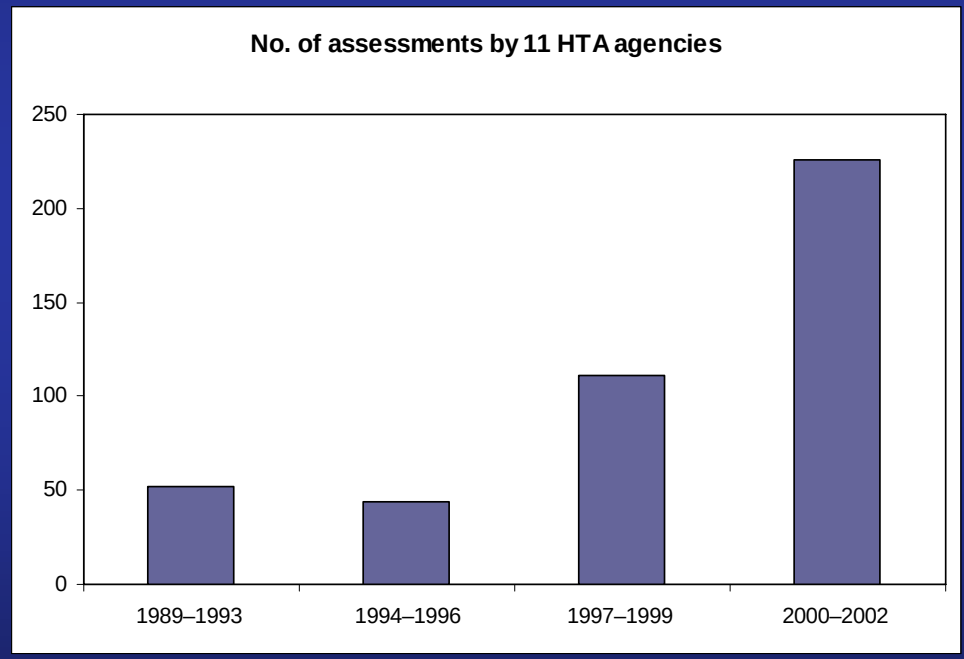
- Increasing demand for public accountability and evidence-based health care (depending on the presence of budgetary restraints)
- More international collaboration: EUNetHTA is a good example (DES)
- Increased quality in clinical research
- Continuing safety concerns
- Innovation policy: more professionalism in research governance & transparent partnership between government, researchers and industry (joint ‘research council’)

www.kce.fgov.be

Increasing demand for public accountability and evidence-based health care

- Within the past 25 years, there has been a considerable growth in HTA activities due both to the expansion in number of HTA agents and to the production levels of these agents

e.g. 433 HTA's from 1989 to 2002 by 11 HTA institutions



Eva Draborg, Dorte Gyrd-Hansen, International Journal of Technology Assessment in Health Care, 22:2 (2006), 155–160..

More international collaboration

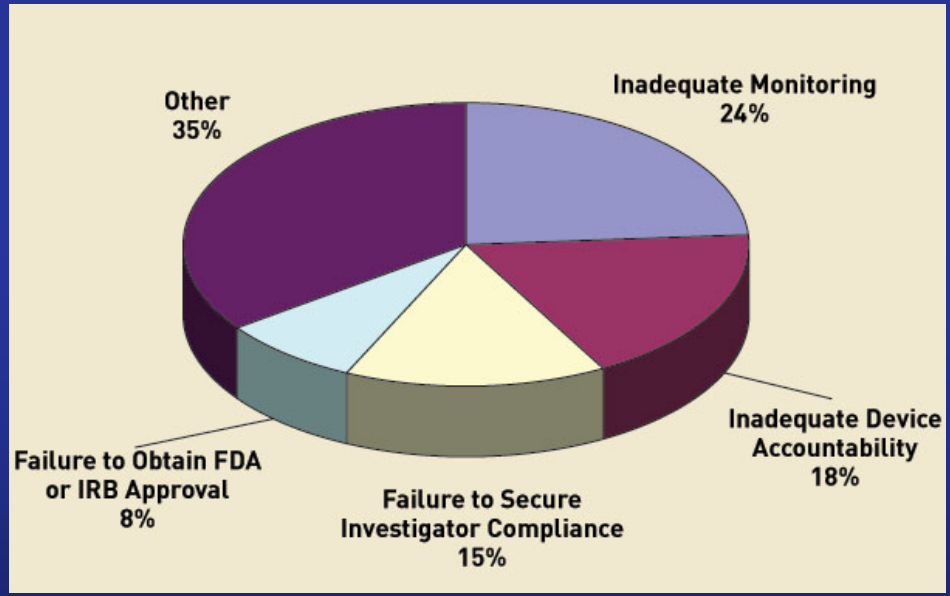
HTA in Europe

Belgium…?

SMM
Oslo
NHSCRD
York
SBU
FinOHTA
Helsinki
Stockholm
NHSC
Birmingham
NCCHTA
London
DIHTA
DSI
NICE
TNO
CVZ
Leiden
Amste
The Ha
MW
Paris
ANAES
CEDIT
SWISS-TA
MTU-FSICS
Bern
AETS
Madrid
ITA
Vienna
AETSA
Sevilla
CAHTA
Barcelona

Increased quality in clinical research

- Monitoring the data life cycle is probably the most important thing a sponsor can do to keep a study on track and to maintain quality.
- In 2005, 24% of FDA inspections found problems with monitoring, and inadequate monitoring continues to be the top deficiency cited in FDA inspections of sponsors (see Figure 1)



‘Research council’

- Physicians, institutions and industry need to work together by providing proven, safe, clinically effective and cost effective new technologies, which require valid pre-market clinical trials and post-market continued surveillance with national and international registries allowing full transparency of new products to the consumer—the patient

(James H. Herndon1 _, Raymond Hwang1 and K. H. Bozic, European Spine Journal, Volume 16, Number 8 / August, 2007)