

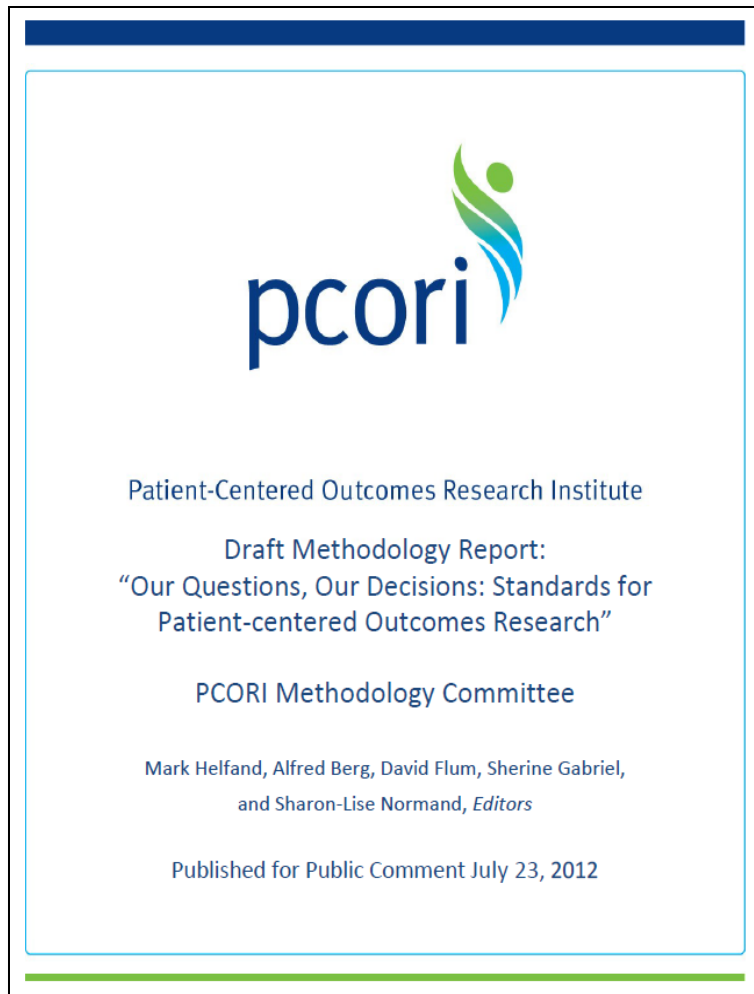
Update on Public Comment Period for Draft Methodology Report

Jean Slutsky, Methodology Committee
Lori Frank, PhD, Director, Engagement Research
Bill Silberg, Director, Communications

PCORI Board of Governors Meeting
Washington, DC
September 24, 2012



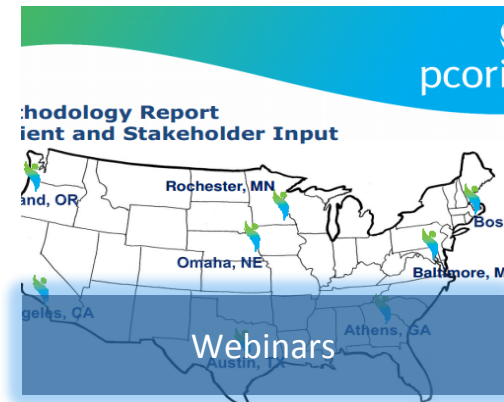
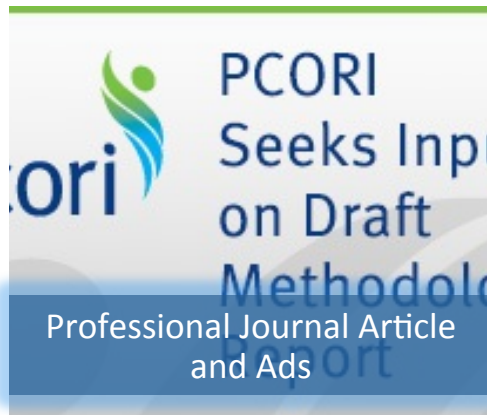
Methodology Report



- Submitted to the PCORI Board of Governors on May 10, 2012
- Approved for posting by the PCORI Board of Governors on May 21, 2012
- **Public comment period: July 23, 2012 through September 14, 2012**
- Revised draft standards to be submitted to the Board of Governors November 2012

