



### INTRODUCTION

Integrating Health Technology Assessment (HTA) into public health systems is essential for evaluating health technologies from clinical, social, ethical, and economic perspectives, encompassing efficiency, effectiveness, safety, and costs.<sup>1</sup> Worldwide, countries have embraced public consultation (PC) to validate social involvement in HTA. PC introduces dynamism by gathering input from various stakeholders, including patients, caregivers, physicians, manufacturers, and other community members. These contributions are crucial for incorporating diverse viewpoints into decision-making, legitimizing societal needs, and potentially leading to more informed reimbursement decisions.<sup>2</sup>

### OBJECTIVES

This study has two primary objectives. First, it seeks to identify Latin American (LatAm) countries that have integrated HTA into their public healthcare systems, particularly those that incorporate PC processes. Second, it aims to investigate the relationship between the volume of public contributions in PC and changes in preliminary HTA recommendations.

### METHODS

Comprehensive literature research was conducted to identify LatAm countries with established HTA agencies implementing a PC process. This involved a review of publicly available information and documentation concerning PC in reports submitted to these HTA agencies. For each report, preliminary and final recommendations and the total volume of public participation and contributions were collected. Subgroup analyses were conducted to examine if differences in contribution volume were linked to changes in HTA recommendations. The non-parametric Mann-Whitney Test in R software was utilized to assess this, and statistical significance was set at  $p < 0.05$ .

### RESULTS

#### LatAm Countries with HTA and PC

Out of the 20 countries in LatAm, 11 (55%) have established HTA bodies. However, only two countries, Brazil and Colombia, representing 10% of the total, currently incorporate PC as part of their HTA processes. Additionally, three other countries, Argentina, Costa Rica, and Uruguay, are in the process of incorporating PC into their HTA procedures, indicating a growing interest in public engagement within the region (**Figure 1**). Public engagement data was exclusively available for the Brazilian HTA agency.<sup>3</sup>

**Figure 1.** LatAm Countries with established public HTA bodies and PC

	ARG	BOL	BRA	CHL	COL	CRI	CUB	DOM	ECU	SLV	GTM	HTI	HND	MEX	NIC	PAN	PRY	PER	URY	VEN
Established Public HTA Body?	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	✗	✗	✗	✓	✗	✓	✗	✓	✓	✓
PC Incorporated?	≈	✗	✓	✗	✓	≈	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗	≈	✗

#### Analysis of Recommendations with PC

CONITEC, the Brazilian public HTA agency, issued 787 decisions from 2012 to 2022. Of these, 640 (81%) included PC data. Among them, 351 (55%) initially had positive preliminary recommendations, with 2 (<1%) changing to negative after public input. Meanwhile, 289 (45%) assessments started with negative preliminary recommendations, of which 68 (24%) switched to positive after the inputs from the PC (**Figure 2**).

