

A Methodological Approach for Measuring the Impact of HTA

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Executive summary

There is a lack of evidence concerning the link between HTA and outcomes in terms of health improvements. This work proposes a framework for assessing the impact of HTA. This impact assessment is a necessary step in then better understanding the value for money of HTA bodies. We emphasis that this is still a work in progress.

iDSI has developed a theory of change-based framework in order to evaluate the impact the iDSI has on institutional strengthening – leading to ‘better decisions’ for ‘better health’. This framework recognises that there is a complex translation process between better decisions and better health dependent on many assumptions about local factors and systems, including linkage between decisions and budgets, delivery, implementation, and data accuracy. Work has been undertaken over the last 6 months developing a methodological approach for measuring the impact of health technology assessment (HTA). Two case studies are used to illustrate the approach.

At the core of impact assessment is a requirement to link causes and effects, to explain ‘how’ and ‘why’ and to identify – and thus improve or adapt - mechanisms leading to impact. Policy makers also want to know ‘to what extent’ or ‘the magnitude of impact’. The framework developed adopts an economic approach nested in theory of change as a means of both quantifying the magnitude of impact (utilising economic models) as well as explaining why and how impact happens (drawing on theory based approaches) in order to reinforce learning as to how to improve our response and optimise the use of HTA to have the greatest impact in a given context. This should also enable us to capture and explain wider impact – perhaps more intangible aspects which cannot be easily quantified. This may also possibly increase policy-makers’ ‘buy-in’.

The work has been presented at an iDSI workshop, York and HTAsialink, Taipei in May 2015 and at iHEA, Milan in July 2015. Feedback received has been around the following issues, and these are reflected on below and in the report.

- The appropriate impact measures of HTA: on health gains or on the decision making process, recognising that there are different types of decision making, namely on priority setting versus planning. A recommendation was made that we consider breaking impact down into two stages – firstly, impact on the decision making level and secondly, on population health.
- The distinction between reimbursement decisions and changes in healthcare practice, and the extent to which the implementation should be incorporated.
- How to capture wider impact, for example, productivity. How to capture iDSI activities, for example, what do better institutions look like?
- The difficulty in specifying the counterfactual.
- Limitations by not evaluating a range of research / package of interventions.

Ultimately, if we want to hold decision makers accountable for lost impact on health, and understand whose health has benefited/dis-benefited, we need to measure impact HTA at this level. However, our methods aim to also capture outcomes on decision making, for example, in terms of how issues arrive (or not) on the policy agenda, how options are chosen as well as implementation which is likely to hold additional challenges for low- and middle-income countries (LMICs) around human resources and infrastructure - and all of which can positively or negatively affect the impact of HTA. We also acknowledge that some do not consider HTA to be about implementation: HTA is about 'depth not breadth'. Rather, HTA is a priority setting tool whereby decisions should not be constrained by implementation issues versus planning processes. Again, we show how we can capture impact on priority setting as well as impact from implementation in our framework.

Finally, we assume the *principles* will be the same in LMICs and high-income countries (HICs). A main difference may relate to the availability of evidence.

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1. Literature review

Effective decision making at multiple tiers is a prerequisite for high performance in health care (1). Much research has been undertaken on establishing what factors influence improved decision making (2, 3); this includes good governance structures, expertise, political and institutional factors, resources, participation, and capacity (1, 4).

However, how such influences on decision making interact with local context and health systems, leading to impact on health outcomes is less explored and arguably of critical importance in healthcare settings in LMICs (1). It would appear that evaluations of HTAs have mainly focused on processes and decision-making rather than outcomes. Straus et al (2004) are quoted in (5) *“...a review of the existing literature on HTA reveals a startling lack of depth, particularly on the impact HTA has had on health-care budgets, efficiency, and on societal health outcomes. Indeed one commentary noted that whereas the previous 10 years have been well-spent on building the HTA/EBM infrastructure and evidence base, the next 10 should focus on the outcomes.”* Another review (6) found that *“HTA reports typically do not define their impact objectives, that is – the effects they would like to achieve (for example, to influence coverage decisions, support guideline formulation or change routine practice)...the stated objectives or research questions are scientific, related to the technology being assessed rather than describing the expected role of the HTA itself”*.

Evaluations have been undertaken to establish what HTA has achieved (2). European country case studies have found marginal impact of HTA and that for HTA to have greater impact in the future, there is a need to better integrate local practitioners into the HTA process; and for greater influence at the policy-making

level, assessment and appraisal to be incorporated within a common structure to provide necessary incentives for policy makers to consider the science and that the HTA agencies will need to be handed greater regulatory powers (14). It is also found that 'on many occasions, such scientific evidence is neglected....discouraging policy makers and practitioners from making use of HTA findings' (15).

The payback measure (ie what you get back from the investment) has been considered to be the most commonly used approach to assess the impact from health research (7) as proposed by Buxton and Hanney (8) (9). The payback approach has 5 categories of impact: knowledge production, research targeting and capacity building, informing policy and product development, health and health sector benefit, and broader economic benefit. Others have similarly identified different levels of impact (6) The payback approach has been recommended as the approach to assess the NIHR's HTA programme in the UK – in the past (10) and continues to be recommended for its current evaluation (11). The payback approach confirmed that impact on knowledge generation was more easily quantified than that on policy, behaviour or especially health gain. Two HTA impact publications related to these evaluations are due to be published imminently: an impact evaluation of the NIHR Health Technology Assessment Programme, 2003-2013 - a multi-method evaluation - is due to be published in October 2015 alongside a systematic review of impact measures in health technology assessment in August 2015. The protocols can be accessed on the NIHR website (12)¹ and (13)²

Impact can be defined according to whose perspective is being considered. Impact may be defined at many levels with different measures of impact: at the policy level,

¹ This has just been published end Aug 2015. 12 case studies are used to illustrate impact using the payback approach. The need to cost for implementation and impact achieved by HTA NIHR's relationship with NICE's decision-making process are highlighted.

