Budget Impact Analysis

Pattara Leelahavarong BSc, MSc*

** Health Intervention and Technology Assessment Program, Ministry of Pubic Health, Nonthaburi, Thailand*

A budget impact analysis (BIA) is used to assess whether the adoption of a new health technology is affordable, given the resource and budget constraints of the context. Increasingly, BIAs are coming to be viewed as an important-if not essential-part of health technology assessment (HTA). BIA data is often examined in conjunction with cost-effectiveness analysis (CEA) data to help inform decisions makers when developing reimbursement policies within the resource constraints of their health care system. This article presents a review of existing BIA guidelines from around the world and makes some initial recommendations for the development of Thai BIA guidelines, as part of the newly-developed Economic Evaluation guidelines for Thailand. Initial recommendations include guidelines on appropriate analytic framework design, study design, perspective, scenarios for comparison, target population, costing and resource use, uncertainty analysis, and discounting.

Keywords: *Budget impact analysis, Economic evaluation, Thailand*

J Med Assoc Thai 2014; 97 (Suppl. 5): S65-S71
Full text. e-Journal: *http://www.jmatonline.com*

A budget impact analysis (BIA) is used to assess whether the adoption of a new health technology is affordable, given the resource and budget constraints of the context. Increasingly, BIAs are coming to be viewed as an important-if not essential-part of health technology assessment (HTA). BIA data are often examined in conjunction with cost-effectiveness analysis (CEA) data to help inform decision-makers when developing reimbursement policies within the resource constraints of their health care system[1]. BIAs serve three main functions: 1) to estimate the financial consequences for a specified population of implementing a new health intervention or technology, 2) to provide data on the affordability of new health-care technologies at a given price for a specified population, prior to reimbursement, and 3) to serve as a budget or service planning tool that policy decision-makers can use to inform their allocation of resources once reimbursement of a given technology has been confirmed[2]. Most HTAs will include both an economic evaluation and a BIA, the results of which should comprise the same data set and should be analyzed together as complementary findings[1,3,4]. However, the two tools do differ in some key ways (Table 1), and their findings may sometimes conflict (for instance, where the economic evaluation indicates a technology does offer value for money but the BIA shows high budget impact). There is, unfortunately, no current scientific guidance on how to resolve these kinds of conflict[1].

Correspondence to:
Leelahavarong P, Health Intervention and Technology Assessment Program, Ministry of Public Health, 6th Floor, 6th Building, Department of Health, Ministry of Public Health, Tiwanon Road, Nonthaburi 11000, Thailand.
Phone: 0-2590-4549, Fax: 0-2590-4369
E-mail: pattara.l@hitap.net

Budget impact analytic framework

Fig. 1 shows an example BIA framework, which is adapted from the BIA framework developed by the International Society for Pharmaco-economics and Outcome Research (ISPOR) Task Force on Good Research Practices[1]. The framework enables a comparison to be made between the treatment and condition status quo and the new situation that would result from the adoption of a new intervention. The BIA examines the impact of this adoption on the healthcare system by assessing its impact on a number of key factors (i.e. disease incidence, diagnosis and treatment, resource used, and costs). Finally, the total costs of each scenario are calculated and compared so that the budget impact of the adoption of the new technology can be estimated.

Six key inputs are required to construct the BIA modelling framework[1,3,5,6]: 1) the size and characteristics of the affected population, 2) the current intervention mix, 3) the cost of the current intervention mix, 4) the proposed intervention mix, which will include the intervention under consideration, 5) the cost of the new intervention mix, which will include the intervention under consideration, and 6) the use and cost of other health treatment-related health-care services or

Table 1. Comparison of economic evaluation and budget impact analysis[1,2,4]

