

## BACKGROUND

- HTA agencies provide decision-makers with evidence-based recommendations founded on comprehensive systematic evaluations in order to best allocate finite public healthcare resources
- The Canadian Agency for Drugs and Technologies in Health (CADTH), established in 1989, provides HTA guidance to all provinces and territories of Canada with the exception of Quebec (1)
  - CADTH carries out its mandate through the Common Drug Review for non-oncology products and has a subdivision, the pan-Canadian Oncology Drug Review (pCODR), that specializes in HTA assessment of cancer therapies (1)
- The National Institute for Health and Care Excellence (NICE) advises the National Health Service (NHS), the publicly funded healthcare system of England (2)
  - The NHS has established the Cancer Drug Fund to help provide access to new oncology treatments via the Managed Access Program, an arrangement where the oncology product becomes available at a discounted price for a limited period of time (2)
- Since 2002, the Scottish Medicines Consortium (SMC) has provided advice to Scotland's NHS about the value of every newly licensed medicine (3)
- Pharmaceutical Benefits Advisory Committee (PBAC) provides recommendations regarding the listing of a new medicine on the Pharmaceutical Benefits Scheme, a program that subsidises prescription drugs in Australia (4)
- Each HTA agency uses a unique set of criteria to evaluate reimbursement submissions and provides recommendations for different types of healthcare systems and payers and as such, a certain level of variability is expected to occur across reviews from different HTAs

## OBJECTIVE

The objective of this study was to identify oncology drugs mutually evaluated across all four HTA agencies for the same indications, assess the recommendations from each HTA, and elucidate the relative difficulty of obtaining market access through positive reimbursement recommendations.

## METHODS

- An assessment of HTA reimbursement recommendations from published reports for systemic oncology treatments was conducted for four HTA agencies: CADTH, NICE, SMC, and PBAC
- The pCODR of CADTH was chosen as the primary agency of reference for this analysis
- To be included, a therapy was required to be present on the pCODR Review Table listing of recommendations issued between January 2016 and October 2019
- The corresponding recommendations from NICE, SMC, and PBAC were identified by generic name and indication
- As the wording of indications and diseases varied across HTA agencies, a clinical expert validated the parings to ensure the indications were clinically comparable
- Only products mutually reviewed by all four HTA agencies for the same indication were retained for the final analysis
- Extracted variables included reimbursement recommendation coded as a binary variable (positive or negative), the conditions for reimbursement, and the reasons for rejection
  - Positive recommendations included those with or without conditions
- The relative difficulty of reimbursement was pre-defined as the proportion of positive versus negative recommendations for each HTA agency
- The agency granting the highest proportion of positive recommendations was considered the easiest, and conversely, the one with issuing the lowest proportion of favorable appraisals was deemed as the most difficult
- The interagency agreement rate, defined as the proportion of treatments that received an equivalent recommendation outcome by all four agencies (all positive or all negative, regardless of conditions/reasons) amongst mutually reviewed treatments, was determined

## RESULTS

- Between January 2016 and October 2019, there were 133 oncology products listed on the pCODR Review Table that either were undergoing review or for which an appraisal had already been made
- After the exclusion of those without a final recommendation, 89 drugs were considered for analysis
- The NICE, SMC, and PBAC websites were searched for reports on the same drugs in the same oncology indications
- A total of 49 oncology drugs with matching indications that underwent mutual assessment across all four HTA agencies were identified and retained for the final analysis
- Based strictly on the absolute proportion of positive recommendations, the ranking of reimbursement difficulty from easiest (proportion of positive reimbursement recommendations) to most difficult is as follows: NICE (92%), SMC (88%), pCODR (86%) and PBAC (73%), though only a minor difference was observed amongst the top 3 ranking agencies (Fig. 1)

Figure 1: Positive and negative reimbursement recommendations across pCODR, NICE, SMC and PBAC

