

Stakeholder Engagement in HTA: A Matter for Consensus?

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INTRODUCTION

- Consensus methods are widely used to facilitate structured, and transparent, engagement with diverse stakeholders, enhancing the understanding and assessment of health innovations.
- As the importance of Health Technology Assessment (HTA) grows under the EU HTA Regulation, the need for effective engagement methods to gather insights from various stakeholders including patients, healthcare professionals, industry representatives, and HTA experts is critical.
- In this context, consensus research could prove useful in structuring stakeholder engagement in the context of evidence generation for HTA.

OBJECTIVES

This study aimed to evaluate the applicability, and use, of consensus research as a tool for enhancing stakeholder engagement in HTA. Specific objectives include:

- Assessing the perspectives of different stakeholders on the benefits, and challenges, of consensus research in HTA.
- Identifying areas where consensus methods can standardize processes, such as PICOS (Population, Intervention, Comparator, Outcomes, and Study design) definitions.
- Highlighting areas for improvement in the use of consensus methods within the HTA process.

METHODS

To gain a clearer understanding of the applicability, and current use, of consensus research in HTA, the study followed two steps: first, a panel discussion and presentation with key experts, and second, broader distribution of a survey.

Panel discussion & presentation

- A panel of experts was assembled to provide foundational insights on the use of consensus methods in HTA. The panel included diverse representatives:

- ✓ **Consensus research expert** to provide technical understanding of the methodologies
- ✓ **Industry representative** to discuss the practical implications of consensus methods for product assessment and market access
- ✓ **HTA agency representative** to offer perspectives on how these methods are applied in regulatory settings
- ✓ **Patient representative** to highlight the importance, and characteristics, of patient involvement in consensus processes

- The panel focused on the current application of consensus methods in HTA, identifying both the strengths, and challenges, of using these approaches in evidence generation and stakeholder engagement.

Stakeholder Survey

- A survey was created based on the panel's insights to gather broader input from the HTA community. The survey covered:

- ✓ **Use of consensus methods in HTA**
- ✓ **Perceived benefits and challenges**
- ✓ **Areas for methodological improvement**

- The survey consisted of statements where responders were asked to express their level of agreement on a 5-point likert scale (strongly disagree to strongly agree), ranking exercises, and multiple-choice questions.
- The survey was distributed via email, at the HTAi 2024 conference, and through relevant interest groups, to ensure a diverse range of perspectives across stakeholders.

RESULTS

Panel discussion & presentation

The panel of experts argued that consensus research (inc. consensus meetings, nominal group technique, Delphi panels, or a mix of those) is becoming increasingly relevant and might improve the quality of HTA processes (see **Figure 1** for more details), but requires careful implementation and can face challenges in design and evaluation:

- In the UK, Delphi Panels have been used in some instances to address uncertainty around cost-effectiveness in NICE appraisals (e.g. Romosozumab appraisal¹).
- Consensus research can increase quality, transparency, inclusivity and consistency for decision-making² and stakeholder engagement in HTA processes (e.g. patient experts or clinicians' engagement).
- However, clear reporting of the methods used, with clear definition of panelists' expertise and panel composition is key. Guidelines development is recommended to address present gaps (e.g. prespecifying analyses, stakeholder-specific guidance).

Figure 1. Characteristics and potential use of consensus research in HTA

MAIN CHARACTERISTICS			
Panelist anonymity	Iteration with controlled feedback of group opinion	Statistical aggregation of group response	Expert input
POTENTIAL USE			
Identifying Key Outcomes & Designs:		Incorporating Patient Inputs:	
<ul style="list-style-type: none"> • Defining key and new outcomes; • Defining best fit study designs; • Acceptability of RWE studies & sources; • Defining indirect comparisons details. 		<ul style="list-style-type: none"> • Refining analyses to meet disease needs; • Defining disease burden & challenges; • Structures patient voices to shape technology evaluations. 	
Informing Health Economic Analysis		Addressing Uncertainty:	
<ul style="list-style-type: none"> • Informing model inputs and outcomes; • Informing approaches for costing studies, models structures, etc; • Informing future methods. 		<ul style="list-style-type: none"> • Informing and improving evidence synthesis; • Addressing differences between stakeholders (e.g. PICO scoring); • Guiding decisions despite incomplete data. 	