² Publication date now pushed back to May 2016.

in terms of clinical behaviour and also impact on health gains or wider benefits to patients. Measuring health in terms of health gains necessarily requires implementation to be addressed, this being the means by which to translate evidence into impact on health. Much research has been undertaken around facilitators and barriers in implementing the findings of HTA (17) and how policy actually changes practice (2): the main elements to successful implementation being: a) defining a clear policy question; b) defining a clear research question; c) making recommendations commensurate with the evidence; d) identifying the implementation mechanism; e) paying attention to incentives and disincentives; and f) clarifying the roles and responsibilities of the various parties (17).

Recommendations have been made as to how these factors can then be used to improve impact, notably that key stakeholders (for example, patients, providers and industry) are adequately involved; decision-makers give a prior commitment to use assessment reports (and assessments meet their needs); the necessary resources are available for implementing decisions; there is transparency in the assessment and decision-making processes; and collaboration, knowledge and skills are transferred across jurisdictions (3).

A conceptual model of health care systems and HTA is presented by Towse et al which depicts how the impact of spending levels, degree of centralisation, impact and the focus/breadth of HTA results in outcomes; the ‘impact of HTA ...depends on a wider set of health system factors that define the underlying architecture of the health care system...The regulatory framework and reimbursement systems...define the incentives and behaviours of the actors in the system’ (16).

For countries with greater capacity constraints, it is important to consider the total available budget, available human capital (trained HTA evaluators), accessibility of

data, and the capacity of the health care system to use the results (3, 18). Given the lack of HTA capacity and its use in LMICs (19), tools have been proposed in the absence of a formal HTA structure (20). Also, given the poor infrastructure in many LMICs, 'macro HTA' aimed at developing performance in the healthcare system may be of greater importance in this context than in HICs where HTA has had a more traditional 'micro HTA' role of appraisal of single/related technologies (21).

In conclusion, it is clear that the impact of the HTA depends in large part on the quality and transparency of the assessment and decision making process in addition to the broader institutional, political and cultural dynamics. However, it is also evident that the least researched area of HTA is around its implementation and its impact on health. It would appear that the implementation - and impact - of HTA can be facilitated if there are: appropriate policy instruments and regulatory levers available; a prior commitment by decision-makers to use assessment reports in decision-making processes; available resources to implement decisions; stakeholder involvement; and transparency in both the assessment and the decision-making process. It nevertheless remains a challenge and one of the least developed areas of the overall HTA process (3).

From this initial brief overview of the literature, our sense is that the evidence base of the impact of HTA on health outcomes is very weak/lacking in HICs, let alone LMICs. Given the lack of an evidence-base in the literature, this report proposes a methodological platform to understand better the mechanisms by which HTA can be effectively implemented into policy and practice, underpinning a 'theory of change' with an evidence-base as to how 'better decisions' translate into 'better health'. Even in the light of poor existing evidence from the literature, our proposed realist approach (see below) would allow all evidence, including naturally occurring primary

evidence from grey literature within the organisations of interest as material for analytical consideration.

2. Research question

Our aim is to develop a methodological approach for measuring the impact of HTA, with a focus on applying this learning specifically to LMICs. We propose a conceptual framework which we envisage would help to optimise the use of HTA in any given context. Our focus in this report is on presenting the conceptual framework but our intention is to develop or test a programme theory against the evidence – proposing a realist methodology. Our approach would be to start with reality in wanting to understand how it works, ie deriving a theory, in this case, a ‘theory of change’ from the facts or evidence.

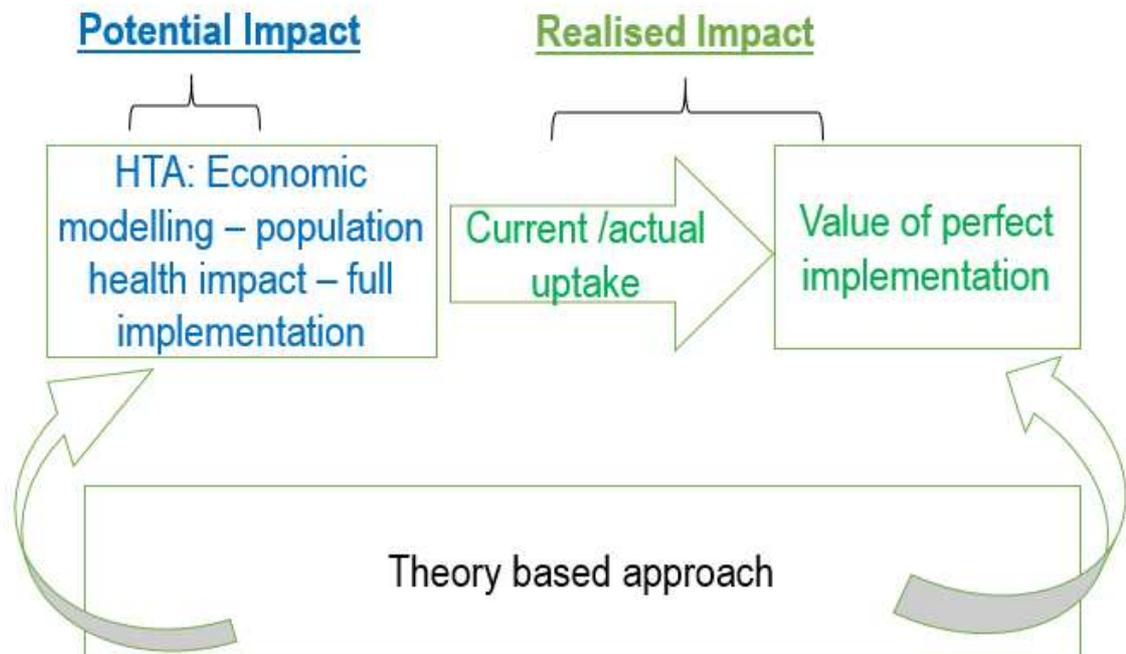
We also hope that in better understanding how and why impact happens, this enables international donors and decision makers to make better decisions given the local context (22); and that it is not sufficient to demonstrate that the gain in health from a new intervention be valued purely by a return on investment but whether the value of the health gained exceeds the value of the health (and resources) forgone.

By drawing on theory based methods, we are also interested in exploring how welfare theory underpinning the economic approach (and our rather static decision models) can tie into other social science theories on change – and vice versa. We are still playing with these ideas as possible informants to the overall approach. At the very least, it should encourage greater interdisciplinary collaboration.

