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A Health Economics Approach to US Value Assessment Frameworks—Summary and Recommendations of the ISPOR Special Task Force Report [7]

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ABSTRACT

This summary section first lists key points from each of the six sections of the report, followed by six key recommendations. The Special Task Force chose to take a health economics approach to the question of whether a health plan should cover and reimburse a specific technology, beginning with the view that the conventional cost-per-quality-adjusted life-year metric has both strengths as a starting point and recognized limitations. This report calls for the development of a more comprehensive economic evaluation that could include novel elements of value (e.g., insurance value and equity) as part of either an “augmented” cost-effectiveness analysis or a multicriteria decision analysis. Given an aggregation of elements to a measure of value, consistent use of a cost-effectiveness threshold can help ensure the maximization of health gain and well-being for a given budget. These decisions can benefit from the use of deliberative processes. The six recommendations are to: 1) be explicit about decision context and perspective in value assessment

frameworks; 2) base health plan coverage and reimbursement decisions on an evaluation of the incremental costs and benefits of health care technologies as is provided by cost-effectiveness analysis; 3) develop value thresholds to serve as one important input to help guide coverage and reimbursement decisions; 4) manage budget constraints and affordability on the basis of cost-effectiveness principles; 5) test and consider using structured deliberative processes for health plan coverage and reimbursement decisions; and 6) explore and test novel elements of benefit to improve value measures that reflect the perspectives of both plan members and patients.

Keywords: augmented cost-effectiveness analysis, benefit-cost analysis, multi-criteria decision analysis, value frameworks.

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Preamble

During the course of this work of the Special Task Force (STF), we invited external input on two earlier versions of draft reports. The first draft report was sent to the STF's External Advisory Board and Stakeholder Advisory Group on May 4, 2017. In response to feedback received, we posted a revised

version to the full International Society for Pharmacoeconomics and Outcomes Research (ISPOR) membership on July 7, 2017.

These efforts resulted in many thoughtful and often detailed comments from a wide range of individuals representing diverse stakeholders, including patient organizations, payers, academic researchers, and the pharmaceutical and medical device

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industries. The STF greatly appreciates this input and the final report is much improved because of it. We begin this final section with a summary of what we heard and how we responded.

Some reviewers praised the tenor and scope of the report and recommendations. Some underlined generally the need for more emphasis on transparency and stakeholder input into value framework methods and processes.

Many reviewers offered constructive criticism. A number of them emphasized that the report should be more “patient-centric.” Specifically, they emphasized that the patient perspective and patient voice needed to be reflected in all discussions about value—for example, that value measurement should consider patients’ personal goals and preferences for different treatment options.

Some commenters highlighted the shortcomings of the quality-adjusted life-year (QALY) metric, noting that QALYs often do not capture patient preferences well and potentially discount the value of an individual’s disability. Numerous reviewers addressed the STF’s recommendation regarding the use of the cost-per-QALY metric to inform public and private decision making. Some spoke in favor of this recommendation, although others cautioned that such use could impede access to important new treatments, and, more generally, argued that any overarching STF recommendations calling for payers to apply cost-per-QALY analyses and cost-effectiveness thresholds were not consonant with the pluralistic, market-based US health system. Some pointed out the US government’s own restrictions on the use of cost-per-QALY thresholds as evidence of the metric’s limitations and public opposition.

The STF considered each comment carefully as we revised the report, mindful of the diverse membership of ISPOR and the organization’s mission to advance good methods and informed decision making in pharmacoeconomics and outcomes research. Compared with earlier drafts, the final report contains more text on the importance of patient centrality, for example. In numerous places, we qualified language in response to feedback. We recognize that given the varied opinions of ISPOR members, not everyone will be satisfied with our judgments. Inviting the external commentaries that accompany the formal publication of this effort is one further attempt to ensure that diverse views are aired. The larger conversation about value metrics will undoubtedly continue on many fronts.

This summary section presents a list of key points from each of the six sections of our report, followed by a section listing our six key recommendations [1–6]. It is important to note that this report reviewed five recent US value assessment frameworks that differ by perspective and decision context. From a health economics perspective, the primary focus of our recommendations is on US payers—private and public. Broadly, our STF recommends greater use of cost-effectiveness analysis (CEA) in their decision making in order for them to best serve the interests of the plan members and patients who they represent. We also recognize, however, that there are challenges in applying CEA as well as a need for more research on the elements of value, on their aggregation, and on how they are used in deliberative decision making.

Introduction [1]

- Concerns about rising prescription drug prices have led to initiatives in the United States designed to measure and communicate the value of pharmaceuticals.
- Organizations promulgating value assessment frameworks differ in their missions, activities, and approaches.
- This section is based on the premise that value-based resource allocation decisions—about drugs and other health care

technologies—should consider the full costs and benefits of decisions to relevant stakeholders and the decision contexts they face.

- We define “value” from an economic perspective in two related, but distinct senses: “gross value” is what individuals (or others acting on their behalf) would be willing to pay to acquire more health care or other goods or services. This has to be compared with the “opportunity cost” in terms of what benefits or other resources they are willing to forgo to obtain them. The difference between the two is the “net value.”
- Rewarding health care technology manufacturers on the basis of value is important because it sends signals to them that can influence research and development and ultimately innovation.
- Health economists have long recommended that analysts seeking to inform resource allocation decisions approximate an intervention’s value in terms of incremental cost per QALYs gained (or the similar disability-adjusted life-year used commonly in global health evaluations).
- QALYs may not always fully capture the health (or well-being) of patients, or incorporate individual or community preferences about the weight to be given to health gain—for example, about disease severity, equity of access, or unmet need.

An Overview of Value, Perspective, and Decision Context [2]

- Because individuals vary in terms of their preferences for health care versus other goods, partly because of varying incomes, and in terms of their preferences for different health outcomes (e.g., survival vs. quality of life), for any specific health care technology, there will be a distribution of valuations in a population.
- Insurers—both private and public—act as agents on behalf of their enrollees who are potential patients by obtaining or providing access to health care technologies.
- Given that most medical care is purchased indirectly via health insurance, individuals do not directly face prices, and their agents (insurers and providers) acting on their behalf must assess value.
- CEA, by relating an intervention’s cost to its effectiveness (in terms of some change in health) in a ratio, is thus a standard approach to measuring the net value of a health care intervention.
- Existing guidelines for CEA emphasize the importance of clearly specifying the perspective from which the analysis is undertaken. Relevant perspectives may include, among others: 1) the typical health plan enrollee, 2) the patient, 3) the health plan manager, 4) the provider, 5) the technology manufacturer, 6) the specialty society, 7) government regulators, or 8) society as a whole. A valid and informative CEA could be conducted from the perspective of any of these stakeholders, depending on the purpose of the analysis.
- The five recent value frameworks that motivated this STF vary in the decisions that are being informed by the valuation, ranging from coverage, access, and pricing to defining appropriate clinical pathways, and to supporting provider-clinician shared decision making.
- This economic concept of value does not depend on whether value is being measured within a market-based or a single-payer health care system. Health economics and outcomes researchers generally measure value using the tool of CEA with the QALY as the health gain measure.
- Information about value is, however, used differently in different types of health care systems and by different stakeholders in different decision contexts.

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