

# How Uncertain Is Uncertainty Testing in Budget Impact Models?

Tushar Srivastava<sup>1\*</sup>, Jyoti Sharma<sup>1</sup>

<sup>1</sup>ConnectHEOR, London, UK

\*tushar.srivastava@connectheor.com



## Introduction

A budget impact model (BIM) estimates the financial impact on the payer due to introduction of an intervention in the market. The BIMs form an essential part of comprehensive economic assessment of the new health care interventions.

Sensitivity analysis and scenario testing are often suggested by modelling guidelines, such as ISPOR guidelines, to be included as part of BIMs to understand how variation in uncertain inputs and assumptions impact the model results.

Uncertainty Analysis is carried out to assess the precision of the model and to assess sensitivity of the input parameters around true mean values. Conducting the uncertainty analysis also helps determine the significance of the input parameters.

Scenario analyses are used to test alternative assumptions or scenarios in the model and their impact on results.

## Objective

We conducted a targeted literature review to assess whether uncertainty is tested in recent BIMs published for the European countries for various drugs.

## Methodology

- A search on PubMed was conducted with keywords such as Budget Impact and Budgetary Impact, to review recent literature published. Country or region name keywords were also used in to include Europe-region only.
- The time span for inclusion of studies was from January 2021 till June 2022.
- Studies including combined cost-effectiveness and budget impact model found in the search were also included, however information was only extracted for BIM within these.
- Studies conducted outside of EU were excluded, Also, studies assessing drugs were included; however, diagnostics and vaccines were excluded.
- MS-Excel was primarily used for data extraction, compilation, visualisation.
- A data extraction form was developed to comprehensively identify and compile the data on sensitivity analysis and scenarios in the included studies.
- Two reviewers were involved to conduct the targeted literature review and any disagreement about the inclusion or exclusion of studies was resolved via discussion among them.

## Results

- The titles and abstracts were screened for 72 studies identified via search strategy in PubMed.
- Of these, 26 were selected for full-text screening.
- Based on the inclusion criteria, 17 studies were incorporated in the final analysis.
- Less than 50% of the BIMs (N=7) reported conducting a one-way sensitivity analysis (OWSA) and 5 of these presented results using a tornado diagram. One study tested scenarios but reported this as univariate sensitivity analysis.
- Only two studies (out of 17) reported to conduct a probabilistic sensitivity analysis (PSA), however only one of them presented its results.
- Only ten studies included testing of different scenarios such as market share uptake, price, and population changes.