Finally, given the particular challenges faced in the context of LMICs, the research being undertaken by the iDSI methods working groups will be critical in understanding how best to translate the use of HTA into impact on health. We have tried to make explicit the links with this impact research to each of the other methods working groups’ research on evidence, constraints and thresholds.

3. The Conceptual Framework

Figure 1: The Conceptual Framework



3.1 Overview

IDSi defines impact in terms of improved health outcomes (QALYs/DALYs) and observed impact on cost-effectiveness. We have built on the IDSi framework by proposing a methodological approach to assess the impact of HTA on health outcomes using the measure of net health benefits (NHBs), ideally, cost per QALY gained. The framework aims to convey the concepts of potential population health benefit and realised population health. The mixed-method framework proposed adopts an economic approach embedded in theory of change as a means of both quantifying the magnitude of impact (utilising decision models to derive potential population health benefit and realised population health benefit) as well as explaining why and how impact happens (drawing on theory-driven approaches) in order to reinforce learning and optimise the use of HTA to have the greatest impact in a given context.

We use decision models to generate estimates of the expected cost-effectiveness, decision uncertainty associated with each option and the cost of uncertainty (ie the potential value of further research) as HTA has, on the whole, represented a move from effectiveness alone to an assessment of costs and effects in maximising healthcare given the available budget. This is also reflected in the fact that iDSI, in its theory of change, measures impact on both health and observed cost-effectiveness. We envisage theory based approaches will help to show how and why intermediary outcomes (for example, by getting evidence into practice, dissemination and reaching the right people) is achieved in order to have an impact on population health.

Using the initial HTA model based on available evidence, we would predict the expected gain in population health from a policy change given best evidence. This would allow the uncertainty and priorities for research to also be considered. We would then want to understand if HTA has changed policy through direct observation of policy, and make a best assessment of the counter-factual. How has that decision been realised? What changes in practice? Is there a decision to recommend or fund or reimburse the intervention? Have clinicians and/or patients changed their practice? Are there additional costs incurred to change practice? Taking observed uptake and implementation, we would calculate the realised expected gain in population health given best evidence. How we explain the difference between expected and actual gain in population health could involve more qualitative work with relevant stakeholders, drawing on theory based approaches. The model can then be used to define the opportunity cost of not spending money to get something implemented – the value of implementation. This would require evidence on the cost-effectiveness of implementation activities. Finally, by updating the original HTA with further evidence from appropriately designed research, what does additional evidence suggest about expected and actual gains in population health?

3.2 Net health benefits

The aim is to get over the concepts of potential population health benefit and realised population health benefit. The measure of net health benefits (NHBs) (ideally, cost per QALY gained) will be the core information needed to assess health impact. Net health benefits incorporate impact on health as well as layering in costs into a single measure. The cost effectiveness threshold provides a measure of health forgone as a result of additional costs following the decision ie the opportunity costs in terms of health. QALY gains are valued at the healthcare service opportunity cost based on the original threshold used and presented net of costs. The potential population health benefit is quantified (from the original HTA) using available evidence. The realised population health benefit is quantified using available evidence or assumptions or scenarios on the degree of uptake as to how that decision has been realised ie what changes in practice.

3.3 Value of implementation

Healthcare technologies that are deemed cost-effective (or beneficial) do not automatically or immediately get implemented perfectly into clinical practice, resulting in opportunity losses, due to constraints potentially on the supply and /or demand side but also at the legislation and priority setting level (23). We draw on value of implementation to show the difference in impact with and without further implementation (24). The difference between the benefits yielded by the treatment *given existing implementation levels* and those generated *with full implementation* is the 'expected value of perfect implementation'. It is this value that informs the upper bound on the value of what we should be prepared to invest/or on reimbursing implementation strategies to improve implementation of (or adherence to) cost-effective interventions to generate greater impact (25). Imperfect implementation clearly reduces the total benefit of an adoption decision in the population and has an

impact on the estimated value of further research. Methods for calculating the expected value of further information which accounts for the reality of less than optimal implementation have been proposed (26).

Costs of implementation and/or the extent to which adoption requires infrastructure changes in LMICs in particular, must, in principle, be considered when comparing interventions but will vary from setting to setting. This is considered part of the 'constraints' agenda being undertaken by another iDSI Working Group. To what extent the original HTA ignores or addresses information about a technology's implementability (and whether decisions on implementation strategies should be made sequentially (27) or simultaneously (25)), should be captured in our framework in terms of realised net health benefits.

3.4 Theory based approaches

3.4.1 *Formal Theories*

We want to identify tensions and understand the barriers and facilitators to impact (28, 29). To this end, we propose building on the theory of change approach developed by iDSI and also introduce a realist methodology to enable us to build up a programme theory. Realist approaches allow the incorporation of theory (in this case, a theory of change) and will also provide a framework for evaluation.

It has been suggested that many policy programmes lend themselves to the explicit testing of a dual Theories of Change/Realistic Evaluation model (30). Although the latter is relatively untested in the field of healthcare, it is gaining support and use from organisations such as the NIHR and DFID (31, 32). Guidance for researchers in the use of a realist approach in healthcare is currently being developed (33). By using a realist methodology and drawing upon theories of change, we aim to better capture

the multi-dimensional aspect to the impact of HTA: at the individual technology level, at the HTA and the decision making levels, and their interactions.

Theories of change (ToC) is about the identification and confirmation of causal processes – an explanatory pathway of change. Developed by the Aspen Institute (Connell et al, 1995; Fulbright-anderson et al, 1998), it is process orientated as it follows the pathway of a programme from its initiation through causal implementation links (to explain how and why the desired change is expected to come about) until intended outcomes are reached. The ToC is developed through collaborative stakeholder engagement. It requires measurement along the way of all outcomes that must be achieved before the long term outcome, in our case, impact on population health.

Other theories explored include implementation science but our understanding is that this operates at a more micro/individual level than the overarching understanding of change we are trying to capture. Organisational cultural and critical realist theories are about the interplay and tensions between knowledge, power and social control. The premise being that organisations do not make decisions but people with biases, motives, histories etc make the decisions but are required to do so within the confines of power structures (like organisations and governments). The latter especially, are congruent with the philosophy of realist evaluation.

