BUDGET IMPACT ANALYSES: INCONSISTENCY AND BIAS IN CHOICE OF REPORTING MEASURES

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INTRODUCTION

- Budget impact analyses (BIA) are increasingly being used, along with cost effectiveness analyses, by reimbursement authorities for formulary inclusion of a new intervention[1]

- While there are specific guidelines on how to carry out and report the results of a BIA, there are no guidelines on the reporting metrics to present the results of a BIA, leading to inconsistent use of metrics[2]

- Some analysts report only the absolute budget impact while others report the impact in terms of a ratio/percentage of the base budget. Further, in cases where ratio/percentage impact is reported, there is considerable variability in the choice of the base budget or population. While some analyses report on the basis of the overall plan population, others report on the basis of the target patient pool for the drug, and some do it on the basis of treated patients in the indication. The larger the base budget or population, the diminished impact

- The objective of this study was to evaluate whether there is consistency in reporting measures between analyses carried out by drug/technology sponsors and those carried out by academicians/independent evaluators, and examine likely bias

METHODS

- Budget impact studies presented at ISPOR's six most recent annual conferences including the Annual International Meetings and the Annual European Congresses were obtained from ISPOR Scientific Presentations Database[3]

- All cost studies, identified using the keywords "budget impact" were extracted for the review, regardless of the therapeutic area/disease and the technology (drugs, procedures or devices) assessed

- Abstracts of the extracted studies along with the full poster, wherever available, were screened to identify studies that provided relevant and sufficient information on the budget impact results

- Studies included in the analysis were classified into two groups based on the sponsorship

  - Pharma sponsored: BIAs which were sponsored by a drug/technology manufacturer or where at least one of the authors was affiliated to a drug/technology manufacturer

  - Independent evaluators: BIAs carried out by independent evaluators such as academicians and payers

- Results reported in the BIAs were analyzed to see if the drug/intervention resulted in an increase in the budget or in savings

- The studies were then bucketed into one of the four categories mentioned in **Table 1**

Table 1: BIA categories based on reporting measures used

S. No.	BIA categories – those that report	Denominator used in cases where budget impact is reported as ratio or percentage	Examples of measures in each category
1	budget impact as a ratio or a percentage	entire population *(largest denominator)*	per plan member per year
2		population suffering with disease	per diabetes patient per year
3		drug treated population *(smallest denominator)*	per diabetes patient treated with the new drug per year
4	absolute impact	NA	total savings for the plan population of 1 million

- Distribution of studies among these four categories based on the reporting measures adopted were evaluated and compared between the two groups

RESULTS

- A total of 314 studies were extracted from ISPOR Scientific Presentations Database, of which 255 were included for detailed analysis

- More than 3/4ths of the included studies (**Table 2**) were pharma sponsored (n=193) while the rest were carried out by independent evaluators (n=62)

  - 2/3rds of the BIAs were from US/Europe

 - A majority of studies in each group pertained to a drug

Table 2: Distribution of BIAs by geography, disease area and product type

	Overall (N=255)	Pharma sponsored (n=193)	Independent evaluators (n=62)
Geography, n (%)			
US	79 (31)	71 (37)	8 (13)
Europe	84 (33)	52 (27)	32 (52)
Others	92 (36)	70 (36)	22 (35)
Disease area, n (%)			
Oncology	68 (27)	48 (25)	20 (32)
CVM	40 (16)	31 (16)	9 (15)
Auto-immune	24 (9)	22 (11)	2 (3)
Others	123 (48)	92 (48)	31 (50)
Product type, n (%)			
Drugs	171 (67)	126 (65)	45 (73)
Procedures	56 (22)	44 (23)	12 (19)
Medical devices	19 (7)	17 (9)	2 (3)
Others	9 (4)	6 (3)	3 (5)

CVM, cardio-vascular and metabolism
Pharma sponsored: BIAs which were sponsored by a drug/technology manufacturer or where at least one of the authors was affiliated to a drug/technology manufacturer
Independent evaluators: BIAs carried out by independent evaluators such as academicians and payers

RESULTS

Figure 1. Distribution of studies by saving in budget vs. increase in budget in both groups

