EE399

Exploring the Effect of Different Patient Entry Intervals on Budget Impact Estimations

Catarina Neves[1], Adam Kasle[2], Marjolijn van Keep[1], Suzette Matthijsse[1]

[1]Lumanity, Utrecht, the Netherlands; [2]Lumanity, Bethesda, MD, USA

OBJECTIVES

- With the growing interest in affordability and impact of healthcare interventions on population health, budget impact (BI) projections are widely used[1] to inform reimbursement recommendations and manage expected changes in service use[2]
- Estimating the target population size is a key aspect in designing BI analyses. This includes the population covered by the anticipated approved indications for the interventions, adjusted for any planned restrictions on use/reimbursement, as well as uptake[1]
- There are clear recommendations to generally include open populations; patients should enter and leave BI analyses depending on whether they meet the criteria to be included so that changes in the size of the target population are accounted for throughout the time horizon
- However, guidance on the length of patient entry intervals for each reporting period (usually 1 year) of the time horizon is scarce; it is unclear how frequently new cohorts of patients should enter the analysis within a year. It is generally assumed that all patients in the target population for a given year enter BI analyses and initiate treatment at the start of that year
- This simplification does not consider that, in clinical practice, patients may be diagnosed and initiate treatment throughout the year. Therefore, costs may not be accounted for in the period that they occur. If a patient is treated for 1 year, yearly entry would account for these costs in a single year, but more continuous entry may spread these costs over 2 years
- This study explores whether modelling more continuous patient entry affects BI projections

Table 1: BI modelling recommendations by selected organizations

Organization	Country	Recommendations			
		Open populations	Closed populations	Patient entry intervals	Additional information
AIFA[3]	Italy	✓	✓	NR	▪ Open populations if closed populations cannot accurately capture target population size over time
HAS[4]	France	✓	✓	Yearly	▪ Use of closed or open populations dependent on natural disease history and treatment effects ▪ Requirement for calculated annual target population to be transparent and justified suggests yearly patient entry intervals are acceptable
NCPE[5,6]	Ireland	✓		Yearly	▪ BI model template set for yearly patient entry
NICE[7,8]	England	✓		Yearly	▪ Company submission instructions to provide annual target populations (Years 1–5) suggest open populations are required and yearly patient entry intervals are acceptable ▪ Selected examples[9,10] implementing the NICE resource impact template suggest open populations are required and yearly patient entry intervals are acceptable
SMC[11]	Scotland	✓		Yearly	▪ BI model template set for yearly patient entry

Key: AIFA, Agenzia Italiana del Farmaco; BI, budget impact; HAS, Haute Autorité de Santé; NICE, National Institute for Health and Care Excellence; NCPE, National Centre for Pharmacoeconomics; NR, not reported; SMC, Scottish Medicines Consortium.

METHODS

- We developed a model in Microsoft Excel® using dummy data to test the impact of different patient entry intervals (yearly, quarterly, monthly and weekly) on BI projections

Figure 1: Analysis overview

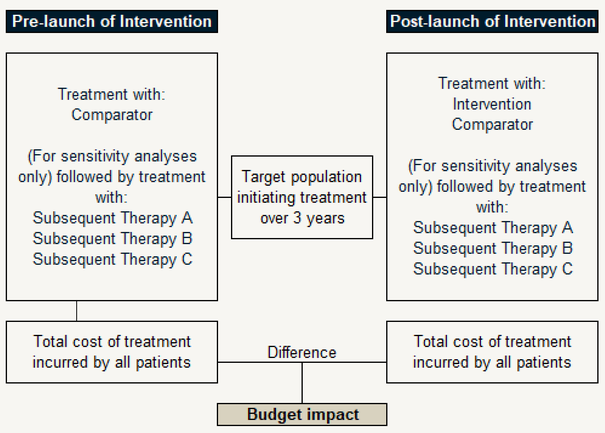


Table 2: Patient population and market shares

	Year 1	Year 2	Year 3
Patients initiating treatment	100	110	120
Market shares for patients initiating treatment each year – pre-launch of Intervention			
Comparator	100%	100%	100%
Market shares for patients initiating treatment each year – post-launch of Intervention			
Intervention	20%	50%	70%
Comparator	80%	50%	30%
Market shares for subsequent treatment on discontinuation of Intervention			
Therapy A			30%
Therapy B			30%
Therapy C			40%
Market shares for subsequent treatment on discontinuation of Comparator			
Therapy A			50%
Therapy B			50%