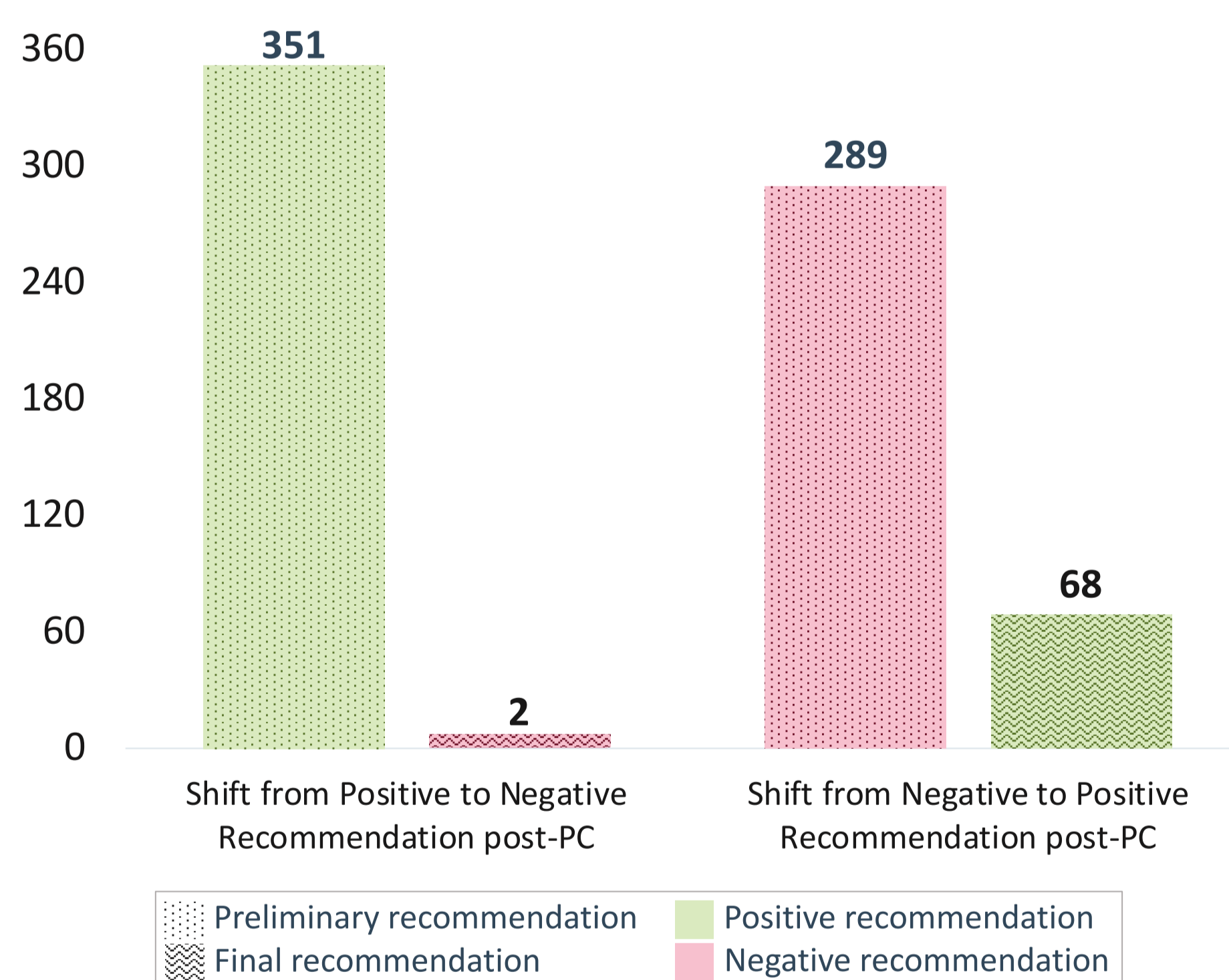
#### Correlation between Preliminary Negative Recommendations and Changes to Positive

When analyzing the 289 assessments with a preliminary negative recommendation, there is a statistically significant difference ( $p=0.0000004262$ ) between the volume of PC contributions in the assessments that shifted the final decision to a positive recommendation ( $n=68$ , 24%) compared to those who maintained the negative recommendation ( $n=221$ , 76%). We did not analyze changes from positive preliminary recommendations to a final negative recommendation due to the limited number of cases (only two technologies), precluding statistical analysis.

#### Subgroup Analyses

Subgroup analyses were conducted to determine whether the correlation between the volume of contributions in public consultations and changes in preliminary recommendations remained consistent if assessments with a higher volume of contributions during PC were excluded from the statistical analysis (**Table 1**).

**Figure 2.** Preliminary Recommendations Before Public Consultation and Final Recommendations After Public Consultation (2012-2022)



**Table 1.** Subgroup Analyses: Correlation between Contribution Volume in PC and Changes in Negative Preliminary Recommendations

PC Contributions per HTA	Preliminary Negative Recommendations	Changes in HTA Decision n (%)	P-Value
Less than 1000	245	48 (19.6 %)	0.00006337
Less than 300	182	27 (11.0%)	0.01411
Less than 200	167	22 (9.0%)	0.03695
Less than 50	98	9 (3.7%)	0.2759
Less than 30	73	5 (2.0%)	0.9477

These analyses show that as we remove the assessments with a higher volume of contributions, the correlation between the contribution volume in PC and changes in HTA recommendations weakens but remains statistically significant. However, for assessments with fewer than 50 contributions, the volume in PC had no discernible impact on the transition from preliminary negative to positive recommendations.

### DISCUSSION, LIMITATIONS AND CONCLUSION



#### Discussion

Our study indicates that from 2012 to 2022, heightened participation in PC can influence the shift of preliminary recommendations from negative to positive. Subgroup analyses have demonstrated that this association persists even when a high volume of contributions is excluded. Nevertheless, additional research is needed to uncover this connection's underlying mechanisms and ascertain if comparable patterns exist in diverse contexts.



#### Limitations

Due to data availability, the research primarily focuses on the assessments issued by the Brazilian HTA agency, limiting its generalizability to other LatAm countries. Establishing a cause-and-effect relationship between public engagement and changes in preliminary recommendations needs to be supplemented by qualitative research, as our study primarily employs quantitative analysis and does not include qualitative examination of the content of public contributions.



#### Conclusion

In LatAm, only a minority of countries have established HTA agencies with mechanisms for PC. Our statistical analyses have unveiled a significant correlation between the volume of contributions in PC and the shift from a negative to a positive HTA recommendation. These findings highlight the importance of promoting more effective public engagement, by legitimizing public participation, which can improve decision-making processes in HTA.

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