
DRAFT
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Introduction

Definition and Intended Use

Budget impact analyses (BIA) are an essential part of a comprehensive economic assessment of a health-care intervention and are increasingly required by reimbursement authorities, along with cost-effectiveness analysis (CEA), before a listing or reimbursement decision. The impact on a particular budget, that is, the difference in health care expenditures with and without reimbursement or listing of the new intervention, is a commonly used measure of forecasting the fiscal impact of a new health care intervention. A BIA also can be used for budget planning and resource management.

Although BIA and CEA use similar data, their focus is very different. CEA evaluates the economic efficiency, in terms of the health outcomes and associated costs, of alternative interventions, for a population over the time period during which changes attributable to the interventions occur. BIA addresses the expected changes in expenditures for a health care system, for each period of interest after adoption of the new intervention. Because the BIAs are specific to the budget holder and oftentimes used for payer and developer price negotiation, they are less likely to be published as a peer-reviewed paper.

Users of BIAs include those who manage and plan health-care budgets, such as administrators of national or regional health care programs, of private health insurance plans, and of health-care delivery organizations, or employers who pay directly for health care. Each has a need for clearly presented information on the budget impact of the adoption and diffusion of new health care interventions. They may differ, however, in their requirements for particular time horizons and for the categories of costs in which they are interested.

History of BIA

Mauskopf et al., published an analytic framework for budget impact modeling in 1998 [Mauskopf, et al; 1998]. Others have stressed the need to include budget impact as part of comprehensive economic evaluation [refs]. Starting in the 1990s, most regions in the world including Australia, North America, Europe (England and Wales, Spain, Belgium, France, Hungary, Italy, Poland), South America (Brazil, Columbia), Asia (South Korea, Taiwan, Thailand) and the Middle East (Israel), have included a request for BIA, when submitting evidence to support national or local formulary approval or reimbursement. Country-specific guidelines for constructing BIAs are also available [refs]. These guidelines vary in terms of defining what constitutes a BIA and most of them provide limited details on the important factors in a BIA. An exception are the Polish guidelines [ref], which provide precise recommendations on perspective, time horizon, reliability of data sources, reporting of results, rates of adoption of new therapies, probability of redeploying resources, inclusion of off-label use, and uncertainty.
A recent search in the MEDLINE database covering the period 2008-2012 showed that 88 budget impact analyses have been published in peer-reviewed journals. Some of these publications present cost studies that focus on the annual, 2- to 3-year or lifetime costs for a specific cohort of people or a representative individual being started on alternative interventions. However, many published studies estimate explicitly the budget and health-care service impact of a new intervention for a well-defined national or health plan population for the first year after introduction of the new intervention [refs]. Some include results of both the CEA and BIA in the same publication [refs].

**Task Force Process**

This Task Force Report represents an update of the Task Force Report on Budget Impact Analysis that was published in 2007 [Mauskopf et al, 2007]. The update was needed, in part, because of developments in budget impact modeling methods as well as a growing interest, particularly in emerging markets, in matters related to affordability and population health impacts of health care interventions. The updated Task Force Report includes updated recommendations on the design of the budget impact model and appropriate data sources and reporting of the results in line with the needs of health-care decision makers. Specific issues that are addressed in this updated report include: 1) incorporation of adherence and persistence into a budget impact analysis; 2) prediction of changes in treatment mix after adoption of a new health care intervention; 3) representation of uncertainty; 4) estimation of changes in other disease-related costs; 5) whether and how to coordinate the structure and inputs for the CEA and BIA; 6) whether to estimate health care benefits as well as costs; and 7) how best to present the results in a format useful for the decision maker.

The co-chairs of the ISPOR Task Force on Good Research Practices – Budget Impact Analysis - Updated, Josephine A. Mauskopf and Sean D. Sullivan were appointed in 2012 by the ISPOR Board of Directors. The members of the Task Force were invited by the co-chairs to participate with advice and consent from the ISPOR Board of Directors. Individual members of the Task Force are experienced as developers or users of budget impact models. Since the purpose of this report was to produce guidance on the preparation of BIAs that meet the information needs of health-care decision makers globally, most of the individuals on the Task Force represent or advise Payers and Health Technology Assessment agencies in North America, Europe, Latin America, and Asia. The document also draws from the methods used in the growing literature and web-based BIAs that are in the public domain. However, it is not intended as a comprehensive review of the literature.

A primary review group of ISPOR members experienced in developing and communicating budget impact analyses was identified. Comments were sought from them before wider circulation for review.
Task Force held an organizational meeting at the ISPOR 17th Annual International Meeting in Washington, DC and held an open forum at the ISPOR 18th Annual International Meeting in New Orleans, LA.

Before preparing the first draft of the updated report, a targeted search of recent publications of BIAs was performed to evaluate the methods being used in BIAs appearing in peer-reviewed journals. The costing templates produced by the UK National Institute of Health and Clinical Excellence (NICE) and the Taiwan HTA body were reviewed and the methods used to complete these BIAs evaluated. Published national and local guidelines were also collected and used as reference documents. The Task Force held telephone conference calls and used electronic mail to exchange outlines and ideas during subsequent months. Sections of the revised report were then prepared by subgroups of the Task Force members and a draft of the complete report was then prepared by the co-chairs and circulated to the Task Force for review. A telephone conference call followed by a face-to-face meeting of the Task Force was held to discuss the draft and make revisions. Following review by the primary reviewers, a new draft was prepared by the Task Force members and made accessible for broader review by all ISPOR members. This final report reflects the input from both primary and “all-ISPOR member” reviewers.

Purposes of the Document

The purpose of this report is: 1) to present an updated set of coherent guidelines for those developing or reviewing budget impact analyses; and 2) to present an updated format for presenting the results of budget impact analyses that is useful for decision makers.

The intended audience for this report are: (1) research analysts who perform budget impact analyses, (2) technology developers responsible for undertaking BIAs and (3) health-care decision makers who are responsible for local, regional or national budgets. Others who may find this document useful include members of the press, patient advocacy groups, health care professionals, and those developing BIA guidelines for their settings.

The panel recognizes that the methods for performing and reporting budget impact analyses continue to develop. This report highlights areas of consensus as well as areas where continued methodological development is needed. The guidance is divided into three main sections: 1) analytic framework; 2) inputs and data sources; and 3) reporting format.

