

HTA AND INNOVATION OF VALUE: GETTING TO KNOW YOU

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Fostering innovation for societal gain has been a core attribute of technology assessment (TA) since its inception. Although many observers were concerned that TA would be a means by which government would impede the development and use of technology, this was not the intent of policy makers or the agencies that conducted the original TAs. A 1969 report of the National Academy of Engineering to the U.S. Congress emphasized that:

Technology assessment would aid the Congress to become more effective in assuring that broad public as well as private interests are fully considered while enabling technology to make the maximum contribution to our society's welfare (1).

Those engaged in health TA (HTA) and innovation must continually revisit and enhance their mutual understanding. What health care wants from innovation has evolved. At base, innovation has meant the creation of *new* or *different*, including what can be recognized as intellectual property. Too often in health care, we find ourselves still paying for just new or different. Beyond new and different, we have sought to pay for innovation that produces real and desirable improvements in health outcomes or such attributes as less invasive, more efficient, and more reliable. Increasingly, though, we demand *innovation of value*: Does this technology achieve real and desirable improvement per incremental expenditure? Innovation of value is innovation that's worth it.

Life sciences companies are adjusting to their markets' valuations of innovation. Asked recently about how he is changing his company, one CEO emphasized:

I also started to shift our business away from a transactional model that was focused on physically selling the drugs to delivering an outcome-based approach to add value beyond just the pill. I really believe that in the future, companies like Novartis are going to be paid on patient outcomes as opposed to selling the pill (2).

Recognizing the need to add value beyond the pill acknowledges that patient outcomes are mediated by more than what innovators can pack into their molecules, devices, or other technologies. It means extending beyond their traditional core businesses and spans of direct control to such matters as patient adherence, therapeutic monitoring, management of comorbidities,

and avoiding unnecessary emergency room visits and hospital readmissions.

Perspectives on how health technology confers value are diverse. Benefits, harms, and costs accrue differently to patients, clinicians, provider institutions, payers, and societies at large. Herein is potential misalignment for HTA: Which perspective are the data streams and assessment methodologies serving? How does an HTA function that may have been established to inform policy making by a fixed-budget national health authority or a sickness fund then go about operationalizing primacy to the patient perspective of value? How equipped are we to capture the requisite quantitative and qualitative patient-centered data and run the analyses?

In fact, HTA will have to account for multiple perspectives reflecting the technology and circumstances at hand. For example, multi-criteria decision analysis, which has been applied recently to HTA (3;4), identifies and weighs the attributes of alternatives (e.g., therapeutic options) from multiple stakeholder perspectives by ranking, rating, or pairwise comparisons, drawing on such stakeholder elicitation techniques as conjoint analysis and analytic hierarchy process.

However difficult it might be to assess, the value of health technology is hardly fixed at the point of market entry. The relative magnitudes of benefits and costs can evolve with changes in, for example, the technology itself, clinical indications, patient populations and subgroups treated, evidence about health outcomes, alternative technologies, clinician experience, dosing regimens, and adherence. We have developed and shared insights concerning why, when, and how to reassess technologies (5). However, when value changes, are payers prepared to adjust payment levels accordingly?

Value of innovation is demonstrated with evidence. The HTAi Policy Forum has led the way in candid and constructive exchange of views and experiences among HTA stakeholders regarding evidence requirements for validating new technologies, including challenges associated with the rigor of and variations in these requirements among and between regulators and payers (6;7). Rigorous does not necessarily mean rigid. HTA continues to probe ways of flexing the evidence bar, whether in the form of study design requirements or cost-effectiveness criteria, to reflect societal preferences and ethical concerns. Accommodations are made or considered for great unmet medical

need, such as for the first technology to provide clinical benefit for life-threatening conditions, therapies for serious orphan diseases, end-of-life benefits (e.g., where opportunities for QALYs gained are limited), and demographic equity.

There is rationale for paying for innovation before conclusive evidence of benefit. This is to keep progress in motion in the hope that, for example, follow-on clinical trials will confirm early signals of benefit. This is exemplified by the accelerated approval program of the U.S. Food and Drug Administration, which also enables third-party payment, and provides that market approval can be withdrawn if the required confirmatory trials show insufficient net benefit (8). It is also embodied in managed entry approaches of third-party payers, such as coverage with evidence development and performance-based reimbursement (9;10).

There is sentiment as well for paying for as-yet-unproven innovation in the hope that the next generation or spinoff of the present technology will yield clinically important health benefits. Some also vouch for reimbursing innovation to sustain the broader progress of science and technology, employment, balance of trade, and other economic attributes. These issues pertaining to the value of innovation have arisen in the context of national HTA programs, including recently for the UK National Institute for Health and Clinical Excellence (11). Whether or not there is merit in this argument, we are reminded to distinguish between subsidizing innovation and incentivizing it, and between paying for promise and paying for its realization (12).

In fact, governments and societies subsidize and otherwise fund innovation beyond reimbursing evidence-based uses in substantial ways. These include: government funding for basic sciences and biomedical research; tax codes that favor innovation; education in science, engineering, and medicine; legal and administrative systems for intellectual property protection; regulatory systems that provide and protect market access for innovation; third-party payment that widens population access to innovations and often covers off-label uses; and conditional or temporary payment for innovations of promising benefit.

This issue's mini-theme on HTA and value recognizes and moves to accommodate the diversity of value perspectives, building on the enlightening summary of a recent HTAi Policy Forum on this topic (Henshall and Schuller, in this issue). In this multi-perspective context, Towse and Barnsley proceed to describe methods to identify, measure, and integrate elements of value. Probing the element of change, Gelijns et al. exam-

ine the dynamic nature of innovation and value, particularly as it applies to medical devices. Three commentary letters from leaders in HTA and value help to round out key stakeholder perspectives.

Striving for innovation of value and fostering it accordingly for individual and population health are pursuant to the missions of health technology developers and HTA, and serve patients, clinicians, payers, and society at large. Anything short of continued, candid, and constructive engagement is suboptimal for those missions.

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