PUBLIC COMMENT AND ONGOING OUTREACH

Outreach efforts for MC report comment period



“Why Methods Matter”

Patient-Centered Outcomes Research – Why Methods Matter

July 25, 2012 by Sherine Gabriel, MD, MSc and Sharon-Lise Normand, PhD

Patients today have more health-related options than ever before, with a dramatic increase in the number and types of treatment choices available for the same condition. The healthcare delivery systems of today differ markedly from those of the past, and ... [Continued](#)



Why Methods Matter for Research and Innovation

by Harlan Weisman, MD

The Patient-Centered Outcomes Research Institute is working to develop a new model of research that will benefit innovation and provide all health care stakeholders with the reliable information they need to make good decisions that reflect patients' preferences. The foundation ... [Continued](#)



The Patient's Perspective on Why Methods Matter

by Ellen Sigal, PhD

The U.S. spends nearly \$150 billion on health research every year. Despite this investment, patients do not have, in many cases, the information they need to make significant, sometimes life-altering choices. Even with the help of physicians the options can ... [Continued](#)



PCORI blog columns and associated videos pushed to targeted email lists

Professional Journal Article and Ads

Digital Ads released in *Annals of Internal Medicine*; *Science Translational Medicine*; *JAMA*; *NEJM*; *Nature*; and *Health Affairs*




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Perspective

Getting the Methods Right — The Foundation of Patient-Centered Outcomes Research

Shirine E. Gabriel, M.D., and Sharon-Lise T. Normand, Ph.D.
N Engl J Med 2012; 367:787-790 | August 30, 2012

Article References

Health care in the United States has changed dramatically over the past several decades. Today, patients have more options than ever. Making the right choices, whether for prevention, diagnosis, or treatment, requires a critical appraisal of the potential benefits and harms of the options, within the context of the patient's characteristics, conditions, and preferences.

Many of these choices are available thanks to advances in medical research. Yet most patients and many clinicians find research somewhat mysterious. They have difficulty sorting through the mountains of medical evidence to identify information that is reliable and actionable for their unique circumstances. Patient-centered outcomes research and comparative-effectiveness research promise to enhance decision makers' ability to fully understand and weigh alternatives. But just as health care interventions and delivery strategies have advanced markedly in recent decades, so have

Measures of Reach

6,500
page views

1,600
report downloads

- >**850,000** total anticipated impressions
- Exposure to nearly **13,000** subscribers through a *Health Affairs* e-alert

Professional
Journal Articles
and Ads



- Three blog posts
- **671** total blog views
- **150** total video views

“Why Methods
Matter”



- Two webinars
- >**650** total attendees
- Strong audience interest indicated by low fall-off rate

Webinars



- PCORI mentioned **5,753** times in Twitter and social media conversations over the last six months (mid-April through mid-September)
- Estimated **7.4 million** impressions, reaching individuals through a variety of online media.

Social Media



- Three e-mail blasts to opt-in stakeholder list (~**4,600** names)
- Open and click-through rates above industry norms:
 - First alert: **43.8%** and **50.3%**
 - Second alert: **35.2%** and **37.3%**
 - Third alert: **26.2%** and **22.2%**
- Additional alert to **3,143** researchers through PCORI's contracts platform.

Targeted
Outreach



- News release republished **244** times
- Coverage included: *The Pink Sheet*; *Medical Device Daily*; *Government Health IT*; *Inside Health Policy*; *BioCentury*; and *CQ Healthbeat*