Recommendations for Analytic Framework

Introduction to Analytic Framework
A BIA is a means of synthesizing available knowledge at the time of a coverage decision to estimate a medical technology’s likely financial consequences for a health plan or health care system. Given the highly local nature of health plans and the varying perspectives of health care decision makers, a BIA cannot produce a base case estimate of an intervention’s budget consequences that apply to all decision makers. Instead, the aim of a BIA is to provide a valid computing framework (a “model”) that allows users to apply input values pertinent to their setting to compute the possible financial and organizational consequences of coverage decisions for a new health care intervention (or a change in usage of current interventions). Thus, the outcomes of the BIA should reflect scenarios that consist of a set of specific assumptions and data inputs of interest to the decision maker rather than a scientifically chosen “base” or “reference” case based on assumptions and inputs intended to be generally applicable.

This section presents the Task Force recommendations for the developers of BIAs for the key elements of the analytic framework for BIA. It addresses these for a freestanding BIA but comments are provided for the situation where a companion economic evaluation (“cost-effectiveness”) model exists. Proper design of the analytic framework is a crucial step in BIA. The design must take into account the relevant features of the health care system to be addressed, the coverage scenarios contemplated, estimates of the uptake of the new intervention and evidence regarding the use and effects of current interventions. In particular, changes likely to be prompted by a coverage decision (e.g. broadening of the population to be treated, disinvestment in existing interventions, etc) must be taken into account. These guidelines cannot address the details of design of the analytic framework, but rather highlight the key aspects to consider during the design and make recommendations on choosing a modeling framework. It is important that whatever choices are made, they be clear, justified, and with the goal of preparing the simplest design that will meet the needs of the analysis.

Aspects important for the design of the analytic framework include:

- Features of the health care system,
- Perspective,
- Time horizon,
- Coverage restrictions,
- Treated population size and characteristics,
- Alternative treatment scenarios,
Impact of use of the new intervention on condition-related outcomes, and

Discounting.

These design aspects can then be integrated to determine the appropriate analytic framework with which to generate and assess the budget impact estimates:

- Choice of analytic framework,
- Uncertainty and scenario analyses, and
- Validation.

Recommendations for creating a coherent and valid analytic framework based on a consideration of each of the design elements are described below.

Features of the health care system

The features of the health care systems that should be considered are those that influence the budget and might be directly or indirectly affected by the coverage decision. For example, in some systems, a readmission within thirty days of discharge from hospital is not paid for and thus a change in that rate will not affect the budget from the payer’s perspective. From the hospital’s perspective, however, that readmission will represent an unreimbursed expense and its avoidance would have a significant impact on the hospital or provider budget. In designing the analytic framework, the analyst should consider the factors that potential users of the model will seem important and incorporate these in such a way that they can be excluded or adjusted as needed for a particular analysis.

Perspective

Budget impact analyses are primarily intended to inform health-care decision-makers, especially those who are responsible for national, regional, or local health-care budgets. Therefore, the recommended perspective is that of the budget holder. A BIA needs to be flexible enough to generate estimates that include various combinations of health care, social service and other costs, depending on the audience. Thus, drawing of budget boundaries depends on the perspective and is highly localized. For example, in one location the pharmacy budget holder will only be concerned with the expenses for drugs, but in another, this may be subsumed within a total hospital or regional budget. Thus, the perspective of a given budget holder may cover very different elements. While it is important for the analyst to address the needs of the selected budget holders, the Task Force recommends that the analytic framework be designed to be able to encompass broader or narrower budgetary envelopes. In this way, the analysis will not only be able to show
the decision makers what they need to see, but also can: 1) extend beyond that to provide a more comprehensive view of the fuller economic implications of the intervention; and/or 2) step back from the broader economic implications to provide a view of the impact of the intervention on different budget holders (e.g. those responsible for the drug budget).

Time horizon

Budget impact analyses should be presented for the time horizons of most relevance to the budget holder. They should accord with the budgeting process of the health system of interest, which is usually annual. The recommended time horizon for a BIA is 3 to 5 years with the annual results presented for each year after the new intervention is included in the treatment mix. The framework should allow, however, for calculating shorter and longer time horizons to provide more complete information of the budgetary consequences. In any case, results should be available disaggregated over time in periods appropriate to the budget holder (e.g., monthly, quarterly, annual, etc.). Hence, to be most useful, the output must be the period-by-period level of expenses and savings rather than a single cumulative estimate over the full time horizon of the analysis.

A particularly useful extension of the time horizon that might be considered for a chronic health condition is to reflect the impact that might be expected when a steady state would be achieved if no further changes in treatment are assumed. This will vary with the condition and with the impact of the new intervention, but will generally be longer than the budget period because of costs and benefits that accrue over time. Although time horizons that go beyond a few years are subject to considerable assumptions, they may be required to capture the offsetting disease cost savings from the intervention; for example, interventions for chronic hepatitis B or C that prevent complications such as liver cirrhosis or cancer than occur many years in the future.

Coverage Restrictions

Coverage restrictions for new technologies vary widely across systems. In a few, the only possibilities are to cover fully or not to cover at all; but in most health care systems, there are many more options, including administrative and clinical hurdles to meet, restrictions on for whom and under what conditions the technology is reimbursed, and so on. To properly address the budget impact for a particular stakeholder, these features need to be incorporated in the framework in such a way that they can be customized to the local context. This is important not only for the new intervention but also for existing ones, particularly if coverage restrictions are likely to change for all interventions.

Treated Population Size and Characteristics
The population to be included in a BIA should be all patients who might be given the new intervention during the time horizon of interest based on the coverage restrictions for each health plan. Definition of the target population begins by estimating the size of the population covered by all the locally approved indication for the new technology. It then needs to further reflect any local planned restrictions on use or reimbursement. Other factors that can influence the size of the population include the possible beyond-restriction use (leakage), induced demand (i.e., the proportion of previously untreated patients who now seek treatment because of improved outcomes, greater convenience, or fewer side effects) and changes in patterns of use compared to existing treatments (change in adherence and persistence). For example, a new intervention that has fewer side-effects may make it attractive to treat patients with milder disease who previously went untreated because of an unfavorable risk-benefit ratio; for example people with HIV infection are now treated earlier in their disease because side-effect profiles for antiretroviral drugs have improved (DHHS, 2012).

In a budget impact analysis, the unit of analysis is the prevalent population who are indicated for treatment with the new intervention. Typically, the target populations are open in the sense that individuals enter or leave the indicated population depending on whether they currently meet the analyst’s criteria for inclusion (e.g., by developing the indication, meeting the intended restrictions, no longer having symptoms, dying etc.). A BIA does not track individuals and, if the entering and leaving populations are in a steady state, the size and nature of the prevalent population might not change over time. However, if the new intervention increases time on treatment, slows disease progression, or reduces mortality rates without curing the condition, the size and nature of the prevalent population might change over time. For example, if one of the criteria defining the target population is disease with moderate severity, patients with mild disease who are not part of the target population at the beginning of analysis may enter the target population when their disease progresses to moderate while those starting with moderate disease might leave the target population when their disease progresses to severe or they die. If the new treatment changes the size of the populations entering or leaving treatment during the budget impact model time horizon, the analytic framework should account for the impact of this change on the size of the treated population.

