(Evidence–based) Health Technology Assessment In Indonesia

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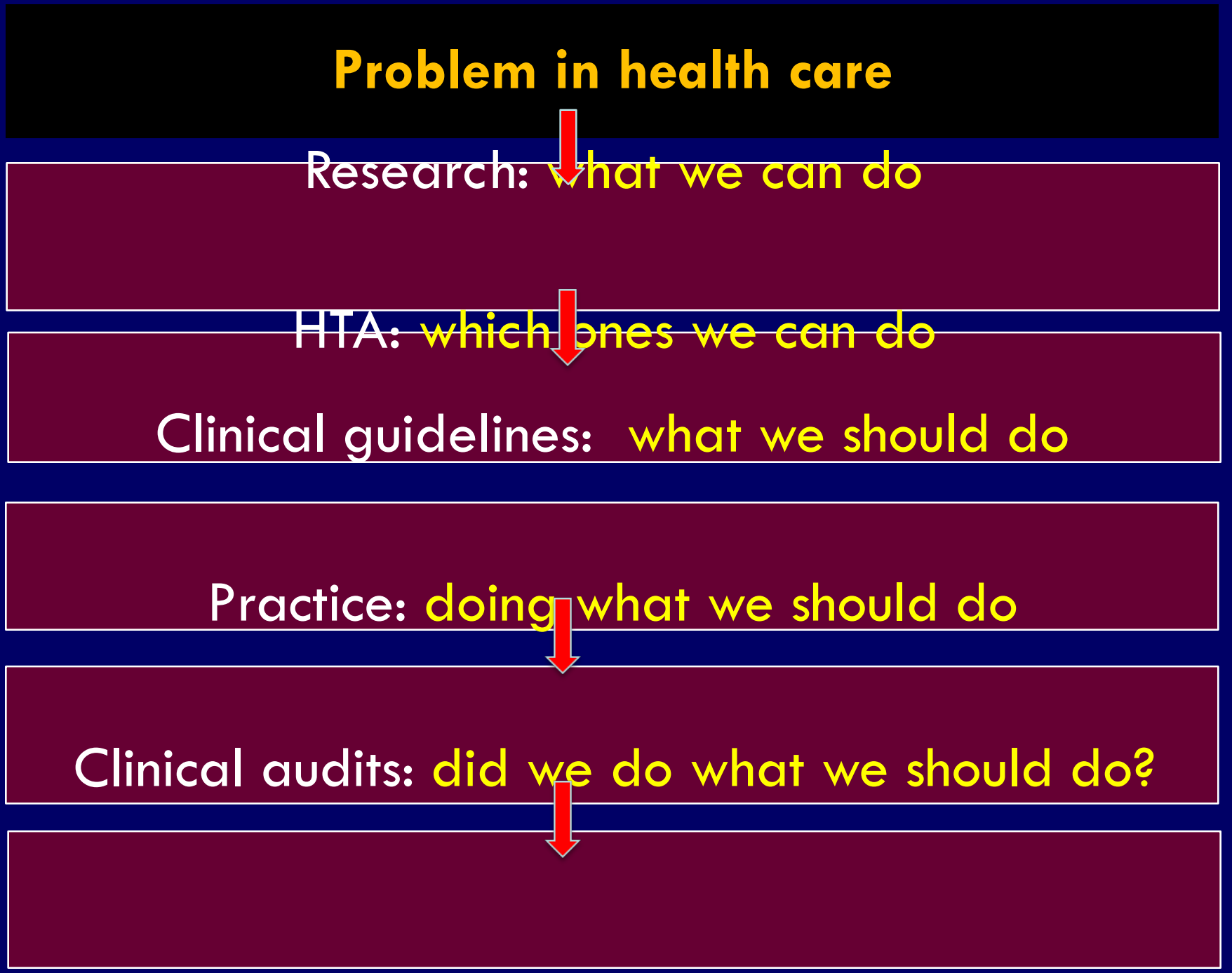
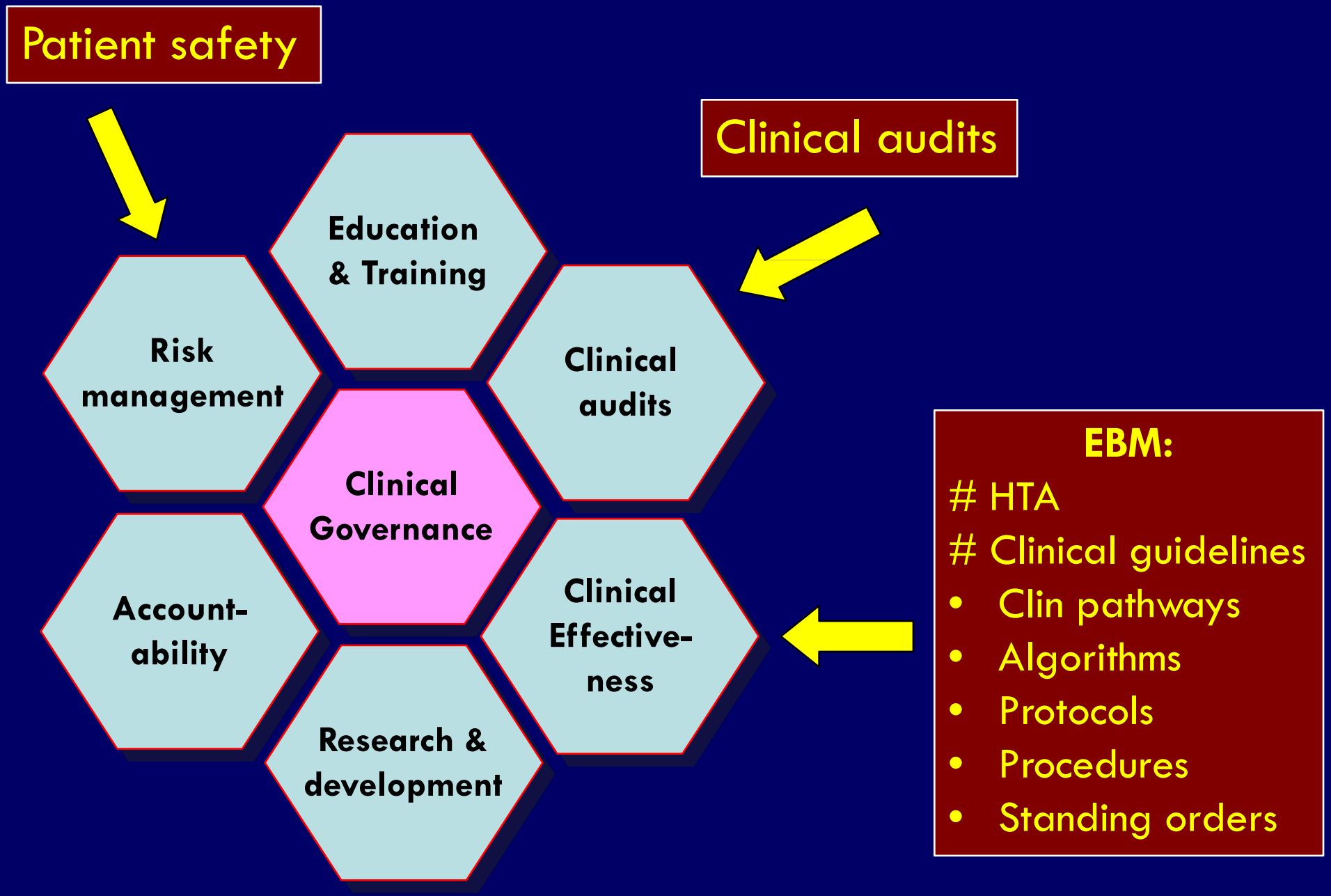
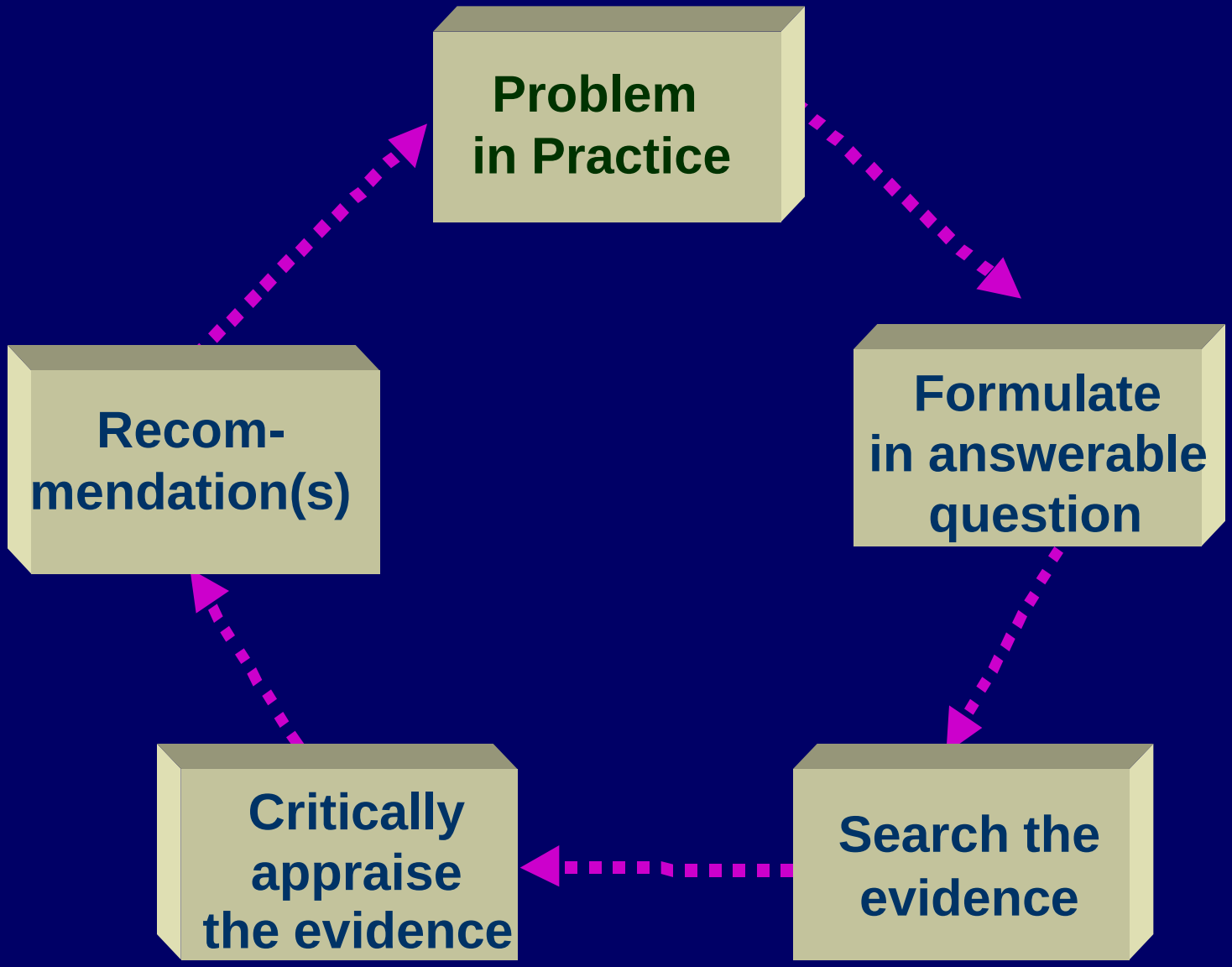