- The yearly target population is evenly distributed across the quarterly/monthly/weekly entry intervals in each year. On entering the model, patients receive treatment with either the Intervention or the Comparator. On treatment discontinuation of either the Intervention or the Comparator, patients leave the model. The model traces the treatment costs incurred by patients in each cohort and treatment arm throughout the time horizon in weekly cycles
  - A constant treatment discontinuation rate is used
  - The sensitivity analyses include treatment with Subsequent Therapy A, Subsequent Therapy B or Subsequent Therapy C on discontinuation of either the Intervention or the Comparator. Costs associated with these are modelled continuously (Sensitivity Analysis 1) and as a one-off event on subsequent treatment initiation (Sensitivity Analysis 2)

Table 3: Treatment duration, administration schedule and costs

Treatment	Median treatment duration	Weekly discontinuation probability	Treatment administration schedule	Cost of treatment per administration
Intervention	70 weeks	0.99%	Once every 2 weeks	€100
Comparator	30 weeks	2.28%	Once every 3 weeks	€200
Subsequent Therapy A	20 weeks	3.41%	Once per week	€30
Subsequent Therapy B	30 weeks	2.28%	Once every 2 weeks	€40
Subsequent Therapy C	40 weeks	1.72%	Once every 4 weeks	€100

RESULTS

- The cumulative BI for Years 1–3 is €53,579, €25,485, €21,072 and €19,347 for the yearly, quarterly, monthly and weekly patient entry intervals, respectively
  - The difference between yearly and weekly patient entry is particularly high for Year 3 (€42,668 versus €22,460)

Figure 2: Detailed base case results for yearly and weekly patient entry intervals

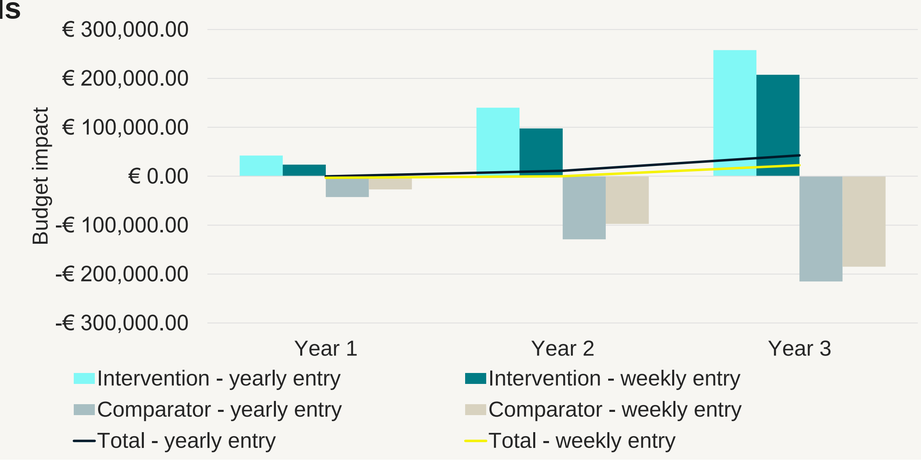
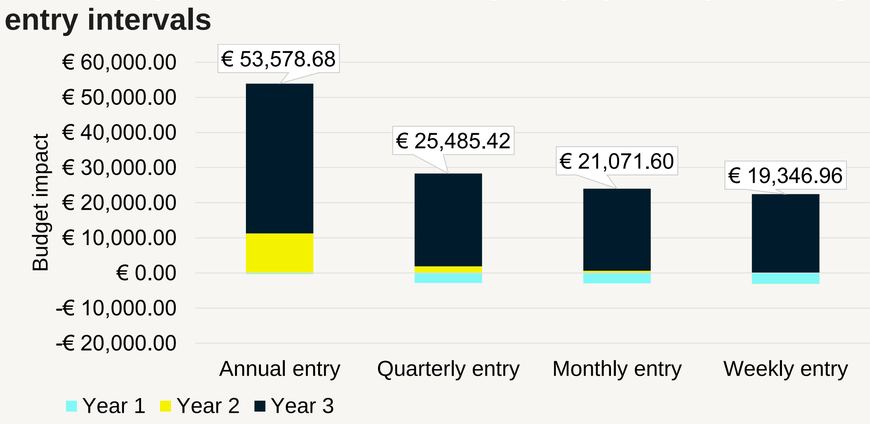
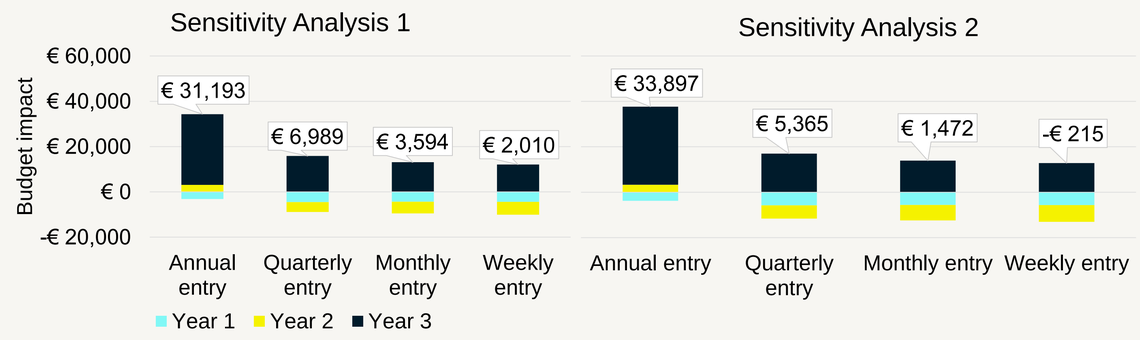


