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The thorny issue of value alignment: how development-focused health technology assessment can help find win–win situations for patients and healthcare systems and commercial investors

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Letter

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We thank Anastasia Chalkidou for her thoughtful response to our recent article "A different animal? Identifying the features of health technology assessment for developers of medical technologies" (1). Dr. Chalkidou considers that we missed an opportunity in our framework to attempt to reconcile the tension between the interests of commercial innovators on the one hand and patients and healthcare systems on the other (2). In particular, she considers that by focusing on the positive analytical stance (which we claim is characteristic of development-focused health technology assessment [DF-HTA]), we fail to capture the value proposition adequately and thereby amplify tensions between innovation stakeholders.

We agree that there is always likely to be some tension between commercial interests and maximizing societal value. Commercial entities must return profits to their shareholders in order to be sustainable in the long term, and innovation, which returns profit, will not necessarily maximize societal benefit. In theory, payers should be able to design reimbursement systems that are (i) transparent and predictable and (ii) incentivize private sector developers financially for developing technologies that are socially useful. They would also need to take into account other factors that might influence developers' decision making, such as the total costs of development, the strength of intellectual property protection, the potential for future competition, and other payers' reimbursement systems. At the moment in the UK, we seem to be incentivizing the development of treatments for rare diseases and late-stage cancers, and, therefore, we should not be surprised if developers respond to these incentives.

DF-HTA may contribute to a reduction in these tensions while maintaining a positive stance of analysis. Firstly, at the earliest stages of development, innovators are often unsure about the placement of their technology in the clinical pathway, and adopting a positive stance ensures that the HTA analyst remains open to all alternative jurisdictions, indications, and positions in the clinical pathway where the technology has potential. This positive exploration will involve the consideration of how the technology will impact upon costs and service and health outcomes. Ideally, it would involve exploring the value proposition with potential customers (patients and healthcare providers) to ensure that it works and it delivers value to them in the suggested indications/positions in the pathway. If this early DF-HTA indicates that the technology would have little clinical utility in this indication, then the developers are able to refocus at a very early stage and target alternatives. Kluytmans et al. (3) is a good example of this early exploratory analysis.

A second way that DF-HTA can help to create a win–win situation, in which both innovators and society gain, is by using the normative value framework of reimbursement-focused HTA to set price expectations for developers. Using headroom estimates from cost-effectiveness analysis, DF-HTA can estimate a range of price points at which the technology would be seen as cost-effective in a jurisdiction such as the UK, where there is an explicit threshold for the maximum amount per quality adjusted life year (QALY) that healthcare providers are willing to pay (4). In a response to a rare but useful insight into methods of early health economic modeling to support developers of health technologies by Grutters et al. (5), Drummond said that early cost-effectiveness analysis can provide the manufacturer with "an indication of whether particular price expectations could be met," allowing the manufacturer an opportunity to revise pricing expectations or perhaps address some other aspect of product design, improving performance, or reducing the unit cost of production (6). Our framework may prove useful for those interested in reimbursement systems if it helps them consider the perspective of the developer making decisions in anticipation of the future commercial landscape.

We agree with Dr. Chalkidou that many innovations which come to the attention of regulators do not have much merit or much evidence of merit. Medical devices come to the market after establishing that they are able to do the job they claim to be able to do (analytical

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validity) but often without any evidence of clinical validity or utility. The possibility that fast followers free-ride on the research undertaken by the first to market is a disincentive to invest in evidence generation (7). There is also much uncertainty about who makes decisions about medical device adoption and the evidence that these decision-makers may require (8). These difficulties all contribute to the existence in the market of medical technologies that have no evidence of merit. It is possible for developers to provide evidence and secure recommendations from bodies such as the National Institute for Health and Care Excellence (NICE), but this can be a long and expensive process. Dr. Chalkidou refers to the MedTech Funding Mandate (MFM) and Accelerated Access Collaborative. We agree that such bodies may be useful for accelerating the diffusion of technologies that are already relatively far down the line in terms of development (for example, in 2020–21, only four technologies are to be funded by the MFM and these have all previously been approved by NICE). DF-HTA can help developers by identifying the kind of evidence that is required and signpost them to organizations such as the NIHR Medical Innovation Cooperatives (formerly Diagnostic Evidence Cooperatives) (9–11). These entities are embedded in healthcare environments and work with developers from an early stage to help them to develop an appropriate and relevant evidence base as well as engaging with clinicians and other relevant stakeholders, taking into account human factors related to the usability of the technology and how well it integrates with current working practices.

We again thank Dr. Chalkidou for taking the trouble to comment on our article and for giving us the opportunity to set out the ways in which DF-HTA, with a positive stance of analysis, can help developers to position their technology and to set prices that provide value for both the commercial developer and patients and the healthcare system as well as developing evidence that demonstrates this win–win situation.

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