VALUE IN HEALTH 17 (2014) 3–4

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Improving the Usefulness of Budget Impact Analyses: A U.S. Payer Perspective

The report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force [1] updates the previous guidance published in 2007 [2]. We review many budget impact analyses (BIAs) in our practice and find them to be of widely varying quality; thus, we hope that this report will improve overall value and consistency of the models we receive.

Clinical validity, transparency, and flexibility are the most important user requirements. Models based on unrealistic clinical assumptions or clinical care pathways bearing little resemblance to those in the user's setting have little or no value. The report gives particular attention to emerging markets, reflecting the growth of ISPOR membership in these countries. This growing diversity of user settings makes flexibility even more imperative.

The updated guidance reflects methodologic advancements made since the last report. The clarity and specificity of the new recommendations set expectations that, if followed, will improve the ability of model developers to meet today's needs. BIA is usually designed for budget holders but may be applied by others, such as health systems and policymakers. Hereafter, we refer to these parties collectively as users.

Information from BIAs complements cost-effectiveness analysis. With increasingly tight budgets, payers face difficult decisions when evaluating expensive new technologies. Cost-effectiveness of the new technology may set spending priorities, but coverage decisions require an estimate of the resulting expenditures and potential cost offsets. Budget holders need both tools to accurately predict the clinical and financial impact of formulary listing and coverage decisions and manage the health of their populations. In the United States, actuaries need this information to calculate the following year's insurance premiums.

The analytic framework section is clearer and more detailed than its predecessor. Key points include: 1) flexible user inputs to adapt to setting and perspective, 2) transparency and simplicity, 3) estimating target populations, 4) predicting changes in intervention mix with introduction of the new treatment, and 5) estimating cost offsets. This guidance should be followed closely to produce more meaningful models for users.

The report's discussion of data and data sources offers key recommendations to both BIA creators and users. Data must be relevant to and ideally drawn from the user's population. If local data are unavailable, they can be estimated through the use of credible sources clearly referenced and readily accessible to the user. Relevant cost data should be decomposed and presented in a manner that the user can readily compare to costs actually incurred by their population. Summarized or "rolled-up" treatment costs are insufficient for this purpose and should cause the user to question the transparency of the BIA. Furthermore, for a model to reflect the actual financial flows of private sector health systems, the users must be able to enter actual costs into the models. This means that the model developers should leave behind a working copy of the model.

Modeling reports should clearly and succinctly describe methods, epidemiology, disease burden, and clinical impact. An interactive, easily understood version of the model should be provided by using common spreadsheet software, rather than requiring the user to purchase special software. Graphs and figures facilitate user understanding and support presentation of the results by the user to others. Tornado diagrams are very useful to identify key model drivers, and so users can focus on accurate estimation of these inputs. We recommend that users reject any BIA lacking such documentation because such omissions directly call into question the overall transparency and validity of the model.

The task force recommends that model developers not model off-label use of the new product routinely but provide this additional analysis on user request; however, they agree that budget models are descriptive rather than normative. Inclusion of off-label use should not be construed as advocating it, because the models merely depict existing practice patterns without judging appropriateness. We encourage users to request it routinely because off-label use is to be expected in most cases. A model that does not include it is unlikely to reflect the user's setting realistically. For this reason, the Academy of Managed Care Pharmacy's *Format for Formulary Submissions* includes a specific request for "significant off-label uses and potential new indications being studied" [3].

It cannot be overemphasized that the usefulness of an economic model to a user is limited by the accuracy with which it represents the realities of clinical practice in that user's setting. Common threats to validity include unrealistic assumptions about clinical care pathways, frequency of certain diagnostic tests, and patient adherence outside of controlled trials. Models based on unrealistic clinical assumptions have little or no value to us.

With these caveats in mind, we believe that following the guidance provided by the task force will meaningfully improve the validity, transparency, and flexibility of BIAs provided to payers and other users in an increasing variety of different settings.

Source of financial support: The authors have no other financial relationships to disclose.

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1098-3015/$36.00 – see front matter

http://dx.doi.org/10.1016/j.jval.2013.09.007

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