Figure 3: Summary base case results for yearly, quarterly, monthly and weekly patient entry intervals



- For both sensitivity analyses, the BI difference between yearly and weekly patient entry is particularly high for Year 3 (€31,257 versus €12,103 for Sensitivity Analysis 1, and €34,405 versus €12,828 for Sensitivity Analysis 2)

Figure 4: Summary sensitivity analyses results for yearly, quarterly, monthly and weekly patient entry intervals



CONCLUSIONS

- The length of patient entry intervals affects BI estimates. This can distort reimbursement decisions and price negotiations if it determines whether the BI estimates meet a certain threshold. For example, exceeding the £20 million and €10 million thresholds for the National Institute for Health and Care Excellence and the Zorginstituut Nederland in any of the first 3 years may trigger commercial discussions or requests for statutory funding[12], or exclude the need for pharmacoeconomic evaluation[13], respectively
- Our BI model attempts to correct the limitation of most models that account for patient entry at the start of each year; however, our model is still limited because it assumes even distribution of patients across the quarterly/monthly/weekly entry intervals within each year. Ideally, BI models would reflect seasonal variations in screening and diagnosis that affect the moment patients start treatment in clinical practice, as seen, for example, in a large retrospective, observational cohort study that concluded that all 10 major cancers in Korea showed seasonal variations in diagnosis, with a significant Winter peak[14]
- Results from our BI model show that the BI difference is very marked when moving from yearly to quarterly entry intervals, but substantially smaller when moving from quarterly to monthly or weekly intervals. This suggests that, generally, the longer the treatment duration, the higher the need to lower the patient entry intervals so that costs are smoothed over time (and that modelling quarterly patient entry intervals already leads to substantial improvements in the accuracy of the results without adding significant complexity to the analysis)
- We recommend that BI analyses account for costs in the period that they occur (e.g. not by lump-summing costs for subsequent treatment) and that they generally use patient entry intervals shorter than 1 year

REFERENCES

1. Sullivan SD et al. *Value Health*. 2014; 17(1):5-14. **2**. Mauskopf J et al. *Budget-Impact Analysis of Health Care Interventions: A Practical Guide.*, 2017, p.1-10. **3**. AIFA. 2019. https://www.aifa.gov.it/web/guest/linea-guida-capitolo-9. Accessed: 18 October 2022. **4**. HAS. 2016. https://www.has-sante.fr/jcms/c_2730306/fr/choix-methodologiques-pour-l-analyse-de-l-impact-budgetaire-a-la-has. Accessed: 18 October 2022. **5**. Lamrock F et al. 2022. https://www.ncpe.ie/submission-process/submission-templates/budget-impact-model-template/. Accessed: 18 October 2022. **6**. HIQA. 2018. https://www.hiqa.ie/sites/default/files/2018-01/HIQA_BIA_Guidelines_2018_0.pdf. Accessed: 18 October 2022. **7.** NICE. 2022. https://www.nice.org.uk/about/what-we-do/into-practice/resource-impact-assessment. Accessed: 18 October 2022. **8**. NICE. https://www.gov.uk/guidance/budget-impact-analysis-health-economic-studies. Accessed: 18 October 2022. **9.** NICE 2015. (Updated: 2022) https://www.nice.org.uk/guidance/ng14/resources. Accessed: 18 October 2022. **10**. NICE. 2019. (Updated: 2021) https://www.nice.org.uk/guidance/ng131/resources. Accessed: 18 October 2022.

11. SMC. 2021. https://www.scottishmedicines.org.uk/media/6164/working-with-smc.pdf. Accessed: 18 October 2022. **12**. NICE. 2017. https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/budget-impact-test. Accessed: 18 October 2022. **13**. ZIN. https://www.zorginstituutnederland.nl/over-ons/werkwijzen-en-procedures/adviseren-over-en-verduidelijken-van-het-basispakket-aan-zorg/beoordeling-van-geneesmiddelen/richtlijnen-voor-economische-evaluatie. Accessed: October 2022. **14.** Yoon JY, et al. J *Gastroenterol Hepatol*. 2021; 36(12):3371-80.

An electronic version of the poster can be viewed by scanning the QR code.

Poster presented at ISPOR Europe 2022; 06–09 November 2022; Vienna, Austria.