Detail	Budget impact analysis	Economic evaluation
Underlying concept	- Affordability	- Value for money
Objective	- Financial impact of introducing a technology	- Economic efficiency of alternative technologies
Study timeframe	- As manager of the convenience (usually 1-5 years)	- Preferably lifetime
Health outcomes	- Excluded	- Included (e.g. quality-adjusted life years)
Perspective	- Budget holder/Manager	- Society/Third payers/other
Comparison	- Scenarios in which they can design the degree of incorporation of the new technology in population with a mixture of utilization	- Specific technologies: a new technology will be used throughout cohort intervention
Study population	- Open cohort: individuals can be included or excluded alongtime, considering rate incorporation of technology,incidence of disease indications and treatment effect of the new treatment on survival	- Close cohort: cohort of individuals defined a priori
Discounting	- Not recommended	- Highly recommended
Presenting result	- Total and incremental annual costs	- Incremental cost per unit of health outcome achieved
Generalisation of results	- Inadequate: budget impact studies are designed to specific circumstances	- Possible, with limitations

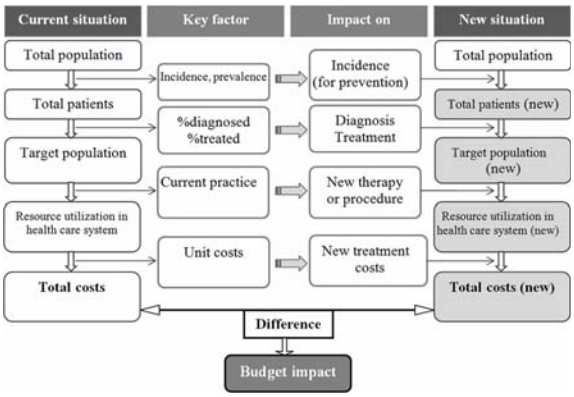

Fig. 1 BIA framework. Adapted from International Society for Pharmacoeconomics and Outcome Research (ISPOR) Task Force on Good Research Practices[1].

treatment-related health care services.

All key data for the BIA should be country-specific, including target population data, epidemiological data, data on resource use and unit costs, and data on which therapies, if any, are likely to be replaced by the new intervention[3]. Other data need not necessarily be country-specific, including data on the influence of the new intervention on mortality, progression, prevalence of disease, and side effects. All relevant data should be researched, appraised, and presented according to the principles and methods of evidence-based medicine and systematic review.

Review of published BIA guidelines

The first analytic framework for BIA was published in 1998[7]. Since then, a number of country-specific guidelines have specifically recommended that a budget impact analysis be included in any health technology economic evaluation where the findings will be used to inform national or local formulary approval or reimbursement decisions[7-12]. To date, most BIA guidance has aimed at providing recommendations to ensure that policy-makers and those responsible for health care insurance budgets are provided with standardized, reliable, and good quality information. Until now, specific guidance on appropriate BIA methodologies, implementation, and good practice have largely been lacking. This article reviews existing methodological guidelines on a series of issues that should be considered by all who are involved in BIA development[1-4,6,8,13,14].

Study design

All existing guidelines recommend that a BIA should use the same input parameters, economic

models, and model assumptions as the economic evaluation, so that the results of both analyses can be examined together. Moreover, there is widespread agreement that all BIAs should also take into account the type of health condition (i.e. whether it is chronic or acute) before deciding upon an appropriate analytical approach (i.e. whether it is prevalence-based, incidence-based, or both) and type of intervention (i.e. whether it is preventive, curative, palliative, one-time, ongoing, or periodic). Decision modeling (e.g. Markov models and decision trees) are recommended instruments for use in BIAs, as they offer high levels of transparency and allow the model calculation formulae, model parameters, and findings of the analysis to easily be reviewed by other researchers.

Perspective

The primary objective of a BIA is to assess the affordability of incorporating a new technology within the existing health care insurance context. As a result, the budget holder perspective (whether within a national healthcare system, managed care organization, social insurance institution, or hospital context) is the perspective recommended by almost all BIA guidelines.