We envisage one of the outputs of the process would be a 'Theory of Change' map informed by the richness of what we find, for example, any contextual issues and specific barriers related to that particular HTA – and that the methods proposed should help (re-)inform such a mapping process/framework.

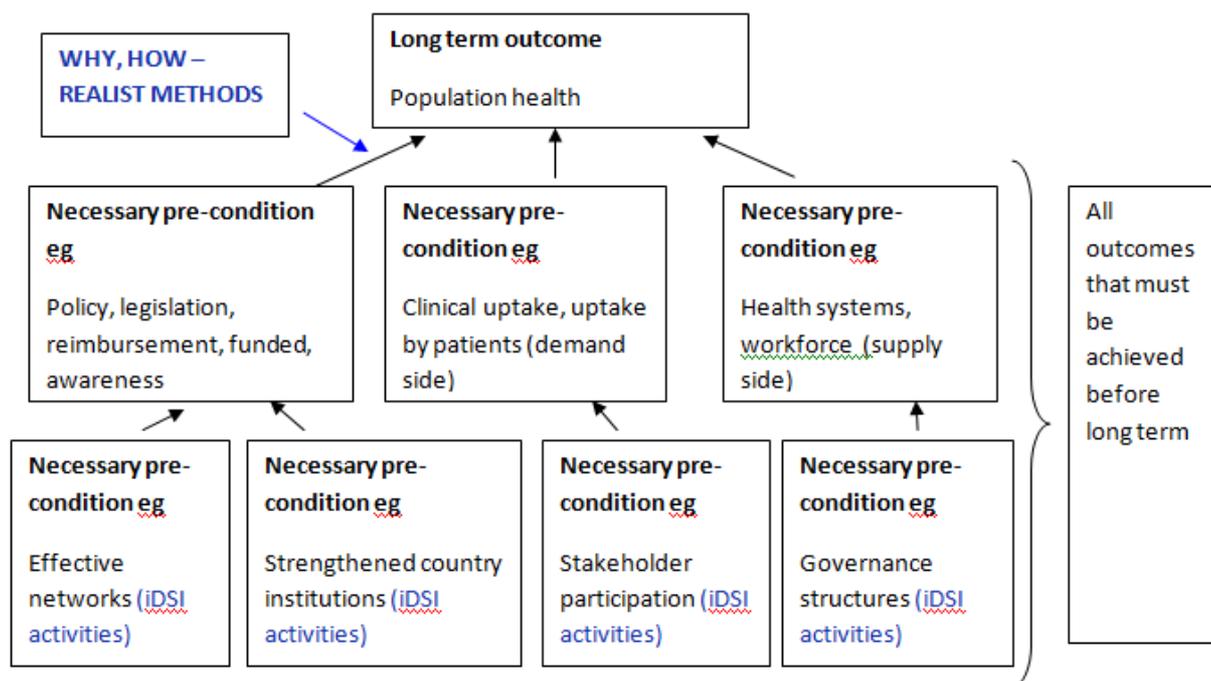
3.4.2 *Realist Evaluation Methodology: a theory-based methodological approach*

A realist approach (Pawson, Tilley 1997) recognises that there are many connected variables operative at multiple levels, and within varying contexts, with varying resources available to help understand intervention and policy changes success or failure. As such, realist evaluation lends itself to the purpose of evaluating complex social interventions. This approach thus contributes to knowledge beyond traditional ‘does the programme work?’ questions and cause-effect analysis, to understanding what it is about a programme that makes it work, and allows for the identification of supporting factors – proximate, contextual, historical. Adopting a realist methodology would allow us to build up a programme theory by testing and refining hypotheses to explain the routine embedding of new practices in healthcare by reference to the role of context, mechanisms, outcomes (34). For example, the system in which HTA operates will already have policies, procedures, ways of doing things, values and a challenge to generalisability will be that context is likely to influence the impact so incorporating this is key. As HTA works differently in different contexts and impact is likely to be achieved through different change mechanisms, it is unlikely that HTA can be replicated from one context to another and automatically achieve the same outcomes. Good understanding about what works, for whom, in what contexts, and how – are, however, portable. These portable explanations can be presented as explanatory theories. Mechanisms are at the heart of the explanation: it is not interventions, but people who change problem situations. Mechanisms are usually implicit, and therefore require theory to inform how contexts could trigger transformative variables. In the case of HTA, one could envisage impact is achieved through an interaction between policy makers, practitioners, their rationale and the resources for implementation. However, empirical work would refine and specify this. Realist evaluations’ strength is its explanatory basis, to make sense of the complex

processes underlying programmes by formulating plausible explanations *ex-post* and thus building upon what is known and learning while doing becomes important. It operates between the necessary workings ‘on the ground’ (at the individual technology level?) and efforts to explain social behaviour, social organization and social change (at the HTA decision making level?). We propose this could help better understand how iDSI activities (on governance, accountability, institutional support, democratic and stronger institutions) shape or contribute to outcomes and impact.

Whilst data sources and methods are left open to choice, the evaluator maps out/hypothesises a series of potential mini theories (the casual and situational triggers) that relate the context of a programme to the multiple mechanisms by which it might operate to produce different outcomes. This would draw upon what is already known about factors influencing the implementation and impact of HTA (see literature review Chapter 1). However, in realism, you are also looking for experiences observed in your data so that new knowledge is identified. A realist methodology would allow all data and impact to be captured. This could include literature, interview data, policies, written recording of meetings, and feedback. Thus, we could address feedback received that the impact of HTA should be captured not just on distal outcomes (population health) but also on more proximal outcomes, such as the impact on decision-making, and analyse this using realist evaluation principles of extracting context-mechanism-outcome configurations of variables at play, and iterative, participative, and collaborative approaches to interpretation.

Figure 2 below provides an example of how we might use theories of change as a framework for analysis of all evidence. It is a suggested example of Theory of Change ie our programme theory, and using a realist method to ‘home in’ on mechanisms at play which are in turn, likely to differ by the context of the HTA.

