Policy Note [1]

Process Matters for Priority Setting and Health Technology Assessment
April 2015

This discussion outlines some key principles and activities which can be used to support open, consultative and independent processes for health technology assessment in Indonesia.

Introduction

At its core, moves towards universal health coverage (UHC) have the aim of ensuring everyone has access to quality health services they need without risking financial hardship from paying for them. The challenge for most countries is how to expand health services to meet growing needs with limited resources.

Health Technology Assessment (HTA) is an evaluative process and structured analysis of healthcare interventions, which can be used as an input to decisions on which interventions can be covered in a public benefit package and support the goals of UHC. With that aim in mind, in April 2014, the Indonesian government established a HTA programme, with a HTA Committee under the auspices of the Minister of Health. This was created to support the UHC programme known as JKN (Jaminan Kesehatan National) operating since January 2014.

Broadly speaking, HTA includes components of **assessment**, which involves generating evidence about the likely costs and effects of a technology or service, and **appraisal**. During appraisal, the evidence or knowledge generated during the assessment is considered by a multidisciplinary team in light of additional social and scientific values. This appraisal process would lead to recommendations and decisions which can be taken up into policy. These activities may be undertaken by one or several institutions; Figure 1 shows how the UK's National Institute of Health and Care Excellence (NICE) interacts with other institutions to translate evidence into policy recommendations for the National Health Service (NHS).

NICE, established in 1999 with an initial remit focused very much on treatment, particularly around individual health technologies and clinical guidelines, is responsible for turning evidence into direct guidance for the NHS, in addition to gathering and synthesising the relevant evidence. Indeed as shown in Figure 1, NICE, as part of its health technology *appraisal* process, relies on external organisations to generate the evidence needed for its deliberations, most notably academic bodies but also the manufactures and sponsors of the technology under appraisal.
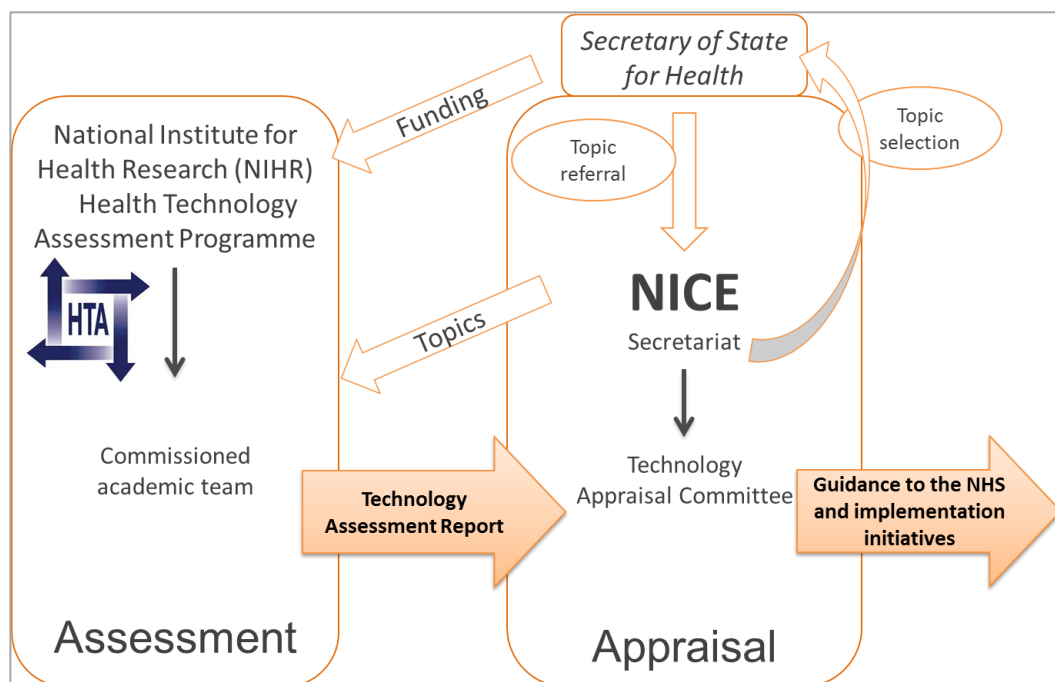
HTA initiatives have been implemented globally and differ in terms of their responsibilities and relationships to the final coverage decisions. Depending on their legislative position and resourcing, HTA agencies may conduct technical assessment processes themselves, or appraise external submissions, as in the case of NICE[2].

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[1] This Policy Note was written by Kalipso Chalkidou, Laura Morris and Francis Ruiz of NICE International.