Scenarios to be compared

There is widespread agreement among existing guidelines that all scenarios that the BIA compares should be based on the reimbursement packages and mixed treatment interventions that would be implemented in reality for the target population. When making budgetary comparisons in BIAs, the new technology should only be analysed within the appropriate mixed treatment scenario; that is, the budget should be assessed in terms of total intervention budget, rather than an examination of the technology in isolation. Thus, the analysis should consider how the current mix of interventions is likely to change when the new intervention is made available[1]. This kind of analysis is different to that adopted by economic evaluations, which compare specific technologies on an individual basis, rather than examining how their adoption might change the current mixed treatment scenario(s). The existing guidelines make the following recommendations on the methods and data sources that should be used to generate these mixed treatment scenarios[1,2,4,6,8]:

1) Current technologies mixed treatment scenario: In many treatment programs, a number of treatment regimens are prescribed for patients with the same condition. As such, the proportion of patients undergoing each treatment needs to be estimated, and the resource use and costing values adjusted accordingly, before inclusion in the BIA. In addition, additional costs related to current treatments, such as those associated with managing side effects, related administrative costs, and costs associated with related procedures, should be calculated and included in the BIA. Consideration might also be made of any price discounts offered by the pharmaceutical reimbursement package and patient contribution charge.

Recommended data source: National reimbursement databases/health insurance databases

2) New technologies mixed treatment scenario: The precise mix of the new technology's treatment mix will depend on the rate of uptake of the new technology as well as the extent to which it will either replace or complement current technologies[1]. Moreover, the rate of uptake is likely to change over time, as physicians and patients become familiar with new technology.

Recommended data source: Producer estimates of market share

Where producer estimates of market share are not available, an extrapolated estimate of market share based on product diffusion data from either the same technology in a different setting or a similar technology in the budget-holder's setting could be used.

Target population

Deciding on an appropriate target population size is a very important part of any BIA, as this can significantly affect the results of analysis. A number of data sources can be used to inform the decision, including epidemiology of disease data, the proportion of patients who are covered by health insurance, and the accessibility of health care services (usually given as a percentage of the total number of patients who are covered by health insurance). These factors should all be taken into account in the comparative analysis, with appropriate estimates made for the new technology treatment mix scenario. Some BIA guidelines recommend that no off-label use should be included in the dataset[1], while other guidelines recommended they should be included, even though off-label use is not included in reimbursement packages[6]. Other guidelines suggest instead that off-label use should be included in the uncertainty analysis[3]. Table 2 shows the parameters and data sources that can be used to estimate target population size in a BIA. It also illustrates how the size can change over time, and how this too should be included, through open cohort analysis[13].

Table 2. Parameters and data sources that can be used to estimate target population size in a BIA[9,13]

Parameter	Data sources (ranked by the level of valid evidence)
Prevalence and incidence (Total number of patients)	1. published country-specific literature, or 2. international epidemiology data may also be used, where validated by a Delphi panel of national clinical and epidemiology experts
Proportion of patients eligible and accessible for treatment with the current technology	1. relevant national registry databases, or 2. published literature, e.g. a previous BIA for medications with similar indications, or 3. estimated from Delphi panel of national clinical experts
Proportion of patients eligible for treatment with the new technology	1. publishedcountry-specific literature, e.g. a previous BIA for medications with similar indication, or 2. registered patients for the new technology, but it might be restricted prescription by reimbursement authorities, or 3. estimated from Delphi panel of national clinical experts
Proportion of eligible patients actually treated with the new technology	1. estimated from Delphi panel of national clinical experts
Other input parameters: 1) the annual growth in utilization of the new technology over the time horizon of the BIA 2) the changes in treatment patterns or guidelines and off-label used 3) the treatment sequencing	1. estimated from Delphi panel of national clinical experts

Time horizon

Budget impact analyses should be presented within time horizons that are most relevant to the budget holder[1]. BIAs are typically concerned with costs over short time horizons (e.g. 1-5 years)[2-4,14]; however, the general rule is that the time horizon should be able to capture the period within which meaningful differences between the costs and outcomes of competing technologies become apparent. This period will vary according to the conditions under which the intervention is to be introduced, and sometimes according to the predicted impact of the new intervention[1]. However, generally, it will be longer than the current budget period because of the costs and benefits that accrue over time. In any case, results that can be disaggregated should be available over time within a period that is deemed appropriate by the budget holder[1,8].