Figure 2: Programme Theory

3.5 The counterfactual

Finally, the issue of the counterfactual needs to be addressed. In the studies where payback methods were used, it was noted that they were unable to identify the counterfactual (7) and the difficulty this presents (2). Whose health has benefited and whose health has dis-benefited? The relates to the hypothetical or unobservable counterfactual ie what would have happened without the HTA process - would policy would have changed anyway? The issue is the extent to which something changed (policy change) conditional on the HTA so we need to know something about if the HTA had not happened, what the effect is. It is possible to look at different scenarios given the status quo/treatment at the time of the HTA/before the decision and what would have happened had the HTA not taken place.

As well as what would 'standard care' be had the decision not been taken, this is also partly about thresholds (how much health are we forgoing). The framework is predicated on the threshold representing opportunity costs, and we make explicit the

assumption that the threshold originally used in the decision reflects the opportunity cost. Whatever the threshold that was used for the original decision will be the starting point for the impact estimates (with discussion and sensitivity analysis around what if it is different). It is not in the scope of this work to estimate an appropriate opportunity cost threshold. If one does not exist, we will explore the sensitivity of impact using a range of possible thresholds. This will tie into the work being undertaken around thresholds by one of the iDSI technical Working Groups, quantifying what is displaced to enable the net population health impact of the intervention to be determined.

However, “because the realist analysis uses mainly intra-programme comparisons (i.e., comparisons across different groups involved in the same programme) to test the initial theory, a realist evaluation design does not need to construct comparison groups. Rather, the refined programme theory will be tested subsequently in a different context in a next study. Often the case study design is used, whereby case selection is typically purposive, as the cases should enable ‘testing’ of the initial programme theory in all its dimensions” (35)

Finally, should we include the cost of HTA in an impact assessment? This is considered unlikely to be a major issue. There are lots of positive externalities likely to arise from HTA, such as better payment mechanisms, better information, better administration etc. Nevertheless, there is a need to consider ways in which international cooperation, global public goods, donor funds (and iDSI) can help minimise costs. Importance of time it takes to do an HTA (hence delaying, for example, good vaccines getting into practice) may be viewed as an obstacle. It has been suggested that this could be quantified using option pricing methods as a way of reconciling investment costs, uncertainty and delay into a single coherent framework (*ref iDSI correspondence, Pete Smith*).

Figure 3: Summary of conceptual framework

Summary of conceptual framework

What is the predicted expected gain in population health from a policy change given best evidence? What is the uncertainty and priorities for research?	Initial HTA model based on available evidence
Has the HTA changed policy?	Observation of policy, best assessment of counter-factual
What is the realised expected gain in population health given best evidence?	Observation of uptake and implementation
How do we explain the difference between expected and actual gain in population health? What is the maximum we can pay to increase uptake?	Qualitative work with relevant stakeholders; quantitative analysis
What implementation activities and policy changes can help address the gap between predicted and realised?	Evidence on cost-effectiveness of implementation activities
What does additional evidence suggest about expected and actual gains in population health?	Update of initial HTA with further evidence from appropriately designed research

We would hope that through this work, policy makers would be in a better position to:

- measure the actual impact of an HTA on health outcomes vis-à-vis potential impact (quantified in net health benefits) through monitoring of uptake and coverage;
- assess the value of what the health service provider can invest in (cost-effective) implementation strategies – and the cost of not doing so - to ensure utilisation of the intervention by all those eligible (value of implementation);
- understand better the mechanisms by which HTA can be effectively implemented into policy and practice in any given context to optimise its use and impact.

4. Case Study - Myanmar

4.1 Background

Myanmar's Maternal and Child Health Voucher Scheme (MCHVS) provides new demand-side health financing options with the goal of improving the utilisation of MCH services, especially for poorer households. GAVI's Health System Strengthening (HSS) initiative in Myanmar comprises three major elements, including financing reforms, human resources and infrastructure to tackle the supply-side of services. There is, however, a need to also tackle the demand side. The MCHVS subsidises pregnant women to receive 4 ante-natal care visits (ANC), delivery and postnatal care (PNC) free-of-charge in order to help women overcome financial barriers to access as well as raising awareness of the benefits of ANC and delivery with skilled birth attendants (SBA).

4.2 The Health Technology Assessment

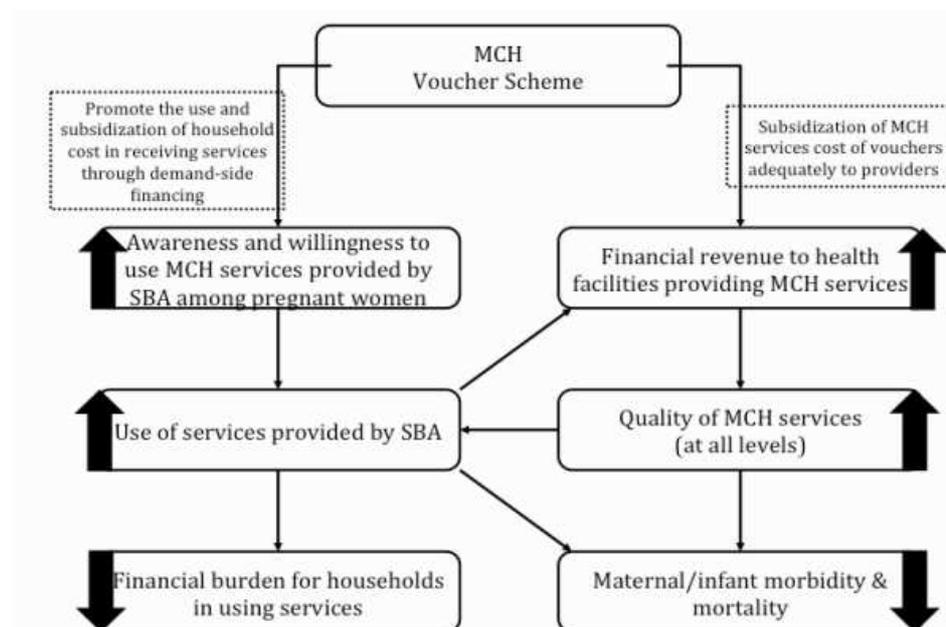
The HTA consisted of a feasibility study (37) and ex-ante economic evaluation based on three visits from May 2010 – March 2011 by HITAP in collaboration with Myanmar's Ministry of Health (MoH) and WHO's South-East Asian Region Office (SEARO) (38). Decision analytic modeling was undertaken to estimate costs, health outcomes and cost-effectiveness. Full details of the model have been published (36-38).