DISCLOSURES

All authors of this research are employed by OPEN Health, and the study was not sponsored or financially supported by any external company.

Stakeholder Survey

Descriptive statistics:

- A total of 18 responses were collected. Most responders were industry representatives (7/18, 38%) or HTA agency/Payers (7/18, 38%); there were 3 responders from academia and 1 from consultancy. Most responders operated in Europe (14 /18, 78%).
- The average familiarity with Consensus research was 2.8g out of 5. Level of familiarity varied between stakeholder types: 3.7 for Academia, 3.0 for HTA Agency/Payers, and 2.7 for Industry representatives.

Added Value and challenges of consensus research in HTA

- There was a high level of agreement among stakeholders that consensus research can be valuable within HTA, and that several actions can be taken to increase the quality and trust in these methods (**Figure 2**).
- Stakeholders identified the addressing of uncertainty (e.g. PICO scoping) as the main area of use for consensus research, followed by identification of key outcomes (**Figure 3**). Indeed, stakeholders agreed that consensus methods could be used to better understand and potentially **address some of the heterogeneity for PICO scoping within the EU HTA process** (77.8% agreed or strongly agreed).
- Stakeholders also expressed strong support for incorporating patient perspectives, and inputs, through consensus research for HTA (**Figure 4**)

Figure 2. Level of agreement around statements on consensus research (n = 18)

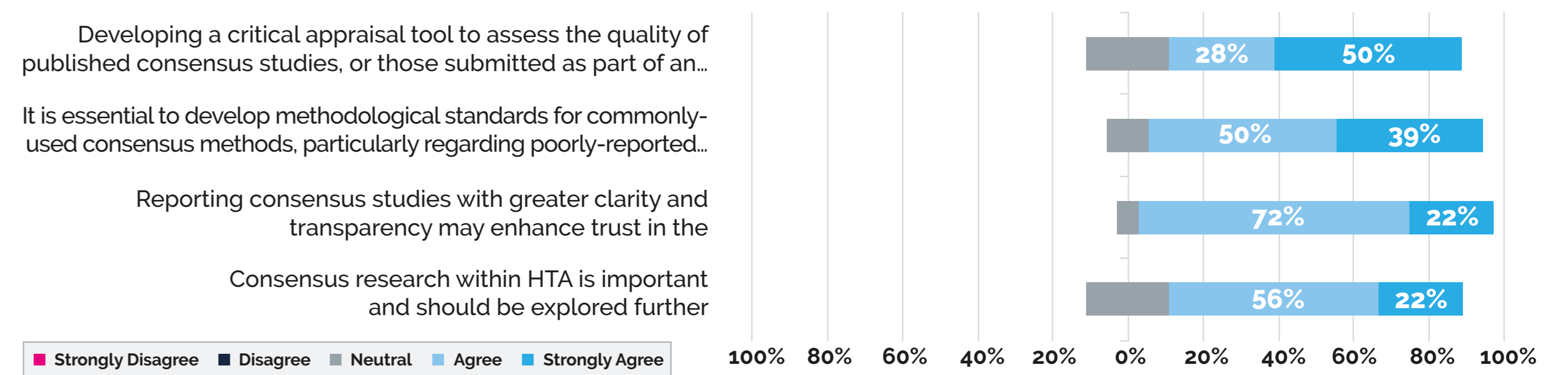


Figure 3. Most relevant use for consensus research in HTA (n = 16)

