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Background

- ▶ Cost-effectiveness models (CEMs) are essential tools in health technology assessments (HTAs), providing evidence to demonstrate the economic value of new health interventions
- ▶ Manufacturers often encounter unique challenges when adapting global CEMs — initially developed for high-income markets such as the United States, United Kingdom, and European countries — for use in low- and middle-income countries (LMICs)¹
- ▶ Currently, there is limited documentation of these adaptation challenges, highlighting a critical need to identify key barriers and develop practical solutions to enhance the HTA process in LMIC settings

Objectives

- ▶ To characterize key learnings from adapting global CEMs for LMICs
- ▶ To identify effective strategies for overcoming challenges when adapting global CEMs to LMIC-specific HTAs

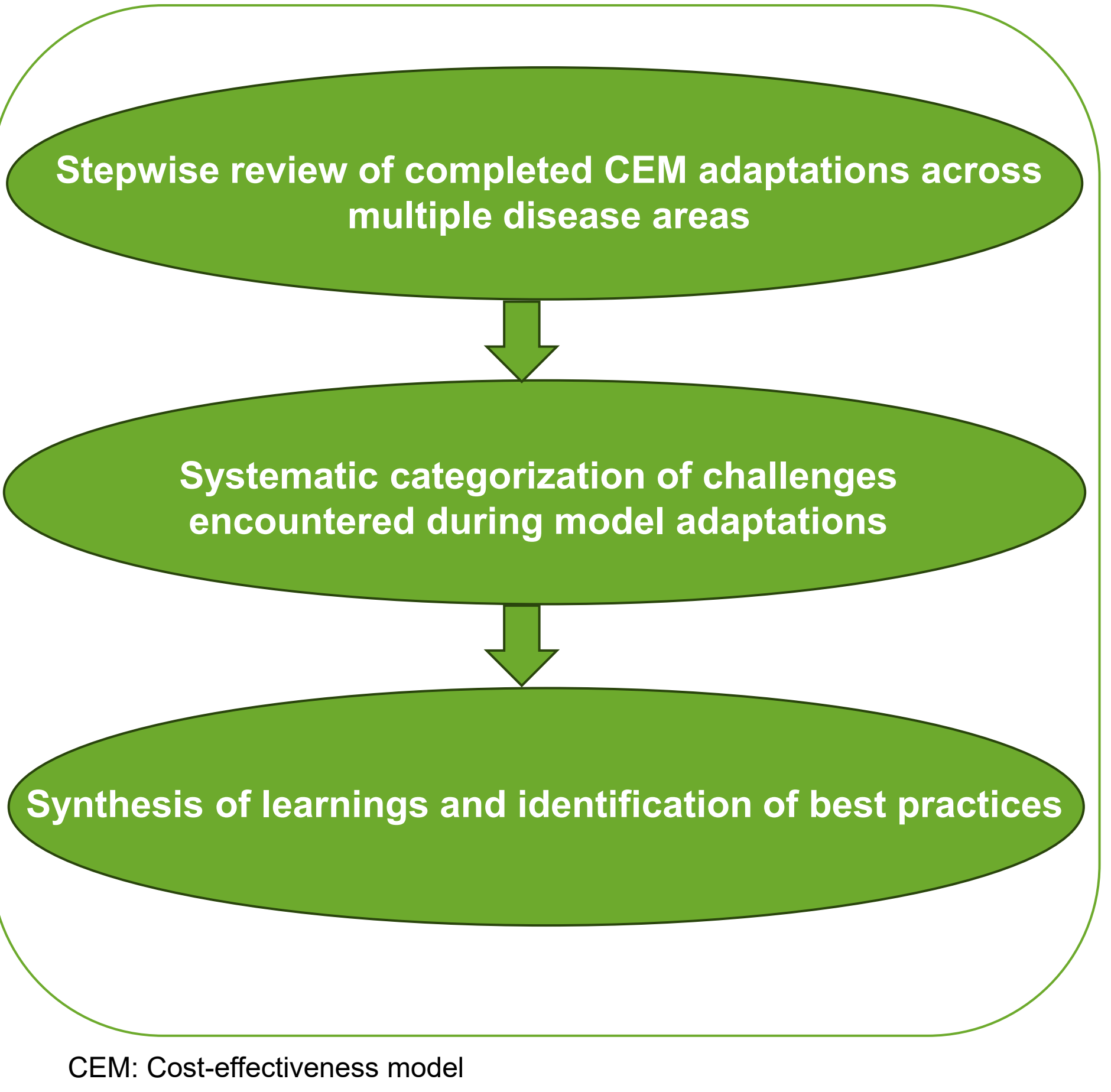
Methods

- ▶ A retrospective analysis was conducted on 11 completed CEM adaptations for LMICs across the globe and multiple disease areas (**Table 1**). The country was considered a LMIC based on International Statistical Institute data.² The stepwise retrospective analysis process undertaken has been visualized in **Figure 1**

Table 1: Included LMICs and Associated Disease Areas	
Country	Disease Area
Colombia, Malaysia, Mexico (x3), Peru, Philippines, Venezuela	Respiratory syncytial virus
Colombia, Montenegro	Advanced and metastatic melanoma
Argentina	Chronic obstructive pulmonary disease

LMICs: Low- and middle-income countries

Figure 1: Stepwise Retrospective Analysis Process



Results

Nine issues were identified for adapting global CEMs for various LMICs (**Table 2**). The recommendation(s) for each identified issue was summarized below