[2] For details of the different types of HTA bodies in operation, see *Policy Note #22: Considerations for Establishing a Health Technology Assessment Process or Program*

There is no single "correct" way to design and operate a HTA agency; decision-makers contextualise the processes of HTA to their local setting and political context. A key aspect of these processes, however, is their ability to increase the legitimacy of decisions made. Establishing processes that include multi-stakeholder engagement and expert advice based on independent consideration of the available evidence, can help manage conflicting interests and reduce the risks of serious dispute, including legal action. Moreover, a credible process for conducting HTA can help ensure that purchasing decisions are clearly linked to the value of the intervention, as in various access schemes or risk sharing arrangements. In short HTA agencies of all types can adhere to procedural principles which help strengthen their position and credibility.

Figure 1: Example of assessment and appraisal functions in the NHS[3]

Secretary of State for Health

Funding

Topic referral

Topic selection

National Institute for Health Research (NIHR) Health Technology Assessment Programme

HTA

Topics

NICE

Secretariat

Commissioned academic team

Technology Assessment Report

Technology Appraisal Committee

Guidance to the NHS and implementation initiatives

Assessment

Appraisal

The value of open, consultative and independent processes

In brief, open, consultative and independent processes matter because:

- They confer **legitimacy** because of their inclusive nature and make even controversial decisions more defensible and more likely to have an impact and those who make them more accountable to service users and tax/premium payers

- They improve the quality and **relevance** of the decisions as they draw on a wide range of sources of opinions and information

- They protect against **vested interests** and bias of those participating in them

The concerns and needs of stakeholders mean that prioritisation decisions are likely to lead to controversy, even when using the most robust possible methods for analysing evidence. Some demand will inevitably go unmet in a health system with finite resources. The question therefore is not whether prioritisation decisions can be

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[3] Adapted from Walley, T. (2007) Overview of Health technology assessment in England: assessment and appraisal. MJA 187: 283–285

made but *how they should be made*.

Individual *patients* and their families often expect to be able to access all potentially effective interventions, and *professionals* similarly prefer to be able to offer as many treatment options as possible. *Manufacturers* aim to ensure coverage of their products by public and private insurance systems, and prefer to cooperate with processes which are predictable and as timely as possible (see table 1).

Table 1: The motivations and ambition of different stakeholders

Stakeholder group	Motivation	Ambition/Goal
Users	Improvements in quality, length of life; a sense of entitlement and social solidarity	Access to treatment
Life sciences industries; manufacturers	Shareholder value, return on investment	Product sales
Professionals	Duty of care, professional curiosity, esteem	Better outcomes (and sometimes increased income)
Health system	Equity of resource allocation, good outcomes, cost control	Return on investment, financial control
Politicians	Result for constituents, consistent decision-making	Improved health
Media	Story, editorial line, insight	The story
Academia	Methods development, influence	Publication, opportunity to influence practice

Such tensions make legitimate processes even more important as a means of defending the decisions arrived at by HTA agencies. For example, the UK's NICE manages these tensions by setting out rules for engagement by multiple stakeholders, allowing interest groups to "have their say, [but not necessarily] have their way".[4] The NICE process for technology appraisal also includes mechanisms to allow stakeholders to launch a formal appeal against the preferred recommendations of its independent, multi-disciplinary committees. If the disagreement persists, rules exist for stakeholders to launch a judicial review which applies to all public bodies including NICE.

One of the motivations behind the creation of Colombia's HTA body, the Instituto de Evaluacion Technologia en Salud (IETS), for example, related to the frequent and

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[4] The Lancet interview with Professor Michael Rawlins – see: http://www.thelancet.com/pdfs/journals/lancet/PIIS0140673609607601.pdf [accessed April, 2015]

costly use of the courts to deal with disputes concerning the provision of services within the benefits package. These problems partly stemmed from the fact that inclusion and exclusion decisions took place within an implicit decision making framework, with no effective process for stakeholder consultation and little or no use of evidence to inform those decisions[5].

It is possible to highlight a set of key procedural principles that can support good governance in HTA. These are summarised in Table 2. While the detailed implementation of these principles will differ according to context, adherence allows the HTA body to defend its decisions, even when these decisions are difficult or unpopular. For NICE, following these principles have allowed it to build a reputation globally, attract high calibre academics, clinicians and policy makers, and defend some tough decisions in Parliament, the Court, academia and the public media.

