



An analysis of how health care providers, industry and patients influence health technology assessment around the world

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ABSTRACT

To achieve the goal of improving the health of the population, all health systems need to take decisions on what interventions they need to provide and how to finance them. For making decisions in a scientific way, policy makers are increasingly looking into rigorous and methodical evidences. With the rapid proliferation of new technologies in health care, health care providers and policymakers want the most cost-effective and efficient technologies. On the other hand, the industry perspective is also important to drive this change. This article looks into the different aspects of health technology assessment (HTA) from the view points of the providers and the industry. Then, the perspective of the patients in the HTA process is also highlighted. The article describes the fact that there is divergence between research and policy making and all the different stakeholders in a HTA process need to come together to augment this process.

Keywords: Health Technology, Assessment, HTA, Policy Formulation, Health Providers

INTRODUCTION

All health systems around the world have a common goal which is to improve the health and well-being of their populations. To achieve this target a health system initiates an array of activities, most prominently coming up with a framework to finance and deliver health services. This involves making decisions to try and make the most optimum use of scarce resources.¹ A lot of decisions are made on the interventions that are provided to the population and how they should be offered so that one can maximise the health benefits with respect to the available resources. Those at the helm for making decisions require data about the possible options and the consequences of those interventions. With the proliferation of new technologies at a rapid pace, it is quite clear with closer scrutiny that some of the older interventions have no benefits compared to the resources spent. But the advent of technology in health care and its increased usage has also added to expanding costs of health care, and as such

technology is sometimes considered as a “culprit” for the burgeoning costs.^{2, 3} This awareness has been behind the concept of “evidence-based medicine” and “health technology assessment”, which contends that policymakers must use rigorous scientific research to make their decisions.^{4, 5}

WHAT IS HEALTH TECHNOLOGY ASSESSMENT?

World Health Organisation (WHO)⁶ defines Health technology assessment (HTA) as “the systematic evaluation of properties, effects, and/or impacts of health technology. It is a multidisciplinary process to evaluate the social, economic, organizational and ethical issues of a health intervention or health technology. The main purpose of conducting an assessment is to inform a policy decision making.” The important message here is that it is a tool for policymakers to examine systematically the consequences in the short term and also in the long term of health care technologies.⁷ The aim of HTA is to help decision makers for formulating health

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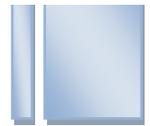
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policies which are both clinically and economically effective and are patient centric. In spite of the policy goals, the foundation of HTA should be based firmly in explicit scientific research methods.⁸

HTA addresses different types of consequences within the health system, namely organisational, societal, clinical and financial implications of using health technologies. It asks some essential questions about the health technologies like pharmaceutical drugs, medical devices, intervention procedures etc. like: Is counselling necessary and better than drugs for mental conditions? What is the best treatment for osteoporosis? Should paracetamol be used as a first line treatment for migraine? It addresses these queries by inspecting four aspects: if the technology is really working, who it works for, what is the cost of using it, what are the alternatives.⁹

POLICY PROCESSES

In formulation of any policy, the context is important: who sets the agenda, who are the stakeholders and what the implications are.¹⁰ It is convenient to believe that policy formation is a linear process but it is very rarely the case. In the literature a number of models are present which try to give an overview of the policy process. Lindblom's '*Muddling through model*' (1959)¹¹ considers policy formation as an incremental process and is evolutionary in its ways. On the other hand the '*Garbage can model*'^{12, 13} believes that uncertainty is the main catalyst for decision making. This is certainly the case for low and middle income countries (LMICs) including India. The 2015 Global Survey on HTA by World Health Organisation suggests that LMICs suffer from lack of analysis and so require an HTA framework to determine what interventions are cost-effective.¹⁴ Another model in the literature is the '*Advocacy coalition framework*'.^{15,16} This model takes into considerations developments over a long term rather than specific short term goals. It can be analysed by understanding the alliances struck by policy-makers, influential stakeholders and patient pressure groups. For example, in Germany for any HTA process, the companies have to consult with both the HTA body i.e. the '*Gemeinsamer Bundesausschuss*' (G-BA) and also the regulatory body '*Bundesinstitut für Arzneimittel und Medizinprodukte*' (BfArM). An