The model incorporates baseline levels of ANC (73%) and SBA (51%) uptake from a community survey conducted as part of the feasibility study and country level epidemiological data on the current maternal health status in Myanmar. Parameters relating to the relative risk of high-risk pregnancy and the relative risk reduction on maternal and neo-natal morbidity and mortality associated with ANC and SBA was

informed by the literature, predominantly taken from other countries. Costs are taken from a survey conducted during the feasibility study. The effectiveness of the voucher scheme is based on the price elasticity of demand (E_d) for ANC and SBA services in response to a change in price. This was informed by data from another country with a similar economic status. Impact is then modelled as the number of lives saved and DALYs averted for both mother and child. Using a conservative value of 0.2 for E_d and 100% voucher cost recovery for the women in the base case, the intervention was found to be cost-effective at a threshold of one GDP.

A closely monitored pilot study was recommended to ensure that parameters and assumptions were revised before scaling up the programme nationwide. This was initiated in Yedarshey township in May 2013. A mid-term review at 6 months (38) was undertaken of the pilot in January 2014 by HITAP, MoH and WHO. This review did not update the economic evaluation and modelling but did include developing a theory of change model (Figure 2)

Figure 2: Theory of Change MCHVS



4.3 Assessing Impact

4.3.1 *Potential impact*

The model was updated to incorporate evidence obtained from the 6 month mid-term review of the pilot scheme (Table 1). In particular, the feasibility survey samples had a much higher rate of ANC uptake (73%) than the national average (56%). It was possible that hard-to-reach individuals who would not receive ANC and delivery services were unlikely to have been included in the feasibility study.

Table 1: Parameters

Parameters	Feasibility study	*Pre-implementation pilot	Review of pilot at 6 months
Baseline probability of seeking ANC with SBAs	0.73, (0.03) – mean, SE Community survey	1.81 average visits 0.56	2.37 average visits
Baseline probability of delivery with SBAs	0.51, (0.04) – mean, SE Community survey	0.67	0.77
Effectiveness of CHI/elasticity of demand	0.2 Nepal study, 2005	0.2	0.2
Average immunisation obtained per infant: Vaccinations (DPT/OPV)	-	2.45	2.99

Using the decision model, potential NHBs were estimated using the original parameters from the feasibility study and then revised to give a better indication of impact using best available evidence at that time from the pilot. This was scaled to the pilot level ie coverage of 11,532 pregnant women in Yedashey township. Using

the original threshold used of 1 GDP, the NHBs associated with full implementation are presented in Table 2.

Table 2: Potential net health benefits

	Ex-ante GBP £	Ex-post GBP £
Incremental cost	96	94
Incremental life year saved	0.2513	0.2782
Incremental DALY averted	0.2531	0.2789
ICER per DALY averted	384	336

GDP Myanmar (2010) 414
Threshold used = 1 GDP

NHBs = $\Delta H - \Delta C/\lambda$

Net health benefits (per person)	0.02	0.05
Scaled to pilot (11532 pregnant women)	231 DALYs	576 DALYs

Note that the study refers to the original model as an ex-ante evaluation and the pilot review as an ex-post evaluation. We have continued to use this terminology but make clear the distinction between up-dating the model with new evidence with what is now known to be different, and an impact assessment.

4.3.2 Realised impact

Using the monitoring data collected from the 6 month review of the pilot, *realised* NHBs (actual impact) and the expected value of perfect implementation (maximum potential impact) were calculated.

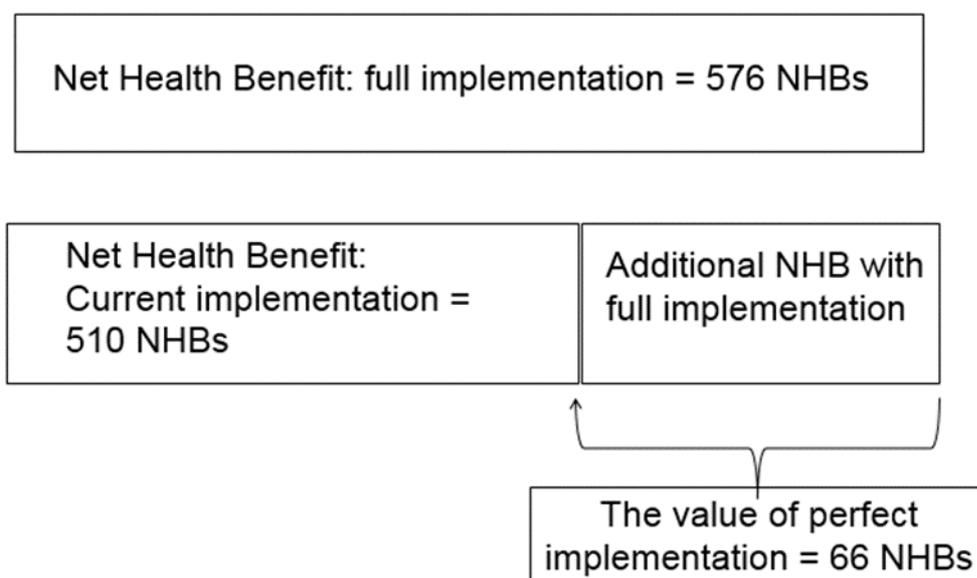
The mid-term review reported an increase in SBA uptake to 77% (from 67%). Taking the total population eligible for treatment (N = 87%, ie 67% baseline + 20% increase

in uptake modelled) and the proportion of these patients already receiving the intervention (p), the current value is defined as:

$$N * p * NHB = 11532 * 77\% \text{ (of 87\%)} * 0.05 = 510 \text{ NHBs}$$

The expected value of perfect implementation represents the maximum possible gain from implementation of the health care technology and is calculated as the difference in value of all eligible women being covered and those currently receiving the intervention ie the current value. Figure 3.

Figure 3: The expected value of perfect implementation



The shortfall in NHBs indicates that coverage, and thus impact, is sub-optimal. This provides a ceiling value for investing in implementation strategies ie that the cost and magnitude of change achieved by an implementation method does not load treatment cost-effectiveness to such an extent that normal bounds of cost-effectiveness are exceeded.

