

What guidance is available for budget impact analysis?

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Introduction

There is a wealth of literature and guidance available for cost-effectiveness research, but the guidance available on budget impact analysis (BIA) is less familiar to many investigators.

In times of increased budget constraint, however, the importance and popularity of budget impact analysis is growing.

The objective of this review was to assess whether guidance on BIA methodology is available and consistent.

Methods

Searches were performed in June 2011 to identify published guidelines or recommendations on BIA from any country. The guidelines were then reviewed for whether they gave advice on certain pre-determined categories.

Results

National guidelines have been produced in Australia¹, Canada², Ireland³, and Poland⁴ specifically on how BIA in each of these countries should be performed. Other countries such as the UK, Italy and Hungary include minimal recommendations on BIA within guidelines on healthcare economic assessment, but their focus is largely on cost-effectiveness analysis.

An ISPOR Task Force has produced international guidance for budget impact methodologies, which are designed to support national guidelines rather than supersede them and also to improve consistency across BIAs developed for different settings.⁵ Annemans has also recently developed overarching recommendations for BIA.⁶

As shown in Table 1, all guidelines made recommendations on perspective, time horizon, scenario analysis, data sources, costs to be included and discounting. However, the actual recommendations were only consistent in agreeing that

multiple scenarios should be modelled. The perspectives differed depending on who the budget holder is in each country. The guidelines were split on whether costs should be discounted (Figure 1). Additionally, one third of the guidelines (Australia¹ and Canada²) were interested in drug costs only (Figure 2).

The guidelines were not consistent in whether they gave advice on how to determine market share or whether off-label use should be included. Figure 3 shows that while half of the guidelines recommended inclusion of off-label use, one third gave no recommendations and one guideline (Canada²) recommended against inclusion of off-label use in the main analysis.

All guidelines claimed they wanted 'incremental BIA'. However, some guidelines were only interested in the cost incurred by the new drug, while others offset this cost with savings produced from the displacement of other medications.

Figure 1: Is discounting necessary?

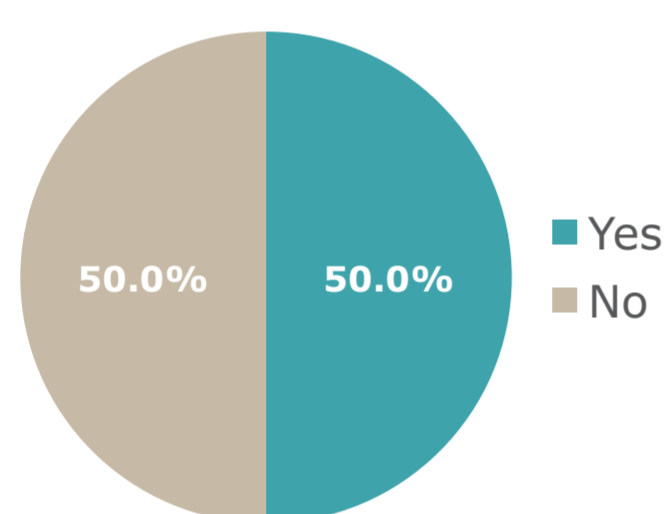


Figure 2: Should non-drug costs be included?

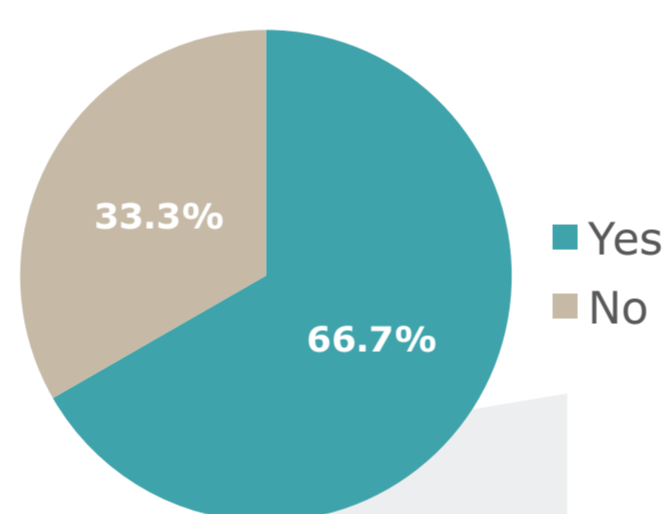


Figure 3: Should off-label use be included?