The analytic framework should allow for subgroups of the population to be considered so that budget impact information can be adjusted to reflect the mix of subgroups in a specific health plan or national population. Subgroups defined by disease severity or stage, co-morbidities, age, sex, and other characteristics that might affect access to the new intervention, or its impact on the budget, should be considered since their representation may vary across health plans or national populations. This may also inform decisions regarding use of the new intervention as a “first line” intervention or reserving it for use in
patients failing other alternatives. The choice of subgroups must be founded on available clinical and other evidence from epidemiological studies and local knowledge.

**Alternative Treatment Scenarios**

Budget impact analyses generally compare scenarios defined by a set of interventions rather than specific individual interventions. The starting scenario should be the current mix of interventions for the population and subgroups for which the new intervention is indicated. The current mix may include no intervention as well as interventions or combination of interventions that might or might not be replaced by the new one. It may also include use of off-label interventions as long as they are currently being used in the indicated population. The existing intervention mix must be well characterized and the analytic framework should allow for the variations that are likely to be encountered. These include the specific interventions to be considered, their usage (prevalent) and cost-relevant details of how they are used (e.g., monitoring, titration, use only on site, etc.). Any changes expected in the current intervention mix should be considered.

Uptake of the new intervention is, by definition, not known at the time of analysis and neither is the impact on the current treatment mix. Whether the framework should be limited to very simple rates over fixed periods of time (e.g., annual) or should consider more complex functions where uptake depends on other factors (e.g., the coverage details themselves) and is non-linear over time, depends heavily on the context of the analysis and should be influenced by information on similar interventions, if possible.

Introduction of a new intervention sets in motion various marketplace dynamics, including product substitution and possibly market expansion. Uptake of the new intervention, and its impact on the current treatment mix are core components of the BIA. Unfortunately, in most cases, there may be little data on this while the results of the BIA may be very sensitive to alternative assumptions. From the point of view of designing the analytic framework, it is important that it allow users to readily test the impact of alternative assumptions about uptake and impact on current treatment. Three types of change in the use of the current interventions should be included in the model: the new intervention replaces one or more current ones (substitution); the new intervention is added to existing interventions (combination); the new intervention is used as a treatment either where there is currently no active treatment (only supportive care), or in patients who have stopped treatment or would not use available treatments due to intolerance, inconvenience, loss of effect or any other reasons (expansion). These three types of change could apply to different subgroups of patients according to their clinical status and local features of the healthcare system and the distribution of changes can itself vary over time; that is, the changes do not happen instantaneously when the new product hits the market. Forecasts of these changes over time constitute an important component of the new scenarios.
The types of change have different implications for the budget holder. In the case of substitution, the expenses for the new intervention could be offset to some extent by reduced use of the older intervention(s). The offset should consider not only the cost of the interventions displaced but also the costs of any associated aspects such as laboratory testing, management of side-effects, and so on. Where the use of the new intervention is in combination new expenses would be incurred, resulting in increased budget impact. There may also be additional costs due to changes in the side-effect profile of the combinations or new requirements for monitoring. For example, the direct thrombin inhibitors for blood thinning do not require the frequent monitoring tests that are mandated with warfarin (Goel & Srivathsan, 2012). Use of these drugs will reduce the need for the services that have been developed to deliver that monitoring.

Market expansion also introduces new intervention costs but there may also be offsetting savings due to reductions in the expense of managing patients who previously went untreated.

These scenarios need to be modeled explicitly, with realistic and justifiable assumptions about the degree and type of changes, to enable comparisons among scenarios. The analysis should be transparent regarding the assumptions made about the current mix of interventions and the changes expected as the new intervention is added to the mix. The budget impact analytic framework should be designed to allow alternative assumptions regarding the scenarios to be compared. This is a type of structural uncertainty analysis that is of particular importance when estimating budget impact.

Off-label use of the new intervention may also occur in those who are not indicated for treatment with the new intervention. However, since there are typically no clinical data on the effectiveness and safety of such off-label use and the extent of such use is difficult to justify, the Task Force does not recommend inclusion of off-label use for the new intervention in the primary BIA. However, if the substitution of current treatments by the new intervention in an off-label situation cannot be completely ruled out (e.g., some oncology conditions) and if the health-care decision makers are concerned about the budget impact from such use, the Task Force recommends designing the budget impact model to allow inclusion of off-label use of the new intervention as an alternative analysis.

Impact of Use of New Intervention on Condition-Related Outcomes

In addition to estimating the cost associated with current and new interventions, the budget impact model should include estimates of the changes in condition-related costs. The efficacy of the new intervention in the condition for which it is indicated compared to the efficacy of current interventions may have a significant impact on the costs associated with treating that condition either through increasing the treated population size or decreasing the disease severity mix, as described above or in reductions in condition-related costs for each health state or event. The estimation of changes in condition-related costs is important to attain a reasonable level of accuracy in the budget impact estimates.
Although the changes in condition-related costs might not be relevant for all health-care decision makers, the Task Force recommends that they be included in the analysis using the best available data. The model should be designed so that the budget impact can be viewed with or without the changes in condition-specific costs. Depending on the perspective of the health-care decision maker, some (e.g. drug-related costs only) or all of the changes in condition-related costs will need to be included in the budget impact estimates. Thus, the analytic framework should be designed to allow for the user to select the condition-related cost elements that they wish to be included in the budget impact estimates.

The Task Force considered the issue of cost impacts of new interventions that occur beyond the time horizon of the budget impact analysis. These include additional condition-related costs that might be incurred when the new intervention results in additional survival without cure or when long-term complications associated with the condition are reduced. In most cases these costs are not relevant in the short time horizon of the budget impact analysis but could be important in the recommended steady state analysis for chronic diseases. On the issue of whether or not to include future costs unrelated to the condition of interest that might be incurred when life expectancy is increased, the Task Force proposes that the analyst should use her/his best judgment, given local payer requirements and perspectives for the particular condition. For example, for HIV infection, typically all health care costs are included in both cost-effectiveness and budget impact analyses, though they may be reported separately as HIV-related or non-HIV related costs.

The impact of the new intervention on productivity and other resource use outside the health-care system should not routinely be included in a BIA as these are generally not relevant to the budget holder. One exception may be when BIA is intended to inform the decision making of private health insurers or employers. Such organizations may have a vested interest in maintaining a healthy and productive workforce and, thus, they may be able to offset productivity gains against increased health-care service use. Another exception may be health-care systems relying on tax payments where lost production due to morbidity could have important implications for the funding for the national health system.

