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EDITORIALS

Creating Models That Meet Decision Makers' Needs: A US Payer Perspective

The ISPOR-SMDM Modeling Good Research Practices Task Force Report in this issue is a welcome update to the previous ISPOR guidance published in 2003 [1]. In the past decade, cost-effectiveness analysis has proliferated and its use in coverage and pricing decisions by governmental authorities has spread across much of Europe and elsewhere [2]. Modeling methodology has evolved in ways that should improve its usefulness, but despite these enhancements, significant challenges to adoption by US payers remain. The Task Force members have identified several challenges and suggested ways to address barriers to the acceptance of economic models as decision support tools. To do this, it will be necessary to gain a better understanding of the decision support needs of payers.

Caro and colleagues [3] observed that models reduce complex realities to a set of essential elements. Given the complexity of disease, the interpatient variability, and the diversity of health care systems and processes, reducing medical reality and identifying the elements that are essential to a particular health care decision is a daunting task. Creating a useful simulation of a medical decision will always require a great deal of simplification. The Task Force report first addresses identifying the principal determinants of decision outcomes. Decision analysis is most needed when we are least certain how to proceed and probably cannot identify all the relevant elements or understand all the relationships between them. Selecting the best model structure and limiting the number of inputs to reduce complexity to a manageable level may require subjective judgment, upon which stakeholders may disagree. To achieve understanding among stakeholders, a minimum threshold of agreement must be reached.

The first step in the logical process outlined by the Task Force is conceptualization [3]. It is unlikely that a useful model will result without careful thought and planning at its inception. Before drug manufacturers appreciated this, they often left outcomes model planning until after the pivotal trials, only to find that necessary inputs to the model could not be obtained from trial results. Consultation with pharmacoeconomists and decision makers earlier in the product development process can prevent this impasse, but it requires a paradigm shift from trial designs driven by regulatory requirements to trials that support a convincing value proposition.

Models must be grounded in clinical reality as experienced by the decision makers who will use them, and model structure must reflect that reality. This involves a trade-off between clarity and complexity. The model should be detailed enough to credibly simulate reality but simple enough to be understood by clinicians with minimal training in economics or decision analysis. This is best achieved by working with end users and incorporating their feedback in successive iterations of the model, a process that requires commitment by both parties. To be helpful, end users must learn enough about models to offer valid criticism, but they need not become pharmacoeconomists. Decision analysts must understand key clinical aspects of the decision problem, but nonclinicians can do this with the help of clinical experts. Decision makers can identify the perspectives, time horizons, comparators, settings, and target populations that will be most useful to them.

Traditional audiences for decision models have been clinicians, payers, and policymakers, but the US government's new program of Patient-Centered Outcomes Research [4] suggests a future role for patient perspective models as well. Patient-Centered Outcomes Research views the patient as decision maker and principal consumer of decision support information. As more patients accept this role, model builders may be asked to present their evidence in ways that facilitate shared decision making. We should learn to communicate model results in ways that are credible, meaningful, and actionable for nonprofessionals.

The last article in this series addresses transparency and validation [5]. This is the other point where thoughtful dialogue with decision makers can be useful. Transparency requires both technical and nontechnical model documentation. Most end users will probably want the nontechnical version, but if they have or can consult technical expertise, they will need a detailed methodologic description. The validation process should be transparently described. Clinicians usually focus on reviewing the input data sources and assumptions, clinical credibility of the decision tree, and other aspects about which they are most knowledgeable and may engage a pharmacoeconomist for technical validation. If the methodology includes specific intellectual property, a nondisclosure agreement is appropriate.

Many of these concerns about economic models apply to retrospective observational studies as well. Payers expect manufacturers to design studies with a subtle bias in favor of their product, and there is reason for this concern [6]. Because ISPOR is also participating in the Comparative Effectiveness Research Collaborative Initiative, the work groups in that project should examine the modeling task force reports for common ground. Central to payer acceptance of both study types is methodologic rigor and transparency, along with tools for the evaluation of the studies that create a reasonably level playing field on which the evidence can be presented and assessed.

Since our plenary session panel discussion on ways to improve the value of modeling to payers and providers was held at the ISPOR Annual International Meeting in May 2010, the dialogue between drug manufacturers' health outcomes departments and payers has improved both qualitatively and quantitatively. We hope that this trend continues and produces pharmacoeconomic models that are more useful to decision makers.

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John B. Watkins, PharmD, MPH, BCPS
Premera Blue Cross—Pharmacy Services, Montlake Terrace, WA, USA

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