

To: Patient-Centered Outcomes Research Institute
Public Comments
1701 Pennsylvania Ave. NW
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Washington, DC 20006

From: American Occupational Therapy Association

Date: September 13, 2012

Subject: Public Comment on the Draft Methodology Report of the Patient-Centered
Outcomes Research Institute (PCORI)

The **American Occupational Therapy Association (AOTA)**, representing the interests of over 140,000 occupational therapy practitioners nationwide, appreciates this opportunity to comment on the Patient-Centered Outcomes Research Institute's (PCORI) Draft Methodology Report.

We applaud PCORI for developing this helpful methodology report and offer our comments for consideration.

1. Executive Summary

We are pleased that the purpose of PCORI was emphasized; “to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed...” Another point that could be added is that the best available evidence, as Sackett (2000) urged, should be considered by the patient and professionals in order to make informed decisions. Otherwise, there is a risk that researchers, clinicians, and policy-makers interpret the term “quality” as Level I evidence only, ignoring other levels of evidence. With rare disorders and many conditions seen in rehabilitation, study designs other than the randomized controlled trial can be helpful to inform patients and clinicians’ decisions, but may not always be considered in the development of practice guidelines.

2. Chapter 1: Introduction

We agree that there is a lengthy timeframe between research results to implementation of research into practice. A discussion between researchers, journal editors, and guideline developers could offer ideas for new strategies and communication/dissemination methods, while preserving researchers’ and journals’ rights.

3. Chapter 2: How the Methodology Committee Developed the Standards

This chapter offered a comprehensive explanation about the process of the committee's work.

4. Chapter 3: Overview of the Standards

This chapter was organized and clearly explained the phases of PCOR. We particularly liked the focus on engaging patients in prioritizing and refining research topics, and look forward to PCORI's resources and guidance on this critically important process of patient-centered care.

5. Chapter 4: Methodological Standards for Patient Centeredness of Research Proposals and Protocols

We agree with PCOR's approach to not prescribe a particular method of patient engagement, given the types of studies and questions PCOR will cover.

6. Chapter 5: Methods for Prioritizing Patient-Centered Outcomes Research and for Peer Review

We wholeheartedly support obtaining patients' input for research topic selection, but we also support clinicians' input as well, since they often have clinical questions that researchers have not yet addressed.

7. Chapter 6: Choosing Data Sources, Research Design, and Analysis Plan: Translation Framework and Development of the Translation Table

In Table 6.1, Selected Study Designs for Assessing the Effectiveness of Therapeutic Interventions, would Regression Discontinuity Designs be a valid non-randomized design? With its high internal validity, Regression Discontinuity Designs could be useful.

8. Chapter 7: General and Crosscutting Research Methods

The section discussing Missing Data is greatly appreciated. There are published intervention studies who have not handled missing data in a valid way, such as including the last collected data from subjects who dropped out in the analyses, citing intention-to-treat analysis. It would be helpful to inform researchers more about options for analyses when there are certain percentages of missing data.

9. Chapter 8: Design-Specific Methods

We appreciate the standards for adaptive and Bayesian trial designs. We agree that registries have the potential to contribute valuable information about PCOR, but we think there should be more forethought to the design and structure of registries. For example, it is critically important to identify the research questions, as much as possible, in advance,

so that the data collected can answer these questions. The quality of data's output is commensurate with the quality of data's input.

10. Chapter 9: Next Steps

We look forward to future resources and education/training opportunities to build capacity among researchers to understand, deploy, and improve PCOR methods. Our association is willing to help with informing and disseminating opportunities and resources to patients and clinicians.

The American Occupational Therapy Association (AOTA) is grateful to PCORI for providing this opportunity to comment and we look forward to collaborative opportunities to improve patient-centered outcomes.