The international community is increasingly recognizing the importance of evidence-based policy development and decision-making in health systems, including decisions on resource allocation, service system designs and translation of policies into practice. This is particularly salient as many low and middle income countries (LMICs) move towards the adoption of universal health coverage (UHC), and are beginning to focus on methods to best structure their health system to address increasing health care demands and unmet medical needs.

UHC is likely to feature prominently in the health-related post-2015 development agenda. (i) This will require policymakers and other relevant stakeholders, particularly in LMICs, to engage in the assessment of health interventions and technologies to generate evidence that can inform prioritization, selection, introduction, distribution and management of interventions for health promotion, disease prevention, diagnosis, treatment, rehabilitation and palliation.

(ii) The current capacity of many LMICs to assess, research and document the public health, economic, organization, social, legal and ethical implications of health interventions and technologies is generally considered to be inadequate.

(iii) Reliable information on the safety, quality, appropriateness, cost effectiveness and efficiency dimensions of technologies, such as medicines, vaccines, medical devices and equipment and health procedures, will require rigorous and structured research methodology as well as transparent and inclusive processes.

Evidence-informed Decision-making in Achieving UHC: the Role of Macro HTA

IFPMA, in collaboration with PhRMA, organized an interactive panel discussion during the Global Health Forum held in Geneva on 15 April 2014. The session sought to explore the role of evidence-informed decision making in achieving universal health coverage (UHC), looking specifically at the role of “macro” health technology assessment (HTA), as it is applied to overall health system efficiency and quality of care.

**Background**

The international community is increasingly recognizing the importance of evidence-based policy development and decision-making in health systems, including decisions on resource allocation, service system designs and translation of policies into practice. This is particularly salient as many low and middle income countries (LMICs) move towards the adoption of universal health coverage (UHC), and are beginning to focus on methods to best structure their health system to address increasing health care demands and unmet medical needs.

UHC is likely to feature prominently in the health-related post-2015 development agenda.

**Moderator**

Nick Drager MD, PhD - Honorary Professor, Senior Fellow, Global Health Programme, The Graduate Institute, Geneva

**Speakers**

Adrian Griffin, VP - HTA & Market Access Policy, Johnson & Johnson

Franz Pichler, PhD - Director, Global Public Policy, Eli Lilly and Company

John-Arne Rottingen, PhD - Norwegian Knowledge Centre for the Health Services;

Eva Maria Ruiz de Castilla, PhD - Executive Director, Esperantra (NPO, Peru).
Evidence-based decision-making

Research-generated evidence is an important tool to support decision-making in health care systems. In the context of developed countries, an emphasis has been placed on decisions related to coverage and reimbursement of new healthcare technologies, such as medicines and diagnostics. However within the scope of LMICs, research-generated evidence has the potential to inform decisions across the continuum of health care delivery in the pursuit of UHC. This includes addressing health priorities for UHC expansion, structural aspects in the organization and financing of health services, and the quality and timeliness of health care the patient receives.\(^1\)

All speakers agreed that evidence-based decision-making plays a key role in priority setting and HTA was a "crucial tool" to inform policy decisions. John-Arne Røttingen added that "good evidence needed to be underpinned by sound underlying frameworks". It is important though, that the scientific assessment be separated from the policy-making dimension, as Adrian Griffin said "we shouldn’t let the science blur the policy; the science should inform policy making, but it is not a replacement for difficult policy decisions."

The use of HTA to inform decisions

The organization and delivery of a health care system is a complex matter, which requires a number of decisions regarding the resources necessary to ensure access to services, the mix of interventions required and the means to achieve optimal results. Emphasizing this point Adrian Griffin said that "HTA can become complex and may not be easily understood by non-technical experts". It was therefore

\(^1\) Garrido et al. “Developing Health Technology Assessment to address health care system needs.” Health Policy 94 (2010) 196–202
necessary that there was an “understanding of the decision(s) that you are seeking to inform”, and that methods and processes are designed accordingly, and not unnecessarily over-engineered. He added that it was important for LMICs to consider the “what”, the “when” and the “where” when planning to introduce HTA.