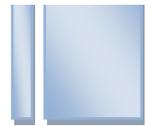
example in this regard is the case of linagliptin which did not get regulatory approval for type-2 diabetes even after an assessment from G-BA.¹⁷

HEALTH TECHNOLOGY ASSESSMENT IN EUROPE

Till the early 2000's the requirements for assessment and reimbursement of new health care interventions like pharmaceutical drugs were relatively straightforward in most of the countries in Europe. However, with the escalating costs and constraints in resources obtaining access to markets has become challenging. Currently, decisions for market access and reimbursement are on the basis of appraisals by HTA bodies, all of which have different requirements for technology assessments.¹⁸

For matters pertaining to health care delivery and organisation, there are a number of decisions which need to be taken at different levels. In cases of health technologies there are mainly two important decisions which need to be taken. First is about making them available to the market and the coverage provide. The second decision is about how to supply the technology and make it available. In Europe, HTA is usually undertaken at a country level, rather than at the European level. These decisions are normally taken by government authorities or the health authorities who are closely associated with the general policy making process. The countries in which a formal body has been established, the government usually mandates them to carry out HTA as a part of policy making process. For example, in England, the National Institute for Health and Care Excellence (NICE) is in charge of Health Technology Assessments. In spite of some differences across the countries in Europe, most of them have a definitive structure in place and established steps from the start of the HTA process to the final results.¹⁹

The organisations which are in charge for HTA processes may range from independent institutions to governmental organisations. These reflect the different socio-political and health-care systems existing in the country. NICE considers itself to be at an 'arm's length' from governmental interference and typically gives guidance in four kinds of interventions in the National Health Service (NHS): appraisals of new technology, guidelines for clinical procedures,



guidance on public health processes and for interventional processes. Usually, NICE authorises technology assessment groups to produce reports for assessment by the Technology Appraisal Committee (TAC).²⁰ The HTA process is generally initiated within a framework of decision making and the stakeholders involved may include government, providers, industry and the patients. There may also be consultations with other stakeholders like patient groups, industry and medical professional bodies. They can present evidence on their own, comment and appeal against the recommendations of the TAC. Usually, NICE follows a cost-utility analysis (Cost/QALY) for reimbursement decisions. But in France, the reimbursement decision and negotiation of price is decided after market access has been granted following clinical therapeutic effectiveness. Similarly, Germany too has distanced itself from the NICE process by separating HTA process into two parts where clinical and cost effectiveness are evaluated separately.

HOW HTA POLICIES ARE SHAPED

The association between policy-making and HTA is formed with an attempt to answer a very definite policy question. This gets divided into many HTA questions for which systematic reviews and randomised control trials are used. Ultimately, the results are compiled into a report which can act as a basis for decision-making which is evidenced based.^{21, 22}

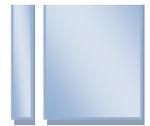
In practice, HTA's role in shaping up policies depends on numerous factors which include the importance of the HTA agency and the pathway followed by the HTA process. However, it cannot be denied that HTA brings an explicit rational process to the policy making process, which may otherwise suffer from a lack of solutions.²³ In UK, NICE is very explicit in the HTA process and has given appraisals guidelines which can be used as a template for submissions by the manufacturers.

With a trend towards evidenced based policy making,^{24, 25} the formation of NICE led to a surge in demand of very stringent trials which can lead to policy formation. An example that is found in the UK is the CRASH-2 study.²⁶ In this trial 20000 patients

were randomly divided into two arms to receive tranexamic acid as treatment for heavy haemorrhage or placebo. The overall results showed decreased mortality by up to 15% for those receiving tranexamic acid and overall there was a 9% reduction in mortality. This directly led to the usage of tranexamic acid in the army and by paramedics in UK and subsequently NICE, the Wellcome Trust and NIHR (National Institute for Health Research) have funded more HTA studies looking into the usage of tranexamic acid.²⁷