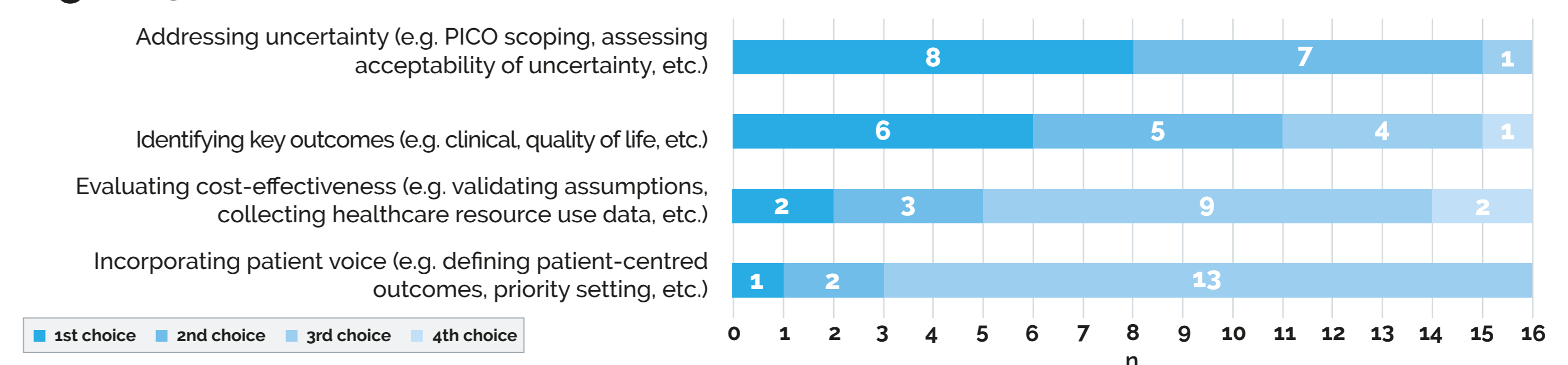
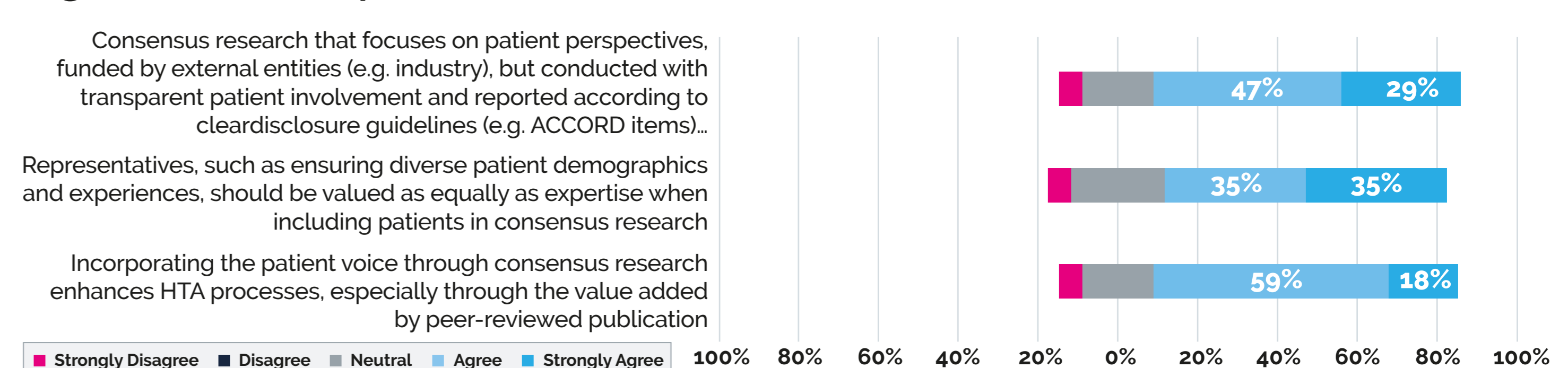