Table 2: Principles of good governance for HTA

Principles	Examples of how bodies can adhere to these principles
Independence	Maintain arm's length from government, payers, industry and professional groups; Strong and enforced conflict of interest policies
Transparency	Meetings are open to the public; Material placed online; decision criteria and rationale for individual decisions made public
Consultation	Wide and genuine consultation with stakeholders; Willingness to change decision in light of new evidence
Scientific basis	Strong, scientific methods and reliance on critically appraised evidence and information
Timeliness	Decisions produced and published in reasonable timeframe
Consistency	The same technical and process rules are applied to all priority-setting channels
Regular review	Regular updating of decisions and of methods, with review dates specified in final reports
Contestability	The decision-making process can be challenged, through legal challenges or non-judicial appeal mechanisms

As can be seen from Table 2, it is important for any HTA body to be (and be seen to be), independent from any particular interest. Part of this relates to the legislative framework underpinning the creation of the HTA body or process, the rules around the recruitment of staff and involvement of expert advice, including having a well-defined conflict of interests policy, and the consistent and transparent application of its own rules. In terms of conflicts of interest, any policy should indicate how these would be *managed*, since it may not be possible to run an effective HTA programme without involving some people with an interest. Notably having an interest may not

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[5] Colombian Health System on its Way to Improve Allocation Efficiency – Transition from a Health Sector Reform to the Settlement of an HTA Agency. Vargas-Zea N et al (2012). Value in Health Regional Issues, Volume 1, Issue 2, Pages 218-222. http://dx.doi.org/10.1016/j.vhri.2012.09.004

exclude an individual from the entire HTA process, but may mean that at critical points (e.g. when recommendations are being drafted), the conflicted individual would be excluded from the discussion. All interests should be transparently set out by the responsible HTA body and subject to public scrutiny.

Other key points to highlight:

- Stakeholder consultation can inform not only choices around individual technologies (e.g. whether to include a new drug into a benefits package), but also have an important role in up front topic selection, and also in decisions around whether to review existing advice

- Consultative multistakeholder processes can enhance the local relevance and impact of health technology and increase the accountability of those making investment decisions locally

- Consultative multistakeholder processes can highlight data gaps and help drive future research

- Consultation and transparency can cause controversy, but openness is worthwhile, and the alternative (implicit and opaque decision making) can also generate controversy

- Open and consultative processes are being adopted by decision-makers around the world, offering greater transparency to key stakeholders such as patients and industry

Methods of engaging with the public and stakeholders

As noted earlier, the creation of legitimacy involves stakeholder participation in the day-to-day operation of the HTA body. Indeed engagement with stakeholders, including the public, can go beyond judgements on individual technologies to also explore social and ethical factors influencing decision-making more broadly. For example, involvement of the public and stakeholders in NICE's work is multifaceted and multi-level. In addition NICE's methods are seen as a model for consultation in public services more broadly in the UK. In a report by the Picker Institute, "Not NICE" (2009), the authors encouraged local health commissioning bodies in England to follow NICE's example in using methods for public engagement such as citizens' advisory panels.[6]

Decision making bodies can engage with service users and the broader public in a number of ways, including:

- Including key stakeholders, including lay members, in decision-making committees;

- Subjecting all guidance, as well as the methods and processes for its production, to public consultation and mandating publication of responses to consultation comments;

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[6] Chisholm A, Briggs K, Askham J (2009). Not NICE: Can PCTs engage patients and the public in commissioning new health technologies? Oxford: Picker Institute.

- Seeking patient and professional testimonies at committee meetings;

- Inviting all stakeholders groups to submit written evidence which are then made publicly available;

- Defining clear processes for stakeholders (including payers, industry and patient organisations) to appeal against decisions;

- Sponsoring dedicated "Patient and Public Involvement Programmes", to engage with and draw on the expertise of individual patients and patient groups;

- Issuing all decisions and their rationale in lay-friendly versions and distribute to patients directly and through the internet;

- Establishing and consulting Citizens' Councils or Citizens' Juries, which are composed of lay members of the public, who representing the socioeconomic structure of the country. These deliberate on challenging value judgements such as whether age should be a factor when making healthcare resource allocation decisions and whether efficiency ought to be sacrificed, to a point, in order to favour the most disadvantaged groups within society. Their reports can form the basis of "*Social Value Judgements*" guidance for decision-making committees.

Combining scientific and medical considerations with the views of patients and the wider public, has been increasingly seen as important when implementing evidence-informed decision making such as HTA and its variants, and engaging in priority setting more widely. For example:

- The **Australian Pharmaceutical Benefits Advisory Committee**[7] who, in 2003, following a direction by the Australian government, announced that it will publicise the reasons for every negative or restrictive decision on listing a new technology and allow manufacturers to comment on the proposed decision before publication. Furthermore, since the Australian-US Free Trade Agreement of 2007, a number of measures enhancing transparency and particularly focused on increasing private sector/manufacturer engagement were introduced, including an independent review in the case of a negative decision.[8]