Problem in health care
Research: what we can do
HTA: which ones we can do
Clinical guidelines: what we should do
Practice: doing what we should do
Clinical audits: did we do what we should do?

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."


Patient safety
Clinical audits
Education & Training
Risk management
Clinical audits
Clinical Governance
Account-ability
Clinical Effective-ness
Research & development
EBM:
HTA
Clinical guidelines
• Clin pathways
• Algorithms
• Protocols
• Procedures
• Standing orders


Problem in Practice
Formulate in answerable question
Search the evidence
Critically appraise the evidence
Recom-mendation(s)

What is ….

- Technology
- Health technology
- Health technology assessment

Technology → *The application of scientific knowledge for practical purposes*

Health technology

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

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

Health Technology Assessment → *A systemic evaluation of properties, effects and impacts of difusion 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 an 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 diethylstilbesterol (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

Organizational complexity	Focus of action: Clinical practice	Focus of action: Managerial decision making
Low (Individual)	Ambassador Model	Mini HTA Model
High (Team, Unit)	Internal Committee Model	HTA Unit Model

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

Oral presentation in HTA – Intl Congress, Washington, 2013

- 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

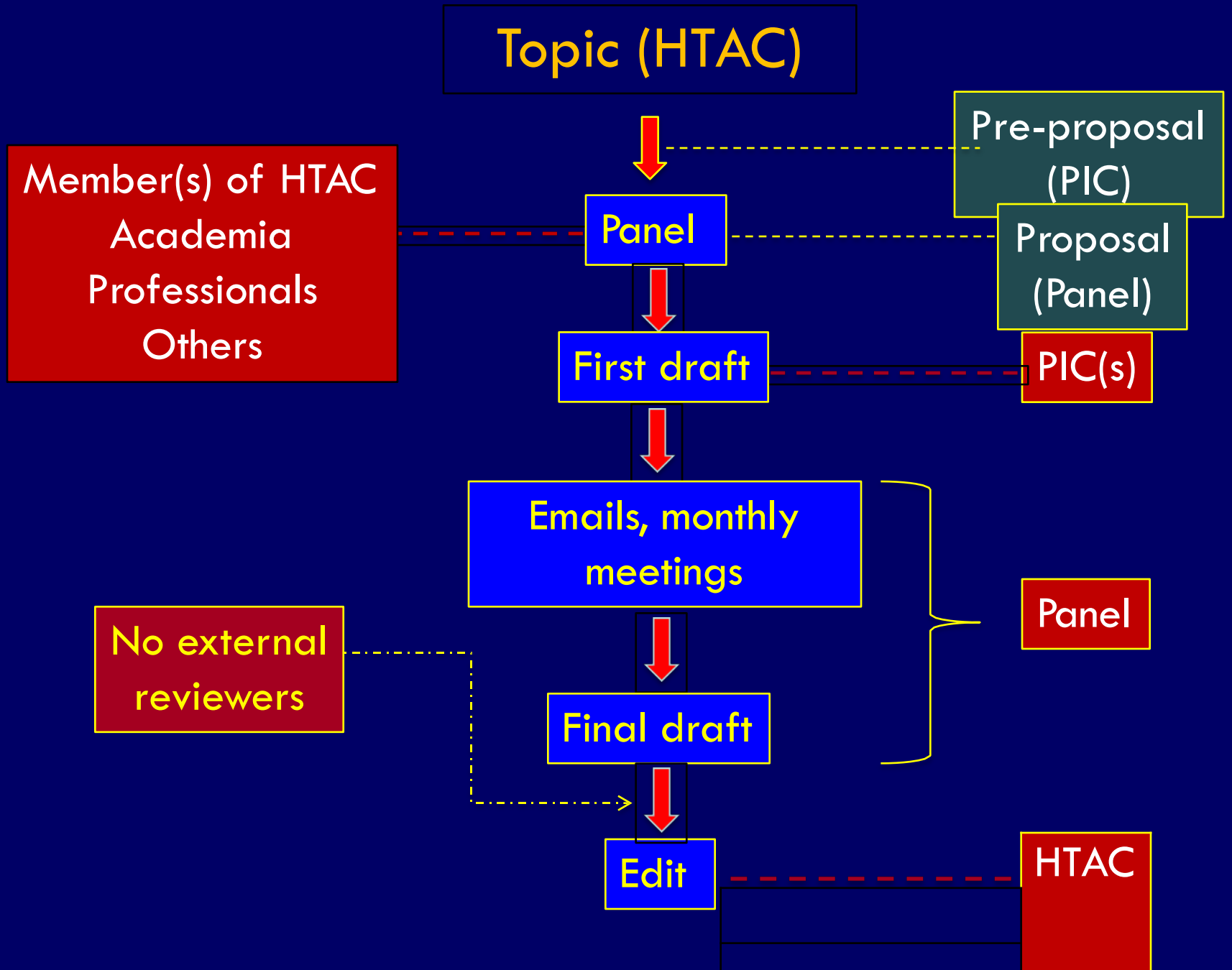
- Menyusun konsep dan kegiatan
- Menyusun buku pedoman / panduan PTK
- Menerima usulan PTK dari fasyankes, PBJS, organisai profesi dll
- Menyaring dan membuat prioritas
- Membentuk Tim Panel ad hoc untuk melaksanakn PTK
- Memberi rekomendasi kepada Menteri

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) ← HTA Committee
- Pre-proposal (PIC) ← Person-in-Charge: Member of Secretariat who has attended EBM, HTA, Medical Writing workshops
- 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)


Topic (HTAC)
Pre-proposal (PIC)
Member(s) of HTAC
Academia
Professionals
Others
Panel
Proposal (Panel)
First draft
PIC(s)
Emails, monthly meetings
Panel
No external reviewers
Final draft
Edit
HTAC

Format pra-proposal (lk. 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

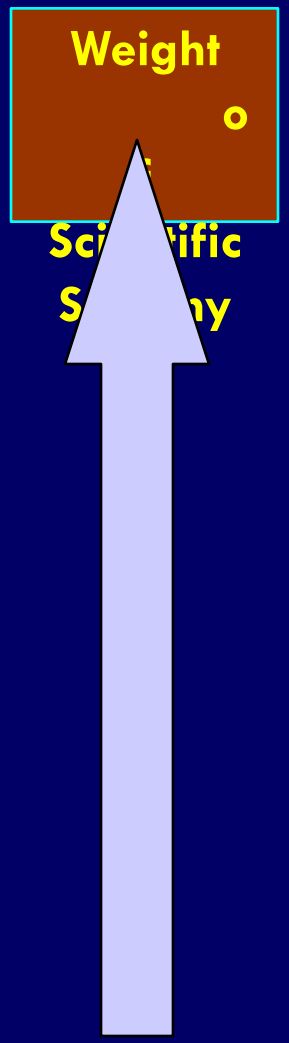
Format draft awal

- 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



		Rec
Meta-analysis of RCT	Level 1	A
Large RCT		
Small RCT	Level 2	B
Non-Randomized trials		
Observational studies	Level 3	
Case series / reports		C
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)

Thank you