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ISPOR's Initiative on US Value Assessment Frameworks: Seeking a role for Health Economics

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ISPOR's Special Task Force report on US Value Assessment Frameworks includes some helpful material that will contribute to the US 'value' debate [1]. It also betrays long-standing disagreements about the role of economics in resource allocation in health care. The report's recommendations are sensible and, broadly, in line with methods guidelines for economic evaluation used in countries such as the UK and Canada. However, the six previous chapters contain diverse views about the specification of economic evaluation ('value frameworks') in health care. Should it seek to define social value - its elements and how these are traded-off – and, as such, effectively determine how resources are allocated in health care? Or should economics have a more modest role: informing specific decisions in a way that reflects the objectives and constraints of those making them? This debate is long-standing in applied economics [2], but lacks clear acknowledgment by the authors. This results in inconsistencies in how the challenges of decision-making in health care are conceptualized, and hence in the prescribed characteristics of a 'value framework' and the analysis to support it.

Which decisions?

Rightly, the focus of the Task Force is defining a set of methods for economic evaluation which are appropriate to support decisions. The Task Force draws attention to the complexity of the US health care system, with its multiple sources of funders, providers and, therefore, decision makers. But the US is not unique – many systems are characterized by complexity, the absence of a single payer and private insurance with and without co-payments and deductibles; and most countries have numerous decision makers determining how available funding is allocated, which individuals benefit and, indirectly, who forgoes interventions from which they could benefit.

Economic evaluation has contributed little to supporting *patients'* decisions about, for example, choice of insurance plans or personal costs for treatments. This may explain the recent emergence of 'value frameworks' focused on the decision needs of patients in the US [3]. There is, however, an extensive body of research on decision-support tools more generally for patients [4], and further work seems warranted to incorporate financial considerations. The practical use of economic evaluation in health has concentrated on decisions regarding the allocation of collective resources drawn from private or social insurance, or taxation, and this is reflected in the Task Force's focus. However, rather than the US being exceptional in the nature and complexity of its health care decisions, its characteristics are on a spectrum, and it shares the core features and challenges of many countries in supporting its decision makers with appropriate evidence and analysis.

Which benefits?

Establishing whether the tools of economic evaluation are fit for purpose in supporting these decisions requires a number of questions to be addressed, with the Task Force's concentrating on what constitutes value. There is some inconsistency in how the term 'value' is used by the Task Force, particularly whether it incorporates opportunity costs: the benefits some individuals do not experience as the decisions of interest allocate resources elsewhere. However, the report's main theme is what *should* be considered a benefit which decision makers *should* reflect in their decisions. The emphasis on 'should' indicates that this is a normative question, the answer to which is not technical but is ultimately a value judgement. But's whose value judgement? The Task Force seems to believe economists should supply this, by asserting its own normative starting point for its deliberations: that individuals' preferences should determine benefit. It justifies this on the basis of "microeconomic principles": "value is best defined as what individuals (or others acting on their behalf) would be willing to pay to acquire more health care or other goods or services" (Section 1, p4). The Task Force also points to "the market-based US system" to support its focus on individuals' willingness to pay. However, the normative basis of resource allocation decisions and economic evaluation has long been contested, with factors such as health outcomes, wellbeing and capability, as well as the distribution of these quantities in a population [5], also being seen as central to 'value'.

What is considered to contribute to social value in health care is inevitably nuanced, as evidenced by the very fact that the US health system, like those of most countries, does not rely on individuals' willingness and ability to pay within an unregulated market to determine how resources are allocated. This is implicitly acknowledged by the Task Force in the forms of analysis it considers –

(e.g. decision makers' preferences as part of multi-criteria decision analysis (MCDA)). The report's different authors reflect the range of viewpoints on the normative underpinnings of economic evaluation that exist in the field more generally, but this is not made plain to the reader and is likely to be considered a source of confusion.

The reality is that it is not possible to specify a complete and consensual definition of social value, and this is acutely true in the area of health care. But what does this mean for the evidence and analysis developed to support decisions? Few would contest that impacting on *health outcomes* is a key source of benefit from health care interventions – without such an effect, it's difficult to see how any intervention can confer value. As such, economic evaluation needs to include a suitable measure of health that reflects its two key components – length and quality of life, provides consistency across different disease areas and reflects individuals' views about health. The quality-adjusted life-year (QALY) represents such a measure, and is rightly recommended by the Task Force. It is a well-understood and widely used measure of health, but like all outcome measures, has limitations – in effect, the QALY is a model and, as such, follows Box's adage [6] of being wrong but, nonetheless, useful. Although health outcomes may be the starting point of the value of health care, there are numerous views about how such outcomes determine benefit. For some it is through the preferences of individual recipients of care as reflected through market prices or their hypothetical willingness to pay. For others health outcomes generate different levels of benefit depending, for example, on the nature of the disease (e.g. rare, severe, high financial risk), recipient (e.g. children), intervention (e.g. innovative), or the impact on the distribution of health. Again, the challenge is not just defining sources of benefit, it's also in specifying a coherent and acceptable set of trade-offs between them.

Who resolves all this? It's not analysts – there can be no basis for their claiming any legitimacy in defining relevant benefits. In reality, this responsibility falls with the decision-maker, as the location of the stopped buck! Furthermore, they have a claim to legitimacy in the role, as they are agents of the institutions that have evolved to fund and to provide health care. Of course, there may be problems with how organizations work and how decisions are taken, and it is entirely reasonable for this to be highlighted and solutions proposed through research. Importantly, this helps to hold decision makers accountable. However, those undertaking economic evaluation need to generate evidence and analysis that reflect the objectives and constraints set for decision makers. Such analysis will rarely reflect all factors that may be deemed relevant by decision makers. Inevitably organizations have processes that are left to bridge the gap between analysis and decisions. The

extent to which these processes are deliberative, systematic or structured will vary considerably, and research to support their development should be a priority.

Opportunity costs

The concept of opportunity cost is the first concept a budding economics student learns. Despite this, it has been forgotten by many undertaking economic evaluation in health care. The Task Force discusses the concept of opportunity costs, although this is more prominent in some sections than others, but it is disappointing that no recommendation is made for further research into its quantification in the US. Empirical estimates of the magnitude of benefits that others forgo when decisions are taken to fund new technologies needs to be a key evidential support to decision making. This is regardless of the specification of benefits or whether the system has a fixed budget or more flexible sources of finance [7]. It reflects the system's marginal productivity and, therefore, informs decisions about appropriate levels of aggregate expenditure by indicating the benefit the system is currently able to generate with more or less resource. This 'supply-side' information needs to be considered alongside an assessment of how the benefits the system delivers compare with those generated by other consumption activities.

Estimates of opportunity costs also provide evidence to support 'demand-side' decisions about how to allocate resources to interventions. This is true of all systems, including those in the USA that may not have formal budgets: no system plausibly funds every intervention offering marginal benefit over standard of care for everyone, so there are always other funding options, the benefits of which represent relevant opportunity costs. Research in the UK indicates it is feasible to estimate health opportunity costs [8], and similar research is underway elsewhere and should be encouraged in the US.

The Task Force deserves credit for producing a set of recommendations that offer a sensible basis for informing decisions about the funding of new medical technologies in the US. Perhaps unknowingly, the report also provides an interesting insight into a set of divergent views about the role of evidence and analysis in informing policy. Clarity about the competing normative foundations for economic evaluation, and acceptance that economists should not be the source of judgments relating to 'value', may go some way to getting these methods more extensively used in the US.

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