Defining HTA/priority-setting system (CGD PS working group, 2012-3)

- Entire decision-making process and context, including the legislative, regulatory, policy, payment, and reimbursement framework within which evidence is developed and used to inform public spending decisions.

- Reflects that HTA
  - ...involves multiple actors and processes, and is based on inputs provided by health systems, the legal framework, and social values prevailing in each society...
  - ...leading to different types of outputs such as coverage decisions, guidelines, protocols, or other evidence-based recommendations that will be reflected in public budgets and spending for health.

- Specific system emerges from each country’s starting point
What are we talking about when discussing ‘HTA institutionalisation’?

Potentially:

1. **Structure** of priority-setting mechanisms and institutions, including human capacity
2. **Process** of priority-setting, from evidence generation through knowledge translation and policy/decision-making
3. **Content and outcome**: UHC objectives, population health outcomes, health system efficiency gains

Not necessarily a new bureaucratic entity…

…but infrastructure and a clear focal point are important factors!

There are many different paths countries can take…
Objective
To identify characteristics of successful HTA agencies, and contextual factors where priority-setting capacity has been developed.

Frequent contextual factors
- High public expenditure, Strategic Purchasing
- Political will, leadership and legislation
- Good health information technology infrastructure
- Local training on HTA-related disciplines
- Effective collaboration - HTA agencies & local stakeholders
- Work conducted independently from aid budget

Source: Chootipongchaivat et al. (2016)

4 key barriers identified to the development of HTA agencies

- Poor decision-making criteria
- Strict controls on research – conduct and dissemination
- Silo-based decision making, weak to no consultative practice
- Undue influence of expert opinion (opposed to evidence synthesis)

Source: Chootipongchaivat et al. (2016)
The iDSI Theory of Change: Understanding cause and effect in priority-setting

- Theory of change is a critical thinking exercise to understand the short-term / intermediate changes required for long-term change (Vogel, 2012)
- Provides testable hypothesis of how an intervention works, and underlying assumptions

Some criteria or indicators of strengthened institutions

- A clear, well defined and legally recognised remit to act as the focal institution for evidence informed priority setting;
- Independence from arbitrary stakeholder influence and operationally independent from government (including day to day decision making powers);
- Financial sustainability;
- Sustainable levels of expertise and capacity, with processes to ensure renewal;
- Systems for management of potential (or actual) conflicts of interest.

*Itad (2016) iDSI monitoring, evaluation and learning framework*
Key recommendations

1. **Build human resources / national capacity**
   - HTA research organizations
   - Decision-making bodies
   - Relevant stakeholders

2. **Establish a core HTA team or agency**
   - HTA process involves multiple actors
   - Essential to have an HTA focal point or agency

3. **Link HTA to policy decision-making mechanisms & processes**
   - No single pathway, highly dependent upon local context

4. **Establish legislative authority of HTA agency & processes**
   - Participation, transparency, systematic application of HTA processes

5. **Take advantage of international collaboration during formative stage of development**
   - Guard against substitution effect

*Source: Chootipongchaivat et al. (2016)*

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Do you need an ‘agency’?

- “Institutionalising” HTA emphasises the role of developing accepted *norms and rules*, and effective working relationships between relevant policymakers and academic/research institutions

- Good norms and rules (based around notions of transparency, accountability, stakeholder participation etc) support priority-setting based on evidence

- *Good governance* becomes routine and more resilient to vested interests and political change

- But no “one-size fits all” for institutional arrangements
DEVELOPMENTS IN INSTITUTIONALIZATION OF PRIORITY SETTING IN SOUTH AFRICA

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South Africa profile

- Population: 54 million (annual GDP growth 1.6%)
- Upper middle income, GNI/capita US$6,800\(^1\)
- Central Govt and 9 provinces
- Income Gini: 0.70, 58% of income in top decile, 8% in bottom half of population
- Life expectancy at birth 62 years
- HIV prevalence 18.9\(^2\)
- Maternal mortality ratio 138/100,000 births
- Physicians 1,000 people: 0.8
- Health expenditure
  - annual per capita: US$570
  - Total % of GDP: 8.8%

Health Care provision in South Africa

**South African Population**
- 64% Privately Insured Patients
- 20% Public Sector Patients
- 16% Privately Self-Funding Patients