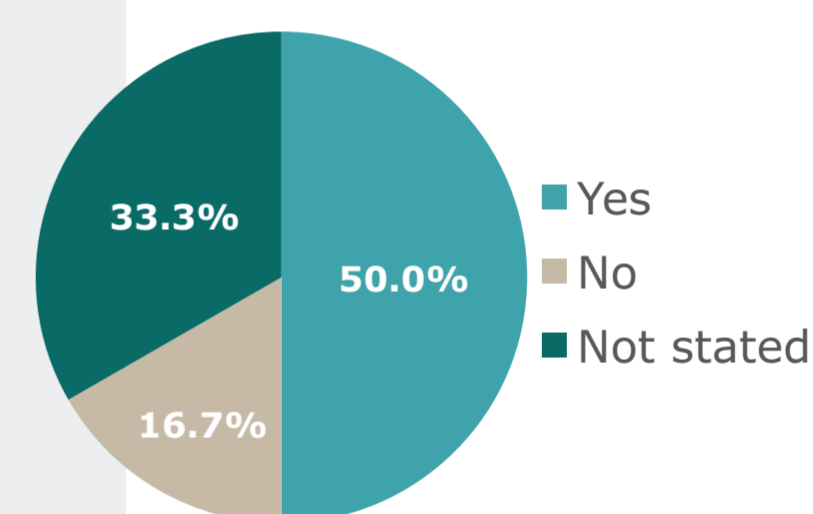


Table 1: Comparison of the BIA Guidelines

Country or organisation	Perspective	Time horizon	Recommendations for scenario analysis?	Advice on market share prediction?	Sources of data	Inclusion of resource use other than drug cost?	Guidance given on the inclusion of off-label use?	Is discounting deemed necessary?
Australia ¹	Many governmental bodies	5 years	Yes	Minimal	Australian databases, studies or surveys	No	No	No
Canada ²	Drug plan	3 years	Yes	Yes	Population data, claims data, formulary price list	No	Yes – not included in main analysis	Yes
Ireland ³	Health and social care system	5 years	Yes	No	No Irish central cost database, therefore costs from other countries are acceptable	Yes	No	Yes
Poland ⁴	Public purchaser	Until peak or steady state	Yes	Yes	Epidemiological, resource use and cost data should be country-specific	Yes	Yes – should be included	Yes
ISPOR Task Force ⁵	Budget holder	Until steady state	Yes	Yes	Comparative studies	Yes	Yes – should be included	No
Annemans 2010 ⁶	Budget holder	3-5 years	Yes	Minimal	Clinical trials, population statistics, healthcare databases. Expert opinion if gaps remain	Yes	Yes – should be included	No

Discussion

Several national and international bodies have developed guidelines for developing and reporting budget impact analysis. However, different specifications exist and not all methodological aspects are made explicit in every case. Consensus guidelines such as those produced by the ISPOR task force⁵ and Annemans 2010⁶ are required to shape future national BIA recommendations.

References

1. Australian Government Department of Health and Ageing. Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (version 4.3). December 2008.
2. Patented Medicine Prices Review Board (Canada). Guidelines for conducting pharmaceutical budget impact analyses for submission to public drug plans in Canada. May 2007.
3. Health Information and Quality Authority (Ireland). Guidelines for the budget impact analysis of health technologies in Ireland. 2010.
4. Orlewska E, Mierzejewski P. *Value in Health*. 2004;7(1):1-10.
5. Mauskopf JA et al. *Value in Health*. 2007;10(5):336-347.
6. Annemans L. *Pharmacoeconomics: From Theory to Practice*. 2010:109-117.