News Release

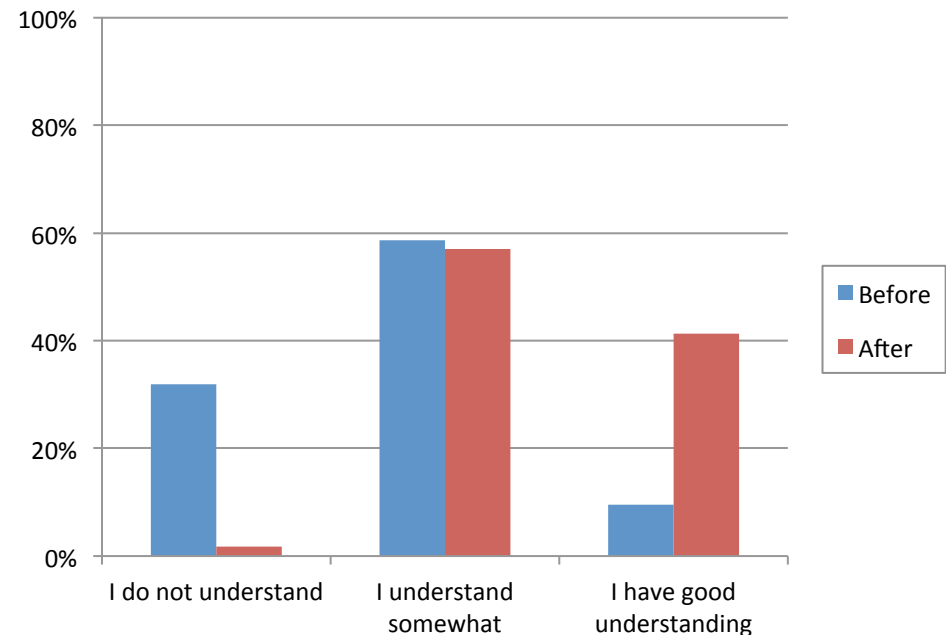


* As of 9/19/2012

Webinars

- Two webinars
 - Setting Standards for Research Methods, August 3
 - Setting Standards for Patient-Centeredness and Patient Engagement in Research, August 14

Rate your understanding of the process the MC used to generate standards



* Actual responses from both webinars combined

PCORI Draft Methodology Report Public Comment Survey

[Tell Us about Yourself](#)

**[Provide General
Comments on the Draft
Report](#)**

[Provide Comments on
Specific Report Chapters](#)

[Submit Your Comments](#)

About this Survey

Use the survey tool below to submit your comments on PCORI's Draft Methodology Report. Do not close this window until you have completed and submitted your comments or you will lose your work.

[Read the Draft Methodology Report](#)

[Read Comments Submitted by other Patients and Stakeholders.](#)

Provide General Comments on the Draft Report

1. Are the standards and recommended actions consistent with PCORI's mission and vision?

- ☐ Yes
- ☐ No

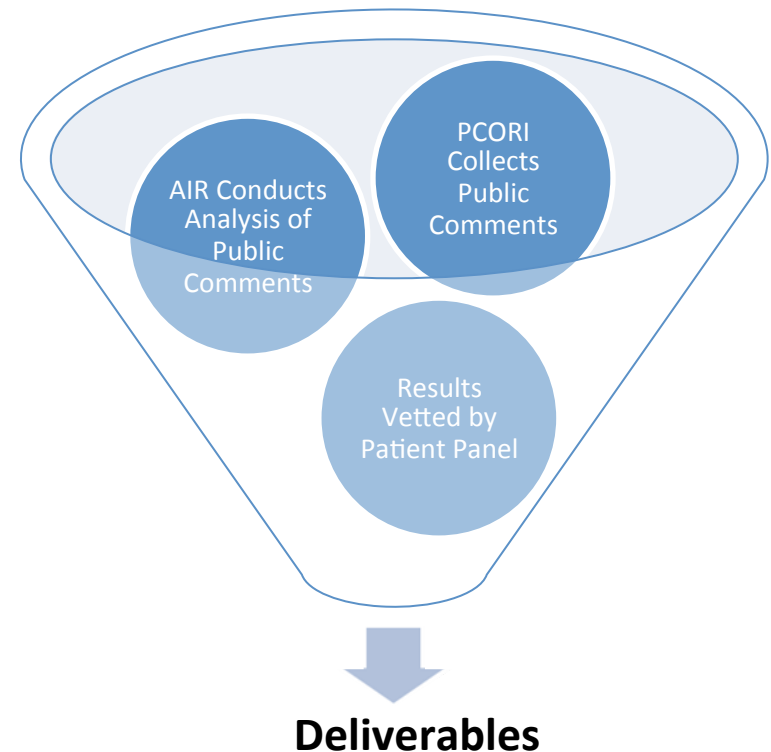
Enter comments here

2. What methodological gaps should be addressed in future reports?

Collecting, Analyzing, & Transparently Communicating Public Comments

- **Public Comment Contractor:**
American Institutes for Research (AIR)
- **Criteria:**
 - Patient panel to review and refine comment analysis
 - Extensive patient and stakeholder engagement experience
 - Expertise in qualitative research methodology
 - Significant experience with public comment process