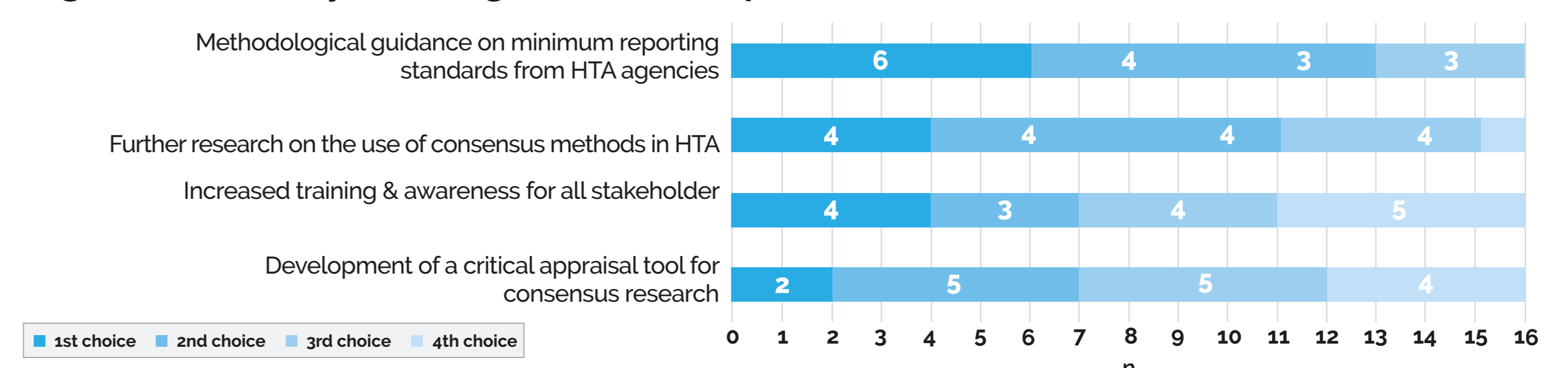
Figure 4. Role of patients in consensus research for HTA (n = 17)



What's next?

- The top priority for next steps, chosen by most respondents as their first choice, is **methodological guidance on minimum reporting standards from HTA agencies**, followed by further research on the use of consensus methods in HTA and increased training and awareness for all stakeholders (**Figure 5**).
- Stakeholders also agreed on the need to build on existing reporting guidelines such as ACCORD³ or DELPHISTAR⁴ to develop a tool for critical appraisal; this may supplement existing guidance provided by the RAND corporation⁵. However, this was not highlighted as a priority area for next steps (**Figure 5**).

Figure 5. Priority ranking for next steps (n = 16)



CONCLUSIONS

- Consensus research has significant potential to enhance the quality, transparency, and inclusivity of HTA processes, particularly in addressing uncertainty, identifying key outcomes, incorporating patient inputs, and informing health economics.
- HTA stakeholders broadly agreed on the value of consensus research in addressing uncertainty, particularly in two key areas: managing heterogeneous requirements and resolving uncertainties around the evidence. For example, consensus methods can improve PICOS scoping processes and stakeholder engagement within the EU HTA, while in the UK, Delphi panels have been used to address cost-effectiveness uncertainties in NICE appraisals. Patient engagement also emerged as a critical factor, with 77% of stakeholders agreeing that incorporating patient perspectives through consensus methods strengthens HTA processes.
- Priorities include developing clear methodological guidelines and critical appraisal tools, alongside increasing training and awareness across stakeholders to maximize the value of consensus research in HTA.

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SCAN THE QR CODE TO PARTICIPATE IN OUR SURVEY
Our survey aims to gather insights on Consensus Research in HTA. Your responses will help us to understand the experiences, perspectives and preferences of professionals in this field and identify key areas for the effective implementation of consensus research in HTA evidence generation.

Presented at: ISPOR Europe 2024