**Privately Insured Patients**
- Strong infrastructure, Fragmented
- Prescribed Minimum Benefits Legislation
- 80 Medical Schemes with formularies, protocols “private HTA”

**Publicly Funded Patients**
- Weak infrastructure
- Fragmented (provincial autonomy)
- Subject to existing national and provincial programmes
- EDL
- Variable quality
- Free at point of use for majority

**Privately Self-Funding Patients**
- Purchase OOP from private and public facilities

**Spend Per Patient Per Annum**
- ZAR 2,400 (households)
- ZAR 280 (tax-funded)

Adapted from: Shelley McGee, ISPOR SA, SAHTAS meeting June 2016

WHO Global HTA survey: South Africa profile

**Governance**
- National HTA organization: not yet established

**Purpose**
- Clinical practice guidelines and protocols
- Pricing of health products
- Reimbursement/”package of benefits”

**How HTA is used in decision making**
- Advisory
Priority setting in South Africa

- Growing demand for health resources
- Need to define Essential Medicines Lists and Standard Treatment Guidelines
- Access to medicines to treat priority conditions

- Growing demand for health resources
- Quadruple burden of disease
- UHC benefit definitions
- Strengthening systems and processes to support UHC ambitions

1994 ANC National Health Plan
Refers to Appropriate Health Technology as the assessment of the association of "methods, techniques and equipment, which, together with the people using them..." would address public health needs.

1997 DoH Policy Paper on HTA
Recommendations:
- Establishment of National Commission of Health Technology
- Training schemes
- Links with academic and research institutions

2001 DoH HTA Framework
Health Technology defined to include devices, drugs, medical and surgical procedures and knowledge associated with these, in the prevention, diagnosis and treatment of disease, as well as rehabilitation, including the organisational and supportive systems within which health care is provided.

2011 Human Resources for Health
Indicates that a Department of Health National Coordinating Centre for Clinical Excellence in Health and Health Care will be established

2011 NHI Green Paper

2013 NHI White Paper
Health technology assessment will inform prioritisation, selection, distribution, management and introduction of interventions for health promotion, disease prevention, diagnosis, treatment and rehabilitation

HTA Legal and policy landscape report, PRICELESS 2016
Back to 2003

- Interim steering committee on HTA
- Series of consultations/workshops locally and internationally
- Review of international “best” practice
- Proposed a National Strategy for HTA, including:
  - legislative framework
  - stakeholder analysis
  - institutional structure
  - HTA process
Key legislation:

  - The state must take reasonable legislative and other measures, within its available resources, to achieve the ‘progressive realization’ for all South Africans of the right to access to health care services (abb. Section 27(1)(a) and 27(2))
  - The establishment of a HTA framework may provide this “accountability for reasonableness within available resources”, as it facilitates consideration of a range of social values (including equity, affordability and efficiency) in the context of the health system objectives.

- National Health Act (2003, 2013) – narrow definition of HT (drugs/devices); OHSC created
- Medicines and Related Substances Act (1965) – regulation of medicines

HTA will also be used to:
- Promote efficient use of resources is a crucial factor for achieving a sustainable health system especially when significant increase in access to essential medicines, medical devices, procedures and other healthcare interventions are envisaged

HTA will inform:
- Prioritization
- Selection
- Distribution
- Management and introduction of interventions for health promotion, disease prevention, diagnosis, treatment and rehabilitation
Legal and Policy Gap Analysis

- No specific provision in the National Health Act for HTA
- Health technology narrowly and incompletely defined within current legislation
- No alignment of HTA Policy (1997) and HTA Framework (2003) with NHI
- Limited attention in the NHI White Paper regarding the mechanisms and structures required to apply HTA, and how it is meant to inform coverage decisions

Challenges to priority setting in South Africa

- Capacity – institutional, human, data
- Fragmentation of how resources are organized in private and public sector
- Acceptability/buy in from the private sector (although potentially an opportunity!)
- Lens through which public and private sector view HTA is variable/ heterogeneous
- Seeking alignment of national and provincial decision making structures
Opportunities for HTA in South Africa

