Estimates of the impact of a new drug on US health care budgets: are published studies done well?

An analysis to estimate the impact of a new drug on health care budgets (budget impact analysis) is desired by many US health plans before adding a new drug to their formulary and providing insurance coverage. However, previous reviews of budget impact analyses have indicated that published analyses often do not use methods that are recommended in guidelines published by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

Element	Recommended Methods
Model structure	For acute conditions, a decision tree framework which considers treatment failure can be used. For chronic conditions, either a simple decision tree framework or a disease progression model to account for the changing size of the population can be used.
Population size and disease severity mix	For acute conditions, allow treated population size to increase with new more effective or safer drugs. For chronic conditions, account for increases in treated population size and/or changes in disease severity mix due to new drug benefits in reducing mortality or slowing the rate of disease progression.
Time horizon	For all conditions, a planning horizon of 3 to 5 years is most common.
Treatment mix	For acute and chronic conditions, provide rationale for uptake of new drug over analysis time horizon and how the uptake of the new drug is expected to change the use of other currently used drugs.
Treatment costs	For all conditions, include all relevant payer-related costs for each of the drugs in the treatment mix – drug purchase, diagnosis tests, administration of the drug, monitoring for safety or efficacy, and treatment of any side effects.
Disease-related costs	For all conditions, include disease-related costs if they will affect budgets within the analysis time horizon; only include if high quality data exist to estimate these costs such as data from head-to-head trials.
Analyses Using Alternative Input Values	For all conditions, extensive alternative analyses are important for understanding the budget impact that may be seen in different types of health plans. Credible alternative values from a health-plan perspective for treatment mix, treatment costs, and disease-related costs should be examined.

Tab. 1. Seven key elements for a budget impact analysis

In our review, we assess the extent to which published US budget impact analyses for new drugs use the recommended methods. We describe recommended methods for seven key elements (Tab. 1). US studies reporting estimates of the budget impact of a new drug were identified by searching the MEDLINE database. The primary finding from this review is that recommended methods are not followed in many published budget impact analyses. For example, we found that

growth in the treated population size and/or changes in disease-related costs expected over the next 3 to 5 years for more effective treatments were not included in several budget impact analyses for health conditions that last for many years. In addition, all drug-related costs were not captured in the majority of the analyses. Finally, for most studies, analyses testing the impact on the results of varying the base case selected for the seven key elements were very limited, and the ranges used for alternative input parameter values were frequently selected without justification or data to support them.

The conclusions from our review are that ISPOR guidelines are frequently not followed in US analyses which may result in over- or underestimates of the budget impact of new drugs. In addition, if published budget impact analyses are to be useful for US budget holders it is also important for published budget-impact analyses to present the results of many different analyses based on realistic alternative scenarios for the inputs that vary by budget holder.

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Publication

A Methodological Review of US Budget-Impact Models for New Drugs.
Mauskopf J, Earnshaw S
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