

INSTITUTIONAL OPTIONS FOR PRIORITY-SETTING:



HOW, WHY, AND SO WHAT?

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Coordinator: Laura Morris
l.morris@imperial.ac.uk

Analyst (Health Economics)
Global Health and Development
(former: NICE International)

Institute for Global Health Innovation
Imperial College London

Tommy Wilkinson
(PRICELESS-SA)

Mardiati Nadjib
(Uni. of Indonesia)

Saviour K. Yevutsey
(Ghana Health Service)

Justice Nonvignon
(Uni. of Ghana)



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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**

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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!

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There are many different paths countries can take...



5

...but also common conducive factors

Collaboration of WHO Asia Pacific Observatory (APO) and Prince Mahidol Awards Conference
Authors: HITAP, Thailand

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)


Asia Pacific Observatory
on Health Systems and Policies

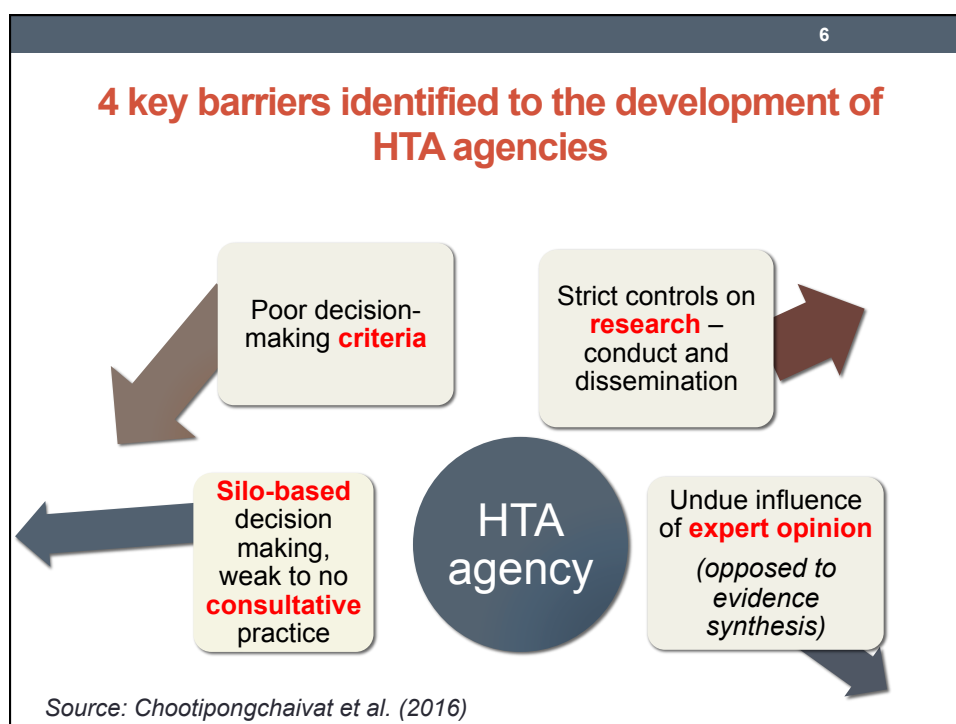
Prince Mahidol Awards
Conference