• High per capita spend on health
• HTA with specific remit to support NHI
• National framework (White Paper) and international remit
  WHA resolution
• Legislation to enable HTA is (theoretically) in place in the
  private sector
• Existing “HTA-like” activities already happening
• Coordinate and network existing capacity
DEVELOPMENTS IN INSTITUTIONALIZATION OF PRIORITY-SETTING IN INDONESIA

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Faculty of Public Health
University of Indonesia

Acknowledgement:
Centre for Health Financing and Health Insurance
Ministry of Health, Republic of Indonesia

BACKGROUND

INDONESIA: over 17,000 Islands, 250 m people
Highly decentralized system
Health Financing: in 2014
- Health expenditure as % of GDP: 3.6%
- High OOP spending: 45% of THE
- Social security funds as % of THE: 12.9%

- The GOI aspires to provide UHC to all 248 million Indonesian by 2019
- Indonesia has started “single payer scheme” in 2014 (BPJS)

A total of 13.6 trillion or 23.90 % of health care costs in 2015 were spent to finance catastrophic illness, which consists of
1. Heart Disease (13 %)
2. Chronic Renal Failure (7 %)
3. Cancer (4 %)
4. Stroke (2 %)
5. Thalassemia (0.7 %)
6. Haemophilia (0.2 %)
7. Leukemia (0.3 %)
The Need of HTA to Support JKN
(UHC Scheme)

Government regulation Perpres No.12 tahun 2013 pasal 43, Minister of Health is responsible to ensure quality control as well as cost control through HTA

HTA Committee has been established (Keputusan Menteri Kesehatan Republik Indonesia Nomor 171/Menkes/.SK/IV/2014 tentang Komite Penilaian Teknologi Kesehatan)

HTAC tasks include continuum of HTA (decision on Safety, efficacy, effectiveness, economic analysis/ cost-effectiveness, and values (as needed))

Continuum of HTA

<table>
<thead>
<tr>
<th>CEA, CUA, and CBA</th>
<th>Budget Impact Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concept</td>
<td>Affordability</td>
</tr>
<tr>
<td>Purpose</td>
<td>Budget impact</td>
</tr>
<tr>
<td>Perspektif</td>
<td>Pharmacy</td>
</tr>
<tr>
<td>Result &amp; Outcome</td>
<td>CER and QALY</td>
</tr>
<tr>
<td></td>
<td>Additional budget needed</td>
</tr>
</tbody>
</table>
KEY PLAYERS

- Drug Registration: FDA (BPOM)
- Medical device: MOH (DG Pharmacy and Medical device/ equipment)
- HTA for UHC
  - National formulary: MOH (Dirjen Farmalkes/ DG Pharmacy)
  - Economic evaluation & Budget Impact: MOH (PPJK/ Center for Health Financing)
    → Assessment (HTA agencies and PIC-MOH)
    → Appraisal (HTAC)
- Provider payment: NCC/ MOH set up tariff using bundling for provider payment, BPJS (single payer) pay to hospital (Ina CBGSS) and primary care (capitation)
- Subsidy through demand and supply sides: MOH and other ministries.

Public health programs remain MOHs responsibility, including EPI, HIVAIDS, TB and malaria.

Approach to implement HTA

Integration of HTA into Public Policies on Health Technologies
Establishment of an Institutional Framework for HTA-based Decision making
Human Resources Development
Promote the Production of Evidence and Dissemination of Information
Rational use of Health Technologies
Promotion of Network Collaboration
HTA is a bridge between “Science” & Decision Making

- Technological innovations are spreading rapidly
- Economic resources are dwindling
- Results decisions & priorities need to be made

Areas Addressed by HTA (related to JKN)

- High volume
- High risk
- High cost
- High variability
- Affects many
- Medical, social, ethic
- Unnecessary health cost
HTA COMMITTEE

• HTAC consists of 9 experts from institutions and academia
• Supported by a secretariat at the MOH PPJK (Center for Health Financing and Social Insurance)
• In general, HTA process related to the Benefit Package is focusing on task to assess any proposed technology whether it has “value for money” and provide recommendation to Minister (inclusion? Exclusion?) and the Budget Impact
• Guideline(s)
  • To select topic
  • Method
  • Who generate the evidence?
  • Appraisal
  • Institutional arrangement

