

# A Strategic National Framework for Managed Entry Agreements to Access Innovative and Breakthrough Medications in Saudi Arabia

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CODE:  
HPR10

## INTRODUCTION

Managed entry agreements (MEAs) between manufacturers and healthcare payers allow health systems to maximize patients' access to treatments and mitigate clinical, economic, and financial risks and uncertainties. However, to efficient implementation, MEAs need to be integrated into a country's formal pricing, reimbursement, and market access processes.

## AIM

This study proposes a comprehensive and tailored framework for MEAs characterized by efficiency, practicality, operational feasibility, and adaptability, and sheds light on the key enablers of optimal implementation of MEAs across diverse sectors in Saudi Arabia.

## METHODS

This mixed-methods study was conducted in 2025 through secondary data collection derived from systematic literature review followed by a half-day multi-stakeholder workshop hosted in Riyadh, Saudi Arabia including official representatives from different governmental, quasi-governmental, and private sectors, all of whom had a job role related to pharmaceutical pricing, reimbursement, and market access. A predefined and validated set of questions was used to guide the workshop discussion with props and prompts to elicit more insights on MEAs design and framework from the participants. The workshop discussion and interactions were digitally recorded to enable verbatim transcription, followed by a thematic analysis.

## FINDINGS

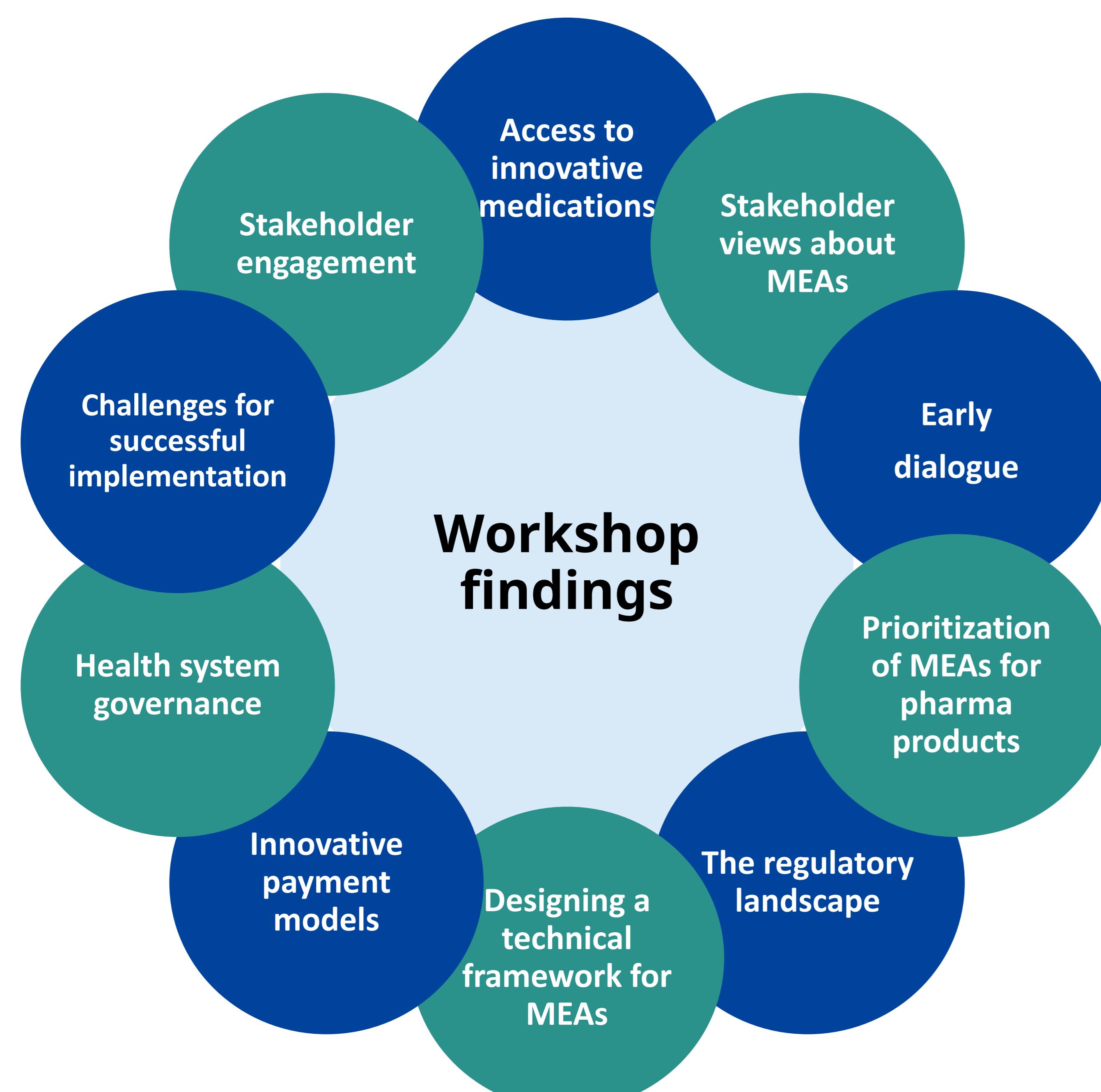


Figure 2. Four-step process to optimize MEA efficiency through sequential implementation.

