OBSERVATORY VENICE SUMMER SCHOOL 2009

Innovation and Health Technology Assessment: Improving Health System Quality

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Innovation, HTA and Quality in Health Care
An introduction

Lecture 1

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Outline

- Health systems
- Quality of care
- Knowledge translation
- Innovation and evaluation
- HTA
- Expansion of HTA?
A health system consists of all organizations, people and actions whose primary intent is to promote, restore or maintain health.

Its goals are improving health and health equity in ways that are responsive, financially fair, and make the best, or most efficient, use of available resources.

WHO
## Functions of a Health System

<table>
<thead>
<tr>
<th>Functions the System Performs</th>
<th>Goals / Outcomes of the System</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stewardship</strong></td>
<td><strong>Health</strong> (level and equity)</td>
</tr>
<tr>
<td><strong>Creating resources</strong></td>
<td><strong>Responsiveness</strong> (to people's non-medical expectations)</td>
</tr>
<tr>
<td>(investment and training)</td>
<td><strong>Financial protection</strong> (and fair distribution of burden of funding)</td>
</tr>
<tr>
<td><strong>Service delivery</strong></td>
<td></td>
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<tr>
<td>(personal and population-based)</td>
<td></td>
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<tr>
<td><strong>Financing</strong></td>
<td></td>
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<tr>
<td>(collecting, pooling and purchasing)</td>
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</tbody>
</table>
Tasks of a Health System

Functions the system performs:
- Stewardship (oversight)
- Creating resources (investment and training)
- Financing (collecting, pooling and purchasing)
- Delivering services (provision)

Objectives of the system:
- Respondsiveness (to people's non-medical expectations)
- Fair (financial) contribution

Health

WHO World Health Report 2000
THE WHO HEALTH SYSTEM FRAMEWORK

SYSTEM BUILDING BLOCKS

- SERVICE DELIVERY
- HEALTH WORKFORCE
- INFORMATION
- MEDICAL PRODUCTS, VACCINES & TECHNOLOGIES
- FINANCING
- LEADERSHIP / GOVERNANCE

OVERALL GOALS / OUTCOMES

- IMPROVED HEALTH (LEVEL AND EQUITY)
- RESPONSIVENESS
- SOCIAL AND FINANCIAL RISK PROTECTION
- IMPROVED EFFICIENCY

Health system building blocks 1/2

- **Service delivery**: including effective, safe, and quality personal and non-personal health interventions that are provided to those in need, when and where needed (including infrastructure), with a minimum waste of resources.

- **Health workforce**: available in sufficient numbers and being responsive, fair and efficient given available resources and circumstances.

- **Health information**: a sub-system that ensures production, analysis, dissemination and use of reliable and timely information on health determinants, health systems performance and health status.

- **Medical technologies**: including medical products, vaccines and other technologies of assured quality, safety, efficacy and cost-effectiveness, and their scientifically sound and cost-effective use.
Health system building blocks 2/2

- **Health financing**: a sub-system that raises adequate funds for health, in ways that ensure people can use needed services, and are protected from financial catastrophe or impoverishment associated with having to pay for them.

- **Leadership and governance**: ensuring strategic policy frameworks combined with effective oversight, coalition building, accountability, regulations, incentives and attention to system-design.

- **People**, i.e. patients, their care givers and citizens: seen at the centre of the system as public participation, civil society organizations, stakeholder networks, actors and institutions when primarily concerned with promoting, restoring or maintaining health.
Health systems:
more than building blocks; more than inputs & outputs

- Service delivery
- Medicines & technologies
- Information
- People
- Human resources
- Financing
- Governance
Needs-based access?

Personnel well qualified?

Institutions of high standards?

Technologies effective?

Services safe and of high quality?

Environment

Nutrition/ agriculture

Other sectors

Population health status (need)

Human resources

Technologies

Financial resources

Patients: demand, access

Structures and organisation

Process

Health care outcome: satisfaction, complications etc.

