Letter

RETHINKING STAKEHOLDER ENGAGEMENT AND TECHNOLOGY ACCESS IN HEALTH TECHNOLOGY ASSESSMENT: REACTIONS TO POLICY FORUM DISCUSSIONS

The need to progress and innovate in health technology assessment (HTA) is a must in a continuously changing environment. The HTAi Policy Forum reflected on two specific areas for development where it was thought there was need for careful consideration and deliberation during the main annual meeting in February 2016. The study by Husereau et al. (1) in this journal presents the discussions resulting from this Forum. To further share the deliberations of the Forum and with a view to opening this debate to the wider HTA community, a panel session during the HTAi Annual Meeting in Tokyo was organized. Presentations at the panel included a summary of the HTAi Policy Forum discussions and perspectives from a patient, a representative of healthcare system provider, and a representative from an HTA organization and industry. This letter presents the issues raised in the panel session.

There is probably consensus that best practice in HTA should be characterized by rapid and precise adaptation to effectively respond to the uncertainties and needs of ever changing healthcare systems. HTA doers are witnesses to this changing environment and are trying to adjust processes to new requirements.

Ten years ago, HTA practitioners focused on report production and internal processes, with limited interaction with stakeholders, assessing technologies with large indications (e.g., statins). Practitioners drew mostly on randomized clinical trial (RCT) data and focusing on clinical aspects, performing a single assessment at one point of time and with a national focus. Ten years on, the HTA doer perspective has changed. Nowadays communication is the cornerstone of any HTA. HTA doers are increasingly focused on external process and interacting with stakeholders. HTA practitioners are assessing technologies for smaller indications, increasingly looking for real world data to complement RCT data, focusing on several aspects, not just clinical aspects, at different time points, each time tailoring the assessment processes.

These changes, and other changes in HTA processes, are leading HTA to "change for the better" (in Japanese words "kaizen"). One of the panelists noted this as an essential condition where continuous improvement is the focus of everybody (doers and users of HTA). Over the years, members of the HTAi Policy Forum have jointly assessed the state of HTA, identified opportunities and challenges for HTA in light of external trends, featured innovative concepts in its sessions and publications, and initiated demonstrative projects. Nevertheless, the innovative ideas have scarcely been implemented in practice. This situation is replicated in the wider HTA community, where scientific and professional debate is continuously ongoing but few ideas and proposals for change implemented.

Movement toward more innovative HTA approaches to meet current needs and requirements will not happen by themselves. This level of change needs to be embraced, owned, and carried forward in action by professionals at all levels. It was suggested that benchmarking current processes against a desired future may help us to make this a reality. The "kaizen way" was mentioned as one example that could inspire and help to achieve a shift of HTA paradigm. Roughly, kaizen or "changing for better" consists of: (a) measuring (examining whether the current process is effective and/or efficient); (b) innovating (searching for new better ways to do the same work or achieve the same results; and looking for smarter, more efficient routes to do the same end-goal that boost productivity); (c) comparing (comparing your measurements against your requirements for the process; does it accomplish the desired result?);

(d) standardizing (creating repeatable, defined processes for those new, more efficient activities). Is this something that could be applied more broadly in HTA? Are members of the HTA community already doing this? If so, how? What are the lessons being learned?

RE-THINKING SCIENTIFIC DIALOGUE AND STAKEHOLDER ENGAGEMENT

Multi-stakeholder engagement is advocated in scientific dialogue. While the concept of who should be involved in these dialogues is widely accepted (i.e., HTA practitioners, industry, clinicians, patients, payers, healthcare providers), it was reflected that these actors are still not evenly participating. Patient involvement in HTA production places a heavy burden and demand on patient organizations. Patient advocates yearn for a shift from a technocratic approach to HTA (i.e., looking for safety, efficacy, and cost-effectiveness) to a more comprehensive and experienced-based approach (i.e. including what really matters to patients and carers in assessments and including them in appraisal debates). HTA needs to do more than just listen to the patient; their voice needs to be central to make a real impact. The view of patients, carers, and the public need to be legitimately included as a "fourth quadrant" alongside clinical views on safety and efficacy, and cost-effectiveness. To do this well, scientific dialogue will need to establish an environment of earned mutual trust, respect, openness, and reciprocity. Power needs to be shared.

Key to advancing and innovating is to obtaining good information about what really matters to patients and their caregivers as well as having access to treatment data held by health technology producers. At present, there is a perception that health technology producers provide minimal information when they are asked by patients. Confounding this issue, HTA agencies believe that, if they want to know more about what is most relevant to patients they need to start to use new channels (e.g., social media) of communication to assess patient experience. Perhaps we should be exploring new ways to share information and resources (e.g., using information technology capabilities such as cloud technologies for easy access to information or the use of social media to capture on key relevant outcomes)? To do this, we will need to look for ways to overcome the current legal and regulatory restrictions in sharing these data and properly communicate them to interested parties.