**Discounting**

As the BIA presents financial streams over time, the Task Force recommends that the budget impacts be presented as undiscounted costs. The computational framework should be constructed so that the decision-maker can readily apply a discount rate to the results according to local practice back to a decision time point if they wish to do so.

**Choice of modeling framework**
As stated earlier, the aim of a budget impact analysis is to provide a valid computing framework (a “model”) that allows users to apply input values pertinent to their setting to compute the possible financial and organizational consequences of coverage decisions for a new health care intervention. Thus this computing framework should be programmed to take into account all the design features that are likely to impact the budget impact of a new intervention that have been described above.

There are two main condition-specific modeling frameworks for budget impact analyses that have been used by HTA agencies and/or in published studies for BIA:

1. A set of simple calculations of the budget impacts and condition-specific outcomes performed, generally, in an Excel spreadsheet, by multiplying estimates of the size of the treated population (either assumed constant or changes during the model time horizon with the new intervention approximated) by the change in average per patient treatment and condition-related costs. Examples of budget impact analyses using the simple impact-calculator approach are the costing templates produced by NICE after making their reimbursement recommendations (accessible at www.nice.org.uk) and in published studies (e.g., Chang and Sung, 2005; Danese et al., 2008; Dee et al., 2012; Smith et al., 2005).

2. Markov (or state transition) or simulation condition-specific models where the computational frameworks are similar to cost-effectiveness condition-specific models but run with population inflows and outflows rather than with a single cohort to generate budget impact estimates for treated populations (e.g. Mauskopf 2000; Mar et al., 2008; Purmonen et al., 2010; Marchetti et al., 2004; Martin et al., 2010; Caro et al., 2006; Mar et al., 2010; Mauskopf et al., 2012). In these models, the condition-specific model is more complex than that using the impact-calculator approach to reflect more completely the changes in treatment population size and disease severity mix and resulting budget impacts and health outcomes that might occur after the introduction of the new intervention.

The Task Force recommends that the impact-calculator approach be used where possible. This is because such an approach is more transparent and generally requires less programming than Markov or simulation model and is more readily understood by decision makers. The impact-calculator approach should be used for acute illnesses, as well as for chronic illness where changes in the treated population size and disease severity mix or treatment patterns (1) do not occur, (2) occur very rapidly and can readily be approximated, or (3) occur beyond the time horizon of the budget-impact analysis. In instances where the changes in treated population size and disease severity mix and/or treatment patterns cannot be credibly captured in an impact-calculator, a Markov or simulation modeling approach is recommended.

A Markov or simulation modeling approach may also be desirable when an integrated cost-effectiveness and budget-impact model is desired for a chronic disease. The advantage of this integrated
approach is that it ensures that the input parameter values and assumptions needed for both will be consistent and it shares most of the same programming elements. However, care needs to be taken to ensure that the budget-impact estimates are generated for the prevalent treated population rather than for the single disease cohort that is typically used for cost-effectiveness analysis. This can be accomplished by adapting the disease progression model used for the cost-effectiveness estimates to allow for new disease cohorts to be added and to leave the model each year. In addition, the CE model program needs to be adapted to allow the budget-impact estimates to be generated through a comparison of a mix of current and future treatments rather than a simple comparison of all patients treated with either a current treatment or a new treatment, as is typically seen in a cost-effectiveness analysis.

**Uncertainty and Scenario Analyses**

The question of how to reflect the uncertainty in the inputs to a budget-impact analysis is also important. There are several different types of uncertainty that can be present in the model inputs, stochastic uncertainty about the estimates of the efficacy of the new and current interventions, heterogeneity in patient characteristics and current treatment patterns in different health care settings, and both parameter uncertainty and heterogeneity in the changes in expected treatment patterns with the availability of the new intervention. Because these analyses are aimed to help health care decision makers estimate the budget impact on the population for which the decision makers have responsibility, the Task Force recommends that budget-impact analysis models are programmed to include both: 1) one-way uncertainty analyses, using ranges of both stochastic uncertainty in efficacy inputs, parameter uncertainty in the impact of the new intervention on treatment patterns, and heterogeneity in patient characteristics and current and future treatment patterns (e.g., NICE costing templates), 2) and plausible scenario analyses where several of these input parameter values may be changed to produce scenarios that more closely match the health care decision maker’s population and estimates of the impacts of the new intervention. The use of probabilistic uncertainty analysis is not recommended for BIA because uncertainty about the results is more readily demonstrated through one-way deterministic and scenario analyses because of the importance of plan or system-specific differences in patient characteristics and treatment patterns and because of the large uncertainty about the impact of the new intervention on the current treatment mix. However, it can be included if considered of value by the decision makers.

**Validation (heading level 2)**

Like all models, those used for BIA must be valid enough to provide credible information to the decision maker. There are four key steps for validation of a budget impact model: 1) determine face validity through agreement on the model structure and default input parameter values by relevant decision makers before programming the model; 2) quality-check the program code including all formulae; 3) validate selected outcomes from the model by comparison with observed published data; and 4) validate with health
plan decision makers the results produced by the budget impact model for the current treatment mix after adjusting the input parameter values and perspective to reflect their plan characteristics and information needs (see Eddy et al., 2012 for more a more detailed approach to model validation).
Recommendations for Inputs and Data Sources

Introduction to Inputs and Data Sources

A BIA relies on either a condition-specific impact calculator using a simple set of calculations or a more complex condition-specific model to provide the health-care decision maker with a tool to estimate the impact on their budgets of a new intervention over a specified time horizon when approved as a possible treatment for a particular condition. As with any framework or model, the usefulness of the result depends critically on the quality of the input data used for either model including the accuracy of the estimates of how the new intervention will be used and the impact that it will have on population size and severity mix, treatment patterns and patient outcomes. In this section the Task Force recommends possible data sources for deriving the inputs for each of the elements of a BIA.

To provide credible estimates of the budget impact, input data should be obtained from the best available sources and these need to be clearly identified, justified and referenced along with any assumptions, calculations or transformations made from the original data. The input data should be measured from the perspective of the decision maker or budget holder and reflect transaction prices rather than either opportunity costs or manufacturer’s list prices or published estimates of wholesale acquisition costs or list prices.