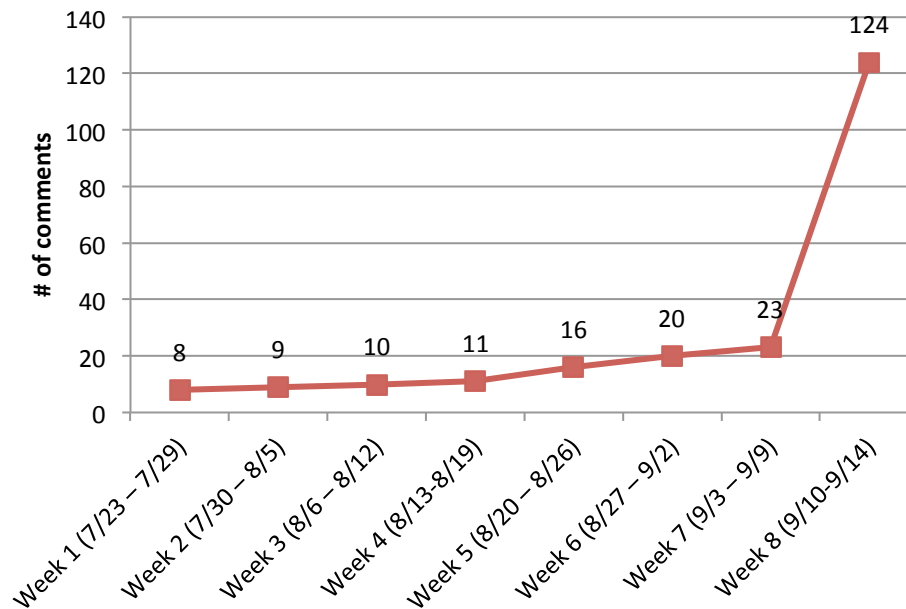
MC Standards and Report Public Comment Process



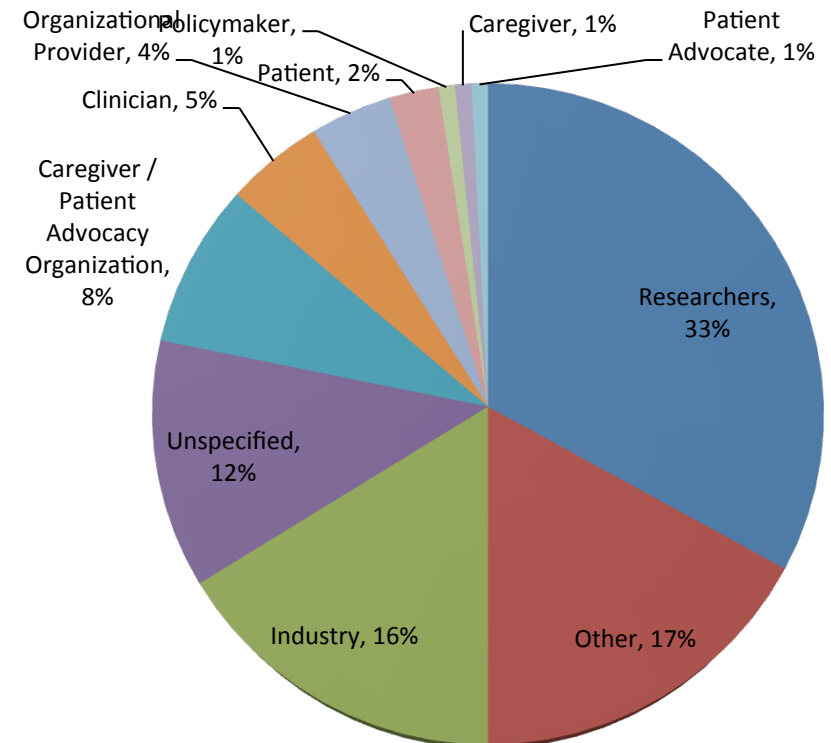
Public Comment Analysis Delivered to MC
Transparent Comment Disposition Table