Accountability principle

• Since the UHC/JKN money is owned by all people, the HTA team must make decision representing solely of the members (people) interest.
• Representatives of the team should come from stakeholders’ elements who understand the UHC, dedicated to the public interest, high integrity.
• For efficiency
  • The core team consists of 9 reputable persons
  • Ad hoc panels comprising additional 1.5 persons, representing experts on certain HT to be assessed
  • The Team is supported by Persons In Charge (PICs) who are researchers with adequate competencies
  • Certain centers (universities, etc) may conduct assessments to be integrated in the assessment being made for a related topic
Components to be Assessed

- First priority is assessment for benefits of the UHC
  - Diagnostic procedures
  - Therapies/medical interventions to cure/alleviate causes of diseases
  - New technologies
- Criteria for assessments
  - Effectiveness, not efficacy
  - Efficiency (CEA, QUA)
  - Egalitarian equity consideration
  - Ethical consideration

HTA process

Stakeholder Involvement

- MOH, RIS, universities, professional organization, patient organization, industry, etc.
- InaHTAc
- HTA agents: Academic institutions/university, hospitals, Professional Organization, others units in MOH, etc.
- InaHTAc

One of Agenda to develop HTA system and institutionalization is involving Academic Institutions/ university, hospitals, Professional Organization, and others units in MOH to conduct the study or assessment.
CHALLENGES

- Despite government is committed to support HTA, challenges on secure funding remain. Potential funding sources (with different challenges)
  - Central Budget (MOH?) : rigid/ not flexible to be used to support research
  - BPJS budget: bureaucracy
- Lack of capacity :
  - Need more involvement of academia, research centers to conduct assessment
  - Need to increase interest of experts to become HTAC (in the future it is planned to have selected HTAC members from various background on education, work, experience etc) with full support from GOI, HTA task is focusing on appraisal)
  - International support is expected (particularly to accelerate and improve capacity of HTA agencies)
- Method:
  - Model-based CEA and alongside clinical trial/ primary data on outcome
  - Variability of costs
  - Value set (utility to reflect Indonesian perspective on QoL)
  - Threshold (value for money decision)
  - Off-label drugs
  - Hospital role ?
- Fragmented process (of the “continuum” of HTA): Registration (BPOM), Fornas (Farmalkes), economic evaluation and budget impact (role of PPKJ,BPJS, NCC)
- Potential “joint cost” PH programs and UHC scheme”
  - Integration (payment) of some program components into BPJS payment and MOH,
  - Role of subnational level (decentralization)

International collaboration and supports

- WHO
- NICE -UK
- HITAP (Health Intervention and Technology Assessment Program) - Thailand
- PATH (Program for Appropriate Technology in Health) - Seattle USA
- AIPHSS (Australia-Indonesia Partnership for Health System Strengthening) –closed in early 2016
SUPPORT AND PROGRESS

- Early stage:
  - HTA for new vaccines
  - HTA under DG Medical Care/ NHRD focusing on EBM
  - Support from IDSI and Hitap (Health Intervention and Technology Assessment Program of Thailand) to strengthen national institutions and processes – includes incorporation of economic evaluation as part of the HTA as part of HTA process – started in 2014

- Key HTA outputs since engagement begin
  - Evaluation of WHO package of Essential Non Communicable Disease Intervention (PEN) program (DALYs)
  - Evaluation of treatment PAH (QALYs)
  - Evaluation of PD vs HD (QALYs)

- Strengthen capacity of PIC and universities in 2016

- The future? Strengthening link between HTA output and policy “roadmap for HTA” – refining methods and processess