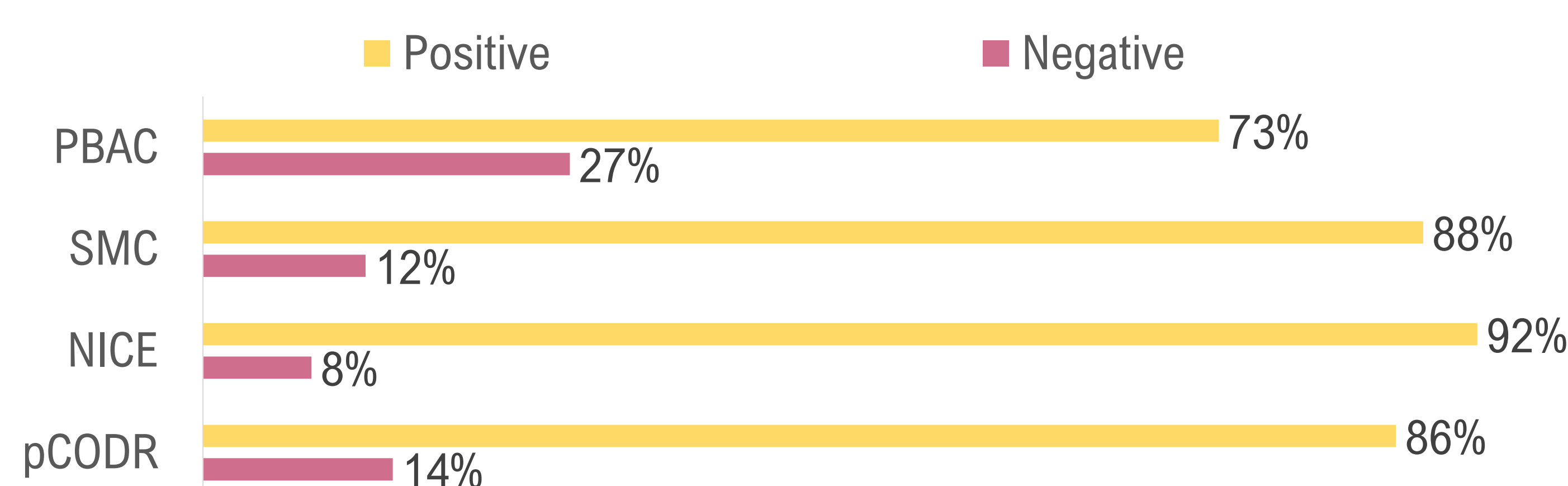


Figure 2: Breakdown of reimbursement assessment outcomes from pCODR (n=49)