Costing and resource utilization

When BIA guidelines recommend adopting the budget holder's perspective, the model should take into account the resources used and the costs incurred, including all direct medical care costs and all other costs that exert an impact on the budget or health care system. The charge levied for the new technology should be based on its value according to the benefit package-not its market price. The ISPOR Task Force's guidelines[1] suggest that impacts on areas outside the health-care system-such as those incurred by loss of productivity-should not be included in a BIA, as these are not generally relevant to the budget holder. However, this may not apply when budget impact analyses are intended to inform the decision making of employers or private health insurers, nor in contexts where health-care systems rely on tax payments where lost production due to morbidity could have important implications for healthcare funding.

In general, therefore, all costs that might result from the introduction of the new technology within the BIA time horizon, including health outcomes and side effects, should be included, and the resource use profile should reflect the actual usage and the way the budget holder values these resources[1]. Thus, the expenditure calculation will include all of the costs that are expected to result from adoption of the intervention (variable costs in the short-run and fixed and variable costs in the long-run). The published guidelines do not agree on whether or not future costs should be included for other health conditions that might be incurred in patients who survived as a result of the new intervention. The choice whether to include or exclude

future unrelated costs will depend on the payer requirement and perspectives.

Uncertainty analysis

BIAs include a considerable level of uncertainty[1]. Therefore, a single "best estimate" is not a sufficient outcome. Instead, the BIA should compute a range of results that reflect the plausible range of circumstances the budget holder will face. It is useful to consider both the most optimistic and the most pessimistic scenario. The ranges that are presented must be based on realistic scenarios regarding various inputs and assumptions, such as the size of the target population, the different uptake rates for the new technology, the costs of the new technology, and other assumptions for which data were not available.

The identified plausible range of parameters and assumptions should be developed collaboratively with the decision makers, because they are best placed to make many of the key assumptions and to supply data for the ranges of input parameter values[1]. In some cases, it may also be advisable for the decision-makers to review the BIA model to assess the scenarios therein and undertake their own sensitivity analysis[8]. It should be understood by the decision-maker that some analyses might be sensitive.

Although a probabilistic sensitivity analysis (PSA) is required in any economic evaluation, the role of PSA within BIA has been questioned because of the accountability that PSAs requires[2]. Moreover, while PSAs require the use of estimated variance data, input data used in BIAs often comes from panel expert discussion data, from which it is notoriously difficult to generate estimated variance. Most guidelines suggest that a deterministic sensitivity analysis should be conducted to identify the range of the budget impact[1-3,13,14].

Discounting

The published BIA guidelines recommend that discounting should not be factored into BIAs because discounted costs do not reflect the actual budget in given year[1,2,4,14].

Guidelines for Health Technology Assessment in Thailand (second edition): Recommendations for budget impact analysis

BIAs should be regarded as economic evaluation tools that policy decision can use in the following circumstances: 1) when a new technology seems to be cost-effective at either its current price or its submitted price used in the reimbursement package. In this case, the BIA should use the price that is most cost-effective; 2) where the new technology does not seem to be cost-effective, a threshold analysis should be conducted to assess whether the reduced price would make it value for money. This price could be used for negotiation processes, in which case the BIA should then use the negotiated price; or 3) when the target patient group of the technology under assessment is small (e.g. in the case for treatments for rare diseases), the treatment may not seem to be cost-effective. However, a BIA should be employed to inform policy decision-makers who might be interested in developing a reimbursement package for vulnerable patients.

Study design

BIAs should be conducted in conjunction with the economic evaluation; they should use the same input parameters, economic models, and model assumptions.