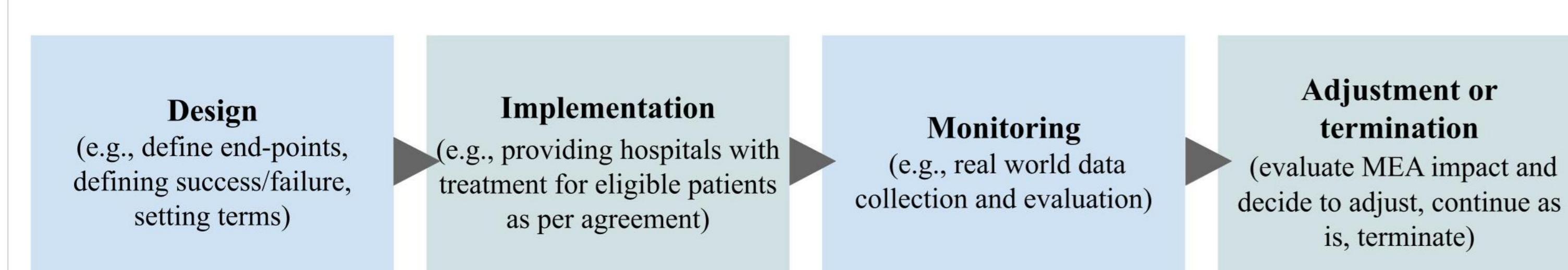
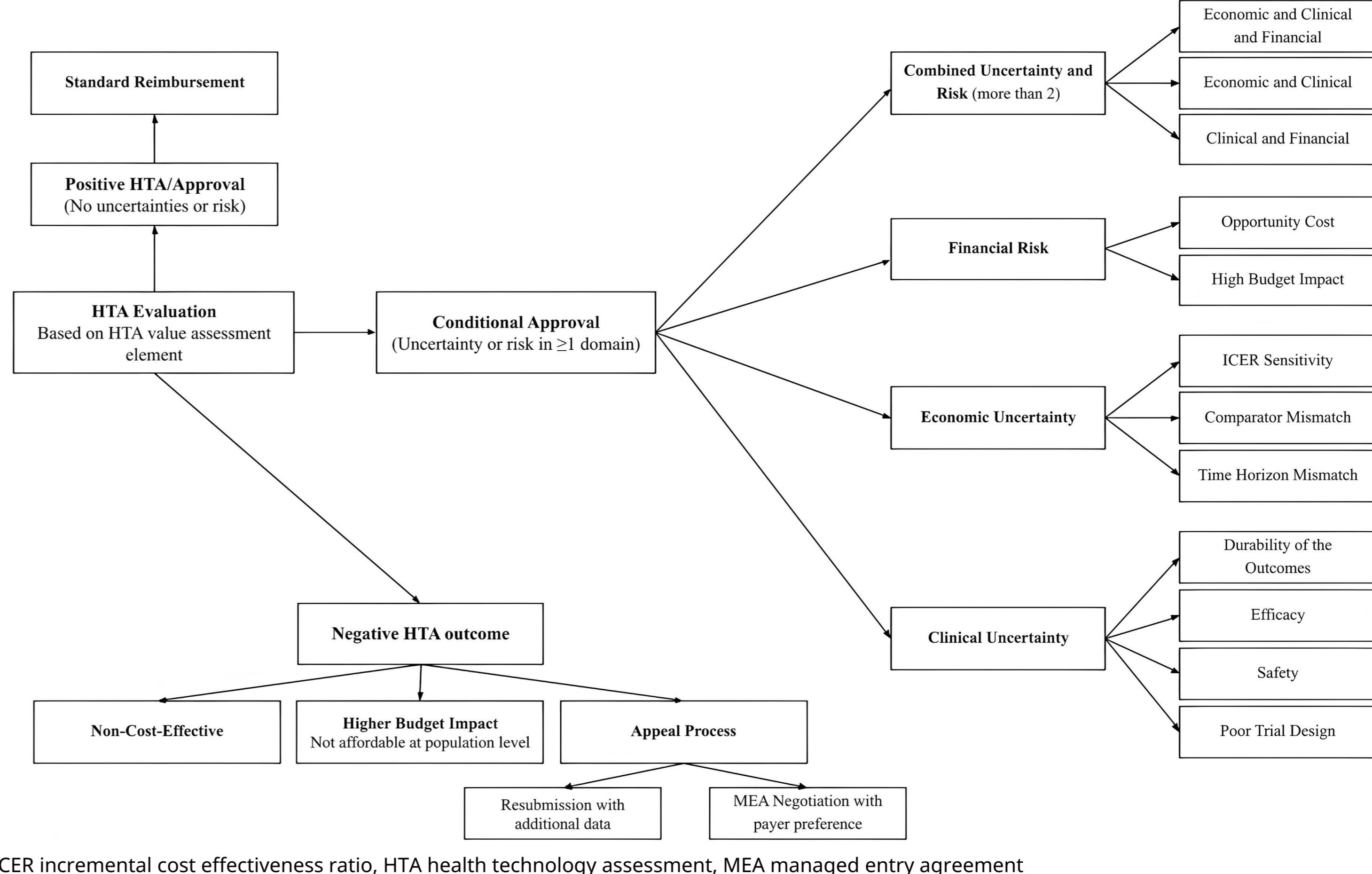