The expected value of actual implementation represents the actual gains from an implementation initiative resulting from those patients receiving the intervention who would not have done so otherwise (as initiative will not necessarily result in perfect implementation), where α is the proportion treated with the initiative.

$$n * \alpha * NHB - n * p * NHB$$

Finally, an implementation initiative is worthwhile if its benefit in terms of increased utilisation of the intervention (the expected value of actual implementation) is greater than its opportunity cost. This is the incremental net benefit of the implementation initiative.

$$n * \alpha * NHB - n * p * NHB - \text{Implementation Cost} / \lambda$$

4.4 Discussion and next steps

We understand there is an external evaluation of the pilot at 12 months currently being undertaken. Should tying this work into the results of that evaluation help serve evidencing the planned expansion of the work to GAVI, we are very happy to collaborate. There is mention of possibly expanding the scheme to include further vaccination coverage, in particular measles, mumps and rubella (MMR) vaccines at 9 and 18 months. Potential impact could be re-estimated using models such as, for example, LiST (The Lives Saved Tool) (40) which specifically incorporates vaccinations. Its general principle is to model scale-up of multiple MNCH interventions over time at a population level. We also envisage one of the outputs of a future process could be a 'Theory of Change' map re-informed by the richness of what is found relating to, for example wider contextual issues, impact on financial protection and poverty reduction, quality of services and unintended outcomes.

Finally, the original analysis did not employ a probabilistic sensitivity analysis (PSA) though this was undertaken for a publication later (36) with changes, namely the cost of production of voucher was updated, and low birth weight split into anaemia and all sequelea. We use the original model.

Key considerations:

- Given observed uptake and implementation, realised impact is sub-optimal compared to the potential impact modeled.
- Can the HTA / intervention's theory of change help us to understand why this shortfall exists, does it need to be re-informed?
- We provide a ceiling value of investing in (cost-effective) strategies to improve implementation and thus impact.
- What is known about the cost-effectiveness of relevant implementation strategies in this context to improve impact?

5. Case Study – Thailand

5.1 Background

HPV vaccines are effective against two oncogenic subtypes of HPV infection, have good potential to avert incidences and save the treatment costs of cervical cancer. In Thailand, HPV vaccine was found to not be cost effective relative to the recommended threshold. The most cost-effective policy option was to improve the performance and coverage of the existing screening programmes. There is an existing decision model and this case study enables us to look at the impact of a decision not to adopt. The continuing advocacy for HPV vaccination provides a conducive context for the government to strengthen the screening service provision as it is the only affordable choice currently available, and for us to look at impact around strengthening of the existing screening programmes.

5.2 The Health Technology Assessment

At the then current [2007] price, HPV vaccinations for girls aged 15 years compared with the current national policy of Pap smears for women aged 35-60 years every 5 years was found to be not cost-effective at the recommended threshold of Bt160 000 per QALY as set by the Subcommittee for Development of the Health Benefit Package and Service Delivery of the National Health in Thailand. Instead, visual inspections with acetic acid (VIA) every 5 years for women aged 30-45 years, followed by Pap smear test every 5 years for women aged 50-60 years was the dominant screening strategy compared with doing nothing (at 20% uptake of screening) (41). This screening strategy is now national policy with a coverage aim of 80%. Combined vaccination and screening was found to be more cost-effective than vaccination alone.

5.3 Assessing Impact

5.3.1 *Potential impact*

Using the existing model and published paper on the HPV health technology assessment, potential net health benefits were calculated for each of the following comparators:

Existing screening strategy: Pap smears for women aged 35-60 years every 5 years

Recommended screening strategy: VIA every 5 years for women aged 30-45 years, followed by Pap smear every 5 years for women aged 50-60 years

Vaccination: HPV vaccinations for girls aged 15 years + VIA every 5 years for women aged 30-45 years, followed by Pap smear every 5 years for women aged 50-60 years.

Table 3: Cost and QALYs, NHBs

Strategy	Total costs Bt	Total QALYs	NHBs
Existing screening @ 20% uptake	\$9090	28.07	28.01
Recommended screening @ 20%	\$8819	28.08	28.02
Recommended screening @ 70%	\$7291	28.10	28.05
Recommended screening @ 80%	\$7044	28.10	28.06
Vaccination @ 100%	\$18,306	28.13	28.02

Strategy with highest NHB at this threshold is the recommended screening strategy.

This was then scaled to a population level for both the target level (80%) and the current level of coverage of 70% for the recommended screening strategy versus the alternatives.

Table 4: Population level NHBs

Strategy	Population eligible	Coverage	NHBs at population level
Existing screening (1)	14,000,000	20%	78,428,000
Recommended screening (2)	16,000,000	20%	89, 664,000
Recommended screening (2)	16,000,000	70%	314,160,000
Recommended screening (2)	16,000,000	80%	359, 168,000
Vaccinations (3)	19,000,000	100%	532,380,000

(1) <http://pubmedcentralcanada.ca/articlerender.cgi?accid=PMC2705003>

(2) Estimated in relation to the other numbers

(3) http://www.indexmundi.com/thailand/age_structure.html

5.3.2 Realised Impact

Our understanding is that whilst there has been a strengthened screening strategy, coverage remains just below the target level, at around 70% (ref. <http://www.who.int/whr/2013/report/en/>).

This, however, would still represent a potential gain of over 10,000 000 QALYs in terms of impact upon population health by having moved from the existing screening strategy to the dominant screening strategy even if coverage had remained at 20%..

Not achieving the target of 80% screening coverage results in unrealised impact to the magnitude shown in Table 4 above.

5.4 Discussion and next steps

A qualitative assessment was undertaken by HITAP (42) to better understand why the government's original attempt to scale up the new strengthened screening programme had failed to increase implementation. It was found that despite good evidence, the scaling up of the screening service did not achieve any impact as it was largely driven by political factors and was not well devised largely due to the

political crisis of mid-2008. There had been no participation from stakeholders such as clinical experts and health providers during the policy formulation and implementation process, and no solutions to counter the already known obstacles to the provision of screening services were identified. No operational plan was in place, nor any monitoring and evaluation of the service extension.