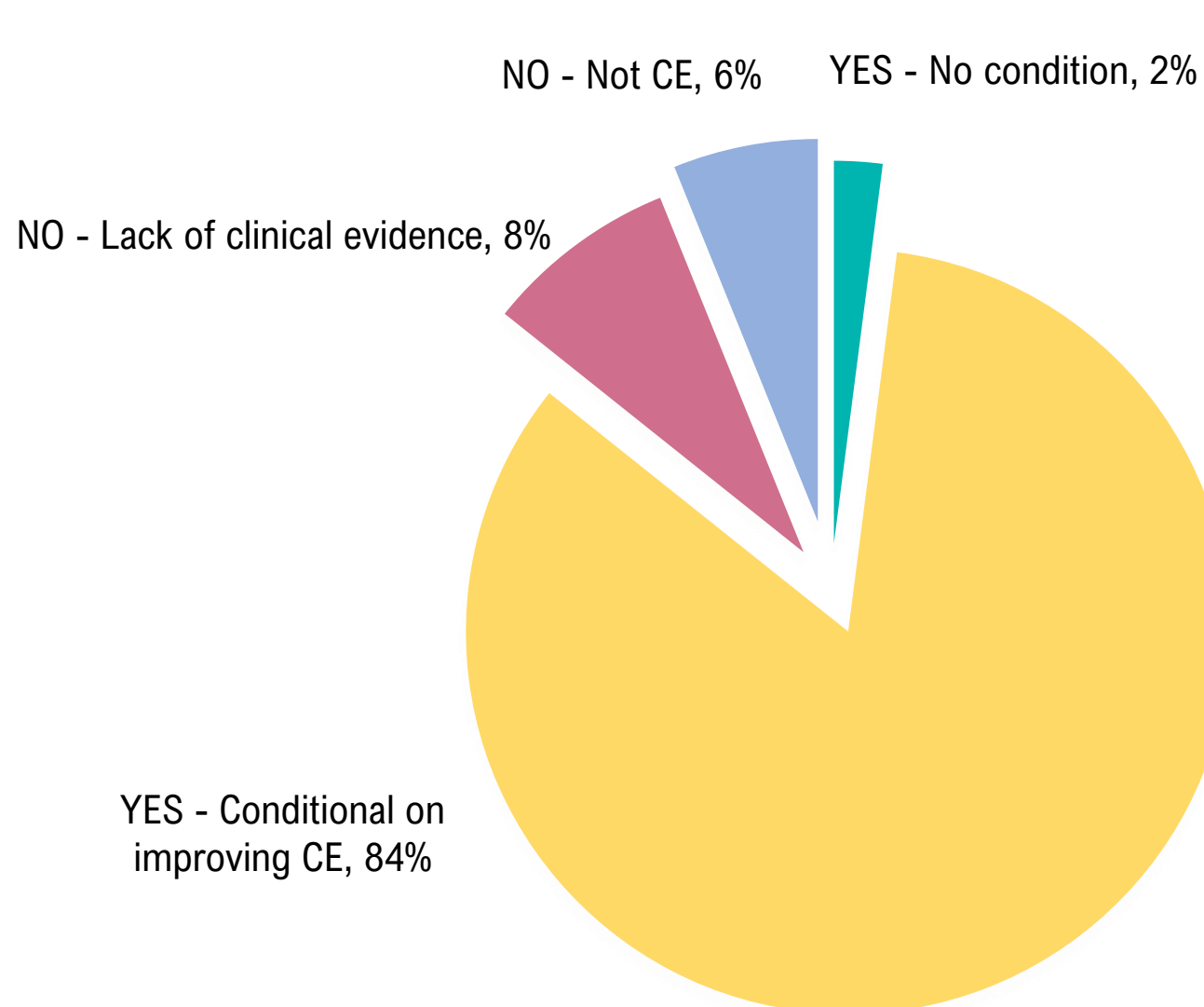


Figure 3: Breakdown of reimbursement assessment outcomes from NICE (n=49)