Data used in a BIM may be obtained from a broad variety of sources, including:

- Published literature, epidemiological surveys, registries, health plan databases for epidemiological information (including incidence, prevalence, disease natural history)
- Product labels or published literature or submissions to health technology assessment (HTA) agencies for pharmacovigilence or safety-related information
- Clinical guidelines for information about treatment pathways, clinical outcomes, and resources used (including for administration, monitoring and treatment of side effects or complications) for the alternative interventions evaluated
- Clinical studies or claims databases for clinical outcomes and associated resource use for all alternative interventions
- Administrative or claims databases, patient registries, ad hoc surveys, market information, standard costing sources and HTA agency submissions for cost and resource use information.

Justification of default data sources selected should be provided, and the methodology for identification should be included (e.g., process to identify, select and use the data included in the analysis). Different default data might need to be provided for different types of decision makers. In addition, the model should
be designed so that the decision maker can readily change the default data for selected parameters to match their health plan costs, population characteristics and treatment patterns.

Data sources must be appropriate to address the study question, and their reliability must be specified based on the quality of the data source and the applicability to the particular decision maker. For example, data from a clinical trial may not be relevant for the whole population indicated for treatment or data from one country may not be applicable for a different country. Preferred data sources will depend on the condition evaluated and data availability, but inputs should be based on evidence to the extent possible. Where data are not available or are only available for different populations, expert opinion, possibly using Delphi techniques to reach consensus, could be used to help inform the assumptions and estimate parameter values. In this case extensive uncertainty analysis should be conducted around the parameter values.

As for other types of evaluation of new health-care interventions an evidence hierarchy can be applied for budget impact analyses. When selecting each input parameter value, the following evidence hierarchy should be used:

- Real-life data from the decision-maker database at their level of decision (hospital, region, state, etc)
- Data from clinical trials adapted or extrapolated to the health plan population
- Data extrapolated from the national population (official and updated data),
- Data from international sources, preferably those with similar populations and practice patterns

For each of these data sources a second evidence hierarchy should be applied as follows:

- Published, peer-reviewed sources
- Unpublished, or not peer-reviewed sources
- Market research data only to evaluate distribution of use of intervention alternatives and trends in treatment patterns
- Expert opinion either using a Delphi approach or from individual experts

There are five key elements requiring data inputs to populate the analytic framework of a BIA:

- Size and characteristics of affected population with and without the new intervention;
- Intervention mix with and without the new intervention;
- Costs of current and new intervention mix;
- Use and cost of other condition-related health-care services; and
- Ranges and alternative values for sensitivity and scenario analyses
These five elements can be combined to calculate the budget impact of changing the intervention mix. Apart from efficacy and safety, which are generally assumed to be the same across all jurisdictions, the inputs are local to the health plan or system for which the budget impact is being evaluated. For many health plans or health systems, the required data may not exist or may be difficult to obtain. Nevertheless, analyses should be as evidence-based as possible, with expert opinion only used where alternative sources of data are not readily available. If expert opinion is used, care should be taken to frame the questions and choose the experts in ways that generate reliable and locally applicable information. For example, the experts should be asked for responses only to questions that they should know the answer to (e.g., how often do you schedule follow-up visits for a certain type of patient). The available data sources for each input parameter value should be used to provide both base case estimates as well as a range of estimated input values.

Size and Characteristics of the Population (level 2 heading)

The estimated sizes of the indicated and/or reimbursed population and of the relevant subgroups over time are critical for a determination of the budget impact. The ideal way to obtain this estimate would be from epidemiological and treatment pattern data on the decision-maker’s own population before and after the introduction of the new intervention. As these data are not usually available even for the current interventions, various alternative methods can be used to provide estimates for a BIA.

One approach is to obtain directly from providers their estimates of the number and characteristics of people in their setting who would be part of the indicated and/or reimbursed population based on their current and anticipated new treatment patterns.

Another approach is to employ national epidemiological data on incidence, prevalence, and disease natural history (if available), including expected changes over the budget impact model time horizon, and either apply them directly to the health plan or health system population or adapt them if the characteristics of the health plan or health system population differ from the national population. For example, to estimate the number of people with HIV infection in a regional health plan, national prevalence estimates may not be appropriate if the proportion of high-risk individuals covered by the regional health plan differs markedly from that in the national data. Also, if the incidence or prevalence of the disease differs by patient characteristics (e.g., sex, age, race, etc.), calculations required to determine the size of the indicated population should be presented (for example, see Danese et al. Clinical Therapeutics. 2008; 30 (4): 775-784).

Once the number of people with the condition of interest has been estimated using incidence or prevalence data, the proportion of these people who are diagnosed and treated and the mix of disease
severity within this population must be estimated. This generally involves the application of successively
more restrictive inclusion criteria to estimate the number of people eligible for treatment with the new
intervention including estimates of the proportion of those with the condition who have been diagnosed and
are currently being treated and the proportion of those currently being treated who are indicated for the new
intervention; for example those with the appropriate level of disease severity or those who have previously
failed specific treatments or those with moderate or severe disease symptoms. Figure 1 provides an
example of such a set of filters that was applied to the health plan or health system population to derive the
indicated population for a new intervention for refractory overactive bladder in Spain (Arlandis et al., 2011).

[Figure 1 – a population “funnel” under development]

If changes in the population size and/or disease severity mix are anticipated over the time horizon of
the model because of improved efficacy with the new intervention, these need to be accounted for in the
budget impact analysis. Examples of such changes in the population size and/or disease severity mix
because of improved efficacy include increased life expectancy for those with end-stage cancer, decreased
disease severity because of increased CD4 cell counts for those with HIV infection, and lower episode
frequency and/or severity for those with migraine or epilepsy.

Using the impact-calculator approach, if changes in population size are small and occur very quickly,
the old and new treated population sizes can be estimated for the before and steady state after adding the
new intervention. Thus: multiply the annual incidence by average duration on treatment with the current
intervention mix to obtain the size of the current prevalent treated population; and multiply the annual
incidence rate by the average duration on treatment with the new intervention mix to obtain the size of the
new prevalent treated population. Changes in the mix of disease severity in the prevalent treated population
that occur very quickly can also be approximated using the impact-calculator approach based on the
outcomes from the clinical trial data. An example using the impact-calculator approach to estimate the
impact of treatment for multiple sclerosis on disease severity measured using relapse rate is given in Dee
and colleagues (2012). For those situations where changes in population size or disease severity mix occur
more slowly and longer time horizons are being included in the budget impact analysis using a Markov or
simulation model, changes in the size and/or severity mix of the indicated population can be derived using
the Markov or simulation model run using an open population rather than a single cohort as described in
Section x.x above. Good examples of estimating changes in population size and disease severity mix over
time using Markov models are described by Mauskopf (2000b) and Mar and colleagues (2008).