POLICY BRIEF

Factors conducive
to the development of health
technology assessment in Asia

IMPACTS AND POLICY OPTIONS

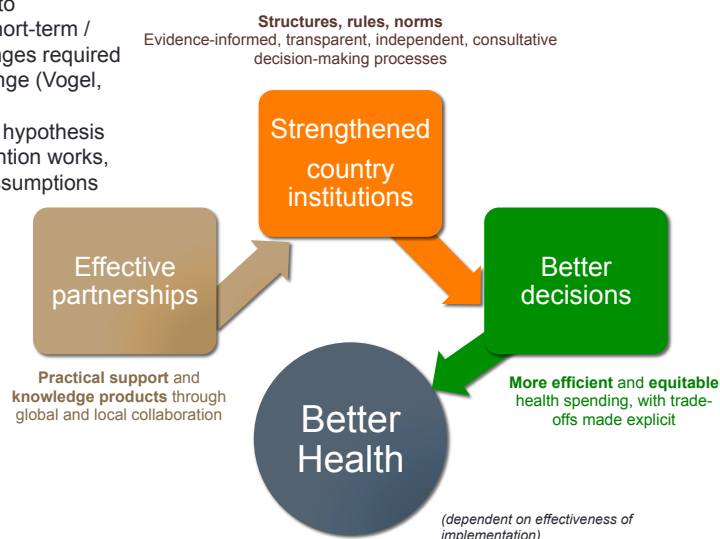




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The iDSI Theory of Change: Understanding cause and effect in priority-setting

- 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



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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)

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



Tommy Wilkinson, BPharm, MSc (health econ)

Senior Technical Advisor, IDSI
PRICELESS SA, Wits School of Public Health
Johannesburg, South Africa
Email: tommy.d.wilkinson@gmail.com



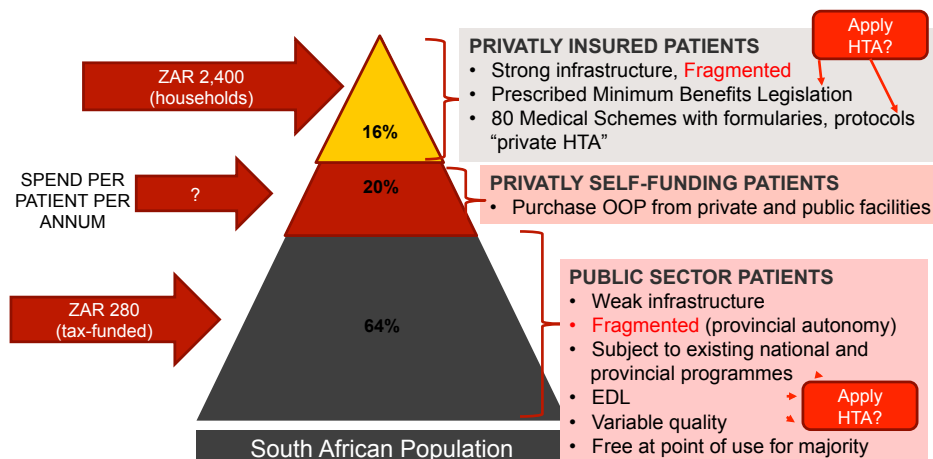
South Africa profile

- Population: 54 million (annual GDP growth 1.6%)
- Upper middle income, GNI/capita US\$6,800¹
- 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%



Source: World Bank 1. Atlas method, 2014 2. Ages 15-49, 2014

Health Care provision in South Africa



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"

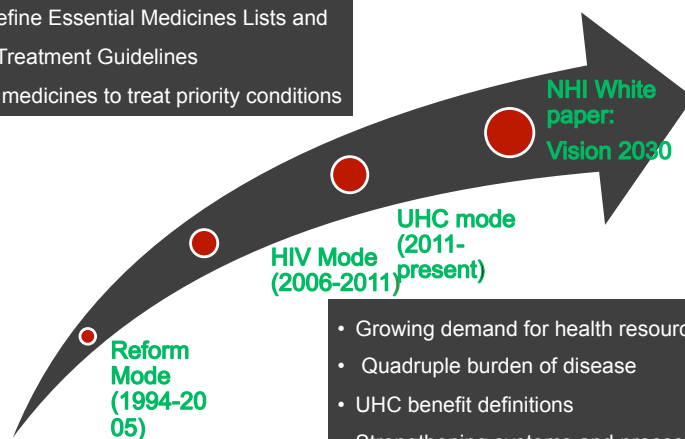
How HTA is used in decision making:

- Advisory

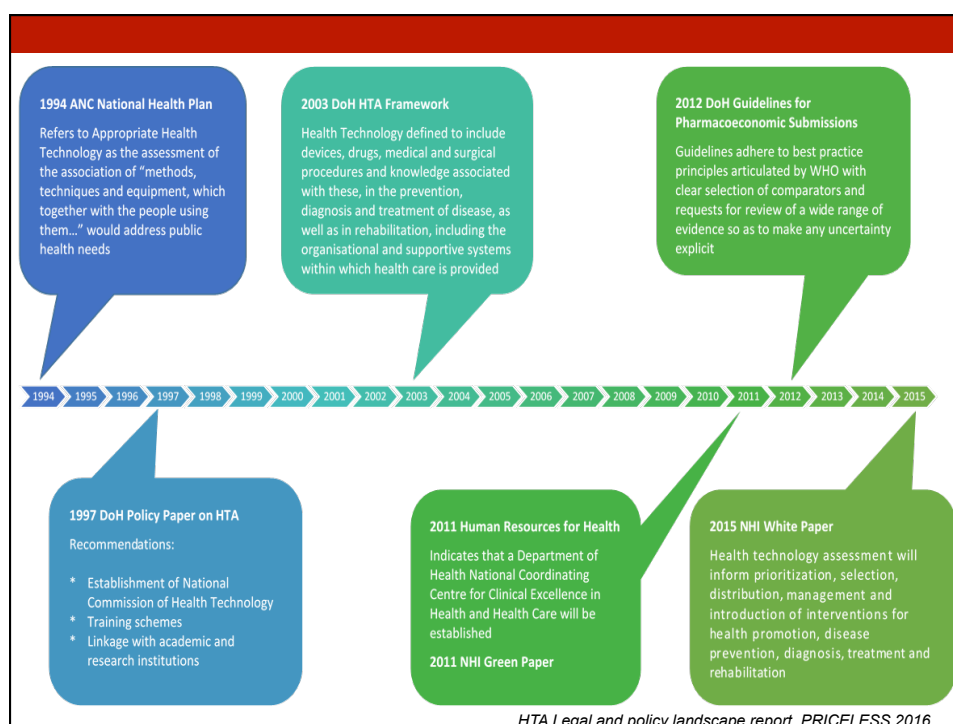


Priority setting in South Africa

- 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



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

December 2012 [GUIDELINES FOR PHARMACOECONOMIC SUBMISSIONS]		Published PE Recommendations Key Features:	
 <p>health Department: Health REPUBLIC OF SOUTH AFRICA</p> <p>GUIDELINES FOR PHARMACOECONOMIC SUBMISSIONS</p> <p>December 2012</p> <p>http://www.ispor.org/PEguidelines/countrydet.asp?c=38&t=4</p>		Key Features:	Guidelines for Pharmacoeconomic Submissions (December 2012)
		Title and year of the document	National Department of Health
		Affiliation of authors	To describe the process to be followed for PE applications and the criteria for medicines which require submissions. To create a forum which provides independent and objective review of the value of medicines
		Purpose of the document	Yes
		Standard reporting format included	Nothing required
		Disclosure	Pharmaceutical companies, researchers, decision makers
		Target audience of funding/author's interests	Default perspective: third-party payer. Option to use a broader perspective where justified according to specific considerations.
		Perspective	Approved indication
		Indication	If submission pertains to a specific subgroup, within the registered indication, this must be clearly defined
		Target population	Yes (only if the group has been defined a priori in the clinical trial protocol and the study was sufficiently powered to analyse specified arms)
		Subgroup analysis	The main comparator is deemed to be the standard of care for local practice. All possible comparators need to be listed and justified.
		Choice of comparator	Time horizon is based on the natural course of the condition and the likely impact of the treatment. Depending on the type of intervention, it may be necessary to present a short-term analysis based on the primary clinical data.
		Time horizon	Yes
		Assumptions required	Any of OVA, CEA, CUA and CBA considered but choice of analysis must be clearly justified. The modelled evaluation should be based on the outcomes measures which most closely validly estimate the final outcome.
		Preferred analytical technique	Direct costs. Indirect costs should generally be excluded.
		Costs to be included	No preferred source specified, although source needs to be provided clearly identifying the source of the reference for unit costs.
		Source of costs	Yes - where randomised trials available do not provide sufficient information. Modelling options include spreadsheet analysis, decision analysis, Markov models and Monte Carlo simulations.
		Modelling	Yes, including criteria for inclusion and exclusion of sources of evidence, evaluation of clinical trials for inclusion, assessment of measures taken to minimize bias, meta-analysis and indirect comparison. Benefit strategy to be clearly defined and be reproducible.
