

INTRODUCTION

- > Despite consensus across stakeholders on the need for greater inclusion of underrepresented patient populations (e.g., racial/ethnic minorities) in healthcare research, it remains challenging for research teams to recruit participants from some patient subgroups.
- > Improving representativeness in healthcare research is likely to lead to more generalizable study findings with respect to disease burden and treatment effectiveness, and subsequently more informed decisions in health resource allocation through value assessments.
- > The Innovation and Value Initiative (IVI) solicited feedback from different stakeholders representing or working with diverse patient communities on ways to enhance participation from underrepresented subgroups in its engagement efforts and research projects.

STUDY OBJECTIVES

- > This qualitative study aimed to identify and summarize best practices in (1) establishing criteria for a representative patient population and (2) recruiting underrepresented patient subgroups.

METHODS

- > A three-stage approach was used (Figure 1).
- > **Stage 1:** We conducted a targeted literature search and sought input from two patient-centered research experts to identify guidance documents in the U.S. setting to extract insights on (1) how representativeness was defined, and (2) what strategies were recommended to overcome barriers in recruiting underrepresented subgroups. Twenty-three documents from nine organizations with extensive patient engagement and research experiences were reviewed.
- > **Stage 2:** We administered a survey to a targeted group of individuals and organizations (N=26) with experiences in patient-centered research. Fourteen (response rate: 54%) complete responses were received. The survey responses helped prioritize the findings from stage one and identify gaps.
- > **Stage 3:** We aggregated findings from the first two stages to prioritize strategies to inform patient-centered research projects.



Figure 1. Three-Stage Study Approach

Contact

- > Email: richard.xie@thevalueinitiative.org
- > Website: <https://www.thevalueinitiative.org>
- > For more information, access the white paper at <https://www.thevalueinitiative.org/publications/>

RESULTS

- > In defining representativeness of a data sample, guidelines recommended that researchers clearly define research objectives and pre-specify “who” and “how many” individuals to include. Ten patient characteristics were identified to inform the criteria development (Figure 2).
- > Practical recommendations to recruit underrepresented patient populations were grouped by themes (Table 1).

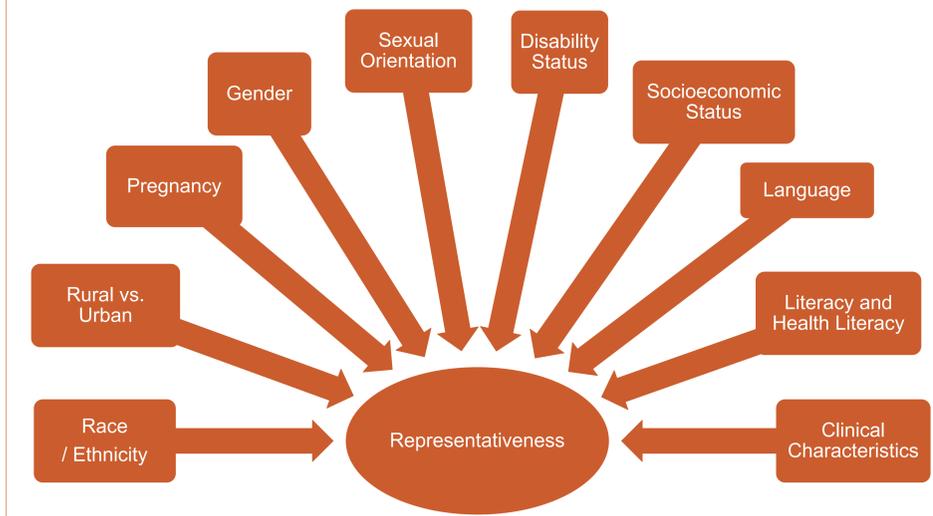


Figure 2. Patient Characteristics Used to Define Representativeness

CONCLUSIONS

- > Improving representativeness in patient-centered research requires an iterative approach where research teams engage with diverse patient communities at the outset, establish clear criteria for representativeness, deliberately integrate findings, and communicate transparently to build trust and authentic relationships.

References (select)

- > FDA, Patient-Focused Drug Development: Collecting Comprehensive and Representative Input Guidance for Industry (2018)
- > MDIC, Maximizing Patient Input in the Design and Development of Medical Device Clinical Trials (2020)
- > PCORI, Strengthening Diversity in Research Partnerships: Knowledge to Action (2017)

For a complete list of references, please refer to the white paper.

Themes	Recommendations
Defining Representativeness	<ul style="list-style-type: none"> – Clearly define research questions – Include “a representative sample” as a research objective – Examine existing knowledge base (e.g., peer-reviewed articles) to identify potential subgroups or gaps – Engage in conversations with patients from diverse backgrounds – Reference patient characteristics highlighted by FDA (Voice of Patients reports) and PCORI to identify potentially underrepresented patient groups
Partnership Development and Stakeholder Engagement	<ul style="list-style-type: none"> – Develop partnerships with community leaders and patient advocacy organizations – Engage patients from the outset and throughout the study, identify patient representatives that can serve as community ambassadors – Form a multi-stakeholder advisory group that can advise on partnerships – Maintain clear, regular, and open communications with all stakeholders throughout the study phases – Understand specific barriers facing different patient subgroups and provide solutions accordingly – Avoid using overly restrictive inclusion/exclusion criteria
Personnel Training	<ul style="list-style-type: none"> – View training of research teams and fielding partners as an ongoing process – Expose research teams and fielding partners to different patient perspectives and enhance cultural sensitivity – Training foci can include: <ul style="list-style-type: none"> – Engagement and partnerships with diverse patient subgroups – Strategies to recruit a representative patient sample – Concept of patient heterogeneity and its importance in research – Establish clear principles of respectful engagement and operational standards – Recruit research team members from diverse backgrounds
Technology and Language Accessibility	<ul style="list-style-type: none"> – Ensure that research instruments and materials use accessible and clear languages – Provide multilingual support (e.g., offer documents in multiple languages when possible) – Simplify enrollment process using strategies such as mobile technologies or through community partnerships – Provide multiple channels for survey response (online, phone, in-person) – Partner with healthcare providers to simplify technology requirements
Cross Validation	<ul style="list-style-type: none"> – Examine final sample against established criteria of representative sample – Apply statistical methods to re-weigh sample if needed
Activation and Recognition	<ul style="list-style-type: none"> – Share study results with participants – Ensure payment of honoraria – Include patient contributors as co-authors – Explore ways in which study results can inform decisions related to the underrepresented patient communities

Table 1. Summary of Recommendation by Themes