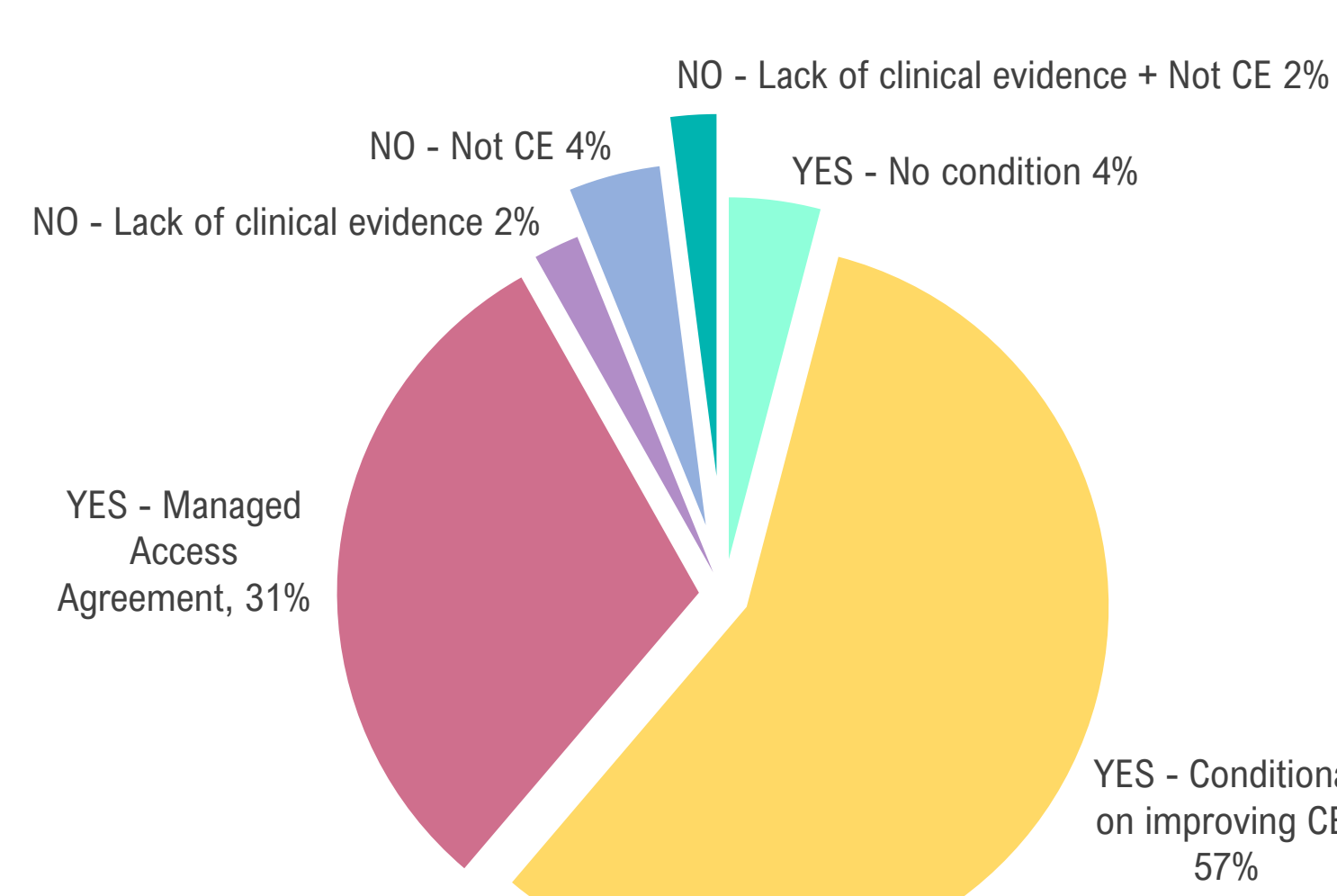


Figure 4: Breakdown of reimbursement assessment outcomes from SMC (n=49)