Perspective

All BIAs should be conducted from the budget holder's perspective (whether within a national healthcare system, managed care organization, social insurance institution, or hospital context), given that that the new technology will impact upon their budget.

Scenarios to be compared

BIA scenarios should be based on existing reimbursement packages and should use sets of mixed treatment interventions (with and without the new technology) to see how the current treatment mix and the proposed new treatment mix would affect the target population. Thus, the resource and valuation measurement for each treatment that is included in the current intervention mix needs to be examined proportionately, using data obtained from the national reimbursement database/health insurance database. To estimate the new technology mix scenario, the rate of uptake should be forecasted from the producer's estimates of market share or extrapolated from previous product diffusion data. Moreover, the rate of uptake is likely to change over time, as physicians and patients become familiar with new technology, so a Delphi panel of national clinical experts might be used to predict how the rate at which this will change.

Target population

A number of data sources can be used to

inform the decision, including epidemiology of disease data, the proportion of patients who are covered by health insurance, and the accessibility of health care services (usually given as a percentage of total patients who are covered by health insurance). These factors should all be taken into account in the comparative analysis, with appropriate estimates made for the new technology treatment mix scenario and within a suitable time horizon. As target population size can change over time, acknowledgement of this too should be included in the BIA, through open cohort analysis. Given that many interventions can be used to treat a number of conditions, it is important that any uses of the intervention that are not recommended in the reimbursement package should not be taken into account in the BIA. The calculation of target population should be clearly reported.

Time horizon

The time horizon used in the BIA should be that which is deemed most relevant to the budget holder. BIAs are typically concerned with costs over a short time horizon (e.g. 1-5 years).

Cost and resource utilisation

The costs and resource that are used in the BIA should be based on the budget holder's perspective, and should thus include all direct medical care costs and all other costs that might impact the budget or health care system within the specified time horizon (e.g. 1-5 year-period). The charge levied for the new technology should be based on its value according to the benefit package-not its market price. The analysis should also include other costs that are related to the new intervention package, such as those resulting from side effects. Future costs associated with other health conditions that might be incurred due to patients surviving as a result of the new intervention should generally be excluded. However, the choice whether to include or exclude future unrelated costs will depend on the payer requirement and perspective.

Uncertainty analysis

A deterministic sensitivity analysis should be conducted to reveal the plausible range of budget impact, including both the most optimistic and most pessimistic scenario, as indicated by the Tornado diagram. The use of a PSA to examine the uncertainty of the CEA results may well be unnecessary in a BIA. The ranges that are presented must be based on realistic scenarios regarding various inputs and assumptions, such as the size of the target population, the different uptake rates for the new technology, and the costs of the new technology.

Discounting

It is not recommended that discounted costs be used in the BIA.

Acknowledgement

The development of these guidelines would not have been possible without the technical support, challenging criticism and encouragement of many colleagues and institutions. As author, I wish to acknowledge all individuals and related organizations that contributed throughout the process for guideline development. In addition, I would like to give particular thanks to the funding support through the Health Intervention and Technology Assessment Program (HITAP) from the National Health Security Office, the Thailand Research Fund under the Senior Research Scholar on Health Technology Assessment (RTA5580010) and Thai Health Global Link Initiative Program (TGLIP), supported by Thai Health Promotion Foundation.

Potential conflicts of interest

None.

References

1. Mauskopf JA, Sullivan SD, Annemans L, Caro J, Mullins CD, Nuijten M, et al. Principles of good practice for budget impact analysis: report of the ISPOR Task Force on good research practices—budget impact analysis. Value Health 2007; 10: 336-47.
2. Scientific Advisory Group of Health Information and Quality Authority. Guidelines for the budget impact analysis of health technologies in Ireland. Cork, Ireland: Health Information and Quality Authority; 2010.
3. Orlewska E, Mierzejewski P. Proposal of Polish guidelines for conducting financial analysis and their comparison to existing guidance on budget impact in other countries. Value Health 2004; 7: 1-10.
4. Ferreira-Da-Silva AL, Ribeiro RA, Santos VC, Elias FT, d'Oliveira AL, Polanczyk CA. Guidelines for budget impact analysis of health technologies in Brazil. Cad Saude Publica 2012; 28: 1223-38.
5. Orlewska E, Gulacsi L. Budget-impact analyses: a critical review of published studies. Pharmaco-

