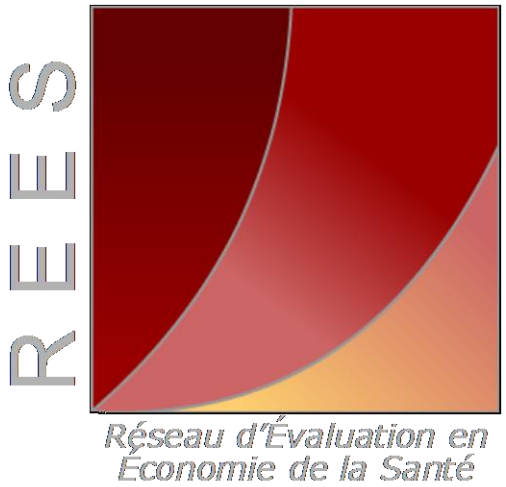

COMMENTS R. LAUNOIS, PhD

Budget Impact Analysis – Principles of Good Practice: Report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force

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1. General Comments

This revisited version of the *"Budget Impact Analysis Good Practice"* guide maintains the formal structure of the previous documents, while adding much-needed operational advice. Its implementation leaves great flexibility for developers, which may be due to the nature of the project itself. It would appear that the authors were aiming at constructing an alternative approach to cost-effectiveness analysis that is devoid of the welfare theoretical foundation that has traditionally underpined it. This alternative approach could be used both for cost-effectiveness, as well as, budget impact analyses. Notwithstanding, they do not state this clearly.

The distinction between the simple impact calculator model and the Markov state model is rather useful (lines 321-343; 609-635). It could be useful to the reader to provide one methodological reference for each of them. It is well known that prevalence can be roughly estimated by the multiplication of incidence and case duration, but I am unable to figure out the bibliographic origin of this rumor! I would appreciate to have a more robust reference on this. The same is true for the multi-cohort model. In this case, I would suggest to reference the article "Population- versus Cohort-Based Modelling Approaches » by Ethgen and Standaert (Pharmacoeconomics, 2012).

The Task Force endorses the use of the impact calculator approach whenever its implementation can be made possible, mainly at short-term. In the same way, it favours one-way sensitivity analyses and the scenario method over probabilistic sensitivity analyses. In doing so, it closes the door to numerical simulation models. I think that it would be a lost opportunity not to combine cross-sectional observational data and probabilistic distributions within a multi-cohort Markov model in order to implement numerical simulations. Would it be too complicated, maybe? But it would be an opportunity to test a diversity of « virtual experimentations », which, in my opinion, could result in methods whose foundations are more solid than the scenario approach. Such an approach is used widely in many other disciplines.

2. Specific Comments

- Line 459 : In the « Definition of the Target Population and Subgroups » section, the Task Force recommends to use population-specific epidemiological and treatment pattern data at the disposal of various stakeholders (i.e. insurers, hospitals, regional authorities, primary care trusts, etc.), and were it not available, national epidemiological data (Line 467).

- Taking into account that the European context is not a multiple payer system, I would suggest to add cross-sectional representative study of the clinical practice in country-specific basis. This is cheap and can be implemented quickly. Moreover, such information is needed to populate the budget model.

- Line 478 : There is a reference to the severity of illness without any explicit reference made to the line of treatment. Later on, it is mentioned implicitely in line 486. This

must be synthetised as we have to keep in mind, specially in oncology, that the prooducts are first introduced in the second line of treatment and after follow a shift to the first line of treatment. In these cases, the rate of sales growth in the first line will be detrimental to the sales in the second line because the product can no longer be used after failure in the first line. Overall, this could be a dissappointing outcome for the manufacturers.

- Line 510 : The mention of the « Catch up Effect » constitutes good advise to be given to analysts.

Paris, April 8, 2013

Professor Robert Launois