		Systematic review of evidences	Yes
		Preference for effectiveness over efficacy	Life Years Gained, deaths prevented or QALYs gained
		Preferred outcome measure	No preference stated for measurement of utilities
		Preferred method to derive utility	No differentiation between QALYs accruing to different groups
		Equity issues stated	Future costs should be discounted at an annual rate of 5% (range 0% to 10% for sensitivity analysis)
		Discounting costs	Future benefits should be discounted at an annual rate of 5% (range 0% to 10% for sensitivity analysis)
		Discounting outcomes	Sensitivity analysis must be conducted on all variables using an appropriate range, as justified and referenced. Results to be presented in table form and tornado diagrams.
		Sensitivity analysis-parameters and range	One-way sensitivity analysis must be conducted on all variables using an appropriate range, as justified and referenced. Two-way sensitivity analysis should be conducted on variables shown to be sensitive in the one-way analysis.
		Sensitivity analysis-methods	Results to be presented in a disaggregated form, and then increasingly aggregated. Present appropriately aggregated and discounted costs results separately for outcomes and resources and separately for proposed medicine and its comparator. The final outcome should be presented as an ICER.
		Presenting results	Yes
		Incremental analysis	Yes
		Total costs vs effectiveness (cost-effectiveness ratio)	The patient population to which the pharmacoeconomic evaluation applies should be consistent with the patient population defined in the clinical part of the reimbursement request submission.
		Portability of results (Generalizability)	Not specified
		Financial impact analysis	Currently, the submission for pharmacoeconomic assessment is essentially voluntary, however, key figures in the Department of Health have to power to 'call a product up' for economic assessment.
		Mandatory or recommended or voluntary	

Key legislation:

- Constitution of the Republic of South Africa (1996)
 - 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
- Medical Schemes Act (1998) – in-house HTA for medical schemes for Prescribed Minimum Benefits (PMB)
- Medicines and Related Substances Act (1965) – regulation of medicines



NATIONAL HEALTH INSURANCE FOR SOUTH AFRICA

TOWARDS UNIVERSAL HEALTH COVERAGE

Thursday, 10 December 2015

Version 40

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

HTA Legal and policy landscape report, PRICELESS 2016

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

Siyabonga - Enkosi - Thanks

www.pricelessa.ac.za



DEVELOPMENTS IN INSTITUTIONALIZATION OF PRIORITY-SETTING IN INDONESIA



Dr. Mardiaty Nadjib

Faculty of Public Health
University of Indonesia

Acknowledgement:

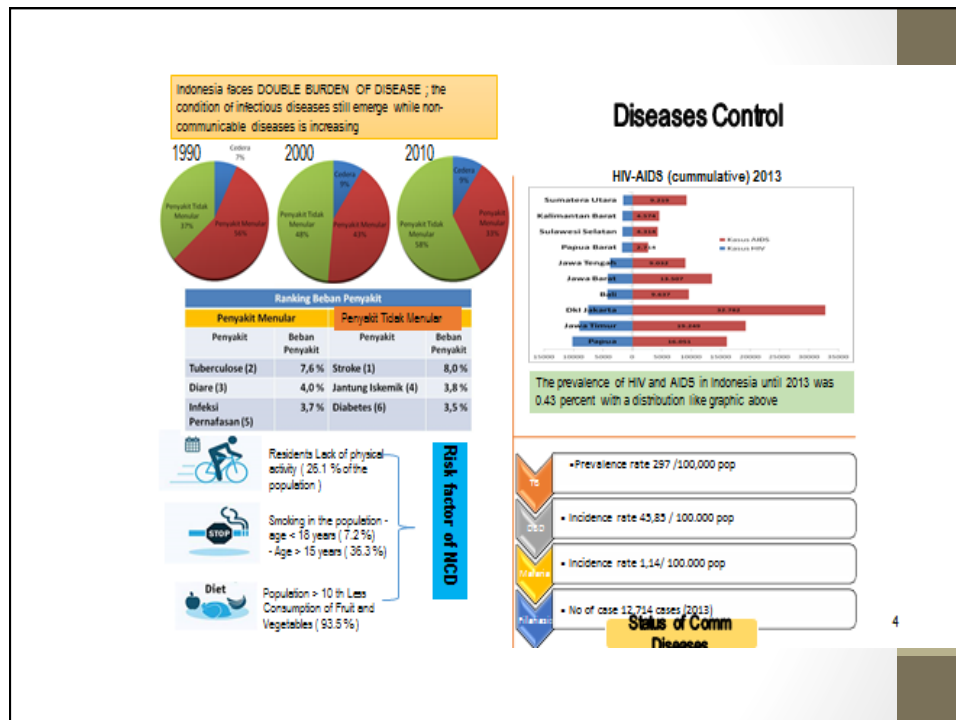
Centre for Health Financing and Health Insurance
Ministry of Health, Republic of Indonesia



BACK GROUND

INDONESIA: over 17,000 Islands, 250 m people
Highly decentralized system





Health Financing: in 2014

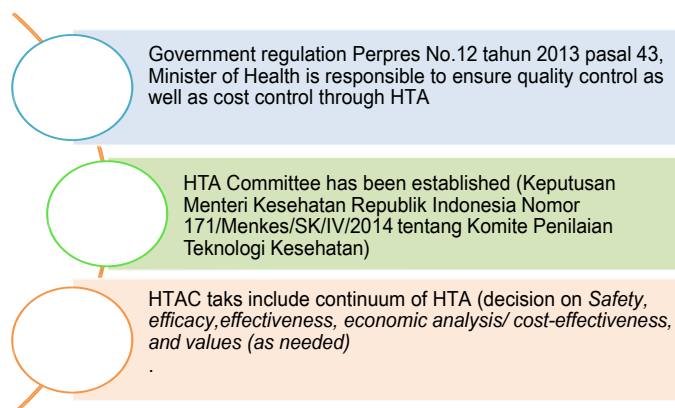
- Health expenditure as % of GDP: 3,6%
- High OOP spending: 45% of THE
- Social security funds as % of THE: 12,9%

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

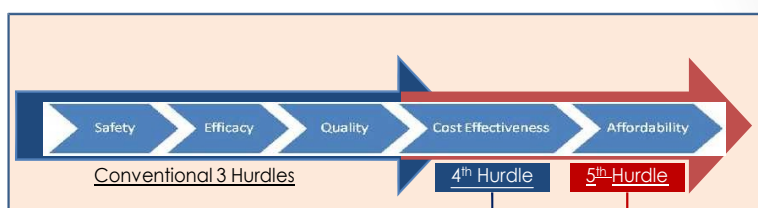
A total of 13.6 trillion or 23.90 % of health care costs in 2015 were spent to finance catastrophic illness , which consists of

1. Heart Disease (13 %)
2. Chronic Renal Failure (7 %)
3. Cancer (4 %) .
4. Stroke (2 %) .
5. Thalasemia (0.7 %) .
6. Haemofilia (0.2 %)
7. Leukemia (0.3 %)

The Need of HTA to Support JKN (UHC Scheme)



Continuum of HTA



	CEA, CUA, and CBA	Budget Impact Analysis
Concept	value for money	Affordability
Purpose	Select health technology (new or alternative)	Budget impact
Perspektif	Societal/ provider	Payer
Result & Outcome	ICER and QALY	Additional budget needed

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.

