

# A Review of Guidelines and Practices for Patient Involvement in HTA Across Europe, North America and APAC, to Identify Opportunities for Advancement in the Nascent Philippines HTA Market

Kochar N,<sup>1</sup> Lampkin A,<sup>1</sup> Penantian R,<sup>2</sup> Xiong A,<sup>3</sup> Yadav V,<sup>1</sup> Eddowes LA,<sup>4</sup> Munoz C<sup>5</sup>

<sup>1</sup>Costello Medical, London, UK; <sup>2</sup>Costello Medical, Cambridge, UK; <sup>3</sup>Costello Medical, Singapore;

<sup>4</sup>Costello Medical, Bristol, UK; <sup>5</sup>Phillipine Alliance of Patient Organizations, Makati, Philippines



## Objective

We aimed to suggest improvements to the patient involvement (PI) processes of nascent HTA bodies, such as the recently formalised HTA Philippines body, by identifying challenges to PI and mitigative strategies in other settings.

## Background

- PI is a growing theme in HTA, with the potential to enhance the quality, relevance and legitimacy of HTA by empowering patients and improving assessors' understanding of their experiences.
- Well-established HTA bodies have developed processes to facilitate and maximise PI, and best practice guidelines also exist.
- HTA Philippines was established in 2019. There has been limited formal exploration of how to effectively maximise the level and impact of PI in the Philippines.

## Methods

- We reviewed PI processes employed by HTA bodies globally, published best practice guidelines, and articles on PI in HTA. Findings were synthesised to develop recommendations (Figure 1).

## Results

- The scope for PI at different stages of the HTA process across markets was identified. The Philippines had existing arrangements to permit PI before, during and after an appraisal (Figure 2).
- Notably, while literature reported on the existence of PI processes and methods at different phases of the HTA process, there was limited information on the effectiveness of these processes in practice.
- Trends in PI challenges across markets were observed, and a set of feasible recommendations to address these was developed to implement in the nascent Philippines HTA context (Figure 3).

## Conclusions

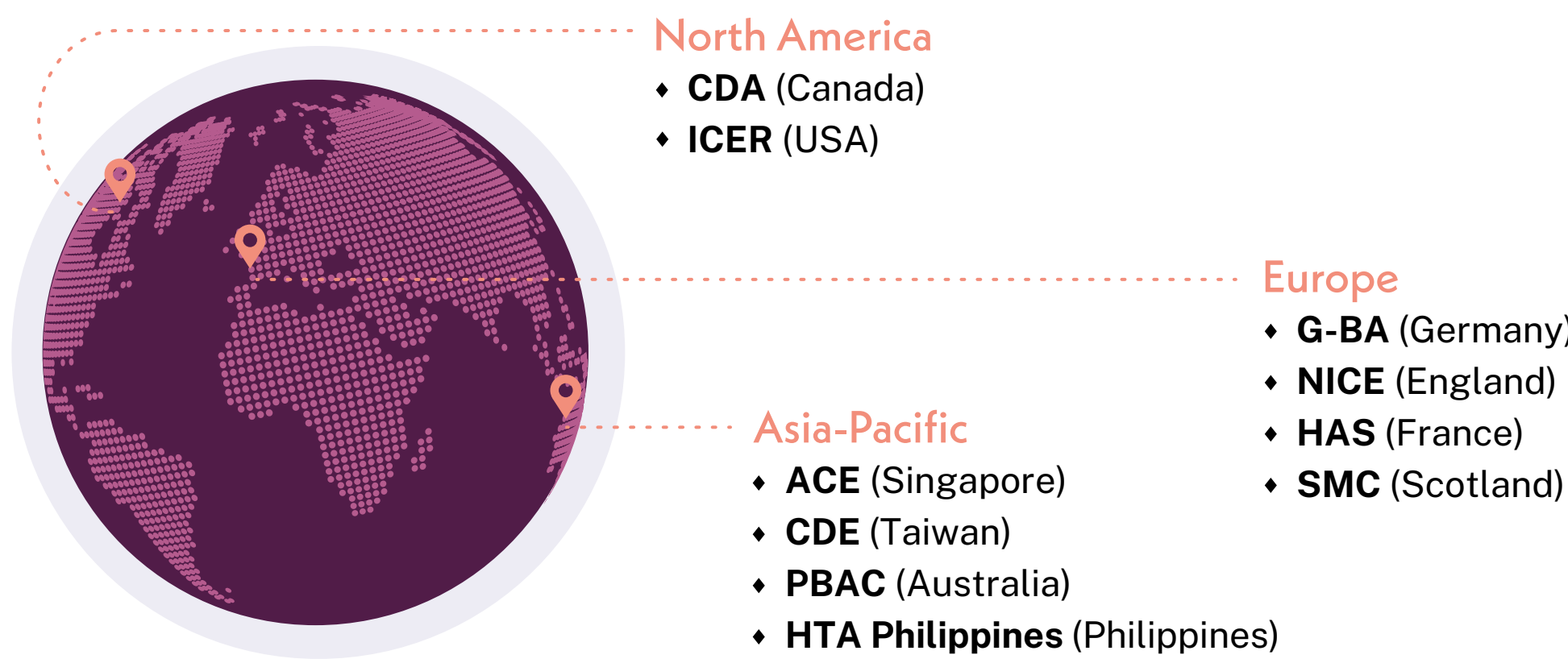
- All explored markets involve patients across different stages of their HTA process, but the **timings of patient involvement vary** across markets.
- Some evidence gaps emerged globally. Notably, **methodology for assessing patient input was scarce**, revealing a need for transparent reporting on how assessors considered patient input in decision-making.
- While originally developed for the Philippine context, the recommendations form a **broadly applicable framework for systemic process change** in nascent HTA markets, evolving towards inclusive and sustained PI and transparent decision-making.
- HTA bodies should **prioritise actions** based on their available resource, current performance in the PI area and the action's potential impact.