PERSPECTIVE OF THE INDUSTRY

With an increased focus on HTA, the industry's role becomes paramount. In countries like Australia and Canada, the policy decisions are quite straightforward. The industry's reports after being evaluated by CADTH (Canadian Agency for Drugs and Technologies in Health) and PBAC (Pharmaceutical Benefits Advisory Committee, Australia) are appraised by the government for both reimbursement and coverage. The process gets trickier for the industry in Europe. Contrary to NICE, both France and Germany have declined the cost/QALY criteria for reimbursement decisions. This means that the industry has to spend extra resources for the same drug to get assessed in different countries. Also, there are issues with the criteria laid down in each country. For example, the NICE method of Cost/QALY is not a rule but only a method of guidance and the methodological problems of QALY has been well-documented. The industry wants NICE to be more flexible and transparent with the HTA process. Similarly, in Germany and France the problem of definition and quantification of 'incremental value' is a big hurdle for the industry.¹⁸ All of these point to the fact that there is a need for greater sharing of information and harmonisation of the HTA process. Otherwise, prices will in fact increase as HTA is a cost driver.²⁸ The establishment of European Network for Health Technology Assessment (EUNetHTA) is a step in that direction. But in practice, the experiences from the newer assessments in important markets show that harmonisation in evidence generation is difficult due to diverse guidelines on pathways of treatment and the comparators.²⁹ What this means is that there must be an increased dialogue and collaboration



between the decision-makers and the industry to develop a prioritization framework for HTA appraisals. Inevitably, there will be trade-offs as it is not possible to include all requirements in an HTA process for all countries.

PATIENT PERSPECTIVE

HTAs are considered to be very technical and there have been calls for it to encompass patient views and not simply be a quantitative exercise.³⁰ HTA has widened its scope to include the opinions of the end users of the intervention, which are both patients and clinicians. Patients can shape up HTAs in three ways. Firstly, patient perspectives need to be incorporated in the early developmental stages of the product and not just to see the outcomes of the intervention on them.³¹ Some countries like Canada, Australia, and the UK have made significant improvements to bring patients to the centre of their decision making and improving their engagements. Some researchers consider the patient involvement as superior to simple method of consultations for decision making process.³² The literature does not give an exact idea of when to involve the patients but Gauvin et al (2010)³³ researched that the usual patient involvement is very late. Even though there are qualitative researches done by the industry with patients, the findings are rarely incorporated into the assessment dossiers. The information from the qualitative research can exhibit the value the patients put to some technologies, which can be quite different from what the industry seeks to achieve.

Also, the data gathered from the patients can be utilised to find out what consequences need to be measured when the technology is being evaluated. A case in point is that of ruxolitinib, where patient perspective was incorporated consistently in the trial design.³⁴

Secondly, as part of the broader agenda of the HTA process, there must be increased engagement of patient advocacy groups. The Cancer Drugs Fund (CDF) in UK is an example of the government's misplaced criteria of evaluating patient involvement. The government believed at its inception that the CDF is a step for better patient involvement. But many patient groups actually believe that the CDF

has led to inequitable distribution of healthcare as resources are diverted to the CDF from other treatments.³⁵

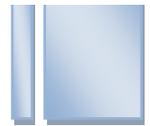
Thirdly, an attempt should be made for regular improvement of the current HTA methods and it should be based on transparency and patient feedback. Coulter's work verifies the fact that the present HTA methods do not have the flexibility and transparency to account for the complexities of the real world.³⁶ Hence, greater transparency and patient engagement can improve the current HTA process and result in decision making which are more reflective of the patients' desire.

CONCLUSION

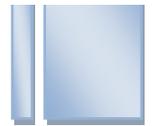
Health Technology Assessments are constantly evolving and their role in decision-making process cannot be denied. HTA can provide decision makers with the tool to see the potential effects of a technology on the patients, their health, the economy and the health system. But there is divergence between research and policy making. Policy making is a complex process and we have tried to explain how different stakeholders have different value judgements and play different roles in shaping up policies regarding the HTA processes. There is a need to recognise the fact that HTA process differs from country to country for the same technology and there cannot be a 'one-size' method which will satisfy everyone. Hence, sharing of information and harmonisation of the HTA process will be beneficial for both the industry and the decision makers. Also, patients must not be ignored for decision making purposes. As mentioned earlier, greater transparency of the HTA methods along with earlier involvement of patients in the evaluation of the technology will be beneficial for the whole decision making process.

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