Pharma sponsored: BIAs which were sponsored by a drug/technology manufacturer or where at least one of the authors was affiliated to a drug/technology manufacturer
Independent evaluators: BIAs carried out by independent evaluators such as academicians and payers
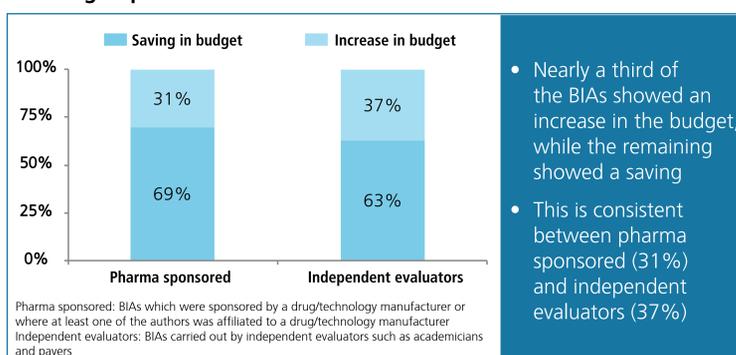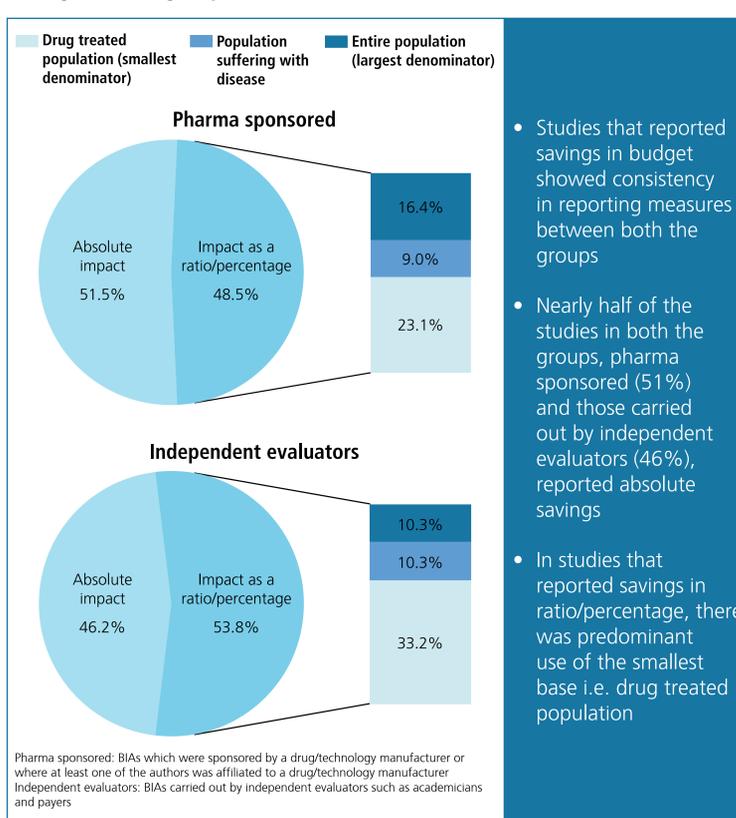
- Nearly a third of the BIAs showed an increase in the budget, while the remaining showed a saving

- This is consistent between pharma sponsored (31%) and independent evaluators (37%)

Figure 2. Distribution by different reporting measures for BIAs showing increase in budget impact in both groups

Pharma sponsored: BIAs which were sponsored by a drug/technology manufacturer or where at least one of the authors was affiliated to a drug/technology manufacturer
Independent evaluators: BIAs carried out by independent evaluators such as academicians and payers
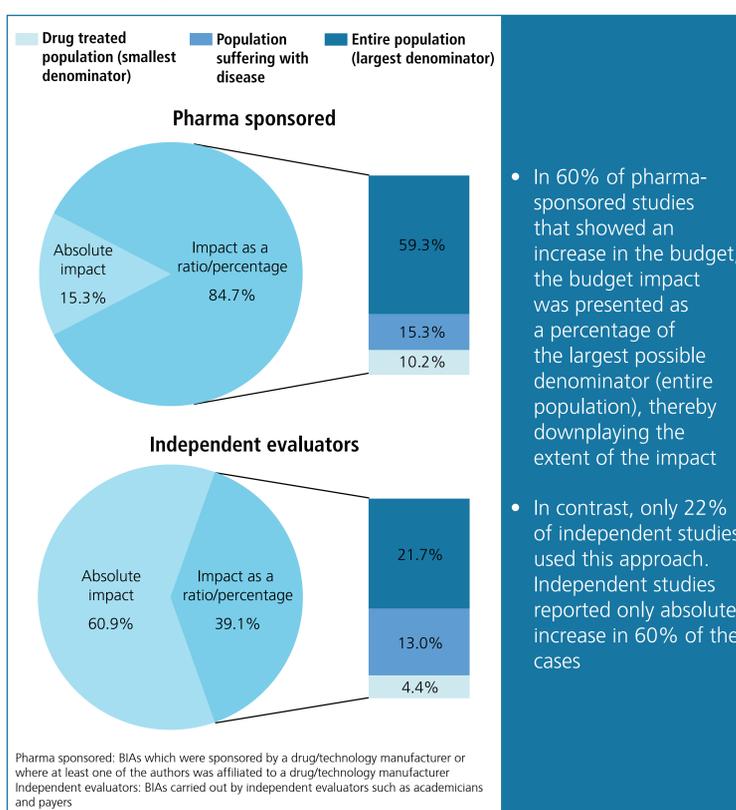
- In 60% of pharma-sponsored studies that showed an increase in the budget, the budget impact was presented as a percentage of the largest possible denominator (entire population), thereby downplaying the extent of the impact

- In contrast, only 22% of independent studies used this approach. Independent studies reported only absolute increase in 60% of the cases

Figure 3. Distribution by different reporting measures for BIAs showing savings in both groups

Pharma sponsored: BIAs which were sponsored by a drug/technology manufacturer or where at least one of the authors was affiliated to a drug/technology manufacturer
Independent evaluators: BIAs carried out by independent evaluators such as academicians and payers

- Studies that reported savings in budget showed consistency in reporting measures between both the groups

- Nearly half of the studies in both the groups, pharma sponsored (51%) and those carried out by independent evaluators (46%), reported absolute savings

- In studies that reported savings in ratio/percentage, there was predominant use of the smallest base i.e. drug treated population

CONCLUSIONS

- The choice of reporting measures was inconsistent, and appeared to be biased by the nature of the evaluators

- Within pharma-sponsored studies, the measures were chosen to amplify (in case of savings) or diminish (in case of increase in budget) the magnitude of the impact so as to influence the perspective of decision-makers

- There is good basis to put in place guidelines to standardize reporting measures, both to remove evaluator bias and to allow easier comparison of different evaluations

REFERENCES

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