Health care system

Services appropriate, at the right time and delivered correctly?

Fair and sustainable funding?

Health gain/ Outcome

How much? Is it worth it?
Small area variation …


Are hospital services rationed in New Haven or over-utilised in Boston?

Wennberg JE, Freeman JL, Culp WJ.

The populations of New Haven and Boston are demographically similar and receive most of their hospital care in university hospitals, but in 1982 their expenditures per head for inpatient care were $451 and $889, respectively. The 98,400 residents of Boston incurred about $300 million more in hospital expenditures and used 739 more beds than they would have if the use rates for New Haven residents had applied. Most of the extra beds were invested in higher admission rates for medical conditions in which the decision to admit can be discretionary. The overall rates for major surgery were equal, but rates for some individual operations varied widely. These findings indicate that academic standards of care are compatible with widely varying patterns of practice and that medical care costs are not necessarily high in communities served largely by university hospitals. They also emphasise the need for increased attention to the outcome and cost implications of differences in practice styles.

PMID: 2883497 [PubMed - indexed for MEDLINE]
However, mostly no clear correlation with the number of interventions per population: "Paradox of appropriateness".

Sources: Chassin et al., 1988; Winslow et al., 1988

Figure 21. Examples of Proportion of Procedures Studied that are Inappropriate or Uncertain
Universal coverage, appropriate entitlements, limited cost-sharing

Professional (re-)certification Provider (re-)accreditation Health Technology Assessment Concentration of services

Quality indicators; registers; patient surveys

Population health status (need)

Environment

Nutrition/ agriculture

Other sectors

Health care system

“Do the right thing“: *ex ante* Guidelines/ disease management programmes/ reminders; *ex post* Review

“Do the thing right“: Quality indicators

Health gain/ Outcome

Human resources

Technologies

Financial resources

Patients: demand, access

Structures and organisation

Process

Health care outcome: satisfaction, complications etc.
Participation/reimbursement in public system

Professionals
Prof. qualif. 2005/36/EC (Re-)validation

Institutions/facilities
Varying, partly certification/accreditation Accreditation

Technologies/interventions
Drugs: EMEA ... Devices: CE mark HTA
Outcomes and number of procedure / hospital

<table>
<thead>
<tr>
<th>Hospital volume /year</th>
<th>Osophagektomie</th>
<th>Pankreatektomie</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>&lt;2</strong></td>
<td>20,3</td>
<td>16,3</td>
</tr>
<tr>
<td><strong>2–4</strong></td>
<td>17,8</td>
<td>14,6</td>
</tr>
<tr>
<td><strong>5–7</strong></td>
<td>16,2</td>
<td>11,0</td>
</tr>
<tr>
<td><strong>8–19</strong></td>
<td>11,4</td>
<td>7,2</td>
</tr>
<tr>
<td><strong>&gt;19</strong></td>
<td>8,4</td>
<td>5,8</td>
</tr>
<tr>
<td><strong>&lt;5</strong></td>
<td>12,2</td>
<td></td>
</tr>
<tr>
<td><strong>≥5</strong></td>
<td>3,0</td>
<td></td>
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</table>

Birkmeyer et al. (2002)

Swisher et al. (2000)
Federal Office for Quality Assurance (BQS)
since 2001 mandatory for all ca. 1,700 hospitals, 169 indicators,
2.8 million cases (17%), with feedback and “structured dialogue”

Indication | Process | Outcome
--- | --- | ---
Beginn | Ende | Inpatient episode

- Is the appropriate thing done? 13%
- Is it done correctly? 27%
- With what (short-term) results? 60%
Federal Office for Quality Assurance (BQS) since 2001 mandator for all ca. 1,700 hospitals, 169 indicators, 2.8 million cases (17%), with feedback and “structured dialogue”