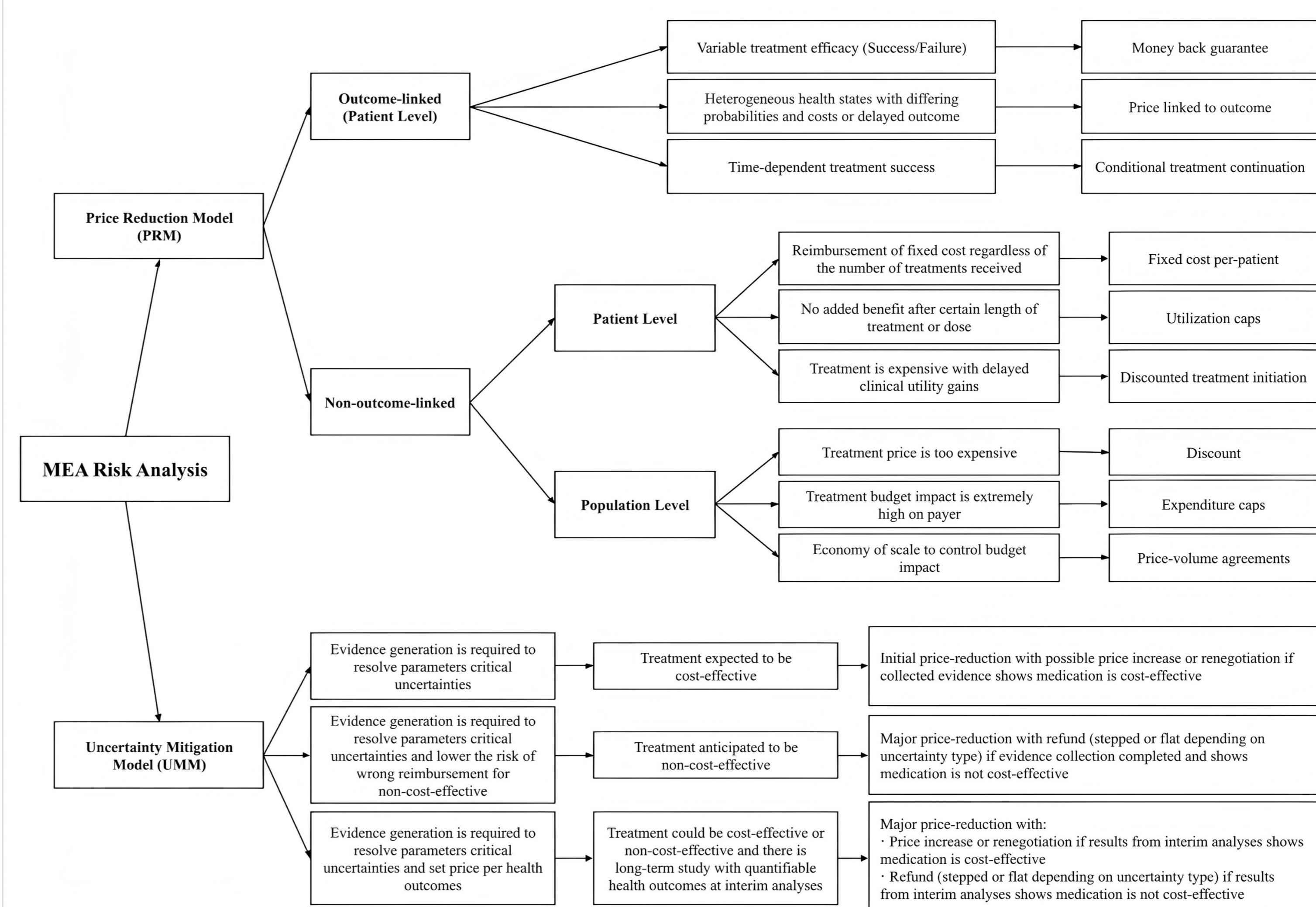


