Developing a Selection Framework for Comparator in HTA-Based Inclusion in China's National Reimbursement Drug List

HTA67

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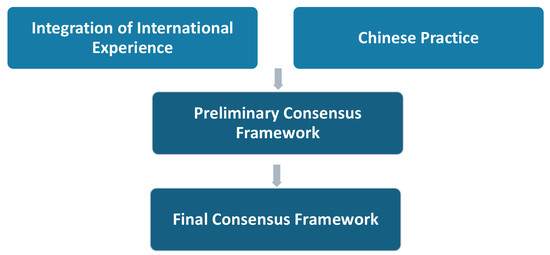
BACKGROUND

- **Health technology assessment (HTA) is widely used** to support inclusion decisions in China's National Reimbursement Drug List (NRDL).
- **No standardized method** exists for selecting comparator drugs, , leading to inconsistent evaluation outcomes when different comparators are used.
- **Inappropriate or unclear comparator choices** may lead to **biased cost-effectiveness results** and undermine HTA credibility.
- A structured selection framework is needed to improve **transparency**, **methodological consistency**, and **policy relevance**.

OBJECTIVES

- To develop a structured framework for **comparator drug selection** in HTA-based NRDL submissions.
- To improve the **design, implementation, and reporting** of HTA studies by ensuring comparator relevance and consistency.

METHODS



- **Systematic review** of 27 HTA guidelines from major international agencies , extracting comparator-related criteria.
- **Key informant interviews** (n=14) to explore real-world challenges and gather suggestions.
- **Expert consultations** (n=72) to refine the preliminary framework content.
- **Delphi process** (4 rounds, n=222) using structured, anonymous feedback to validate and finalize the framework.

RESULTS

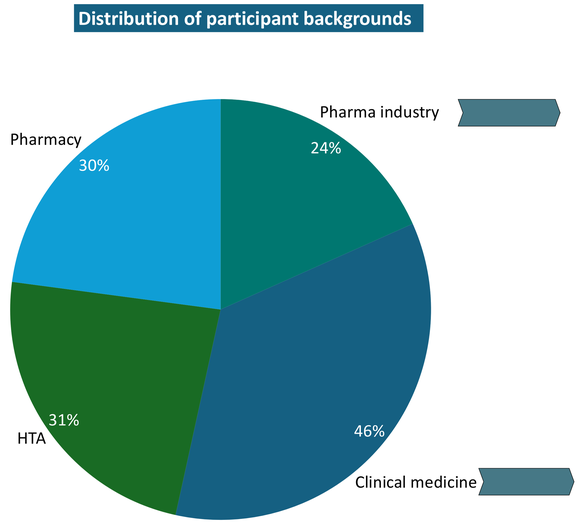


Figure1: Professional Background of Participants (n = 308)

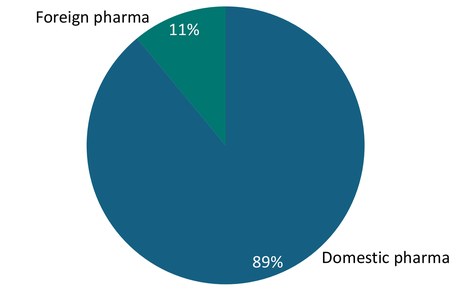


Figure2: Breakdown of Pharma Industry Respondents (n = 73)

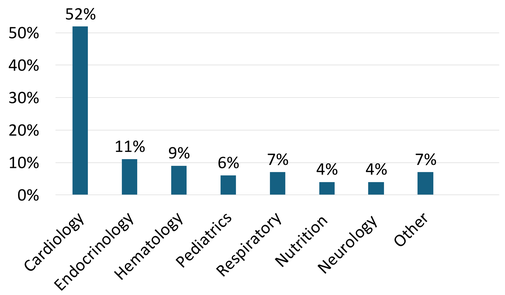


Figure3: Breakdown of Clinical Medicine Respondents (n = 46)

***Table 1:* Structured Framework for Selecting Comparator Drugs in NRDL Evaluations**

Consensus Area	Key Content	Agreement (%)
1. Selection Principle	Use **NRDL-listed**, **same indication** and treatment line	97.30
	Exclude off-label use	93.69
	Exclude non-pharmacological interventions	84.03
2. Selection Criteria		
2.1 Western Medicine	Prefer **standard treatment**	82.43
	Accept **conventional/routine treatment**	68.92
	Consider evidence level and availability	86.79
	Consider same mechanism of action	82.88
2.2 TCM	Prefer TCM with **efficacy and safety evidence**	84.92
	Accept standard treatment	75.40
	Consider same NRDL category	81.75
	Consider same product standard	80.95
3. Number of Comparators	Limit to 1~3 comparators	66.67
4. No Active Comparator	Allow **no active comparator** (including no-treatment or best supportive care) for **first-in-class** drugs when no suitable alternatives exist	86.49
5.Multi-indications	Use a single comparator across indications if possible; if not, assign different comparators by indication based on evidence availability	94.59
6. New NRDL Drugs	Guideline-recommended but not yet widely used are acceptable	84.21
7. Timing	Comparators should be determined before or early in the HTA process	99.06
8. Selection Process	Use structured, multidimensional selection process	79.73
9. Value Orientation	Use clinical value tiers to guide comparator selection	99.06

- **Definitions:**
  - *Standard treatment* refers to the highest-ranked treatment in clinical guidelines (agreement: 54.95%).
  - *Routine treatment* refers to the most commonly used option in real-world clinical practice (agreement: 85.14%).

Application : WTP

- **Value-based drug classification:** classify the evaluated and comparator drugs based on **their intrinsic clinical value.**
  - **High-value** classification may include
    - Evaluated drug: curative therapies, Class 1.1 new drugs, originator innovations, and breakthrough therapies
    - Comparator: exclusive products, top-tier clinical guideline recommendations
- Emphasize the **relative benefit**, which may influence pricing and willingness-to-pay (WTP) thresholds:
  - **No premium** if no added benefit over comparator.
  - **Higher thresholds** when the evaluated drug is compared strictly against a higher-value comparator
  - **Lower thresholds** when the comparison is less stringent, involving a lower-value comparator

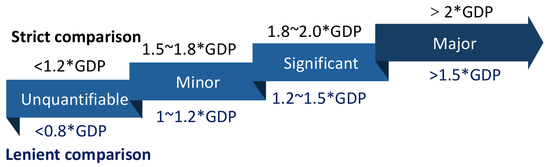


Figure4: WTP Threshold Ranges by Incremental Clinical Benefit (× GDP per capita)

CONCLUSION

- A structured, consensus-based framework was developed for comparator selection in HTA-based NRDL inclusion.
- It enhances consistency and transparency by standardizing selection principles, criteria, and special-case handling.
- It also recommends integrating clinical benefit assessment with economic evaluation to support a more comprehensive value-based framework for innovative drugs.

ACKNOWLEDGEMENT

We thank the China Pharmaceutical Innovation and Research Development Association (PhIRDA) for their support and collaboration in this study.