(Evidence–based) Health Technology Assessment In Indonesia

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HTA Committee, MOH RI
Selected references

- Banta HD. A global perspective on health technology assessment. Available from [www.kanitadayalitip.org](http://www.kanitadayalitip.org)
Problem in health care

Research: what we can do

HTA: which ones we can do

Clinical guidelines: what we should do

Practice: doing what we should do

Clinical audits: did we do what we should do?
Clinical Governance

"A framework through which NHS organizations are accountable for continuously improving the quality of their services and safeguarding high standards of care, by creating an environment in which excellence in clinical care will flourish."
Clinical Governance

Clinical audits

Risk management

Education & Training

Accountability

Clinical Effectiveness

Research & development

Patient safety

Clinical audits

EBM:

# HTA
# Clinical guidelines
- Clin pathways
- Algorithms
- Protocols
- Procedures
- Standing orders
Search the evidence

Critically appraise the evidence

Formulate in answerable question

Recommendation(s)

Problem in Practice
What is ....

- Technology
- Health technology
- Health technology assessment
The application of scientific knowledge for practical purposes

Any intervention that may be used to promote health, to prevent, diagnose, or treat disease or for rehabilitation or long-term care

Drugs, biologics, devices, medical surgical procedures, support systems, organizational/managerial systems

A systemic evaluation of properties, effects and impacts of diffusion and use of HT. It is a multidisciplinary process to evaluate safety, efficacy, effectiveness, social, economic, organizational and ethical issues of HT.
What is Health Technology Assessment?

HTA

is a multi-disciplinary field of policy analysis, which studies the medical, social, ethical and economic implications of development, diffusion and use of health technology.
What is HTA?

Health technology assessment is a structured analysis of a health technology, a set of related technologies or a technology-related issue that is performed for the purpose of providing input to a policy decision. It encompasses safety, efficacy (benefits), costs and cost-effectiveness, organizational implications, and social and ethical issues.
Why HTA?

"...there are many examples of procedures or treatments, .... which had been shown to be ineffective in randomized clinical trials but which were still used".
"The opposite was also true and some effective treatments ... were only recognized after damaging delays".

(Clark et al. 1997)
Why HTA?

- Technological innovations rapidly spreading
- Economic resources rapidly dwindling
- Results decisions & priorities need to be made
Dr. Benjamin Spock: Baby and Child Care

“I think it is preferable to accustom a baby to sleeping on his stomach from the start of he is willing. He may change later when he learns to turn over”.

Later evidence indicates that prone position is a significant risk factor for SIDS (sudden infant death syndrome).
The case of electronic fetal monitoring (EFM)

- Rapid diffusion into health care during 1970s
- Claims of substantial benefits in terms of fetal deaths and injuries not backed by studies
- Synthetic studies (systematic reviews) in 1970s and 1980s showing no benefits
- Use has continued without much change
The case of diethylstilbestrol (DES)

- Synthetic estrogen introduced in late 1930s
- Claims of substantial benefits to mother and child, especially in terms of averted miscarriages
- Claims not supported by studies
- From 1973, cases of clear-cell adenocarcinoma of the vagina in DES daughters
- Other complications gradually emerged (sons, mothers)
- Use continues in many parts of the world, although not North American or Europe
Purposes of health technology

- Promotion
- Prevention
- Diagnosis 🌟
- Treatment 🌟
- Rehabilitation
- Long-term care
Physical nature

**Drugs:** e.g. beta-blockers, HMG-CoA reductase inhibitors ("statins")

**Biologics:** e.g. vaccines, blood products, cellular and gene therapies

**Devices:** e.g., cardiac pacemakers, CT scanners, diagnostic tests

**Medical and surgical procedures:** e.g., psychotherapy, nutrition counseling, coronary angiography

**Support systems:** e.g., electronic patient record systems, drug formularies, blood banks, clinical laboratories

**Organizational and managerial systems:** e.g., prospective payment using DRG’s, rules for referral to specialists
Attributes / aspects to be assessed

- Safety
- Efficacy
- Effectiveness
- Economic
- Socio-cultural
- Ethical
- Legal-Institutional
- Religious
Other examples of HTA

- Organisation of services for diabetic retinopathy screening
- PET imaging in cancer management
- Prevention of relapse in alcohol dependence
- Ultrasound scanning in early pregnancy
- The use of alcohol hand gel to increase hand washing compliance and reduce healthcare associated infection rates
What areas can HTA address?

- High volume
  - affects many
- High risk
  - medical, social, ethics
- High cost
  - unnecessary health cost
- High variability

Who should do?

- Institutionalized:
  - WHO, National, universities, hospitals

- Non-institutionalized:
  - unions, social movements
  - patient organizations

- Industrial:
  - internal,
  - in cooperation with hospitals, universities
Health Technology - Quality

Assessment of the quality of health technology Components of the devices

Standards for the component/s

Assessment of each component

Assessment of all components operating as unit
Health Technology - Safety

Assessment of the safety of health technology
- Safety to the patient
- Safety to the operator/administrator
- Safety of the environment
Health Technology - Efficacy

Assessment of the efficacy of health technology

- Does the health technology do what is claimed?
- How well does it do this?
- How well does the technology work compare to the technology that we currently have?
Health Technology Effectiveness
/ Cost benefit

- Comparative effectiveness of the new technology compared to technology currently available

- Comparative cost of the new technology compared to technology currently available
Cost?