Figure: Distribution of studies by type of uncertainty analysis undertaken

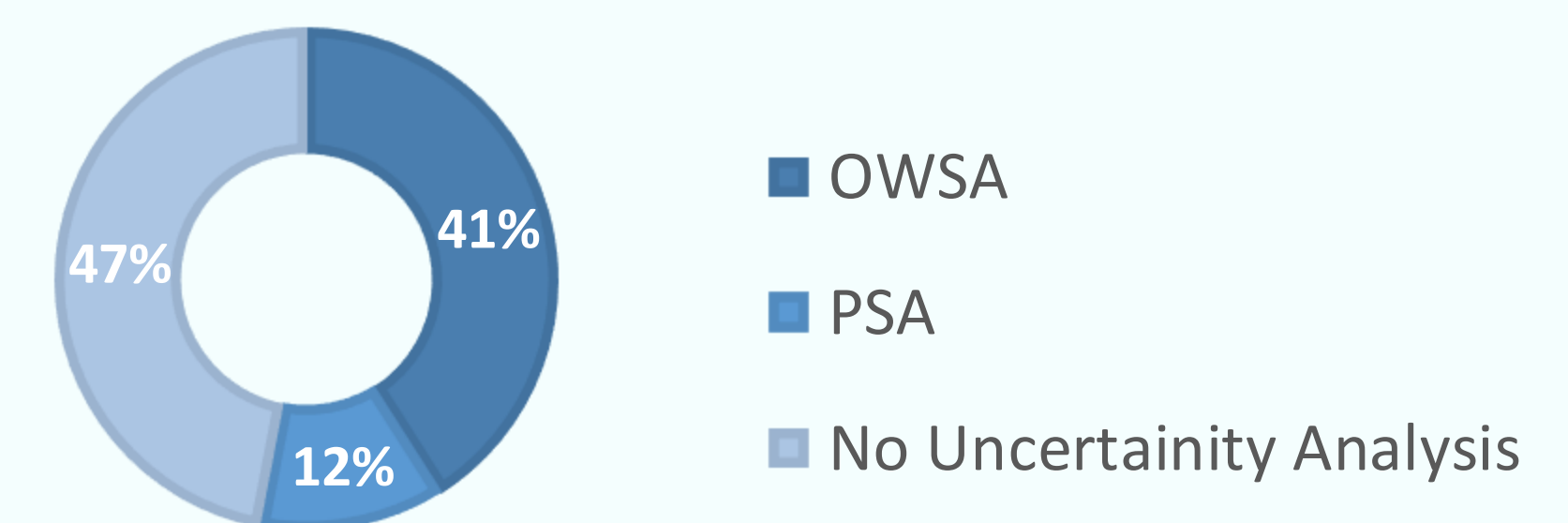


Table 1: Key extracted data on included studies that reported some sensitivity analysis

Study (Author Year)	Indication	Country	Was OWSA tested?	OWSA rules	Was tornado graph presented?	Parameters varied in OWSA	Was PSA tested?	Were any scenarios tested?
Jang 2021	Multiple	EU-5 countries (UK, France, Germany, Spain, Italy)	Yes	Key parameters varied by $\pm 20\%$	Yes	Drug cost, average patient's body surface area and weight, disease incidence	No	Different uptake levels
Manuel García-Goñi 2021	Multiple	Spain	Yes	Key parameters varied by $\pm 20\%$ and $\pm 50\%$	Yes	Biosimilar market share, month of application of reference price order (RPO), biosimilar price prior the application of the RPO	Yes	No discounts and different purchase price scenario
Lisa Aniek de Jong 2021	Hepatic Encephalopathy (HE)	Netherland	Yes	Each input parameter varied within their range of uncertainty	Yes	Hospital and healthcare perspective, prevalence, bed days, percentage of patients experiencing first and second episode of overt HE, hospital admission, hospital cost per bed day, yearly mortality rate	No	Prevalence of cirrhosis, different assumptions around frequency of hospital beds and uptake of rifaximin- $\alpha$
Han Geul Byun 2021	Rheumatoid Arthritis	UK	Yes	Key parameters varied	Yes	Prevalence, eligible for treatment with biologics, intravenous (IV) administration, Subcutaneous administration, proportion of patients receiving IV loading dose.	No	Assuming half of the patients receiving infliximab require dose escalation
Cyril Astrugue 2021	Chronic Myeloid Leukaemia	France	No	Not applicable (NA)	NA	NA	Yes	No
Catherine R. Hanna 2021	Short Course Oncology Treatment	Australia, Denmark, New Zealand, Spain, Sweden, and the United Kingdom.	Yes	Key parameters varied	Yes	Duration of adjuvant doublet on Stage III colorectal (CRC) patients, removing Stage II patients, excluding patients with rectal cancer.	No (only for Cost-utility analysis)	Excluding patients with rectal cancer, budget impact relevant to patients with stage II CRC and stage II/III colon cancer
Beatrice Osumili 2022	Severe Hypoglycemic Events	Spain	Yes	Key parameter: Market share by $\pm 10\%$	No (only tables presented)	Market shares	No	No
Elisabeth Brock 2022	Chronic Heart Failure and Reduced Ejection Fraction and Iron Deficiency	Switzerland	Yes	Key parameters varied	No	Not reported	No	No differences in costs, university versus non-university hospital costs, input values based on single-centre data, including outpatient costs, including patients co-payments, number of eligible patients and updated unit costs.

## Discussion and Conclusion

- Despite recommendations, only some of the recently published BIMs included uncertainty analysis.
- We found that many studies which reported conducting a OWSA used a 20% default range. However, the range should not be arbitrary as these do not reflect the actual uncertainty around the parameters from a budget holder perspective. Wherever possible, the ranges should be obtained from published literature or from consultation with the experts in the field.
- According to guidelines, tornado diagrams should be used to present OWSA results. Also, multiple possible real-world scenarios and their impact on model results should be tested in case of uncertainty. However, many studies in our search lacked such details in reporting.
- One of the limitations of our review is it only captures recent BIMs; however, we expect the study findings to be consistent with previously published BIMs.
- Sensitivity and scenario analysis are crucial for decision making. Thus, stress need to be made on extensively conducting and presenting the results of uncertainty analysis in the future BIMs.



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