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LETTER FROM THE EDITOR

Health technology assessment (HTA) addresses the economics of medical interventions but goes beyond the traditional focus of HEOR to draw upon the perspectives of a variety of other disciplines as well, including clinical medicine, population health, sociology, law, and ethics. This multi-dimensional approach is good because a strict focus on whether or not a given treatment is cost-effective according to established willingness-to-pay thresholds has the potential to lead to adoption decisions that are inconsistent with other societal objectives for health care access, financing and delivery. Different countries have different values and this is why HTA agencies around the world differ in how they balance the economics of a medical intervention against other components of the health technology assessment.

This issue of *Value & Outcomes Spotlight* highlights topics that complicate the conduct and/or interpretation of economic evaluation within HTA. The special cases in HTA described in the pages that follow challenge our usual assumptions regarding how we tally costs and benefits, or they question the norms regarding what constitutes value in health care and how we set price, or they force us to consider the particularities of different kinds of interventions beyond pharmacotherapy, or they lead to methodologic advances in data analysis in the all-important quest to eliminate bias in estimates of treatment effect. Importantly, these special cases serve to highlight the fact that economic evaluation continues to evolve, doesn't have all the answers, and shouldn't be considered in isolation of the other criteria HTA authorities utilize to inform their decisions.

The first article questions the appropriateness of including non-intervention costs in a cost-effectiveness analysis when doing so will increase substantially the intervention's ICER. It is conventional to reflect all induced changes—up or down—in net medical-care costs in the numerator of the ICER, but the ICER will rise when the intervention yields increases in net costs of care that outweigh its QALY benefits. The authors point out that this practice can unduly downgrade the potential value of a new intervention and, taking their argument to the logical extreme, describe four scenarios in which you could even set the acquisition cost of the intervention to zero and still have its ICER remain in excess of acceptable thresholds.

The second article questions the current evaluation paradigm for 'ultra-innovative' therapies for rare diseases, which are often priced at levels that preclude use of traditional cost-effectiveness thresholds. It highlights various reasons why conventional cost-effectiveness analysis adds little value to the health technology assessment and offers an alternative approach utilizing discounted cash flow accounting from business economics as a basis for value-based pricing of ultra-innovative drugs.

The third article addresses the various ways in which HTA of medical devices differs from that of pharmacotherapy, highlighting differences in HTA submission requirements and evaluation processes between NICE in the UK and IQWiG in Germany. The authors argue for the need to reconcile differences across HTA agencies so as to reduce confusion, improve submissions, and reduce uncertainty on the part of patients and providers regarding the safety and appropriateness of a given technology.

The fourth article addresses treatment switching, which is commonly permitted in oncology protocols, even in trials not involving a crossover design, as it may be unethical to deny patients randomized to placebo from opting out of the trial so that they might pursue another treatment option. This undermines estimation of overall survival, which along with progression-free survival is a common measure of treatment outcome in oncology. This article describes naïve and sophisticated approaches to handling this issue, their relative strengths and limitations, and also contrasts the viewpoints of NICE and IQWiG on the matter.

Finally, there is a contribution on the subject of HTA of molecular diagnostics from the ISPOR Medical Devices & Diagnostics Special Interest Group, along with a brief Q&A with the report's lead author.

So HTA is a major theme in this issue of *Value & Outcomes Spotlight*, though as you read on you'll find it's not the only topic of interest.

David Thompson, PhD
Editor-in-Chief, *Value & Outcomes Spotlight*

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