- By definition a cost is understood as a consumption of resources.
- e.g.
  - *health resources* (e.g. manpower, drugs, equipment),
  - *non-health resources* (e.g. patients travel to treatment),
  - *the informal caregivers time* (e.g. use of time for (unpaid) care giving provided by family and friends),
  - *the patient’s own use of time* in connection with the activity, as well as the
  - *lost production* as a result of disease.
Average and marginal costs
Fixed and variable costs
Ancillary cost
Total cost

Direct cost
Indirect cost
Intangible cost
Averted / avoided cost

Acquisition cost
Allowable cost
Out-of-pocket cost
Opportunity cost
Types of economic analysis

- **Cost-of-illness analysis (CIA):** a determination of the economic impact of an illness on a given population, region, or country. Examples: smoking, diabetes.

- **Cost-minimization analysis (CMA):** a determination of the least costly among alternative interventions that are assumed to produce equivalent outcomes.

- **Cost-effectiveness analysis (CEA):** a comparison of costs in monetary units with outcomes in quantitative non-monetary units, e.g., reduced mortality or morbidity.

- **Cost-benefit analysis (CBA):** compares costs and benefits, both of which are quantified in common monetary units.

- **Cost-utility analysis (CUA):** a form of CEA that compares costs in monetary units with outcomes in terms of their utility, usually to the patient, measured, e.g., in QALYs.

- **Budget impact analysis (BIA):** determine the impact of implementing HT on designated budget.
Methods in HTA

Primary data
- Technical studies (functionality, validation)
- Expert (and user) opinion
- Epidemiological and observational studies
- Clinical trials
- Primary data for economic analysis

Secondary data: Integrative / literature synthesis (meta-analysis)

Combined
Methods in HTA:
GOBSAT

Good
Old
Boys
Sitting
Around the Table
Previous HTA Indonesia: Flow (2003-2008)

- Thorough assessment of literatures (Meta-analysis, RCTs, obs studies, case series, etc.)
- Initial draft by HTA Staff
- Panel of experts: Universities, Professional Organizations, Other Institutions / Individuals
- Inputs and revisions via e-mail
- 3 full-team discussions, revisions
- Final draft and recommendations
- Distribution and dissemination
HTA Indonesia, 2003-2009

- No clear organization
- No clear staff
- No experience
- No guidelines
- Budget allocation (?)
- Yet > 40 HTA topics were completed
HTA INDONESIA 2003-2009

Examples

- Vit K prophylaxis
- Blood transfusion
- Preoperative preparation
- Immunomodulators
- Influenza vaccine
- Tonsillo-adenoidectomy
- Ozone therapy

- Ciprofloxacin
- ESWL
- Hormone replacement therapy
- Management of sinusitis
- COPD
- Liposuction
- Hearing screening
Hospital-based HTA

- HTA – International / National level
- Local / Hospital-based: Recommended

**Specific hospitals**

- High technology
- Specific mode of care

**Other hospitals**

- Specific conditions
- May differ from national HTA
Types of Hospital-based HTA

- **Ambassador Model**
  - Organization: Individual
  - Focus of action: Clinical practice

- **Mini-HTA Model**
  - Organization: Individual
  - Focus of action: Managerial decision making

- **Internal Committee Model**
  - Organization: Group, Team, Unit
  - Focus of action: Clinical practice

- **HTA Unit Model**
  - Organization: Unit
  - Focus of action: Managerial decision making
<table>
<thead>
<tr>
<th>Organizational complexity</th>
<th>Focus of action</th>
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<tbody>
<tr>
<td><strong>Low (Individual)</strong></td>
<td>Clinical practice</td>
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<td>Ambassador Model</td>
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**Models in local / hospital-based HTA**
RSCM: Hospital-based HTA

- Management of diabetic foot
- Impact of congestive heart failure management on overall length of stay

Cochlear implant
Megaprosthesis implant
Gamma knife stereotactic radiosurgery
Long-acting antipsychotic injection

Accepted for oral prest. HTA – Int Congress, Oslo, June, 2015
Conflict of interest

HTA should consider the potential for conflict of interest on multiple levels.

1. On the part of investigators who conducted and reported on the clinical trials and other studies.

2. The sponsors e.g., technology companies, who have varying degrees of control over what research is conducted, selection of intervention and control treatments, selection of endpoints and follow-up, and whether the results are submitted for publication.