The Road Map

<table>
<thead>
<tr>
<th>No.</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Prep phase: capacity building within HTA Team PPJK</td>
</tr>
<tr>
<td>2</td>
<td>In-house training for PICs &amp; HTA Team</td>
</tr>
<tr>
<td>3</td>
<td>Preparing guideline and manual for HTA</td>
</tr>
<tr>
<td>4</td>
<td>Collaboration with international HTA agencies</td>
</tr>
<tr>
<td>5</td>
<td>Revision of MOH Decree on HTA Core Team</td>
</tr>
<tr>
<td>6</td>
<td>Capacity building for HTA Team and PICs</td>
</tr>
<tr>
<td>7</td>
<td>Introducing HTA / social marketing</td>
</tr>
<tr>
<td>8</td>
<td>Short term training (1-6 mo) for &gt;15 persons in the MOH and 30 outside MOH</td>
</tr>
<tr>
<td>9</td>
<td>Educating Masters and PhDs on health economics (10-15 persons / yr), MOH and outside MOH</td>
</tr>
<tr>
<td>10</td>
<td>Revising JKN regulations to ensure 0.05 – 0.1% of the JKN fund used for HTA activities</td>
</tr>
<tr>
<td>11</td>
<td>Securing APBN &amp; fund from BPJS, gradually increase</td>
</tr>
<tr>
<td>12</td>
<td>Fully funded by JKN</td>
</tr>
<tr>
<td>13</td>
<td>The HTA fully operates by the National Team</td>
</tr>
</tbody>
</table>
OUR PLAN 2016-2026 (1)

1. Yr 2016-2018:
   • New HTAC established
   • Publish and disseminate guidelines
   • Support and networking: WHO, IDSI, Hitap, HTAI, INAHTA, HTAsiaLink
   • Assess two topics by PIC inside PPJK MOH
   • Start working with university to assess additional 2-3 topics on ec evaluation and BIA
   • Capacity building
   • Initiate collaboration with BPJS (data, funding etc)
   • Secure funding (central GOI budget, BPJS, external partner)
   • Initiate effort to integrate HTA process (fornas, hospital-based HTA, more clear role on who does what? generating evidence and appraisal, institutional arrangement
   • Linking to policy process

2. Yr 2018-2020:
   • continue capacity building and conduct 6-8 topics
   • Strengthen core team (TOT) and start to involve more universities and collaboration with other institutions, set up institutional arrangement
   • Dissemination and monev
   • Secure funding
   • Linking to policy,

OUR PLAN 2016-2026 (2)

3. Yr 2020-2026
   • Initiate to develop an independent HTA unit, with a credible process involving HTAC members, involving universities/ research centers to conduct HTA studies
   • Approx 10 topics/ year
   • Secure funding 0,1-0,2% of BPJS revenue
   • Partnership and stakeholders engagement
   • Dissemination
   • Linking to policy
THANK YOU
TERIMA KASIH

INSTITUTIONALIZATION
OF HTA IN GHANA

Saviour K. Yevutsey, Deputy Director of Pharm. Services
Pharmacy Unit
Ghana Health Service
About Ghana

- **Facts and figures**
  - Total Population (2014) about 26 million
  - Gross National income per capita (PPP international $, 2012) 1,910
  - Total expenditure on health per capita (Intl $, 2012) 106
  - Total expenditure on health as % of GDP (2012) 5.2
  - Life expectancy at birth m/f (years, 2012) 61/64
  - Probability of dying between 15 and 60 years m/f (per 1000 population, 2012) 263/227


Universal Health Coverage
Coverage vrs costs

Three dimensions to consider when moving towards universal coverage:

- **Direct costs:**
  - What proportion of the costs are covered?
- **Services:**
  - Which services are covered?
- **Population:**
  - Who is covered?

Movement toward Universal Health Coverage: Benchmark Events/Policies and Status

**National Health Insurance Act, 2002 (Act 582) passed to revise Act 650**
- Requirement for annual reporting on equity
- Addition of family planning to benefit package
- Exemption of persons with mental disorders and categories of disabled from contribution payment

**National Health Insurance Act, 2008 (Act 650) passed**
- Health insurance mandatory except police and military
- National Health Insurance Fund Created (2.5% VAT & 2.5% SSNIT)
- National Health Insurance Council Created
- Provision for 3 types of health insurance schemes

**First community health financing scheme established 1992**
- 157 Community health financing schemes in operation by 2001

**Exemption from Contributions**
- Under 18
- Persons above 70
- Indigent
- SSNIT Pensioners
- Indigent
- Pregnant Women
- Persons with mental disorders
- Categories of disabled

**Benefit Package**

**Inclusions**
- Inpatient services - accommodation and feeding
- Outpatient services including HIV AIDS symptomatic treatment of opportunistic infections
- Maternal health services (Antenatal, deliveries including caesarean section and postnatal)
- Emergencies
- Investigations including laboratory investigations, x-rays and ultrasound scanning

