



The role of HTA in diffusion and implementation of devices

- present situation and trends future
- impact on patient safety
- devices versus drugs

Jan Persson

IFMBE HCTA Division

BIOMEDEA, Stuttgart 2005



Patient safety

- IOM Report 1999, *To err is human*: 98 000 deaths annually due to medical errors in US
- Leape and Berwick 2005: *Five years after To err is human – What have we learned?* (JAMA May 2005)



Threats against patient safety

- misuse of technology
- overuse of technology
- underuse of technology



Health Technology Assessment

- “the systematic process by which the direct and indirect consequences of a particular technology are assessed;
- it is concerned with evaluating the safety, effectiveness, and cost-effectiveness, and when appropriate the social, ethical, and legal impact of the technology”



Medical Technology

"The drugs, devices and medical and surgical procedures used in medical care, and the organizational and supportive systems within which such care is provided"

Office of Technology Assessment, US Government 1978



Organisation for HTA

- Office of Technology Assessment, US 1978
- IFMBE Working Group 1985
- IFMBE Division for HCTA 1991
- HTAi – International Society of Health Technology Assessment 1987
- INAHTA - International Network of Agencies for Health Technology Assessment: 41 institutes in 21 countries



Costs and effects

The basis for cost-effectiveness



Costs

Economic axiom:
Resources are limited



The concept of costs

Interventions need resources:

Resource use means costs. The use of resources usually has an alternative use.

The value of the alternative use is in fact the real cost (what you must sacrifice).



The discussion on costs and effectiveness is about

providing benefits for one patient
(effectiveness)

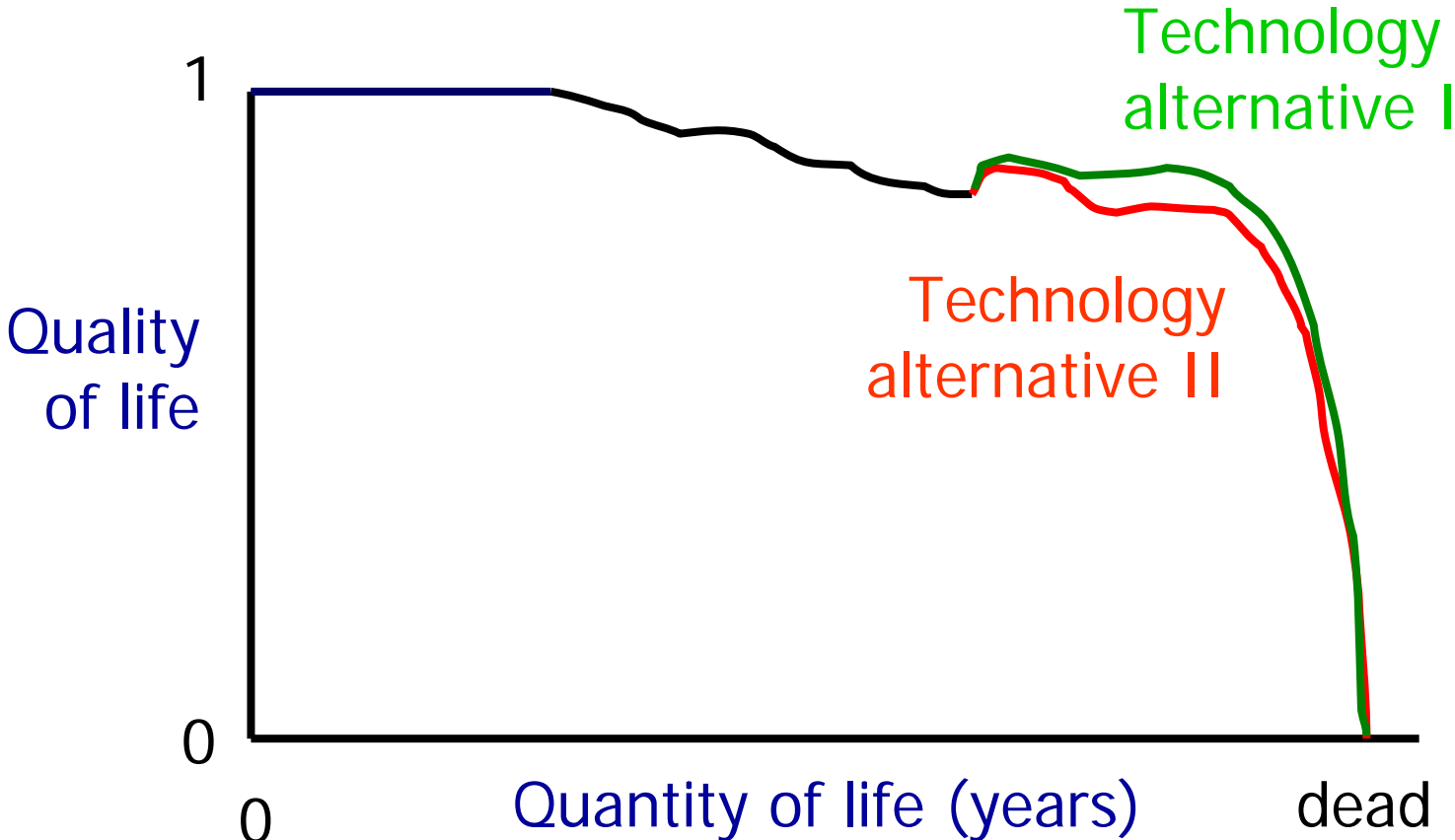
means always

denying benefits to other patients (costs)