3. The health technology assessors themselves, including analysts, panel members, or other experts involved in reviewing the evidence and making findings and recommendations.
Komite PTK RI

SK Menteri No. 171/MENKES/SK/IV/2014
21 April 2014 / Diterima Agustus 2014
Komite PTK terdiri atas

- Ketua
- Sekretaris
- Anggota
- Sekretariat

Bertanggung jawab kepada Menteri
Tugas Komite PTK

- Menyusun konsep dan kegiatan
- Menyusun buku pedoman / panduan PTK
- Menerima usulan PTK dari fasyankes, PBJS, organisai profesi dll
- Menyaring dan membuat prioritas
- Membentuk Tim Panel ad hoc untuk melaksanakan PTK
- Memberi rekomendasi kepada Menteri
Tim Panel *ad hoc*

- Dibentuk untuk tiap topik

Terdiri atas

- Anggota Komisi PTK
- Pakar organisasi profesi
- Akademisi
- Pakar lain yang terkait
HTA Indonesia: Flow

- **Topic selection** (HTAC)
- **Pre-proposal** (PIC)
- **Ad-hoc Panel**
  - HTAC Member(s)
  - Academia
  - Professionals
  - Others
- **Proposal** (PIC + Panel)
- **First draft** (PIC)
- **Discuss and revisions by email** (Panel)
- **Monthly plenary meetings** (Panel)
- **Finalize in 3-4 meetings** (Panel)

**HTA Committee**

**Person-in-Charge:** Member of Secretariat who has attended EBM, HTA, Medical Writing workshops
Format pra-proposal (Ik. 2 halaman)

- Judul
- Pengusul
- Tujuan
- Sinopsis evidence awal
- Daftar Pustaka
- Lampiran
  - Usulan anggota Panel
  - Lain-lain yang relevan
Format proposal

- Sama dengan pra-proposal setelah diberi masukan oleh anggota Panel
- Dikembangkan menjadi draft awal, dilakukan oleh PIC di bawah supervisi anggota Panel
Format draft awal

- Judul
- Pengusul
- Pendahuluan:
  - Mengapa diperlukan PTK
  - Pertanyaan PTK
  - Tujuan: umum, khusus
- Metodologi:
  - Strategi penelusuran bukti
  - Telaah kritis
  - Peringkat bukti
  - Derajat rekomendasi
- Hasil dan pembahasan
- Daftar Pustaka
- Lampiran
Final Report

- Title
- Lists of Tables, glossary, abbreviations, forewords, etc
- Executive summary
- Introduction:
  - Justification for HTA
  - Research questions
  - Purpose: general, specific
- Methods:
  - Search strategy
  - Statement on critical appraisals
  - Levels of evidence
  - Grades of recommendations
- Results and discussion
- Conclusions and recommendations
- References
- Appendices
Hierarchy of evidence

Meta-analysis of RCT  Level 1
Large RCT
Small RCT  Level 2
Non-Randomized trials
Observational studies  Level 3
Case series / reports
Anecdotes, expert, consensus  Level 4

For complete description see www.cebm.net
Laporan akhir

- Sedapat mungkin berupa scientific document
- Penulisan sesuai kaidah ilmiah: ringkas, jelas, lengkap (BCC - brief, clear, complete)
- Hindarkan plagiarisme
- Pustaka mutakhir
- Perhatikan ejaan, frasa, kalimat, paragraf
- Penulisan sitasi dan daftar pustaka baku
Berapa lama per topik?

- **Denmark**
  - Topik besar: 200 halaman, 1,5 – 2,5 tahun
  - Sedang: 100 halaman, 1 - 1,5 tahun
  - Kecil: <100 halaman, 6-12 bulan

- **Thailand:**
  - 40 topik / tahun

- **Indonesia:** 50-100 halaman, 4 bulan

- **Rapid HTA:**
  - beberapa jam / hari
  - yang lengkap menyusul
  - tidak dianjurkan: rapid and dirty
Biayanya?

- Dr. Charles Shaw – NICE: 1 juta USD / topik
- Dr. Yot (HITAP – Thailand): 1 juta USD / tahun, untuk 40 topik, lk. 300 juta / topik
- RSCM (Hospital-based HTA): 400 juta / 4 topik
- Unit HTA (2003-2008) - <30 juta / topik
- Komite HTA (2014 dst) – sedang disusun anggaran tahunan
Info tambahan

- Komunikasi dengan Prof. Sally Green dan Prof. Steve McDonald (Australian Cochrane)
  - Tanya: Berapa dekat integrative literature pada HTA dengan persyaratan Cochrane yang ketat?
  - Jawab: I don't know; as close as possible

- Studi: Hanya <10% clinical practice guidelines yang memenuhi semua 10 kriteria

- HTA Cochlear implant (NICE): 240 halaman – siapa yang mau baca?

- Jadi? ........
International supports

- **PATH** (Program for Appropriate Technology in Health) - Seattle
- **NICE** (National Institute for Health and Care Excellence) International - London
- **HITAP** (Health Intervention and Technology Assessment Program) - Bangkok
- WHO
- **AIPHSS** (Australia-Indonesia Partnership for Health System Strengthening)
RUANG TATA USAHAY
ROOM ARRANGE EFFORT

Thank you