According to Franz Pichler, HTA could be characterized by the scale at which it is applied, whether at a micro-HTA level such as the assessment of new pharmaceuticals at launch, at the meso-level which would include the development of clinical guidelines or at the macro-level where HTA is applied to health systems. For countries with limited resources, he questioned where such resources should most appropriately be spent with respect to HTA activities as countries look to move towards UHC. In his opinion, the controversies that surrounded micro-HTA outcomes for individual products meant that this narrow aspect of HTA received undue attention at the expense of broader applications of HTA and that these broad applications may have a greater impact for improvement of health in LMICs.

John-Arne Røttingen believed that the debate should not be about whether micro- or macro-HTA should be adopted as “both perspectives are needed”. This was because a broad range of technology was being used in various countries, and that this ranged from medicines to complex coverage. However, he stressed that “these technologies should encompass human goals as well as the organization and delivery of more effective care”.

**HTA coverage**

Adrian Griffin considered that ‘evidence-based decision mechanisms needed to be fit for purpose’, particularly in the context of the challenges facing LMICs as they move towards UHC. UHC, as John-Arne Røttingen reminded participants, was about “what is covered, who is covered and how much”, adding that what was needed was “universal and progressive systems which allowed for the poorest to be reached, in order to avoid catastrophic health expenditure”.

It is already clear than many countries have already begun to observe what was happening both inside and outside their borders and have adapted their approaches based on the best available knowledge and evidence. Several speakers agreed that there were other levels of HTA that were more applicable in other settings, and that HTA principles could be applied to entire health systems, particularly in LMICs that were in the process of planning or implementing UHC. Adrian Griffin thought that the principles of HTA were common, but that the key to success was “contextualizing it locally”. He added that “when considering the introduction of HTA systems in developing countries, governments need to incorporate principles used in developed countries, such as stakeholder engagement and transparency, whilst taking into consideration the resources and competencies required to ensure a sustainable process.** Applying HTA models**

Existing HTA models should not be blindly transposed to other settings. According to Adrian Griffin, systems are designed to address a local requirement, either by legislation or other local policy. The processes and methods often informed by local priorities, values and ethos, with the outputs tailored to inform the decision in question, which may vary from a pricing, reimbursement, or extent of coverage decision. Whilst systems therefore may adhere to the same underlying principles of HTA, each system is ‘bespoke’ in design, tailored to the resources and skills available, and the local policy context it is seeking to inform. Furthermore, Franz Pichler stated that it was not appropriate for one country to simply copy the HTA recommendations of another country on the assumption that such decisions are only evidence-based and thus are transferable since, in fact, HTA usually also includes significant policy, economic, local context and political considerations. He gave the example of the European experiment in sharing HTA information across member states that resulted in the development of a ‘lego block’ approach where different countries would use those clinical HTA elements that were specific to their needs rather than accepting a European level HTA decision.

However he considered that the underlying principles of HTA, as often stated at the micro-HTA level, of transparency, scientific rigor, fairness of assessment, and good governance were equally applicable at the macro-HTA level. He noted, however that there were also some significant differences in the approach to HTA at the level of new product assessment and HTA of health system interventions and suggested that while the study design principals might be similar, often macro-HTA interventions that showed great success early on were rapidly adopted nationwide leading to issues in assessing the statistical significance of such interventions which would be unacceptable at the micro-HTA level.

John-Arne Røttingen cautioned that the HTA processes could be costly and resource intensive and that “the only solution is better sharing of information, identifying common denominators, different types of information. Improve collaboration and efficiency of across different context”.