Figure 1. MEA technical framework within iterative HTA process with example on evidence uncertainties and risks.



ICER incremental cost effectiveness ratio, HTA health technology assessment, MEA managed entry agreement

Figure 3. MEAs design guided by the price reduction model and uncertainty mitigation model.



## DISCUSSION & CONCLUSIONS

- From strategic and economic perspectives, MEAs must address two interdependent objectives: macroeconomic efficiency, which is the potential budget impact of overspending, and microeconomic efficiency, which is resource allocation based on product cost-effectiveness. Two clinical factors streamline Managed entry agreements objectives: the degree of therapeutic value uncertainty, and selecting the right patient population to receive the medication.
- Successful implementation requires four critical pillars: 1. A well-governed pricing and reimbursement system. 2. A fit-for-purpose national technical framework. 3. A transparent, rigorous evaluation process. 4. Systematic mechanisms for continual evaluation and monitoring of MEA efficiency and impact on macro-level.
- The existence of challenges that go beyond system readiness and system governance, relating to areas like data collection, administrative burden, insufficient and non-scalable registries, and unresolved governance issues surrounding data ownership, security, privacy, protection, and interoperability. All these challenges mirror similar historical or present experiences from our benchmark countries.
- Future work should focus on piloting the framework with real-world case studies, building local capacity in HTA and MEA negotiation, and investing in data infrastructure (e.g., national registries).

FULL-TEXT



REFERENCES