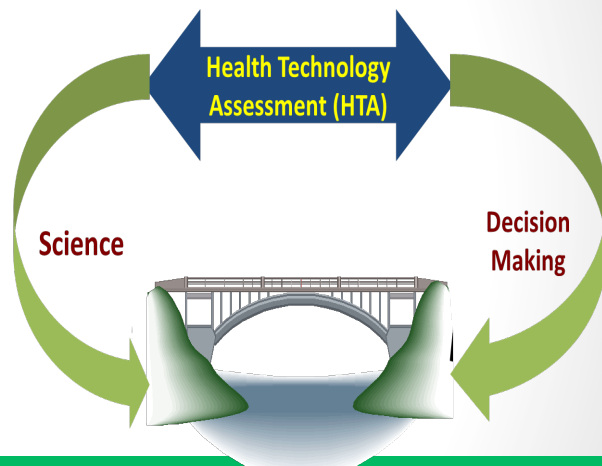
Approach to implement HTA

- 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

Translated into
Action Plan

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

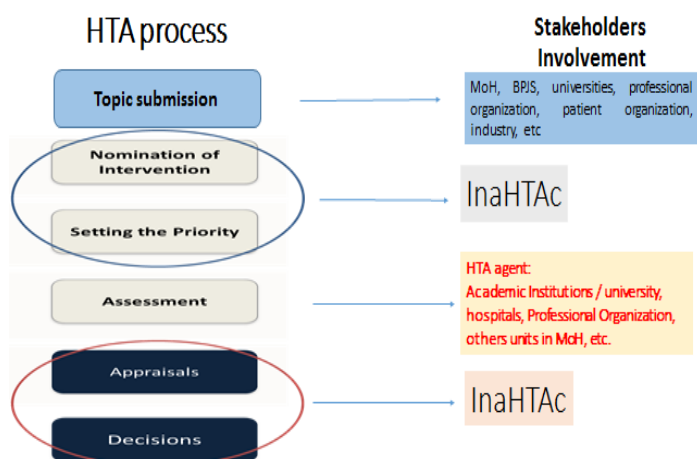


Accountability principle

- 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 15 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, CUA)
 - Egalitarian equity consideration
 - Ethical consideration



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 challenge)
 - 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 PPJK,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

1	Prep phase: capacity building within HTA Team PPJK
2	In-house training for PICs & HTA Team
3	Preparing guideline and manual for HTA
4	Collaboration with international HTA agencies
5	Revision of MOH Decree on HTA Core Team
6	Capacity building for HTA Team and PICs
7	Introducing HTA / social marketing
8	Short term training (1-6 mo) for >15 persons in the MOH and 30 outside MOH
9	Educating Masters and PhDs on health economics (10-15 persons / yr), MOH and outside MOH
10	Revising JKN regulations to ensure 0.05 – 0.1% of the JKN fund used for HTA activities
11	Securing APBN & fund from BPJS, gradually increase
12	Fully funded by JKN
13	The HTA fully operates by the National Team

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 (foras, 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 money
 - 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