economics 2009; 27: 807-27.
6. Mauskopf JA, Earnshaw S, Mullins CD. Budget impact analysis: review of the state of the art. Expert Rev Pharmaco-econ Outcomes Res 2005; 5: 65-79.
7. Mauskopf J. Prevalence-based economic evaluation. Value Health 1998; 1: 251-9.
8. Trueman P, Drummond M, Hutton J. Developing guidance for budget impact analysis. Pharmaco-economics 2001; 19: 609-21.
9. Koopmanschap MA, Rutten FF. The drug budget silo mentality: the Dutch case. Value Health 2003; 6 (Suppl 1): S46-51.
10. Drummond M, Brown R, Fendrick AM, Fullerton P, Neumann P, Taylor R, et al. Use of pharmaco-economics information—report of the ISPOR Task Force on use of pharmacoeconomic/health economic information in health-care decision making. Value Health 2003; 6: 407-16.
11. Baltussen R, Leidl R, Ament A. Real world designs in economic evaluation. Bridging the gap between clinical research and policy-making. Pharmaco-economics 1999; 16: 449-58.
12. Anis AH, Gagnon Y. Using economic evaluations to make formulary coverage decisions. So much for guidelines. Pharmacoeconomics 2000; 18: 55-62.
13. Nuijten MJ, Mittendorf T, Persson U. Practical issues in handling data input and uncertainty in a budget impact analysis. Eur J Health Econ 2011; 12: 231-41.
14. Marshall DA, Douglas PR, Drummond MF, Torrance GW, Macleod S, Manti O, et al. Guidelines for conducting pharmaceutical budget impact analyses for submission to public drug plans in Canada. Pharmacoeconomics 2008; 26: 477-95.

การวิเคราะห์ผลกระทบด้านงบประมาณ

พัทธรา ลีพหวรงค์

การวิเคราะห์ผลกระทบด้านงบประมาณเป็นส่วนหนึ่งของการประเมินเทคโนโลยีด้านสุขภาพ ในปัจจุบันนอกเหนือจากการใช้ข้อมูลความคุ้มค่าด้านสุขภาพแล้ว การวิเคราะห์ผลกระทบด้านงบประมาณก็เป็นข้อมูลสำคัญ ที่ใช้ในกระบวนการตัดสินใจเชิงนโยบายด้านสิทธิประโยชน์ของระบบสุขภาพ ซึ่งมีทรัพยากรหรืองบประมาณที่จำกัด ดังนั้นการประมาณการณ์ภาระด้านงบประมาณที่เกิดขึ้นจึงเป็นข้อมูลที่ผู้ตัดสินใจเชิงนโยบายใช้เพื่อประเมินความสามารถในการจ่ายสำหรับเทคโนโลยีใหม่ วัตถุประสงค์ของบทความนี้เพื่อทบทวนแนวทางการวิเคราะห์ผลกระทบด้านงบประมาณของประเทศต่าง ๆ ที่ได้รับการตีพิมพ์แล้ว และเพื่อให้ข้อเสนอแนะสำหรับการวิเคราะห์ ผลกระทบด้านงบประมาณในแนวทางการประเมินเทคโนโลยีด้านสุขภาพสำหรับประเทศไทย ซึ่งบทความนี้เสนอแนะ กรอบการวิเคราะห์ รูปแบบการศึกษา มุมมอง การกำหนดสถานการณ์และจำนวนประชากรกลุ่มเป้าหมายที่ใช้ในการวิเคราะห์ต้นทุนและทรัพยากรที่ใช้ในการวิเคราะห์ การวิเคราะห์ความไม่แน่นอนและการปรับลด