One important consideration for a chronic condition that can greatly influence the budget impact of a
new intervention over the first few years after it is introduced is whether or not there will be a catch-up effect
or whether only those newly entering the indicated population will be eligible for treatment for the new
intervention. For example, if a new drug is indicated for those who have previously failed a specified therapy for a chronic condition, there are two possible population subgroups to be considered: first, those who have just failed the specified therapy and are choosing a switch therapy; and second, those who failed the specified therapy one or more years ago and have already switched either to best supportive care or to another therapy that may be less effective than the new drug. If all or a proportion of the second population subgroup switch to the new drug when it becomes available, the immediate budget impact of reimbursing the new drug will be a lot higher than if only those newly indicated for the new drug switch to the new drug. Also, the disease severity mix of the population switching to the new drug is likely to be different in these two populations. When using a simple impact-calculator approach for a chronic disease, the estimated market uptake and the assumed disease severity mix in the population taking the new treatment will need to be adjusted to reflect alternative patterns of uptake of the new drug. Similarly, when using a Markov or simulation model, the market share and pattern of uptake of the new drug can be captured by the choice of cohorts assumed to start treatment with the new drug each year in the model time horizon.

Regardless of the method used, it is important for a BIA to estimate not only the starting size of the population and disease severity mix but also the way that these input parameters are likely to change over the model time horizon with and without the new intervention when such changes are likely to occur.

**Current and New Intervention Mixes**

For the population indicated for treatment for the new intervention or for subgroups for whom reimbursement is provided, it is necessary to identify the interventions used currently and estimate the proportion of patients using them, or proportion of episodes in which they are used. These may include no active treatment as well as drugs (on- or off-label), devices, surgical or other modes of treatment. Sometimes the use of these different therapies (drugs, surgical processes, implantable devices) has specific rates that might vary in different health plans or health systems, so this rate must be stated in the tables describing the intervention mix (an example of that might be seen at Arlandis et al. Value in Health 2011; 14(4): 219-228).

Some people may receive combination treatment with more than one of the current interventions. This should be recorded separately in the current mix table. Although labeled “current,” the mix may evolve over time even in the absence of the new intervention and the program should be designed so that this can be taken into account in the budget impact calculations. An example would be if one of the current treatments is scheduled to go off patent within the budget impact model time horizon, with an expectation that its share of the treatment mix will increase when patent protection is lost. If there are many current interventions but only a few of them are commonly used, the current intervention mix can be restricted to
those in common use but with placeholders spaces included in the model for the user to enter other interventions that are likely to be impacted by the new intervention in their health plan.

The best data source for the current intervention mix for the different population subgroups is the decision-makers' own database. If these data are not available, then published information on current treatment patterns, such as the results of primary or secondary data studies or medical textbooks or review articles, can be used. In addition to these data sources, market research data or expert opinion on current and evolving treatment patterns may be used. Regarding medical devices, data from national registries should be used where available (e.g., national joint replacement registries from countries like Sweden, UK, Denmark, and Australia).

The new intervention mix depends on the rate of uptake of the new intervention, as well as the extent to which it replaces current interventions or is added to them or added to symptomatic care in the indicated population. The rate of uptake is likely to change over time as physicians and patients become familiar with a new intervention. There are several ways to estimate the new intervention mix. One way is to use the producer's estimates of market share over the first few years after launch if these data are made available. An assumption must then be made as to whether the new intervention will be given in addition to current interventions or whether it will substitute for some or all of the current interventions. For example, a new intervention might reduce the use of a subset of the currently used interventions equi-proportionately (e.g., all drugs in a particular class) or it might be added to all of the current interventions. The assumptions should be transparent and the model programmed so that the budget impact of alternative assumptions about the new intervention mix can be calculated. Other ways of estimating the new intervention mix involve extrapolating previous experience on product diffusion with the same intervention in other settings or with similar interventions in the budget holder's setting.

Cost of Current and New Intervention Mix

The cost of the current intervention mix involves multiplying the decision-makers’ costs associated with each intervention by the number of people who receive each one. These costs should include the decision makers’ acquisition cost of the product, administration or implantation or other procedure costs, and costs for monitoring the treatment over the relevant time horizon. For drugs, generally wholesale acquisition costs (in the United States [US]) or national formulary costs (in countries with national health systems) should be used as the default values, although the analysis should be designed so that discounts, deductibles and co-payments can be subtracted from these costs to capture the actual payment by the decision maker. For devices, wholesale or health system negotiated prices should be used; for procedures and educational interventions, standard labor costs should be used. Administration and monitoring costs
can be estimated by applying standard unit health care costs to health care services needed based on products labels or publications describing the administration and monitoring requirements.

Costs of managing any side effects or complications should also be included in the cost of the current intervention mix as a separate line item. These costs can be derived from the adverse event rates in product labels or publications for all interventions in the treatment mix and published studies of costs for each adverse event. If published studies of the costs are not available, treatment algorithms can be developed in consultation with physicians who treat the condition of interest.

The BIA should address the impact of compliance and persistence with therapy on the cost of treatments. This must take into account whether the payer bears the cost anyway (e.g., even if poorly compliant, the patient still picks up the prescription). The assumptions regarding compliance rates and persistence with treatment should be based on the best available evidence, which may come from database studies or prospective studies. If patients do not fill all the recommended prescriptions, then the cost of treatment should be reduced accordingly.

Costing of the new intervention mix follows the same process as for the current mix except that for interventions not yet on the market, the acquisition cost may have to be assumed if it is not yet set or is not publically available. In this case, the Task Force recommends that the assumed intervention acquisition cost be transparent and justified. If the new intervention requires extra resources (e.g., a diagnostic test to identify pharmacogenetic targets), the costs of the extra resources should be included in the BIA. In addition, the cost for administration and monitoring and treating side effects for the new intervention should be estimated based on the clinical trial data and label statements on administration and monitoring.