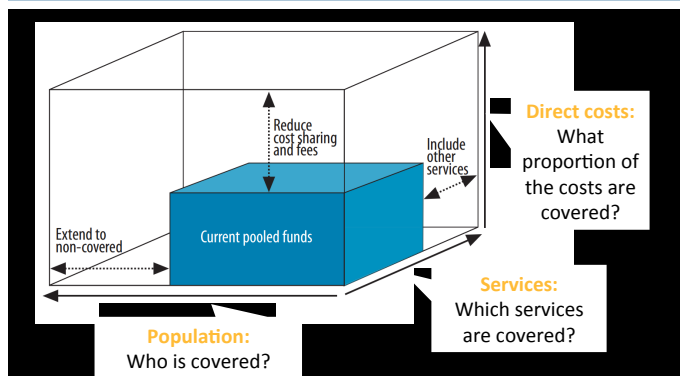
- Total Population (2014) about **26million**
- Gross National income per capita (PPP international \$, 2012) **1,910**
- Total expenditure on health per capita (Intl \$, 2012) **106**
- Total expenditure on health as % of GDP (2012) **5.2**
- Life expectancy at birth m/f (years, 2012) **61/64**
- Probability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



Universal Health Coverage

Coverage vrs costs

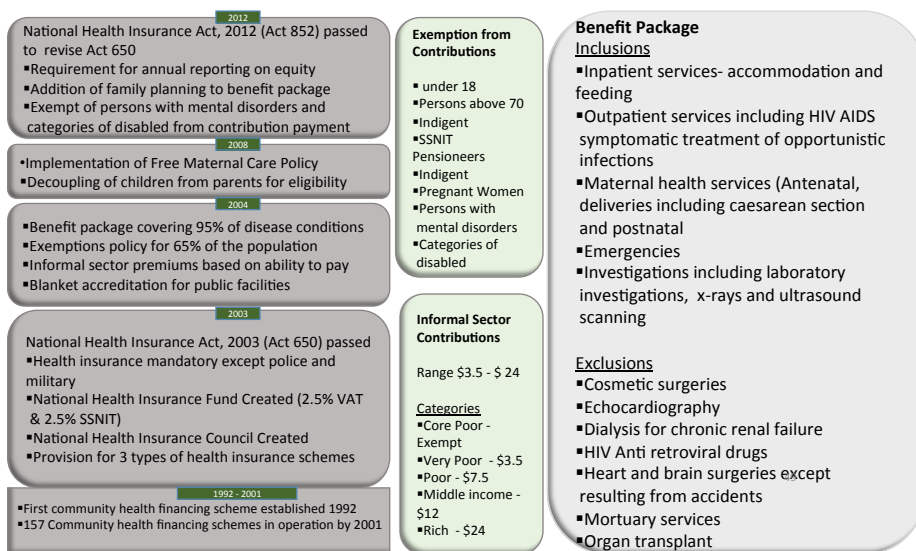
Three dimensions to consider when moving towards universal coverage



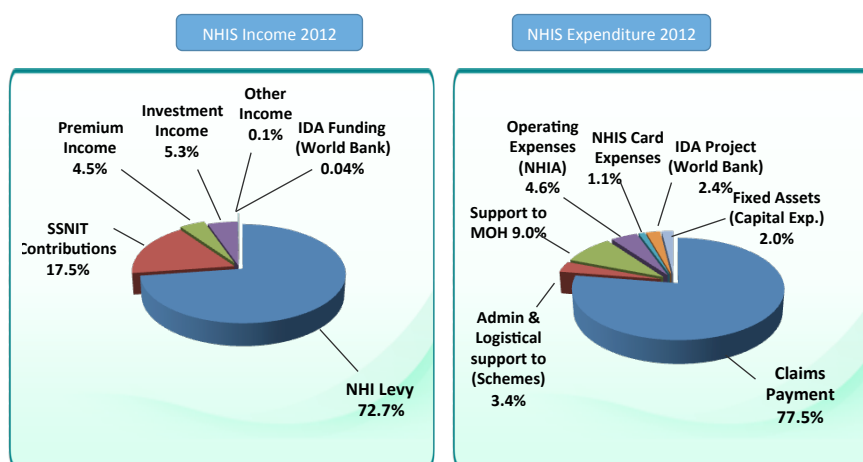
Source: World Health Organization, World Health Report, 2010

