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RESPONSIVENESS, LANGUAGE, AND ALIGNMENT: REFLECTIONS ON SOME CHALLENGES FOR HEALTH TECHNOLOGY ASSESSMENT

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Health systems around the world cope with the challenge of difficult economic times, and the value of health technology assessment (HTA) is increasing. Making the right choices, with limited resources, in the face of increasingly complex technologies requires decisions informed by data and analyses that help us to manage the risks involved. Those who undertake and use HTA can play a greater role in helping decision makers meet these challenges; they need to think how to define innovation and respond to it, how to communicate their analyses, and, critically, how to align their work with the ambitions of their health systems. HTA can become a key health system enabler without compromising its objectivity or independence. It can say that it is too early to determine the value of a new technology when the data simply will not support a safe decision. However, it can also be bold and recommend the managed introduction of new technologies, even when the when the data is immature, provided that the health system understands the risks and there is a plausible case for believing that further research will support the value proposition. The goal for HTA is to be able confidently to do both.

Keywords: Health technology assessment, innovation

RESPONSIVENESS

For the life sciences industries, innovation is the unique selling proposition, making the difference between success and failure in marketing their products. For health systems, innovation offers potential solutions to the twin challenges they face: delivering improved outcomes to increasingly demanding populations and matching capacity with that demand in an affordable way. Innovation is seen by many health systems to be so valuable that it needs to be fostered and adopted at the earliest possible moment. Several countries already have schemes in place to spot and promote technologies that are deemed to offer such potential for improving outcomes, that they should receive special consideration by regulatory agencies and payers.

In the United Kingdom, for example, the Early Access to Medicines scheme offers a "promising innovative medicine" designation to products intended for the treatment, diagnosis or prevention of a life-threatening or seriously debilitating condition with the potential to address an unmet medical need (1). The first products have been awarded this designation although precisely what effect it will ultimately have on advancing access, clinical outcomes and on health system resources remains to be seen.

As the demand for earlier access to novel therapeutics increases, the challenge for health technology assessment (HTA) and those who use it is how to keep pace with their development. Innovation is, of course, essential. It is what has brought the products that allow us to lead the lives we have. However, the tendency of health systems to invest the next generation of products with such expectation and promise, at an earlier stage in their development means that HTA needs to strike a balance between the security of its tried and tested approaches and the uncertainties of more innovative methods and processes, to remain relevant and engaged.

Those responsible for HTA and its application need to recognize and respond to the desire for new solutions to improve outcomes and make better use of resources. We have to adapt our approaches to evaluation in ways which promote innovation that brings real added value while protecting patients and health systems from investing in things that do not. For this, we need clearly stated and realistic ambitions for what our health systems want to achieve, alignment of the organizations and processes involved, and an appetite for risk, appropriately shared between innovators and health systems.

And the challenge for companies, with innovation at the heart of their value proposition, is the need to offer

measurable incremental therapeutic benefit, and a pricing model, that underpins that shared risk. They form a critical element in the innovator-HTA-payer ecosystem that needs to operate efficiently to enable timely access by patients to new treatments.

To retain its relevance and utility, HTA will need to resist the tendency to become ever more elaborate in the face of more complex technologies and health system scrutiny, and instead find ways of rolling with the life cycle of new technologies, nudging and shaping their use on the basis of agile and adaptive processes.

Uncertainty about the best way to use a new technology should not end with the evaluation undertaken at its launch. HTA cannot just be a single event. It needs to be a process in which the emerging data, from clinical studies and real-world experience, is evaluated and interpreted at a series of points in a technology's life cycle. This needs to happen in the context of patient experience, the emergence of competing technologies and the capacities and priorities of health systems. To do this will require agile processes and methods.

LANGUAGE

In writing clinical practice guidance, it is obvious that language is important. It has to convey, to health professionals, patients and system managers, the place of a technology in clinical practice. At NICE, recently, we have been reflecting, on a concern that our guidance, by being too specific about the clinical circumstances in which it should be applied, is failing to adequately reflect the complexity of the context in which it is being used. It does not allow physicians—and their patients—the space to reflect on the uncertainties that inevitably accompany any evidence-based advice. And by taking a population perspective in interpreting the evidence, we risk recommending treatment of patients for whom it may not be appropriate.

And yet, we are also being pressed to be to be clear and precise in our recommendations, because doctors and other health professionals are busy people and do not have the time to read and consider the evidence. They need to know what to do when the problems arise.

Population perspective versus individual choice; evidence uncertainty balanced with the need to say something useful; brevity and precision traded off with the need to enable young minds to explore and develop. Words matter; writing guidance is not easy.

In a recent conversation with a distinguished health economist, about the controversy surrounding the adoption of new cancer drugs in England, he said that he understood why people fear cancer so much. He said that he could see, although he did not necessarily agree with, the connection between that fear and the priority that health systems frequently give to cancer services. What he said is missing is a better understanding of the trade-offs involved. He also argued that the language of health economics (quality-adjusted life-years, cost-effectiveness thresholds, incremental cost-effectiveness ratios, opportunity cost, and so on) fails to engage patients and the public, let alone decision makers. He has reached the conclusion that we need to drop the technical language and lay out the opportunity cost of deciding to adopt high cost treatments by talking about the lives that will be shortened and lost, or lived in poorer quality when we choose to invest in high opportunity cost treatments. In this way, he believes, we will be better able to align decisions on whether to adopt a new technology with the ambition the health system has for its users.

ALIGNMENT

This issue of alignment is really important to those involved in producing and using HTA. Although we need to retain our independence and objectivity, we cannot detach ourselves from the system that develops the products we evaluate or the health systems that use them. We operate at the interface between the two, and we have to actively engage with both. We need to work upstream, in conjunction with our regulatory colleagues, and with technology developers to inform their research and help them refine the data they make available to us. This is already happening, of course, through individual agencies' scientific advice programs and initiatives like EUnetHTA. We need to shape their offer to help it align with what we know our health systems are looking for and what they are able to accept. We should be positioning ourselves as the people who understand both the science and the market and how to bring them together.

CONCLUSION

The difficult economic circumstances we are all in provide us with an opportunity to look again at our relationship with our health systems. HTA is irrelevant (other than as an academic pursuit) unless we can persuade policy makers and professionals to adopt it. Never easy at the best of times but with health systems under huge and increasing financial pressure, it is not getting any easier. If you are managing a tight budget, saying that something is clinically effective is interesting but not especially persuasive. Being told that it is cost-effective is more enticing and makes it a little easier to allocate resources, when they are available. Best of all, of course, is when a new technology improves outcomes, is cost-effective and saves money: perfect alignment with the ambitions of the funders and users of any health system.

HTA has been on a journey from being an academic discipline to becoming a key health system enabler. I believe that it can complete this transition without compromising its objectivity or independence. It can still say that it is too early to determine the value of a new technology when the data simply

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will not support a safe decision. However, it can also take risks and support the use of technologies, even when the when the data are immature, provided that the health system understands the risks and there is a plausible case for believing that further research will support the value proposition. The goal for HTA is to be able confidently to do both.

CONFLICTS OF INTEREST

The author reports no conflict of interest.

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