**Exclusions**
- Cosmetic surgeries
- Echocardiography
- Dialysis for chronic renal failure
- HIV Anti retroviral drugs
- Heart and brain surgeries except resulting from accidents
- Mortuary services
- Organ transplant

---

Health Financing Strategies for Universal Health Coverage

**NHIS Income 2012**

- **NHI Levy**: 72.7%
- **SSNIT Contributions**: 17.5%
- **Premium Income**: 4.5%
- **Investment Income**: 5.3%
- **Other Income**: 0.1%
- **IDA Funding (World Bank)**: 0.04%

**NHIS Expenditure 2012**

- **Operating Expenses (NHA)**: 4.6%
- **Admin & Logistical support to (Schemes)**: 3.4%
- **Support to MOH**: 9.0%

**Source**: National Health Insurance Authority
How HTA has been carried out
Before we start: institutional mapping and political backing

Before we start: institutional mapping and political backing

The stakeholders include:
- Ghana National Drugs Programme
- NHIA
- Academia
- Coalition of NGOs in health (Civil Society Organizations)
- MOH Policy Planning Monitoring and Evaluation directorate
- Ghana Health Service Planning Monitoring and Evaluation directorate
- Food and Drugs Authority (FDA) etc
- There is room to add on
Need for institutionalization of HTA in Ghana: Sustainability Lessons

- Generous benefit package of the NHIA - inability to use HTA that has resulted in the current conditions of the Ghana NHIS
- Depletion of fund reserves of the NHIA
- Political pressure and interference in adding to the benefit package
- Pressure from provider groups
- Development partner agenda
- Low Premiums
- Excludes preventive care
- FRAUD

Who is conducting HTA

- The use of HTA as a priority setting tool is captured in the Health bill and stipulated in the National Medicines Policy (NMP) (2016).
- The parliamentary select committee on health was engaged in the development of the NMP and has adopted the concept.
- HTA has been piloted using hypertension as a case study.
- Broad stakeholder consultation at the pilot phase on the concept
- The concept was accepted by stakeholders and captured in the work plan of the Ministry at the Health Submit.
- Lead institution is the Ministry of Health (Ghana National Drugs Programme/Office of the Director of Pharmaceutical Services)
Who is conducting HTA (Cont.)

- Advisory / decision making committee
  - The steering committee of National Medicines Policy is the final approval authority for any recommendation from HTA TWG
  - Chaired by the Deputy Minister of Health
- Representatives of the stakeholders constituted the larger technical working group (TWG)
- Smaller group forming subcommittee of the TWG

Objective of the pilot HTA

- To compare the cost-effectiveness of the four main classes of antihypertensive drugs
  - In patients with primary hypertension without pre-existing CVD, diabetes or heart failure, and excluding pregnant women
  - for initiation of treatment with ACE inhibitors/ARBs, beta-blockers, calcium channel blockers and thiazide-like diuretics
  - no intervention
  - Cost-effectiveness measured as Cost (GHC) per DALY avoided
How result from HTA been used in Ghana. - Cost effectiveness:
Informing selection and reimbursement

- Health outcomes in terms of Costs per DALYs avoided

Diuretics and CCBs are estimated to be superior to the other classes of antihypertensive drugs: yielding a health gain (more DALYs avoided) for a lower cost.

Decision on HTA outcome

- Decision forwarded to Steering committee of the NMP at the Ministry of health; chaired by the Deputy Minister of Health
- Informing new priority treatment guidelines and medicines lists (ongoing)
- To inform reimbursement lists and reimbursement prices of the NHIA
- Inform price negotiation
  - Cost-effective price ranges for key medicines
Conclusion

• In the spirit of sustainable development and universal health coverage: Ghana’s benefit package needs to be reviewed
• Lessons learnt implementing it for over 10yrs
• Better placed now to use well tested systems to inform and support the review
• Stakeholder engagement is key
  • Several local engagements since October 2014
  • Engaging NICE International
    • Study visit, proposal etc
    • ‘Low hanging fruits’ start small and aim high
• Priority setting mechanisms- invaluable
• Need to strengthen technical capabilities of TWG.
Thank you