- The **Patient Centered Outcome Research Institute**, established by law as part of the healthcare reform bill[9] passed by President Obama in March 2010, contains a special section on process, particularly around transparency and stakeholder engagement. According to the legislation, the Institute will have wide membership drawn from patients organisations, industry, payers, researcher organisations etc; will have an explicit policy for managing conflict of interest and *"…a process to receive feedback from physicians, health care providers, patients, and vendors of health information technology focused on clinical decision support, appropriate professional associations, and Federal and private health plans about the value of the information disseminated and the assistance provided…".*But, most importantly, in a country where evidence-based medicine is often interpreted as "rationing", the legislation

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[7] For an overview of PBAC, see: http://www.pbs.gov.au/info/industry/listing/participants/pbac
[8] Australia_USA Free Trade Agreement, 2007:
http://www.health.gov.au/internet/main/publishing.nsf/Content/health-ausfta
[9] Patient Protection and Affordable Healthcare Act, 2010,
http://democrats.senate.gov/reform/patient-protection-affordable-care-act-as-passed.pdf

allows for evidence to inform coverage decisions as long as due process is followed: "The *Secretary may only use evidence and findings from research conducted under section 1181 to make a determination regarding coverage under title XVIII if such use is through an iterative and transparent process which includes public comment and considers the effect on subpopulations."*

- Since the establishment of **Thailand's Health Intervention and Technology Assessment Program (HITAP)** in 2006, it has worked to refine its processes around stakeholder engagement as part of the entire HTA 'journey' from topic selection to dissemination of the research findings and recommendations, the latter involving different approaches to ensure messages are appropriately targeted to different audiences10. Also, since 2010, Thailand has adopted process guidelines for the use of economic evaluation to inform the national list of essential medicines that includes, among other requirements, the need for a stakeholder consultation meeting prior to completing an evaluation[11].

- In **Canada**, the province of Ontario established a Citizens' Council in 2009, as an advisory body to the Executive Officer of Ontario's Public Drug Programs and the Minister of Health and Long-Term Care. It was "*the first of its kind in Canada, and one of only a handful in the world. The Citizens' Council seeks to meaningfully engage ordinary citizens on an on-going basis in discussions about specific policy questions related to the province's public drug programs* Council was modelled along NICE's equivalent body, to engage with service users when making difficult decisions on prioritising access to new technologies[12].

Key lessons and recommendations for policy makers in Indonesia

In summary, any HTA process that seeks to meaningfully inform decision-making cannot be regarded as a narrow technical exercise that is insulated from the messy and often difficult business of setting priorities, of choosing what should be covered and reimbursed, or what should be excluded or subject to restricted access.

Defensible methodology is arguably the sine qua non of effective HTA, but it is equally important – and indeed, critical – to establish processes that set out transparently, the 'ground rules' for its operation, how interested parties can and should participate in the HTA, how long it takes, who provides the evidence and who interprets that information, and how conflicts of interest are managed.

In conclusion, open and transparent processes enable decision-makers to balance different stakeholders' interests, by creating a structured process for views to be aired since:

- Arguably, payers, manufacturers, and critically, the end user (patients and the public) have a right to be involved
- It may reveal key data gaps or provide additional perspectives that would be missed by simply relying on the published scientific literature

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[10] See: http://www.gai.nus.edu.sg/niha/wp-content/uploads/2013/07/NIHA_Forum_2013_White_Paper.pdf [accessed April 2015]

[11] Teerawattananon Y, Tritasavit N, Suchonwanich N, Kingkaew P. The use of economic evaluation for guiding the pharmaceutical reimbursement list in Thailand. Z Evid Fortbild Qual Gesundhwes. 2014;108(7):397-404. doi: 10.1016/j.zefq.2014.06.017

[12] Ontario Citizens' Council: http://www.health.gov.on.ca/en/public/programs/drugs/councils/

- It can help defuse stakeholder resistance – some is inevitable, but a strong HTA process provides consistent criteria to judge the reasonableness of stakeholders' claims

Table 3 below lists a set of recommendations to take forward discussions around establishing an effective and robust HTA process tin Indonesia that can withstand external pressure. It is also important to note that a clear government commitment to supporting the HTA programme is vital for the committee established in April 2014 to be able to defend its work now, and in the future.

Table 3: Key recommendations for Indonesian policy makers when exploring the establishment of effective HTA processes

Recommendations for Indonesian policy-makers
Agree core **procedural justice principles** to underpin the process – consider including consultation, transparency and contestability
Identify and define key **stakeholder groups** – consider professionals, patients, general public, industry, policy makers, academics, payers…
Establish a clear **stepwise process**, consistent with the principles, for engaging with key stakeholders – consult on the process and share it with all stakeholders in the form of a stakeholder-specific manual
Allow **sufficient time** to conduct a robust and consultative assessment and appraisal process
Develop a scientifically robust **methods manual**
Consider establishing a **Citizens' Council**(s) or Jury to elicit societal value judgements
Develop and implement a **communication strategy** for disseminating decisions and publicising role and activities of decision making agency(ies)