

VOLUME 31: HTA'S EVOLUTION: FROM CONSUMER TO HONEST BROKER TO ENGAGED COLLABORATOR

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In this issue, Facey and colleagues have eloquently summarized the product of the February 2015 HTAi Policy Forum discussion—the need for health technology assessment (HTA) to shift from a historically reactive role in both evaluating current evidence and requesting additional evidence generation to a more proactive role engaging with stakeholders to ensure that evidence produced is appropriate for any given intervention at different stages of the clinical development program. This makes logical *a priori* sense, of course, as proactive and engaged discussion is always superior to reactive and potentially adversarial interaction.

However, it is also increasingly necessary. After a prolonged lull, the pace of pharmaceutical and biotech innovation has picked up again, with high-priced specialty medicines expected to fuel industry growth over the next 5 years (1). In addition, regulatory review timeframes have shrunk considerably due to the emergence of accelerated review pathways. From an HTA perspective, these pathways have the potential to limit interactions with industry and other stakeholders during early drug development. Even more importantly, the lower evidence standards that typically accompany accelerated programs have been associated with increases in postmarketing safety concerns, use of surrogate endpoints that have been invalidated when additional data become available, and a “chilling effect” on future clinical study after drug approval (2).

HTA agencies and research organizations have already begun to innovate in response to these challenges. Also in this issue, Levin describes a pilot approach to health technology assessment in Ontario that involves premarket partnerships between industry and independent researchers to develop evidentiary packages that will meet the needs of both regulators and HTA agencies. Montilla and colleagues describe an Italian post-marketing registry program targeted at high-cost medications that tracks clinical benefits and harms in actual practice, data that are incorporated into periodic re-review of available evidence. Finally, Schneeweiss et al. describe the use of electronic health record data in the United States to perform “rapid-cycle

evaluation” of postmarketing experience to produce trend data on effect size, safety signals, and other important outcomes.

The important innovations described in these papers revolve around a central theme for HTA—the need for greater flexibility and “adaptive” approaches to technology assessment. Dillon argues in this issue that this adaptability requires change along three constructs: HTA’s own innovation, characterized by straightforward and efficient review of evidence as it emerges at several unique points during the technology development life cycle; revisiting the “language” of HTA, so that patients, providers, and policy makers alike understand what is known and what is still uncertain about the evidence base for a given product, can make flexible decisions regarding treatment of an individual within the umbrella of population-based guidance, and can clearly understand the opportunity cost to the system of adopting high-cost interventions; and better alignment with both technology innovators and regulators to create upstream conversations that can inform both research and decision making.

Both Dillon and Facey discuss the unique position that HTA already occupies. HTA groups have the ability to understand both the clinical science behind the innovation in question as well as the potential impact of innovation on the market after approval. These organizations can also serve a “facilitator/broker” role, bringing stakeholders together to define evidentiary requirements, react to initial evidence produced, address gaps in evidence, and brainstorm solutions for future evidence generation and ongoing monitoring.

Is this enough? Creating a more flexible approach to HTA, involving frequent and early interaction with industry, ongoing monitoring of emerging evidence, and better alignment with regulatory and industry needs? I would argue that these elements are indeed essential, but they are not sufficient. HTA’s role needs to grow beyond one of engaged listener or honest broker to that of active collaborator. All of the innovations just discussed have the potential to improve HTA processes without changing the perception by some that the conversation is one-sided. More

discussion is nice, but the notion that HTA “holds all the cards” is what really must change.

How can this be done? Fortunately, methods and processes already exist to help with perception change. For example, HTA can better leverage its internal health-economics expertise in multiple ways. Conduct of value-of-information analysis (3) at multiple points during technology development can help manufacturers and HTA agencies alike prioritize research designs, populations studied, and outcomes of interest. Similarly, use of decision analysis based on early-phase data on effect size, expected target population, and patient preferences can inform conversations on everything from pricing to expected prioritization of product roll-out. In addition, early conversation about investment can be coupled with discussion of *disinvestment*—if elimination of services of lower value will be required to pay for a given innovation, an honest conversation about disinvestment will go a long way toward cementing a good-faith partnership between stakeholders.

To be sure, the requirements for HTA to adapt to both the increasing pace and cost of technology innovation are recognized by all, and important steps have already been taken to adjust to these changes. It is the last piece of the puzzle—changing the relationship between HTA and its key stakeholders—that will surely be the most difficult. HTA organizations should make use of the tools already in their toolbox, such as process transparency and multi-stakeholder outreach, to make this change happen.

REFERENCES

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