Quality Adjusted Life Years gained and cost/QALY



Quality adjusted life years (QALYs)





QALY league tables (cost/QALY by treatment)

Examples of treatments	cost/QALY EURO
safety alarm vs non alarm	neg cost
cholesterol testing and diet therapy	350
pacemaker implantation	1700
hip replacement	1850
cochlear implant	15 600
home hemodialysis	27 100
heart transplantation	38 970

Cost/QALY league table – distribution of Cost/QALY ratios (N=647)

(Source: Peter J. Neumann, Harvard School of Public Health, 2003)

USD per QALY in 1998	Approximate number of studies
cost-saving	70
10-99	25
100-999	35
1 000 -	145
10 000 -	230
100 000 -	60
>1 M	15
Median	12 000 USD/QALY

Types of interventions

(Sources: Neumann 2003, Harvard CEA registry)

- **cost saving** (e.g. seat belts, motor cycle helmets, safety alarm vs no alarm in home settings)
- **cost-effective** (e.g. pacemaker implantation, \$1700/QALY; cochlea implant children, \$2100/QALY)
- **intermediate cost-effective** (e.g. cochlea implant, adult, profoundly deaf, \$15000/QALY)
- **cost-ineffective** (e.g. dialysis vs no dialysis, seriously ill hospitalized patients with renal failure, \$140000/Q)



Evidence based medicine EBM

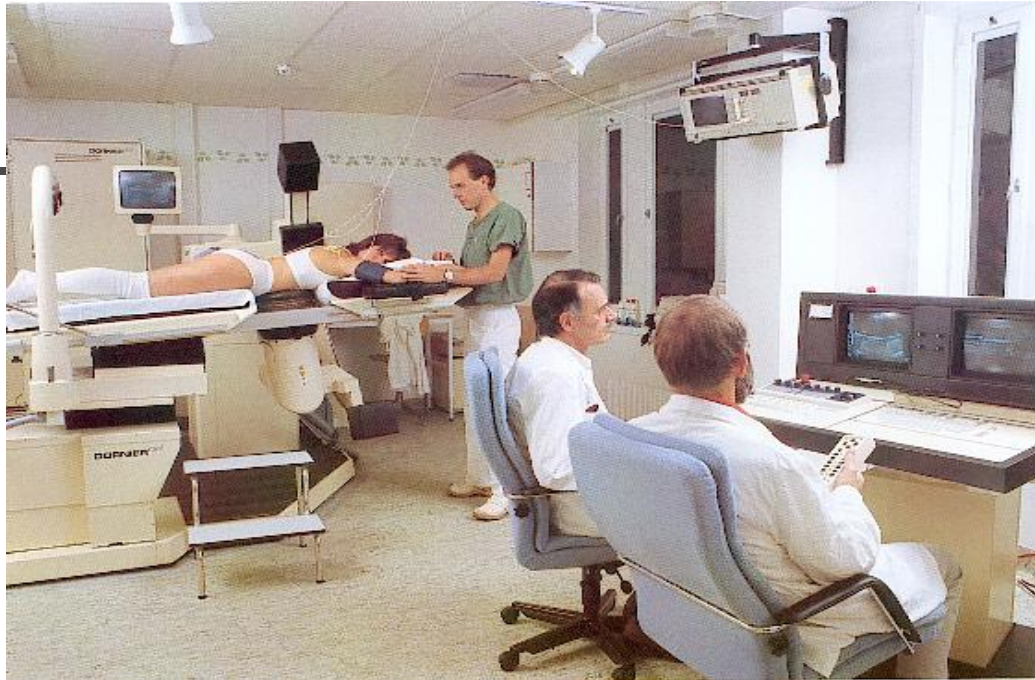


Why evidenced based medicine (EBM)?

Decisions in health care are made under uncertainty and far from rationality.

So it is and will remain – Possibly with better facts and not so irrational?

Gall stone lithotripsy



Disappeared after a short period of diffusion due to lack of evidence for better clinical effectiveness than laparoscopic cholecystectomy





EBM as a method?

Study design (RCT)?

Quality criteria, surrogate outcomes?