Finally, it could be argued that considerable differences between evidentiary expectations and analytical standards, and divergent concepts of "patient relevance" currently exist between regulatory bodies and HTA agencies. This leads to inefficiency and conflict when determining the right outcome to assess. These reflections reinforce the need to look for a more effective way to gather and use patient and caregiver input.

Looking forward, co-production of data relevant to all stakeholders in a trusted environment is essential, and is in-creasingly being required by decision makers. In the panel, some examples were shared that showed the difficulties of involving stakeholders in this shared enterprise. In one case, a coverage with evidence development requirement to assess the value of a drug targeted at allergic asthma, showed that, while some stakeholders were actively collaborating in setting up a register to collect data (such as pulmonologists and patients), others (such as pharmacists and private payers) were reluctant to participate. This experiment also showed that, although putting in place a simple registry, additional bureaucracy was created (for a small targeted population) raising concerns on cost. Since resources to set up these types of registries do not always exist in a health system, a global approach may prove to be more efficient and effective for real world data production.

Central to collecting real-world data are health professionals working at hospitals and primary care, and must include healthcare managers as their engagement in scientific dialogues could help to facilitate both data collection and gathering the key information for investment decisions. The panel reflected that the views and needs of healthcare managers have been scarcely considered in scientific dialogue, and local decision making regarding technology introduction has been shown to frequently differ from those considered by HTA at national/regional level. In conclusion to this point, the panel noted that assessments focused just on technologies that do not consider the complexity of the real world where the technologies are implemented are flawed, reinforcing the need to include different health professionals and service managers working at local/hospital level in HTA.

Finally, the panel acknowledged that enhanced stakeholder engagement requires sustainable resourcing and that this is currently lacking. To truly innovate in multi-stakeholder engagement, appropriate resources will need to be put in place. Can the HTA community find the most effective and efficient way to do this?

RE-THINKING VALUE, AFFORDABILITY AND ACCESS

Affordability is inextricably linked to health system access to potentially valuable health technologies. Health system budgets are influenced by many external factors (such as performance of the economy), and these external factors can make the introduction of new health technologies into a healthcare system complex. The panel proposed that horizon scanning could help to prepare health systems for the impact of new technologies. Such approaches could incorporate strategies to pro-actively identify implementation challenges and to develop access solutions (what could be called "constructive technology assessment"). Together, stakeholders, including health technology assessors, service managers, payers, and industry representatives, could help to prepare the health system for innovation deployment. Used in this way, horizon scanning could also be

used to inform health system budgeting processes. Such an approach would need to be further thought through, tested, and evaluated.

The "value" of health technologies is considered by decision makers when analyzing the appropriateness of introducing them into a health system: the greater the value the greater the efforts to make it affordable. The panel discussed approaches to adjust and adapt reimbursement models to facilitate flexible value-based systems. In some cases, health systems are assessing value and putting in place reimbursement systems that reflect this assessment (e.g., risk sharing schemes). Reflecting on these cases, the panel identified that the prioritization criteria for value-based arrangements need to be clearly defined to maximize efficiency in the processes. Moreover, when assessing value and affordability, two-tier processes are likely needed. Tier 1: supra-national, national, or regional approaches can act as a baseline. Tier 2: local or hospital level analysis carried out to consider budget impact and, therefore, affordability. This tiered approach can then take into account differences in how value is conceptualized between the two tiers.

Finally, when considering affordability, attention must also be paid to disinvestment. HTA has a role to identify opportunities for potential disinvestment and providing the evidence to enable decision makers to identify where and how to create "headroom" in budgets to fund valuable innovations, thus making the emerging valuable technologies affordable. Nevertheless, are these potential approaches workable in a systematic way in the real world?

In conclusion, several still unanswered questions emerged from the panel: How effectively can the HTA community operationalize the new practices highlighted by this paradigm shift? How can we overcome the technical and, sometimes, legal challenges to capture the real-world data that matter to all stakeholders by using the new information technology? Are current value concepts and frameworks appropriate for the new and emergent disruptive health technologies? Can new approaches help to ensure affordability of valuable innovations? Can a horizon scanning system be used to prepare the healthcare systems by pro-actively "engineering" access solutions? The HTAi Policy Forum continues to stimulate debate of these issues and invites the wider community to contribute.

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REFERENCE

1. Husereau DH, Henshall CH, Sampietro-Colom L, Thomas SE. Changing health technology assessment paradigms? *Int J Technol Assess Health Care*. In press.