Documentation of operation distance to breast cancer

Mammachirurgie 2005: Angabe Sicherheitsabstand bei BET (KeZ 68098)
Knowledge as a basis

• Knowledge is the foundation for high quality health care

• Knowledge Management is the explicit and systematic management of vital knowledge - and its associated processes of creation, organization, diffusion, use and exploitation

Skyrme 2001
Need new knowledge

- Existing knowledge is not sufficient
- Need new insights and solutions
- Improvement in health care is driven by innovations — either new technologies and products, new ways of delivering technologies or improved processes of care, or better policies
- Improvement strategies should aim for faster adoption of innovations through spread of information
Diffusion of innovations (Rogers)
Knowledge generation through research

• The most robust way of generating new knowledge is through scientific research
• Improving quality of care is therefore linked to increased use and uptake of findings from research - research utilization
• Linear value chain approach where knowledge is generated, assessed, disseminated and then used by policy makers or practitioners
Research utilization: The health sector value chain
The quality of knowledge

- Evidence based medicine/practice/policy - EBM
- High quality care needs to build on high quality research and the total volume of research, not individual studies
- All information or research is not valid, relevant or of high quality – information overload
- Evidence synthesized in systematic reviews is the most reliable knowledge and should be the primary source for informing decisions
WHY need for HTA and systematic reviews?

Information overload

- 20,000 medical journals
- 2 million biomedical articles/yr
- 20,000 health related web-sites
- “Grey literature”
- Published RCTs
  - 1960ies : 100/year
  - 1990ies : 10,000/year

Information rich but knowledge poor

i.e. find arguments for any decision
Systematic reviews

Database searches → Detailed assessment → Included studies

Excluded studies → Excluded studies
Knowledge translation

- Bringing knowledge into action
- Bridging the know-do gap
- The field builds on these traditions:
  - Knowledge management
  - Diffusion of innovations
  - Research utilization
  - Evidence based medicine/practice
Ballance between innovation and evaluation
Ballance between innovation and evaluation

Innovativeness
- Creatin and improvin
  - Products
  - Processes
  - Policies
- Through
  - Research (basic, translational and some clinical)
  - Innovation

Conservativeness
- Assessing
  - Products
  - Processes
  - Policies
- Through
  - Evaluative research (e.g. clinical trials)
  - Systematic reviews
  - HTAs
  - Monitoring
Two types of evaluation informing research and decisions

HTA

Research (Primary) Research Innovation

Synthesis Synthesis/assessment (SR & CEA) (global)

Appraisal Impact & applicability appraisal (local)

Decision Decision making

Dissemination Dissemination Utilization

Evaluation Evaluation Monitoring
Evaluations – ex ante and post hoc
Informing decisions
Evaluations – ex ante and post hoc
Informing decisions
Evaluations – *ex ante* and *post hoc*
Informing decisions
Evaluations – ex ante and post hoc
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Evaluations – ex ante and post hoc
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Evaluations – *ex ante* and *post hoc*
Informing decisions
Two types of evaluation

- **Ex ante**
  - Before making decisions
  - To inform decision making
- **HTAs and SRs**
  - Based on clinical trials

- **Post hoc/ex post**
  - To monitor the impact of decisions - accountability
- **Effects of products**
  - Post marketing studies/phase IV
  - Registries
- **Performance of delivery system**
  - Clinical/quality indicators
  - Health system indicators
WHY need for HTA?
Technology drive

- Information overload
- New technology
  - 15 new products every day
  - New models every 8-9 mths
    
    Fergal, FDA, June 2001

Expectations

Health budgets

GNP
"The goal of HTA is to provide input to decision making in policy and practice."