Even though scientific evidence concerning the safety, efficacy, effectiveness and value for money of the policy option, with political will, adequate financial support and a well-established infrastructure, the scaling up of the screening service in Thailand did not achieve its promise in its explicit phase of implementation. Whilst often argued that the main obstacles to health system development in resource-limited settings are inadequate financial and human resources, and the lack of relevant and reliable evidence to guide proper policy decisions (43), this illustrates the potential danger of developing models and policies in isolation. We propose that developing models in a theory of change process may help support its implementation and impact of the HTA.

Finally, we noted that there are other papers published (44-46) with conflicting results, and have considered possibilities as to why: comparators (9-12 years versus starting at 15 years), threshold values, cost and efficacy of vaccine (79% - 100%), outcome measure (DALY, QALY, lives saved), discounting, parameters on incidence, vaccine coverage, and costs of care of cancer treatment. The aim here was not to critique the existing model but to use it as a way of illustrating how we might assess impact. It would be useful to update the HITAP model with updated vaccine prices and estimated current coverage of both vaccination and screening.

Key considerations:

- Realised impact is sub-optimal given observed uptake and implementation compared to the potential impact.
- We provide a ceiling value of investing in (cost-effective) strategies to improve implementation.
- What is known about the cost-effectiveness of implementation strategies to improve impact?
- Undertaking HTA in a theory of change process may help support its implementation and impact.

6. Future work

6.1 Data linkage

We could explore the possibility of data linkage to validate this work by enabling linkage to health outcomes. Countries with good data linkage and the established use of HTA might be Scotland (linkage to Scottish Morbidity Records), or possibly Taiwan ie this is only likely to be available in higher income countries but still with wider learning opportunities from an HTA impact assessment applicable to other countries.

6.2 iDSI's monitoring and evaluation framework

We understand the analytical approach will be incorporated within iDSI's monitoring and evaluation (M&E) framework, led by Itad.

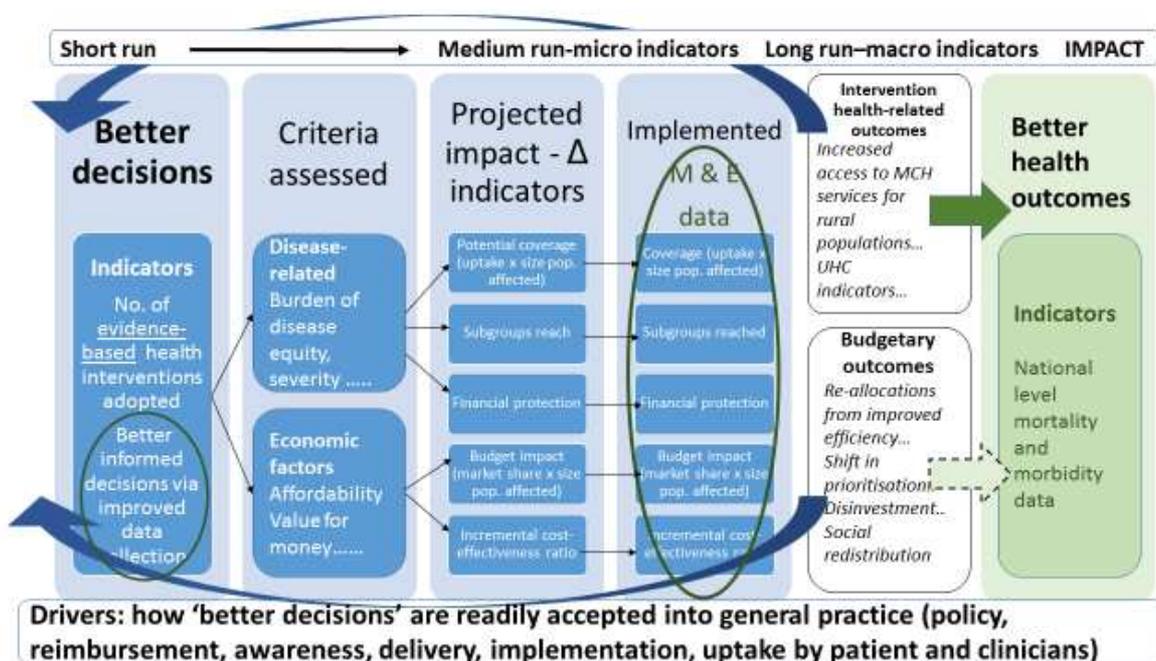
Our theory of change refers only to how and why policy decisions get implemented in practice as opposed to the wider iDSI theory of change that Itad is developing. We see this work fitting into Itad's theory of change in terms of what do better decisions and better health mean in quantitative terms, and how do we get from better decisions to better health. This speaks well to the assumptions at this level made in Itad's framework around the implementation of decisions, and uptake by patients and clinicians.

Unlike Itad's framework, we are not monitoring the implementation of iDSI activities. However, the methods proposed here would involve ongoing measuring along the way of an HTA, and would require size of the eligible patient population and changes in utilisation rates in addition to usual cost and effectiveness measures in order to monitor uptake and coverage. If an impact assessment was planned, this would also

require more qualitative data to inform such an evaluation. An example of different indicators of uptake and coverage is presented below which could be evidenced by (M&E) data.

Perhaps the biggest limitation to applying this framework is knowing something about the cost-effectiveness of implementation strategies.

Figure 3: Monitoring and evaluation



6.3 The case studies

It would be valuable to be involved (ideally) from the start of an HTA process. Regarding how beneficial it is to continue with the same two case studies, we would ask HITAP and iDSI as to what might be considered to be the most useful approach. The timeframe has meant the work on these studies has been confined to desk-based research. Future work would incorporate mixed methods and the theory based approaches.

6.4 Systematic review

A more thorough review of the literature would need to be undertaken. However, as there is a systematic review due to be published shortly on impact measures and models used in HTA impact assessment (13), this should greatly help to inform future work.

6.5 Package of interventions

A limitation has been raised that whilst we are considering the impact of a single technology/intervention, it would be more realistic to measure a package of HTA. Single HTA appraisals reflect the nature of economic evaluations. Alternative options might be to consider the impact of HTA in developing healthcare packages for Universal Healthcare Coverage (47) (48, 49) and/ or to consider HTA at a more macro level in LMICs (21).

Finally, we will follow up with those who provided contact emails to our impact survey at HTAsialink.

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