

the quality of personal healthcare, also one of the largest single budget items for most countries, hangs in the balance, we believe there is a need for a fuller evaluation of the results of HTA implementation. Despite over 20 years of increasingly widespread superposition of HTA onto healthcare systems around the world, little has been published concerning the effects of its implementation on healthcare budgets, delivery efficiency, or even the achievement of patient and population outcomes.

Rationalizing that a consensus of opinions should represent meaningful feedback, we surveyed influential stakeholders in healthcare administration, academia and industry across Canada's decentralized system of independent provincial and territorial public health insurance plans. To elicit objective feedback unbiased by interviewer preconceptions, we employed a panel of directed questions followed by open-ended discussion. From our disparate yet representative collective of participants emerged three key concerns.

First, a fragmented and stratified HTA system impedes timely access for patients to quality healthcare, disincentivizes industry, and introduces costly and time-consuming bureaucratic processes. The prime rationale for a jurisdictionally unique HTA system is the idiosyncratic nature of local infrastructures and economies. Although such disparities undoubtedly exist, it is also true that each local system makes procurement decisions based on essentially the same patient-level data, thus a uniform and transparent HTA process common to all should be both creatable and more efficient.

Second, the timing of HTA assessment poses challenges. Current premarket data-acquisition strategies focus on establishing clinical efficacy rather than healthcare system efficiency. Lack of efficiency data in-hand at the time of HTA may result in denial of reimbursement or even in the utilization of deficient modeling mechanisms by local HTA committees, contributing to disparate adoption decisions across jurisdictions. These in turn translate to significant yet unnecessary wastage of time and capital, stifled incremental investment in basic research and development, and damaged healthcare management. HTA 'feedback' received after marketing approval may thus be too late to permit necessary technology redevelopment or assessment of healthcare system impact. However, performing a transparent efficiency assessment

contemporaneously with the efficacy assessment should allow more efficient innovation development to take place.

Third, although the HTA process is effective at incorporating into its decision making how new products fit into the current healthcare system, HTA is less effective at considering how new treatment paradigms may redesign the system itself. In such cases, 'paradigm changing' innovative technologies could end up not being incorporated into the treatment path at all. For example, many survey participants identified a trend toward preventative point-of-care devices and at-home monitoring systems, which have the potential to greatly reduce the number of patient admissions and, therefore, reduce spending broadly across the entire healthcare systems. Existing funding silos, however, impede the adoption of such new products.

A rational proposition to address these concerns simultaneously is to consider

integrating HTA into the existing clinical efficacy regulatory paradigm overseen by the US Food and Drug Administration, the European Medicine Agency, Health Canada and their counterparts around the world. Processes to resolve transparency concerns, data requirements, maintenance of jurisdictional individuality and sovereignty and balance them against international standards and mutual recognition in healthcare innovation have all been largely developed and implemented by these institutions already, and thus could potentially be efficiently leveraged in support of HTA and its role of promoting efficient resource allocation.

COMPETING FINANCIAL INTERESTS

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The biosimilar price is right

To the Editor:

Your editorial (*Nat. Biotechnol.* 31, 267, 2013) on the recent *Blood* journal piece decrying the pricing of brand cancer drugs rightly echoed concerns about the sustainability of high-priced medicines for the patients who need them most. Your assessments of resolutions, however, had a glaring omission—you failed to identify biosimilar medicines as a key part of the solution.

Biosimilars have been available in Europe for more than seven years and have proved to be as safe and effective as their reference products. Assuming biosimilars become available in the United States, the savings will be substantial. An Express Scripts study issued the same week as the publication of the hematologists' protest showed biosimilars could save the United States >\$250 billion between 2014 and 2024. The same study showed that in Europe and Asia, biosimilar versions of medicines are saving the health system up to 40%, depending on the therapy.



The US health system is complex, but within that system generics companies have a track record of saving patients and the health system substantial money. In fact, IMS data from 2012 shows savings due to generics in the United States top a trillion dollars over the past ten years. In contrast, the high-priced medicines you mention face no biosimilar competition.

To offer choices and lower prices of these life-saving and life-changing therapies, every effort must be made to speed access for Americans to biosimilars.

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