**Use and Cost of Other Condition-Related Health-Care Services**

Although the health outcomes associated with different interventions are not generally presented as part of a BIA, the Task Force recommends that, if credible data are available, they should be estimated and used to estimate the changes in the cost of treating the health condition of interest. Alternative intervention mixes are likely to result in changes in the symptoms, disease duration, disease outcomes, or disease-progression rates associated with the health condition and, thus, in changes in the use of condition-related health-care services. These changes will have an impact on the health plan budget and should be presented as a separate line-item in the budget impact analysis. The steps required for estimating changes in condition-specific costs include: identifying the resource use that may change, estimating the amount of change, and valuation of these changes. In a BIA, identification must be done according to the perspective and interest of the budget holder. Moreover, the resource use considered should be that which is relevant to the health condition over the chosen time horizon.
If an impact calculator approach is being used, to compute these changes in health outcomes and associated use of health care and other resources over the time horizon of the BIA the Task Force recommends using data directly from the clinical studies for the new intervention where available. For example, for the NICE costing template for prasugrel (www.nice.org.uk), they included in the budget impact estimates, estimates of the cost savings from fewer re-hospitalizations for those treated with prasugrel compared to clopidogrel in the year after the acute coronary syndrome requiring percutaneous coronary intervention. These estimates were derived using hospitalization data from a large head-to-head trial of the two drugs (Wiviott et al., 2007). In other examples of impact-calculator budget impact models, published budget impact models for atopic dermatitis or eczema (Chang and Sung, 2005) or for heart failure (Smith et al., 2005) estimated the costs savings from reduced physician visits (Chang & Sung, 2005) or hospital stays (Smith et al., 2005) due to better efficacy than the control treatment based on Phase III clinical trial data. Where data on the comparative efficacy of different interventions are not available from clinical trials, the results of indirect comparison analyses, now frequently performed to include in the cost-effectiveness modeling, may be used to determine weighted average clinical outcomes with the current and new treatment mix.

If a Markov or simulation model is being used to generate the budget impact estimates, the proportion of the treated population in each health state can be generated by the model for each year with and without the introduction of the new intervention into the treatment mix, by modeling disease progression in the initial cohort as well as allowing new disease cohorts to be added and to leave the treated population each year for all the interventions included in the budget impact analysis. The transition or event rates for the model should be the same as those used in the cost-effectiveness model, and are generally derived from the clinical trial data or from mixed treatment comparison analyses. The symptom-related resources for the treated population in each health state or experiencing each event each year in the models may be estimated either using clinical trial data or from a variety of different observational databases including administrative databases, prospective cohort studies and registries. If none of these data sources are available, treatment algorithms for each health state or event may be developed in consultation with physicians who regularly treat patients with the condition of interest.

Once the changes expected in health care and other resource use have been estimated for the budget model time horizon, unit costs should be applied to convert them into costs that will impact the decision makers' budget. In general, changes in resource use should be valued the way the budget holder values these resources. It is the transaction prices that are relevant, including any discounts, rebates or other modifiers that may apply. If transaction prices are not available, cost accounting approaches can be used to estimate the unit costs. In some cases, the intervention alters resource use (e.g. hospital days or physician visits) and, thus, the capacity of the system, but this may have no direct monetary consequence.
for the budget holder because the system will not adjust financially within the model time horizon (e.g., personnel may not be redeployed or let go). It may still be desirable to describe this impact on health services because it has implications for health system planning but there might be no impact on the budget in the short term.

If the impact of adherence or persistence has been accounted for in the cost of the current and new intervention mixes, the BIA must also estimate the impact of adherence or persistence on treatment effectiveness and safety. If there are no published data on the relationship between compliance and health outcomes, then either pharmacokinetic or pharmacodynamic data or expert opinions are possible alternative data sources. Figure 2 presents a hypothetical example of the relationship between adherence and effectiveness that was generated using expert opinion. These estimates can be used in the impact-calculator or Markov or simulation budget impact models.

![Figure 2: Adherence and effectiveness. Notes: The relationship between effectiveness and adherence may be estimated based on observed data or expert opinion or pharmacokinetic and pharmacodynamic data. The relationship in this figure is based on expert opinion: Effectiveness Relative to Trial Data = Adherence rate (AR) if AR ≤ 30% Effectiveness Relative to Trial Data = 1 - exp [-5 * (AR - 0.2287)] if AR > 30.](image)

The Task Force recommends that for people who discontinue from therapy, the default assumption should be that they cease to obtain any residual efficacy unless there are clinical study data indicating residual efficacy over some time period. For example, residual efficacy is generally assumed for women who do not persist with bisphosphonate therapy for osteoporosis or osteopenia (Boonen et al., 2012).

**Ranges and Alternative Values for Uncertainty and Scenario Analyses**

A BIA includes many parameters (e.g., annual population growth, efficacy and safety of current interventions and the new intervention, intervention uptake rates, intervention substitution effects, changes in prescription restrictions, future distribution of the available treatment options, unit costs for the interventions and other health care resources) whose actual values are not known precisely, but are
expected to vary within a range that reflects their uncertainty. Uncertainty analyses assess the effects of these parameter uncertainties on the calculated results. All the uncertainty ranges to be analyzed in the analyses should be based on plausible estimates regarding the inputs and assumptions—a task that should be done collaboratively with the decision makers because they are best placed to make many of the assumptions and to supply data for the ranges of input parameter values. Default ranges can be obtained from a review of published studies or from consultation with physicians who treat patients with the condition of interest. Use of arbitrary ranges such as plus or minus 20% or 50% is not recommended since likelihood of observing these ranges may vary among the input parameters and so the results of such an analysis may not reflect the ranges of results likely to be observed in the health plan or health system.

Budget impact analyses also include many parameters that vary among decision makers, but whose values are known with certainty by each decision maker. These include the population age and gender distribution in the health plan or health system, the health plan or system treatment patterns, the disease incidence and prevalence in the health plan or health system, and drug and other resource costs. The results of the budget impact analysis may be more sensitive to changes in these values than in changes in the values of the uncertain parameter values. For publications or for system-wide budget impact analyses, plausible scenarios for the values of the input parameters likely to be known with certainty by a decision maker should be included in the sensitivity analysis along with the uncertainty analysis. When presenting the model results directly to the decision makers, they should be asked to enter their values for the input parameters known with certainty before the model is run and only the sensitivity of the results to uncertain input parameter estimates shown.

**Recommendations for Reporting Format**

This section presents a recommended reporting format for BIAs. The format presented below should be understood as a guide for the preferred reporting format of any study or report regarding BIA and it is informed by several published guidelines reviewed by the task force (REFERENCES). The intent is to promote transparency in the conduct and reporting of budget impact analyses.

**Report Introduction**

The introduction of a BIA report should contain summaries of the relevant epidemiological, clinical, and economic information.

*Epidemiology and management of health problem.* The introduction should present relevant aspects of the prevalence and incidence of the particular disease as well as information on disease severity, disease progression, undiagnosed or undertreated cases, and risk factors pertinent to estimating the budget impact.
Clinical impact. The clinical information should consist of a brief description of the target population, disease progression, and existing management options, all of which are relevant to the design of the BIA study.

Economic impact. The economic impact information should include any previous related studies on the condition of interest and associated health interventions, for example, previous BIAs in the condition of interest for another intervention, treatment patterns, and cost-of-care studies.

Intervention

This section should contain a detailed description of the characteristics of the new intervention compared with the current interventions: indication, onset of action, length of action or half-life, efficacy, side effects, serious adverse events, intermediate outcomes, and adherence. A summary of the clinical trials should be given, including information on the design, study population, follow-up period, and clinical outcomes.

