EDITORIALS


Introduction

In the current period of financial crisis and budgetary constraints, discussions on the impact of (new) health technologies on health care budgets become more prominent. On different levels, such as on the level of an individual hospital, the level of local and national health care payer, and also on the level of national government, decision makers want to get better control on the financial impact of these new technologies on their budgets. An important tool to control their budget is budget impact analyses (BIAs). Because decisions on reimbursement will rely more on the outcomes of these BIAs, the quality, consistency, and transferability of BIAs is essential. The report of the “ISPOR 2012 Budget Impact Analysis Good Practice II Task Force” [1] aims at giving guidance to improve these characteristics. This leads to the following question: Is it useful for us as BIA practitioners on a national level? We reviewed the report and share our thoughts.

Recommendations on Analytical Framework

The task force provides recommendations on the analytical framework, on the data to populate the framework, and on the reporting format. On the analytical framework, it recommends nine aspects to consider in the design of a BIA. By including features of the health care system and market effects such as uptake as part of these aspects, the task force acknowledges the complexity and dynamics of health care systems. This is crucial for realistic results and makes the guidelines of great value. Therefore, we are surprised that the task force recommends not including off-label use in order to avoid the promotion of off-label use. In our view, all costs associated with a new intervention that the budget holder will have to pay should be included and thus taken into account in a BIA. When planning a budget, one has to consider all costs that have an impact on the budget, with no regard to the extent of, or justification for, the underlying care. Neglecting these costs in the BIA will not prevent them; in contrast, reporting these costs may increase the awareness to control the off-label use.

An important basis for the framework of a BIA consists of the requirements of the budget holder. The task force accounts for this by recommending the consideration of perspective and time horizon. We feel that this is an important part of its recommendation and therefore quantifies the importance of these elements by means of a Dutch case below.

Recommendations on Data Sources and Reporting Format

After designing the analytical framework it has to be populated with data relevant to the budget holder. To deploy the best available sources the task force gives useful guidance for five specific elements of a BIA. For all elements it recommends providing thorough data references to support replication and transparency. The recommended reporting format also supports transparency, and in addition helps in making consistent and transferable BIAs containing all key elements such as explicit uncertainty analyses.

We believe that the ISPOR task force report aids us in producing reliable, consistent, and transferable BIAs, and we hope that these recommendations will be used around the world. We would suggest, however, that in an update of the task force report, the importance of off-label use should be recognized and included as a possible option in the BIA depending on the requirements of the budget holder.

The Combined Lifestyle Intervention: A BIA Case

We illustrate the importance of three aspects of the analytical framework that depend on the requirements of the budget holder (perspective, time horizon, and off-label use) with a real-life case. In 2009, the Dutch minister of health care asked the Health Care Insurance Board (CVZ) to calculate the budget impact of the inclusion of the combined lifestyle intervention (GLI) in the basic insurance package. The GLI is an intervention aimed at overweight and obese persons, advising them on food and eating habits, supporting behavioral change, and supporting physical exercise. The intervention had a potential target group containing 35% of all Dutch inhabitants, and budget restrictions were getting tighter because of the declining economic situation. So, a BIA was needed, for which the CVZ contracted an independent academic group from the Erasmus University of Rotterdam, The Netherlands.

Perspective

The minister works with the so-called Budgetair Kader Zorg, which is a budget limited to health care costs. So, in contrast to our cost-effectiveness assessments we needed to keep the prevented loss of production out of the primary BIA and did not use the societal perspective. On a mid-term horizon (10 years), the

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estimated net benefits of the intervention would be €77 million. Bringing in the prevented loss of production, and using a societal perspective, would change that estimate to more than €900 million.

**Time Horizon**

Another element of the analytical framework with a big impact on the results was time horizon. In the case of the GLI, the intervention costs occur immediately after introduction, while savings elsewhere in the health care system (because of the health effect) will not occur directly. On the basis of a time horizon of 1 year, net costs of €51 million were estimated, while at the horizon of 10 years there was an estimated aggregated net benefit of €77 million.

**Off-Label Use**

After the BIA became public, two leading Dutch professors on (health) economics (Henriëtte Maassen van den Brink and Wim Groot) wrote an article in “Het Financieele Dagblad” [2] in which they suggested that the cost estimates could be an underestimation because indication criteria will often expand. Because off-label use was not part of the BIA, the budget holder could not use the BIA to quantify the effect of the suggested expansion. We think that it would have been better if she had taken off-label use into account.

**Relevance for Decision Making**

After receiving the BIA, the minister stated that she saw no room in the Budgettair Kader Zorg to reimburse the GLI because of the significant cost estimates for the first 4 years [3]. So, the BIA was of great relevance for decision making. (The BIA was not the only factor; the minister also stated that healthy living is the responsibility of the individual.) Both perspective and time horizon played important roles and are deservedly part of the report of the ISPOR task force.

**Discussion**

The minister could use the time horizon of her choice because the results in the BIA were presented in a disaggregated manner, a recommendation of the task force in the section on reporting format. Not only does this provide flexibility for the decision maker, it is also informative to see costs and benefits develop throughout the years.

Likewise, the societal perspective was presented in the BIA, although the minister’s primary perspective is the health care system. Adding the societal perspective informs the decision maker on the broader picture and contributes to optimal resource allocation. We think that every BIA practitioner should at least consider doing the same and guidelines can help implementing this.

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**REFERENCES**

