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Letter to the Editor

TOWARD A SHIFTING HEALTH TECHNOLOGY ASSESSMENT PARADIGM: REACTIONS TO POLICY FORUM DISCUSSIONS

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Are we in a period of significant change? Is health technology assessment (HTA) undergoing a fundamental transformation? Or should it be? Are we in the middle of a paradigm shift? These are some of the questions the paper by Facey et al in this journal (1) raises about the future of HTA, based on discussions at the HTAi Policy Forum in February 2015. To further share the deliberations of the Forum and with a view to opening this debate among the wider HTA community, a panel within the HTAi 2015 Annual Meeting in Oslo was organized. Presentations at the panel included a summary of the HTAi Policy Forum deliberations and perspectives from a patient, a clinician, and representatives of an HTA organization, industry, and a health system. This letter presents issues and thoughts raised in the panel session.

There is a general agreement on shifting to a new HTA paradigm. In this new paradigm, HTA continues to inform decision making. Traditionally, decisions have considered the value of health technologies at the point of coverage or reimbursement by policy decision makers. However, this focus overlooks the range of different decisions that also have to be made over the life cycle of a health technology by different stakeholders. Therefore, informational needs and optimal evidence requirements will depend on the type of decision to be made along the technology life cycle and depending on the type of stakeholder requiring the information. HTA has a central role in this new paradigm to help align stakeholders in order to optimize evidence production through a multi-collaborative stakeholder dialogue.

Evidence production needs to be useful, timely, and affordable; this poses requirements for both producers of health technologies and HTA. Producers need to promote dialogue and collaboration in-company, between different functions, and across countries, to be able to produce useful information for HTA in an efficient way. HTA needs to make an effort to overcome the fragmentation of evidence requirements across countries and regions, presenting a globally consistent view of the main evidence requirements. This approach is dependent on the need to have the right people at the table for a consistent dialogue and collaboration, since research and development of a technology is highly dependent on the outcomes of this dialogue. On deliberations for the quest for evidence, HTA should be aware that speed matters for health technology developers and patients, and that patient numbers and other resources are limited, so that having perfect information will never be possible. Therefore, it is important to agree on when the primary responsibility for evidence generation shifts from the producer to the health system.

Input from All Stakeholders

The usefulness of the evidence produced will depend highly on who provides input to designing the studies. Therefore, the multi-stakeholder collaborative dialogue needs also to include patients and hospital professionals. Patient experience and knowledge are essential to include the right outcomes for assessment, while clinicians and service managers play a key role in both generating the evidence and using it for the adoption of new health technologies. For clinicians, real world data are key for the adoption of health technologies in clinical settings and HTA should be done as soon as possible, since even beneficial new technologies can have significant impacts on hospital budgets and service organization. The need for contextualized information on the impact of new health technologies within hospital settings is contributing to the emergence of hospital based HTA (HB-HTA) in several countries,

such as in Norway and Finland where it is mandatory to perform a mini-HTA when a new technology is considered for adoption.

The types of evidence needed to inform clinical practice decisions for adopting new health technologies include the traditional clinical outcome data (mortality and morbidity) and for devices and equipment, reliability and durability; but also information regarding patient experience. These types of outcomes can be obtained through generic instruments (such as quality of life measures) or symptom specific scales (e.g., pain). However, these generic tools may not capture the real and specific experience of patients; therefore, combining results from these tools with disease-specific measures and qualitative research, for example, structured or semi-structured interviews, is needed. Moreover, data are needed on the impact on costs and opportunity costs for the hospital and other parts of the system if the new technology is introduced. Some new health technologies could be cost-effective but may shift costs between parts of the system and may not be affordable for some or all parts of system. Patient and clinician perspectives could help inform manager and policy decision making in this context.

From a healthcare point of view, providing evidence on health technologies should not stop when the technology enters the clinical arena. In an ideal world, all introduced health technologies should be monitored by research. Moreover, in this ideal world even established health technologies should be followed to find out if the expected results and benefits are obtained. However, limited resources and lack of appropriate methods and expertise make this aspiration difficult to realize. This is why it is suggested that such close follow-up be directed toward the most disruptive health technologies, preferably using controlled studies while others could be followed through other mechanisms (e.g., registries).

Acquiring perfect information to meet the needs of all stakeholders is unlikely. This means that questions regarding how much risk or uncertainty the decision makers accept and how much the commissioners are ready to pay for decreasing uncertainty will influence the adoption of new and disruptive health technologies. The management of uncertainty needs both a trusted dialogue and expectation management between all parties, informed by reflections regarding affordability of the risk level acceptance.

In the new paradigm, HTA continues to inform access and coverage decisions but also has an important role to prepare healthcare systems for early adoption of effective innovative health technologies. The panel session included an example from Korea where HTA gives support to policy decision makers on designing and delivering managed entry schemes (e.g., coverage with evidence development) and working in collaboration with regulatory agencies for market access using parallel scientific review systems.

Toward HTA 2.0

Looking forward, HTA should include consideration of wider issues such as equity and inequalities, but the remit of some HTA agencies currently does not appear to include these aspects. Finally, using the knowledge and expertise from the assessments it undertakes, HTA could help healthcare systems to understand, anticipate, and overcome barriers facing the successful and efficient adoption of valuable technologies. For HTA to take on this wider health system role, there is a need for champions that will be willing to engage and lead.

The HTA new paradigm, or HTA 2.0, is currently emerging. Circumstances in the real world are forcing HTA to become more agile and adaptive as well as more proactive in stating evidence requirements and in supporting evidence production. HTA should provide inputs along the life cycle of the technology, be timely, and go beyond the strict assessment of technologies to help the healthcare system use technologies in most effective and efficient ways. This new HTA paradigm could also broaden the traditional definition of health technologies (drugs, equipment, medical devices) to include other technologies that can contribute to system efficiency, e.g., aspects of care delivery such as nutrition and information technology solutions, to support more effective care delivery and patient engagement in their own care. These ”process of care” technologies do not often have natural champions driving HTA, but nursing and healthcare professionals and managers working in administrative areas may increasingly take this role.

Moving towards an HTA 2.0 poses several unanswered questions. Resources for HTA are not envisioned to increase. Will becoming more adaptive, agile, timely, and following along the life-cycle also require adapting and innovating in the HTA processes and products? Is further differentiation of HTA products needed? Would it lead to a technical sophistication of the assessment and appraisal process? Should HTA 2.0 just be applied to disruptive health technologies? Are there specific disease or treatment areas more suitable for HTA 2.0 than others? Would different funding models for HTA be needed? Is that move possible for all HTA agencies irrespective of their funding development? These are open questions that should be debated by the HTA community as a whole.

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REFERENCE

1. Facey K, Henshall C, Sampietro-Colom L, Thomas S. Improving the effectiveness and efficiency of evidence production for health technology assessment. *Int J Technol Assess Health Care*. 2015;31: 201-206.