FIGURE 1

Overview of the project approach

### Review of PI in HTA in selected countries

The guidelines of key HTA bodies from Europe, North America and Asia-Pacific were reviewed. Experts from Taiwan, Singapore and The Philippines were consulted for additional insights.



### Review of other guidelines and publications

Searches for best practice guidelines and other articles on PI in HTA published in 2019–2023 were conducted in:

- PubMed
- Google Scholar
- Conference proceedings (ISPOR European, International and Asia-Pacific Meetings and HTAi Meetings)

### Development of recommendations

Evidence from the previous two steps was synthesised and used to develop recommendations on:

- PI challenges
- PI timing and format
- Level of patient representation
- Accessibility measures
- Patient input topics
- PI processes in medical technology and rare disease appraisals

FIGURE 2

PI in different phases of the HTA process, across the Philippines and other markets

	PBAC (Australia)	CDA (Canada)	G-BA (Germany)	ICER (USA)	HTA Philippines (Philippines)	NICE (England)	HAS (France)	SMC (Scotland)	ACE (Singapore)	CDE (Taiwan)
1 Pre-appraisal Scoping phase, including topic nomination, prioritisation and appraisal scoping	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
2 During appraisal Topic assessment, evidence appraisal and provisional HTA decision/recommendation development	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3 Post-provisional decision or recommendation Stakeholders provide feedback on the provisional decision or recommendation		✓	✓		✓	✓		✓		✓
4 Post-final decision or recommendation Any activities after publication of the final assessment outcome, including dissemination		✓			✓	✓		✓	✓	✓

FIGURE 3

Recommendations for improving PI in the Philippines and other nascent HTA markets

### Adapt current procedures to sustain PI throughout the HTA process

#### 1 Before appraisal

- Regularly disseminate a **calendar of upcoming appraisals**
- Encourage manufacturers to develop an **objective and evidence-based SIP** ahead of the appraisal process
- Share guidance to outline **patient stakeholder roles and responsibilities**

#### 2 During appraisal

- Ensure patients have **resources and capacity** to participate in virtual or in-person consultations
- Allow patients to **observe deliberative processes**, to understand the rationale behind a decision or recommendation
- **Allocate a point of contact** to provide ongoing support and communication
- **Train assessors** on the principles and value of PI

#### 3 After appraisal

- **Acknowledge patient contributions** by summarising their input in appraisal report
- Develop mechanisms for **providing feedback to patient stakeholders** on their impact on the appraisal outcome
- Develop measures for **regular monitoring and evaluation** of PI (i.e. metrics to gauge the extent to which they were involved)

### Ensure that information is understandable and accessible

- Provide key information in different formats and languages (e.g. *lay-friendly process guidelines, plain language summaries of scientific information, glossaries of key terms*)
- Create patient-focussed training sessions and guidance materials (e.g. *patient workshops, infographics*)
- Signpost to excerpts from previous patient submissions

#### Key training topics

- Understanding the HTA process
- Interpreting scientific evidence
- Providing effective patient input

### Develop methods to capture diverse patient input

- Engage a range of representatives from multiple patient groups (including caregivers), to capture different demographics, geographies and disease subgroups
- Use a wider variety of dissemination methods (including online platforms and social media) than currently used, to reach a broad patient population

### Implement bespoke methods to capture patient input when there is limited clinical evidence

- Identify and use relevant evidence generation methods to evaluate patient preferences and quality-of-life (to be developed and generated by the HTA body)
- Develop specialised processes for (ultra-)rare disease appraisals, such as PACE meetings
- Adapt patient input forms for medical device appraisals to include questions on patients' understanding of the correct and safe use of the medical device

### Establish mechanisms for patient stakeholders to contribute at an above-appraisal level

Establish a standing committee or advisory group for patient involvement

**Abbreviations:** ACE: Agency for Care Effectiveness; APAC: Asia-Pacific; CDA: Canada's Drug Agency; CDE: Center for Drug Evaluation; G-BA: Gemeinsamer Bundesausschuss; HAS: Haute Autorité de Santé; HTA: health technology assessment; HTAi: Health Technology Assessment International; ICER: Institute for Clinical and Economic Review; ISPOR: International Society for Pharmacoeconomics and Outcomes Research; NICE: National Institute for Health and Care Excellence; PACE: Patient and Clinician Expert; PBAC: Pharmaceutical Benefits Advisory Committee; PI: patient involvement; SIP: Summary of Information for Patients; SMC: Scottish Medicines Consortium; USA: United States of America.

**Acknowledgements:** The authors thank Ashleigh Farthing, Costello Medical, for graphic design assistance. We also thank Matt Griffiths, Faye Song and Emma Soopramanien for their contributions. This study and associated medical writing was conducted free-of-charge on a pro bono basis by Costello Medical, for the Philippine Alliance of Patient Organizations (PAPO).