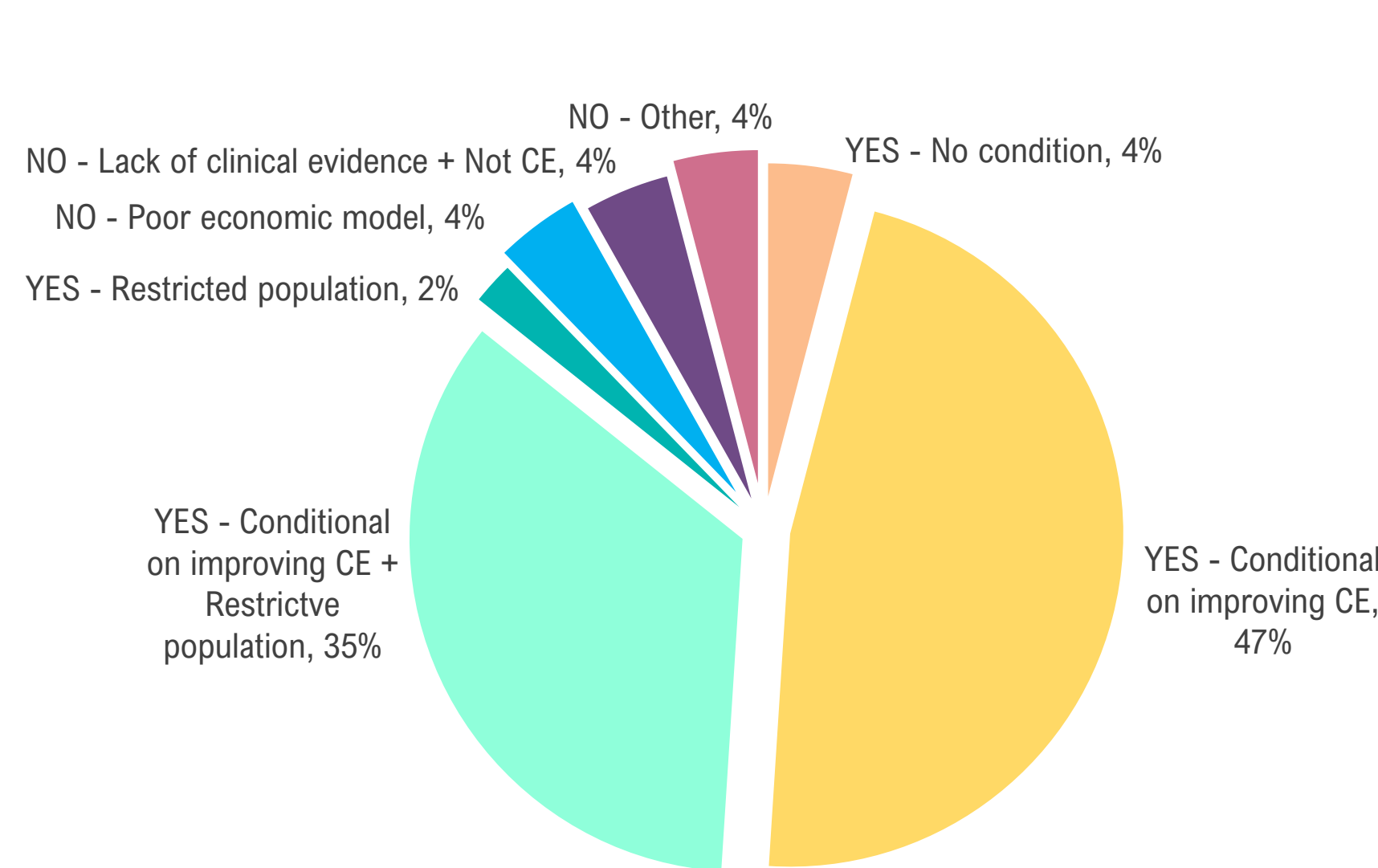
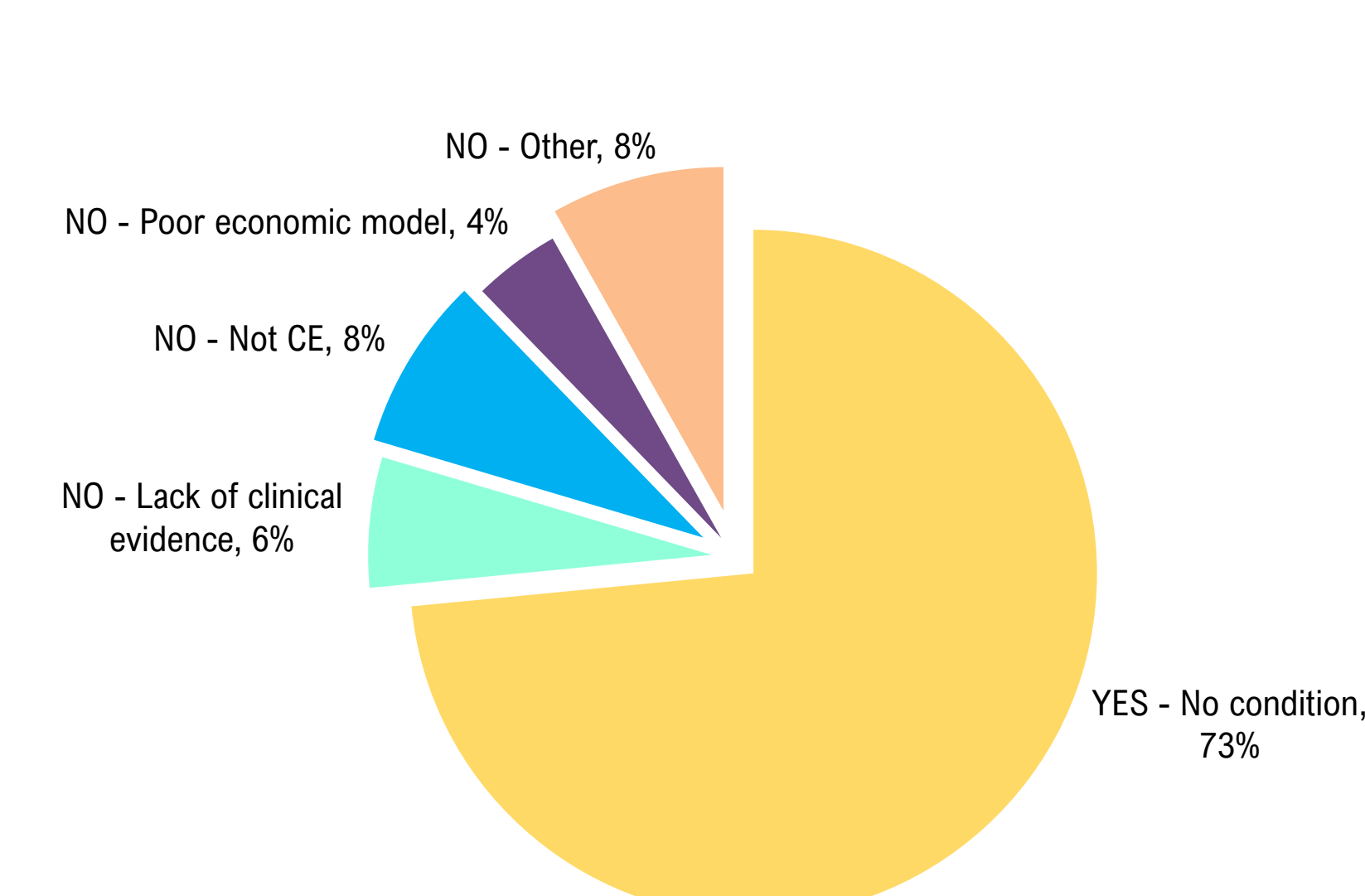