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



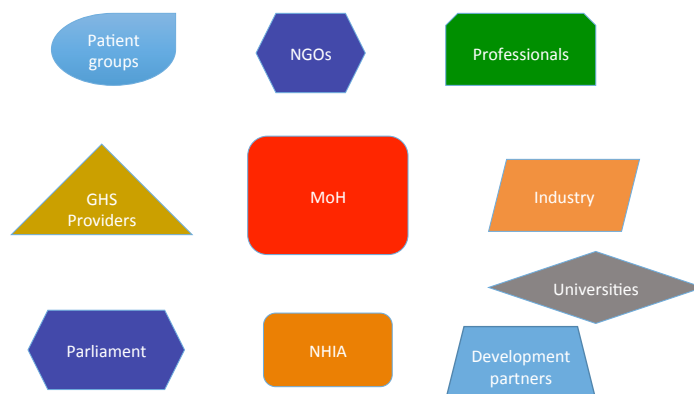
Health Financing Strategies for Universal Health Coverage



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



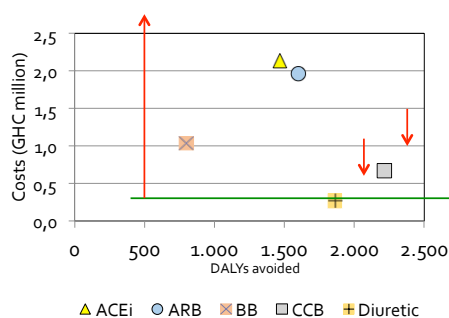
Objective of the pilot HTA

- 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

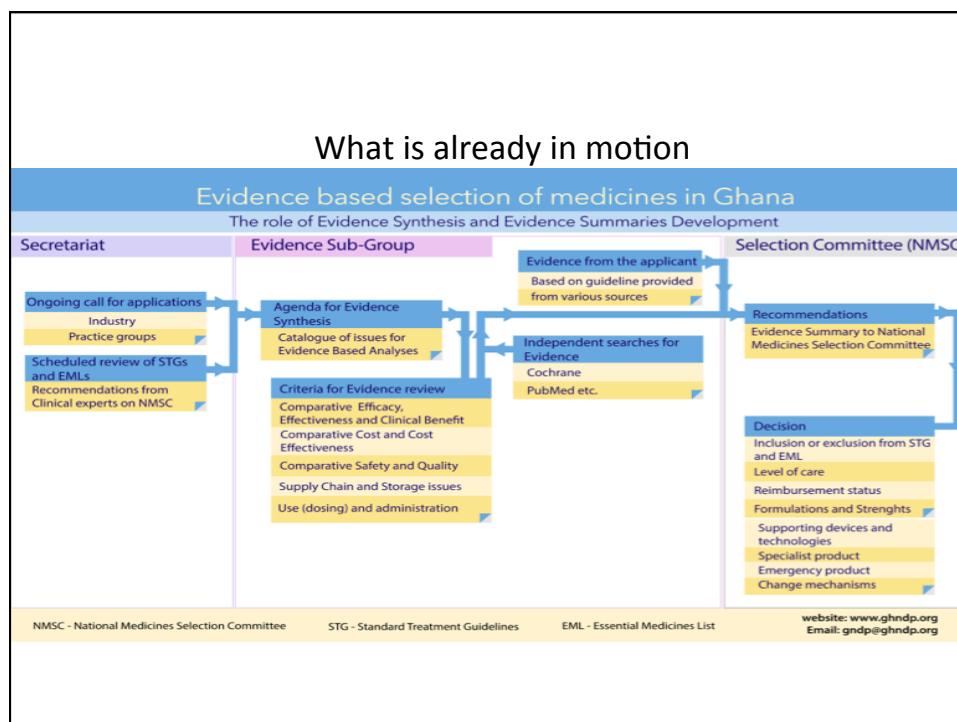
- Health outcomes in terms of Costs per DALYs avoided



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 (on going)
- 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