Henshall et al. 1997

– IF somebody asks!
Use of HTA

Health Technology Assessment / HTA

Clinical research

Assessment | Appraisal
---|---
Scientific documentation | Consequences:
Clinical effect | Organization
Cost-use | Patient perspective

Politics

Reimbursement

Guideline

Priority

Clinical practice
Those involved in HTA

Health Technology Assessment / HTA

Clinical research

Assessment

- Scientists
- HTA-Agencies
- Universities

Appraisal

- HTA-Agencies
- involving Clinicians, Patients, Industry

Politics

Reimbursement

Guideline

Priority

Clinical practice

- Policy makers
- Regulators
- HC Professionals
- Governments
- Industry
- Journalists, Patients

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Layers of questions in HTA

1. **How should we do it here?**
   - Implementation

2. **Should we do it here?**
   - Appropriateness

3. **Can it work here?**
   - Effectiveness

4. **Can it work?**
   - Efficacy

5. **Technical Performance**
Other types of evidence
Policy issues in HIA reports
Organizational and patient related issues

• Only effectiveness 48%, + cost-effectiveness 37% and + ethical and social issues 17%
  – (Lehoux et al 2004)
• Effectiveness 95%, cost-effectiveness 53% and acceptability 25%
  – (Draborg et al 2005)
• Organizational and/or patient related issues 38%
  – Lee and Seest Lindin 2007,
Policy issues in HTA reports  
(based on Lavis et al 2008)

Methods

- **Systematic review** 49%
  - only
- **Economic evaluation** 2%
  - only
- **SR + EE** 38%
- **Full HTA** 5%
  - incl organizational...

(223 HTAs from Canada, USA, England and Denmark)
HTA dimensions in theory and reality

<table>
<thead>
<tr>
<th>Safety</th>
<th>Efficacy</th>
<th>Social</th>
<th>Ethical</th>
<th>Organisational/Professional</th>
<th>Economic</th>
</tr>
</thead>
</table>

**Depth of analysis**

- **In reality**
- **Ideally**

- Methodological standards

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What? "Technologies" in nTa

1. The interventions (drugs, procedures, complex multidisciplinary activities) which can be provided / reimbursed within the system ...en delivering health services

2. The interventions applied to the system to organize service delivery, access, financing, payment of providers, etc.
An example

**Practical Purpose**
„improving survival after myocardial infarction“

**Technologies**
- Aspirin
- Stent
- Early rehabilitation

**Disease Management Programme**
**Payment for Performance**
Policy topics in HTA reports
(based on Lavis et al, in prep)

Topics

- Drugs 28%
- Devices 22%
- Diagnostics 16%
- Surgery 7%
- Other clinical 24%
- Public health 3%
- Delivery 15%
- Financial 2%
- Governance 3%

(223 HTAs from Canada, USA, England and Denmark)
Health technologies applied *within* health care = only one type of technology

Fig. 8.2 Different levels of health-care technologies/interventions

- Health system interventions
  - Research → Synthesis → Appraisal → Decision → Utilization → Evaluation
- Organizational interventions
  - Research → Synthesis → Appraisal → Decision → Utilization → Evaluation
- Population interventions (public health)
  - Research → Synthesis → Appraisal → Decision → Utilization → Evaluation
- Individual interventions (clinical practice)
  - Research → Synthesis → Appraisal → Decision → Utilization → Evaluation
- Technologies (drugs, devices etc.)
  - Research → Synthesis → Appraisal → Decision → Utilization → Evaluation

Other types of interventions
Different health technologies

• “technologies within”
  – health care products like drugs, devices and procedures
    which can be provided within the health care system as it
    delivers health services ( “health care products”)

• “technologies applied to”
  – interventions applied to the health care system, in order to
    organize access, service delivery, payment of providers, etc.
    (regulatory and policy measures directed on “patient
    demand/access”, “structures and organisations”, “processes”
    and “health care outcomes”)

• “technologies outside”
  – interventions for promoting and protecting health outside the
    health care system (other sectors)
• Policy processes and HTA
  • Health systems, health policy and HTA
  • HTA producers
  • Impact of HTA
• Needs and demands of policy-makers
• Future challenges for HTA in Europe

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