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**Event Highlights: Evidence-informed Decision Making in Achieving UHC: the Role of Macro HTA - 15 April 2014**

**At the**

**Geneva Health Forum**

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**Adrian Griffin**

**Franz Pichler**

**John-Arne Røttingen**

**Erichus Brossard**

**Rick Ripper**
Prioritization and determining value for investments in health

HTA is an essential tool for prioritization and determining value for investments in health. “Macro-HTA is the way to drive to investment as it comprises evidence-informed and inclusive processes and a societal perspective,” said John-Arne Røttingen. Eva Maria Ruiz de Castilla said that “new HTA models with smaller budgets were needed in emerging countries”, and that “infrastructure was the most important requirement in LMICs, as well as determining when diagnosis was needed and implementing complex interventions”. This approach was not currently incorporated in HTA models, but efforts are underway to introduce it into UHC.

Cost effectiveness

Given cost-constrained environments, many low and middle income countries have increasingly focused efforts on prioritization and determining value for investments in health. Franz Pichler reminded the audience that “HTA is not about cost containment” and argued that a recent study indicated that the implementation of HTA bodies in multiple countries did not impact their overall health budgets. He indicated that payer pricing mechanisms were already in place with regards to pharmaceutical cost containment. However, “HTA can lead to greater healthcare efficiency if applied to areas of health care where the waste and inefficiency lies”. He went on to stress that regardless of the context, a crucial element was “how HTA was used” and that there was “a gap between what is being preached and what is being practiced”.

Eva Maria Ruiz de Castilla said that the debate on HTA should focus more on the value of the medicine to the patient, rather than its cost effectiveness. Introducing new drugs into a market should be seen as an investment, but all too often it takes too long to introduce them and patients cannot be treated. “We are in love with science and technology and don’t think enough of the patient”. “Some countries,” she argued, “were focusing less on technology and maintained the same list of essential list of medicines”. She went on to say that in Peru, 64% of patients with breast cancer were dying because they didn’t have access to appropriate drugs. Many of these patients seek medical support much too late and efforts to educate them to seek help at an earlier stage have not been successful. In addition, the introduction of a new technology can take anywhere from 3 to 5 years because of lengthy administrative procedures.

Engaging stakeholders

All speakers agreed that inclusive and open debate among various stakeholders was needed to help improve overall access to health care, and identify best practices designed to yield the most efficient and effective investments. Health care policies needed to be designed with the patient at the center, as well as considering the needs and roles of other key stakeholders – provider groups, payers, innovative and generic manufacturers, distributors, academics, non-governmental organizations, and policymakers. Adrian Griffin believed that partnerships between clinicians, patients, governments and industry were necessary and that this could help with the introduction of new technologies of value. He added that stakeholder engagement was “the way to get more people to align behind a policy decision”.

As there was no HIV-like global fund for NCDs, new ways of working together were needed in order to achieve the goal of making life better for people in countries moving towards UHC. Partnering between different groups is the way to move forward, according to Franz Pichler, wider involvement was often needed as “interventions within the health sectors often had an effect beyond the health sector”. John-Arne Røttingen concurred and stated that macro-HTA can drive demand for investment and break through institutional budget silos.

Adrian Griffin considered that it might be more appropriate to have an HTA system that was more clinically driven as these tended to be better understood by most stakeholder groups, and that other approaches (e.g. QALYS, as used in the UK), were more data intensive and non-specialists found them difficult to understand. Indeed, LMICs had the opportunity to devise the next-generation of HTA systems, fit for their local use, rather than be constrained by models developed previously by existing healthcare systems.

Eva Maria Ruiz de Castilla believed that access to information is critical to ensuring decision-making was comprehensive and balanced, and thought that, as we now live in a globalized world, “everyone needed to have access to information” and “promoting access to information can improve global health”.

Universal Health Coverage

While every country is unique and tailored approaches will be required, there are common challenges and opportunities faced by countries at all stages of UHC. Based on these areas of shared experience, the biopharmaceutical industry proposes key guiding principles to inform the design of global UHC policies: Equitable Access, Efficiency, Quality, Inclusiveness, Availability, Adaptability, Choice, and Innovation.

As countries work toward UHC, these principles may offer guidance to policy makers, industry, and other stakeholders who seek to improve health care and meet the health needs of all citizens. These principles cover the areas we believe our industry can contribute given our technical knowledge and experience in providing access to high quality health solutions.

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