Table 2: Issues Identified in Adapting Global CEMs Across 11 LMIC Analyses

Issue	Number of Analyses with the Issue	Countries
1. Sparse or incomplete data for resource utilization estimates and unit costs specific to the local context	11	Argentina, Colombia, Malaysia, Mexico, Montenegro, Philippines, Peru, Venezuela
2. Sparse or incomplete data for epidemiologic estimates specific to the local context	11	Argentina, Colombia, Malaysia, Mexico, Montenegro, Philippines, Peru, Venezuela
3. Incomplete data for uptake of new intervention by disease status and/or age group	11	Argentina, Colombia, Malaysia, Mexico, Montenegro, Philippines, Peru, Venezuela
4. Inability to understand the potential data sources due to language barrier	6	Colombia, Montenegro, Mexico, Peru
5. Viewing and programming restrictions within the global CEM	5	Malaysia, Mexico, Philippines, Peru
6. Critical demographic data not publicly available	3	Mexico, Peru
7. Lack of reliable local utility data	3	Colombia, Montenegro, Peru
8. Lack of comprehensive national, regional, or local economic evaluation guidelines for HTA submissions	2	Montenegro, Peru
9. Limited details on currency inflation	2	Peru, Philippines

1. Sparse or Incomplete Data for Resource Utilization and Unit Costs

- ▶ **Issue:** For all completed CEM adaptations, there was sparse or incomplete data for resource utilization estimates and unit costs specific to the local context. For example, in the context of direct costs, resource utilization and unit cost data specific to emergency department and outpatient visits were often not publicly available. In addition, information regarding indirect costs (e.g. caregiver work loss days and income) were often not publicly available
- ▶ **Recommendation:** Execute regional costing studies and/or include key opinion leaders for elicitation of clinical expert and real-world knowledge

2. Sparse or Incomplete Data for Epidemiology Estimates

- ▶ **Issue:** For all completed CEM adaptations, there was sparse or incomplete data for epidemiologic estimates specific to the local context. For example, emergency department and outpatient incidence diseased rates and case-fatality rates were often not publicly available
- ▶ **Recommendation:** Apply values from a global systematic review and/or include key opinion leaders for elicitation of clinical expert and real-world knowledge

3. Incomplete Data for Uptake of New Intervention

- ▶ **Issue:** For all completed CEM adaptations, there was incomplete data for uptake of the new intervention by disease status and/or age group
- ▶ **Recommendation:** Assume the uptake based on the timing of country-specific implementation of the new intervention. Enquire if the local affiliates have conducted a study to estimate market share infiltration of the new intervention. In the absence of uptake data stratified by disease status/age, apply the equal uptake for all groups

4. Inability to Understand Data Sources Due to Language Barrier

- ▶ **Issue:** For several CEM adaptations, there was difficulty in accessing or interpreting some of the potential data sources due to the language barrier. This also meant that some useful data sources could have been potentially missed in the process of data collection
- ▶ **Recommendation:** Include local affiliates with knowledge of the local language

5. Viewing and Programming Restrictions Within the Global CEMs

- ▶ **Issue:** For several completed CEM adaptations, viewing and/or programming restrictions were observed within the global CEM, hindering the implementation of necessary model modifications for regional adaptations
- ▶ **Recommendation:** Engage early communication with global modelling teams to obtain open-access to the model

6. Critical Demographic Data Not Available

- ▶ **Issue:** For the Mexico and Peru CEM adaptations, critical demographic data such as the annual number of pregnant women was not publicly available
- ▶ **Recommendation:** Apply relevant, conservative, and transparent assumptions based on the available public data

7. Lack of Reliable Utility Data

- ▶ **Issue:** For the Colombia, Montenegro, and Peru CEM adaptations, there was a lack of reliable utility data stratified by age or disease groups
- ▶ **Recommendation:** Apply utility values as per a nearby country or region

8. Lack of Economic Evaluation Guidelines

- ▶ **Issue:** For the Montenegro and Peru CEM adaptations, there was a lack of formal economic evaluation guidelines for HTA submission requirements. This is problematic in the context of choosing the correct perspective, discount rates, and cost-effectiveness threshold
- ▶ **Recommendation:** Conduct a targeted review and analysis on previous regional reimbursement decisions; this can help to provide a framework for HTA submissions

9. Limited Details on Currency Inflation

- ▶ **Issue:** For the Peru CEM adaptation, the consumer price index data specific to health items was not well documented. For The Philippines, the latest available consumer price index data was from 2018. Therefore, any cost data coming from before 2018 could not have been precisely inflated
- ▶ **Recommendation:** Use general and/or latest available consumer price index data

CEMs: Cost-effectiveness models; HTA: Health Technology Assessment; LMICs: Low- and middle-income countries

Conclusions


- ▶ The study captures nine issues and associated recommendations across 11 completed CEM adaptations for LMICs across the globe and multiple disease areas
- ▶ Market access in LMIC requires planning and local knowledge, but implementation of these recommendations will allow manufacturers operating in LMICs to improve the quality and credibility of global CEMs adapted for the local context and increase the likelihood of launch success

References

1. Mullins et al. *Value in Health Reg. Issues*. 2014;5:7-13.
2. International Statistical Institute. <https://isi-web.org/low-and-middle-income-countries-and-regions> [Date Accessed: March 20, 2025]

Acknowledgments

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