Objectives

The objective of the BIA should be clearly stated. This will be tied to the perspective(s).

Study Design and Methods

The report should specify the design of the BIA, which will usually involve a modeling study. The following characteristics of the model should be described and the sources identified.

Patient population. This paragraph should clearly specify the target population. If there are differences, the authors should identify and justify differences between the clinical trial populations and the BIA target population.

Intervention mix. The existing intervention mix and comparators with and without the new intervention should be discussed and justified. The existing intervention mix is based on the local treatment patterns and clinical guidelines and this choice should be supported.

Time horizon. The time horizon(s) for the study should be presented and its choice justified based on decision maker preference.

Perspective. This paragraph should clearly identify the perspective(s) from which the study is performed, the costing that was done and the target audience (i.e., for which decision-making body the study is intended). To be flexible enough to address variations required by the budget holder and other stakeholders with whom the budget holder must interact, disaggregation of the various cost components should be presented.
Model description. This section should contain a complete description of the structure of the BIA model, including a graphical representation of the model, such as a flow diagram, when possible. The description should allow the reader to identify outcomes for all treated patients during the study period.

Input data. The values used for all inputs for all the scenarios analyzed should be presented in the report. The level of detail should be such that the reader could replicate all the calculations in the model.

Data sources. The sources of model inputs should be described in detail. The strengths, weaknesses, and possible sources of bias that may be inherent in these should be described. Selection criteria for studies and databases should be discussed and an indication given of the potential direction and magnitude of bias in the data.

Data collection. The methods and processes for primary data collection (e.g., for a Delphi panel) and data abstraction (e.g., for a database) should be described and explained. The data collection forms which were used in the study should be included in the appendix of the report (e.g., the questionnaire for the Delphi panel, or the abstraction protocol for the database).

Analyses. A description of the methods used to perform budget impact analyses should be provided. The choice of all of the scenarios presented in the results should be documented and justified.

Uncertainty. Uncertainty analysis methods should be described and justified.

Results

The budget impact should be presented for each period over the time horizon. Both period resource use and costs should be presented. The estimates of resource use should be listed in a table (if possible classified by intervention use, intervention side effects, and condition related) which shows the change in use for each period of the time horizon. Another table should show the aggregated and disaggregated (e.g., pharmacy, physician visit, outpatient tests, inpatient care, and home care) costs over time after applying costing information to the resource use. In general, budget impact estimates should be presented as a range of values, based on alternative plausible decision-maker informed scenarios rather than a single point estimate.

Annual health outcomes that have a direct influence on the budget impact should be reported. This promotes transparency to the decision-makers when a large budget impact is accompanied by large health benefits.

The results of the scenarios (sets of assumptions and inputs and outcomes) analyzed should be described. These scenarios may consist of optimistic, pessimistic, and most likely input values determined
from the sensitivity analysis of the key variables from the perspective of the decision-maker. We recommend that the results of all uncertainty analyses be presented as a Tornado diagram.

**Conclusions and Limitations**

State the main conclusions strictly backed by the study results. Report the main limitations regarding key issues such as design aspects, completeness and quality of data inputs and sources, and analysis of uncertainty.

**Inclusion of Graphics and Tables**

Graphical snapshots of the model’s structure and data can be useful in summarizing for the user, who may wish to copy them for inclusion in their own internal reporting. Use of the following tools is recommended:

**Figure of the model.** A graphical representation of the model structure makes it easier for the budget holder to understand what is represented by the outputs. Flow diagrams, such as the Figure below, are recommended to be included with the model description.

**Table of assumptions.** Listing the major assumptions in tabular form can improve the transparency of the model, particularly to the relatively inexperienced user and should be included with the model description.
Tables of inputs and outputs. Similarly, collecting the model inputs and their data sources and outputs in tables provides a useful snapshot for the user and should be included with the text on input data and data sources.

Schematic representation of sensitivity analysis. Analysts should be encouraged to use diagrams (such as Tornado diagrams which show graphically the impact on the budget impact of feasible ranges of each input parameter) as a simple way of capturing the key drivers of the model and presenting them to the user and should be included along with the text on the results of the scenario analyses.

Appendices and References

The enclosure of relevant appendices to reports is encouraged. The appendices may cover the intermediate results (e.g., of individual Delphi panel rounds), study audit reports and the names and addresses of participating experts and investigators.

Reporting Budget Impact Alongside Cost-Effectiveness Analyses

Analysts are now publishing in a single study report the design, methods and findings from jointly conducted cost-effectiveness and budget impact analyses. Though interrelated, these study designs may require different structural considerations and parameter estimates. They frequently take different perspectives and use different time horizons. It is the view of this Task Force, that every effort should be made to fully report on all elements of both analyses, using appropriate reporting formats. If the journal or dissemination vehicle has space restrictions, then we encourage the analysts to prepare and publish separate supplementary material in sufficient detail so that the analyses can be replicated.

Budget Impact Computer Model

Because BIAs need to be flexible enough to provide estimates for different health-care decision-makers, it is critical that the software used to perform the calculations is designed with both default input values and the capability for the users to enter values that they feel better represent their own particular situation. The model should be programmed so that the user can restore the original default parameters easily. The model should be programmed as easy-to-use spreadsheets in a common, easily accessible software platform. For example, all input parameters would be presented on one input worksheet and outputs displayed in one or more worksheets in a logical manner that summarizes the findings for the user. Graphical output is often useful in the model. Introductory worksheets should be included to describe the structure, assumptions, and use of the model. All sources and assumptions associated with input parameters should be displayed with the parameters themselves and full references should be included on a reference worksheet. The model calculations should be accessible to the user and clearly and comprehensively presented.
In some cases, the budget holder may be interested in modeling from more than one perspective. In such cases, model developers are encouraged to design the user interface so that the user can toggle between the different perspectives easily. The user should be able to change easily any of the input parameters. Color coding the input cells is a useful way of doing this. Changing the inputs allows the user to test various input scenarios. It may be useful to provide sample scenarios.

Finally, we recommend that the model be programmed so that the user can readily perform uncertainty analyses of relevance to their population.

Concluding Statement

BIA is important, along with CEA, as part of a comprehensive economic evaluation of a new health intervention. We update the ISPOR guidance for creating budget impact models, the acquisition and use of data to make budgetary projections, and a common reporting format that will promote standardization and transparency. Adherence to these proposed good research practice principles would not necessarily supersede jurisdiction-specific budget impact guidelines, but may support and enhance local recommendations or serve as a starting point for payers wishing to promulgate methodology guidelines.

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REFERENCES