Systematic reviews, metaanalysis

*International databases (Cochrane
Collaboration, DARE, Medline a.o.)*

Conflict between efficacy and effectiveness

Conflict between efficacy and effectiveness



- *Efficacy:*

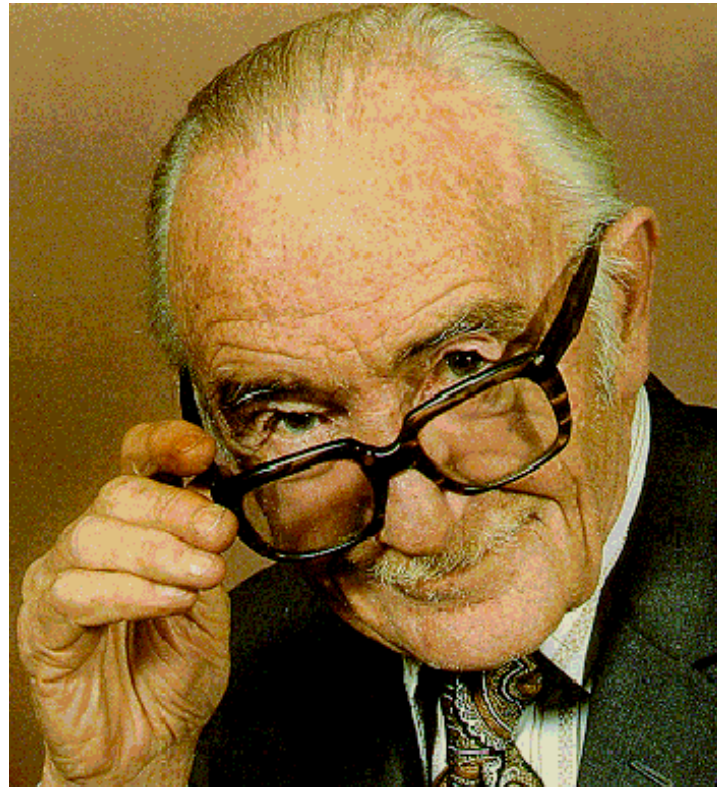
Benefit of using a procedure (or other technology) for a particular clinical problem under ideal conditions of use; for example, within the protocol of a randomized, controlled, clinical trial (RCT).

- *Effectiveness:*

Benefit of using a procedure (or other technology) for a particular clinical problem under average or routine conditions of use; for example, by a physician in a community hospital.

The Cochrane Collaboration is named in honour of Archie Cochrane, a British medical researcher who contributed

**Professor Archibald Leman Cochrane, CBE
FRCP FFCM, (1909 - 1988)**





Archie Cochrane 1979

“It is surely a great criticism of our profession that we have not organised a critical summary, by specialty or subspecialty, adapted periodically, of all relevant randomised controlled trials”



New technologies

"New technologies are, on average, not better or only marginally better than old ones.

Much ineffective and harmful technology will be introduced if new technologies are not tested in randomized trials.

Extrapolation from animal experiments or from trials with surrogate endpoints often lead to wrong conclusions."

(Cochrane)



Cochrane Pregnancy and Childbirth Database

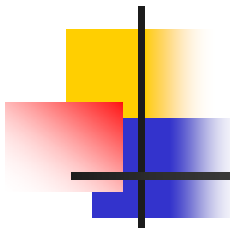
More than 4000 trials of 226 interventions
which are in use

- 19% improve outcomes
- 6% are promising
- 38% have unknown effects
- 27% are worthless or harmful



Medical devices versus drugs

- What's special with devices
- Consequences for HTA
- Consequences for strength of evidence
- What to do



Drugs versus devices - is here a problem?

- user skill affects the outcome; the learning curve must be considered; therefore timing of HTA is very important
- RCT and blinding are difficult in study design



Incremental innovations, short product cycle times, small companies

Devices are subject to frequent, incremental innovations

"Moving target phenomenon": continued use of the older design may be unethical (and non-interesting).

Device manufacturers may be small companies

The manufacturer responsibilities in conducting testing may be practically constrained due to the small volume.

Product-cycle times

0.5-5 years compared with 10-20 years for pharmaceuticals.



CONCLUSIONS



CONCLUSIONS (1)

- Comprehensive cost-effectiveness approach (and NOT short-term cost containment)!
- Credible data on effectiveness and cost-effectiveness is needed for medical devices.



CONCLUSIONS (2)

- Other criteria for the adoption of medical devices than for pharmaceuticals?
- Device industry must accept policy-makers' need for setting priorities.
- Transparent HTA and policy making processes.



CONCLUSIONS (3)

- HTA for medical devices can hamper innovation and make more harm than good!
- Therefore, HTA must use criteria which take into account that the situation is different from that of pharmaceuticals.
- Yet, strong HTAs for devices is needed!

The "Gap" and the competition