Figure 5: Breakdown of reimbursement assessment outcomes from PBAC (n=49)



CE, cost-effective(ness); pCODR, pan-Canadian Oncology Drug Review; NICE, National Institute for Health and Care Excellence; SMC, Scottish Medicines Consortium; PBAC, Pharmaceutical Benefits Advisory Committee

- With pCODR, NICE, and SMC, 84%, 57%, and 47% of recommendations, respectively, were positive but conditional on improving cost-effectiveness (Fig. 2 to 4)
- An additional 35% of reviewed drugs by SMC were recommended favourably on the conditions of improving cost-effectiveness and restricting the targeted population (Fig. 4)
- For SMC, the proportion of positive recommendations sums to 82% with conditions, including the improvement of cost-effectiveness and in some cases, also restricting the target population
- Approximately a third of appraisals conducted by NICE resulted in a positive recommendation conditional on a "Managed Access Agreement", a condition unique to this HTA agency (Fig. 3)
- For pCODR, NICE and SMC, a small percentage (2-4%) of recommendations were positive with no conditions (Fig. 2 to 4)
- Unlike the other three agencies, 73% of oncology drugs appraised by PBAC received a positive recommendation with no published condition (Fig. 5)
- Reasons for a negative recommendation included lack of clinical evidence, a product not deemed cost-effective, poor quality of the economic model in the submission, or a combination of the aforementioned reasons
- Deferred recommendations and absence of submission by company were categorized as a negative recommendation for other reasons. Further details are displayed in Figures 2 to 5
- The interagency agreement rate was 61%
- For a total of 49 systemic oncology treatments mutually assessed by pCODR, NICE, SMC and PBAC, 30 received a positive recommendation across all four agencies
- No treatment obtained a universal negative recommendation
- In some instances, there was alignment in the reimbursement recommendation and the condition provided
  - Ex: alectinib for non-small cell lung cancer, nivolumab for renal cell carcinoma, and venetoclax for chronic lymphocytic leukaemia, amongst others, all received a positive recommendations provided the cost-effectiveness was improved from pCODR, NICE, and SMC (PBAC approvals do not specify conditions)
- In other instances, there was no alignment in reimbursement recommendation and the condition/reasons provided
  - Ex: obinutuzumab for previously untreated follicular lymphoma received a negative recommendation because it was not cost-effective from pCODR, a positive recommendation conditional on improving cost-effectiveness from NICE, a negative recommendation because of a poor economic model from SMC, and a positive recommendation without a condition from PBAC

## LIMITATIONS

- The analysis only used publicly available information regarding reimbursement recommendations
  - As such, the study was limited to four HTA agencies that published detailed reports
  - The results provide a general overview of the HTA landscape; however, it may not be applicable to nations that were not considered in this analysis
- The precise wording for conditions of reimbursement and reasons for rejection were categorized as objectively as possible; however, they were not always worded in a consistent manner across HTA agencies, and occasional interpretation was required

## CONCLUSIONS

- NICE had the largest proportion of positive recommendations and this can be partially attributed to the Managed Access Agreement program
- Additionally, the interagency agreement rate was found to be moderate at 61% demonstrating key differences across various regions, healthcare systems, and HTA bodies
- With the increasing economic burden of oncology, it may be prudent for HTA agencies around the world to re-align efforts to consistently promote accessibility to novel oncology therapies

## REFERENCES

- Canadian Agency for Drugs and Technologies in Health (CADTH) [internet]. 2020 [Accessed 4 Oct 2019]. Available at: <https://www.cadth.ca/>.
- National Institute for Health and Care Excellence (NICE) [internet]. 2020 [Accessed 4 Oct 2019]. Available at: <https://www.nice.org.uk/>.
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