Public Comment Results

Cumulative Comments Received, by Week

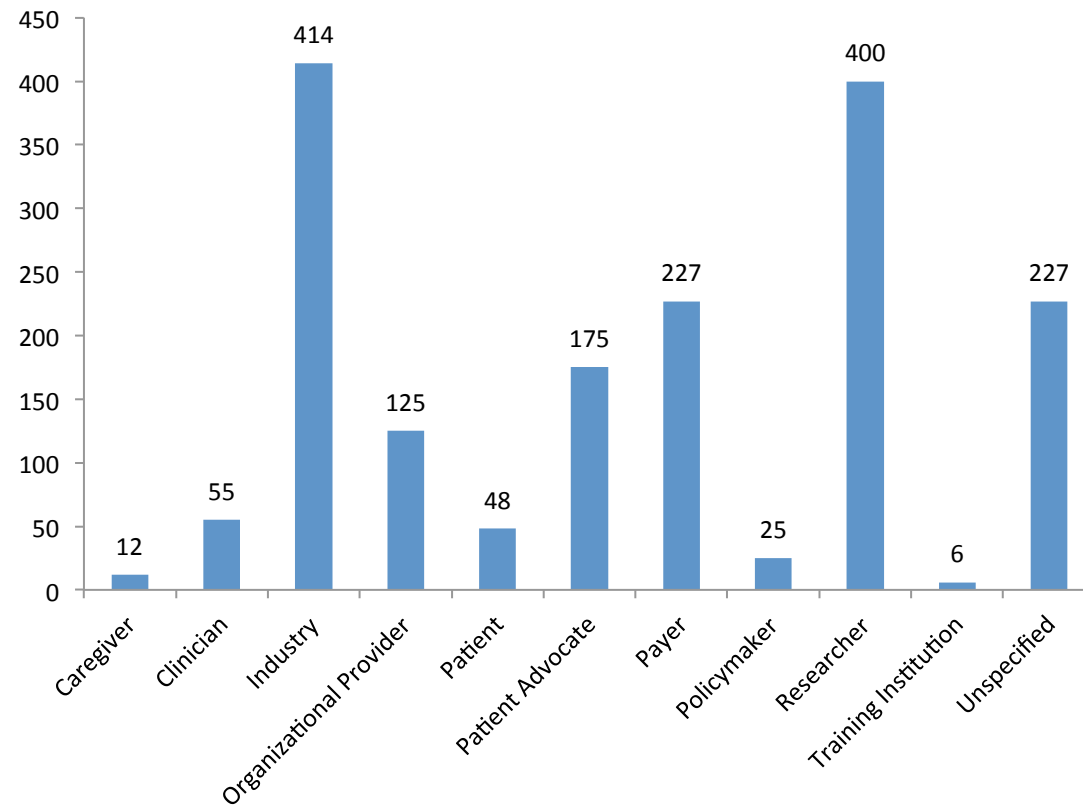


Respondents by Stakeholder Category

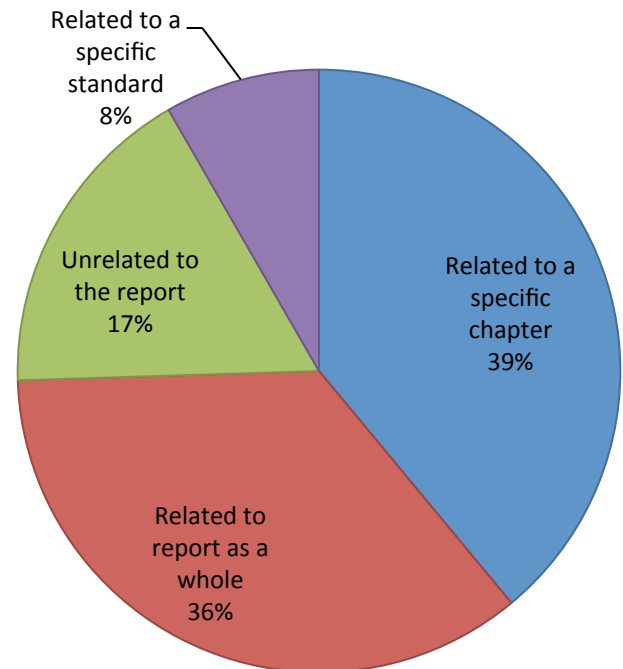


Public Comment Results

Comments by Stakeholder Category



Comments by Type



- Role of standards in PCOR
- Feasibility of standards implementation
- Document accessibility
- Interest in training and resources to support PCOR and standards implementation
- Interest in more specific details regarding research methods

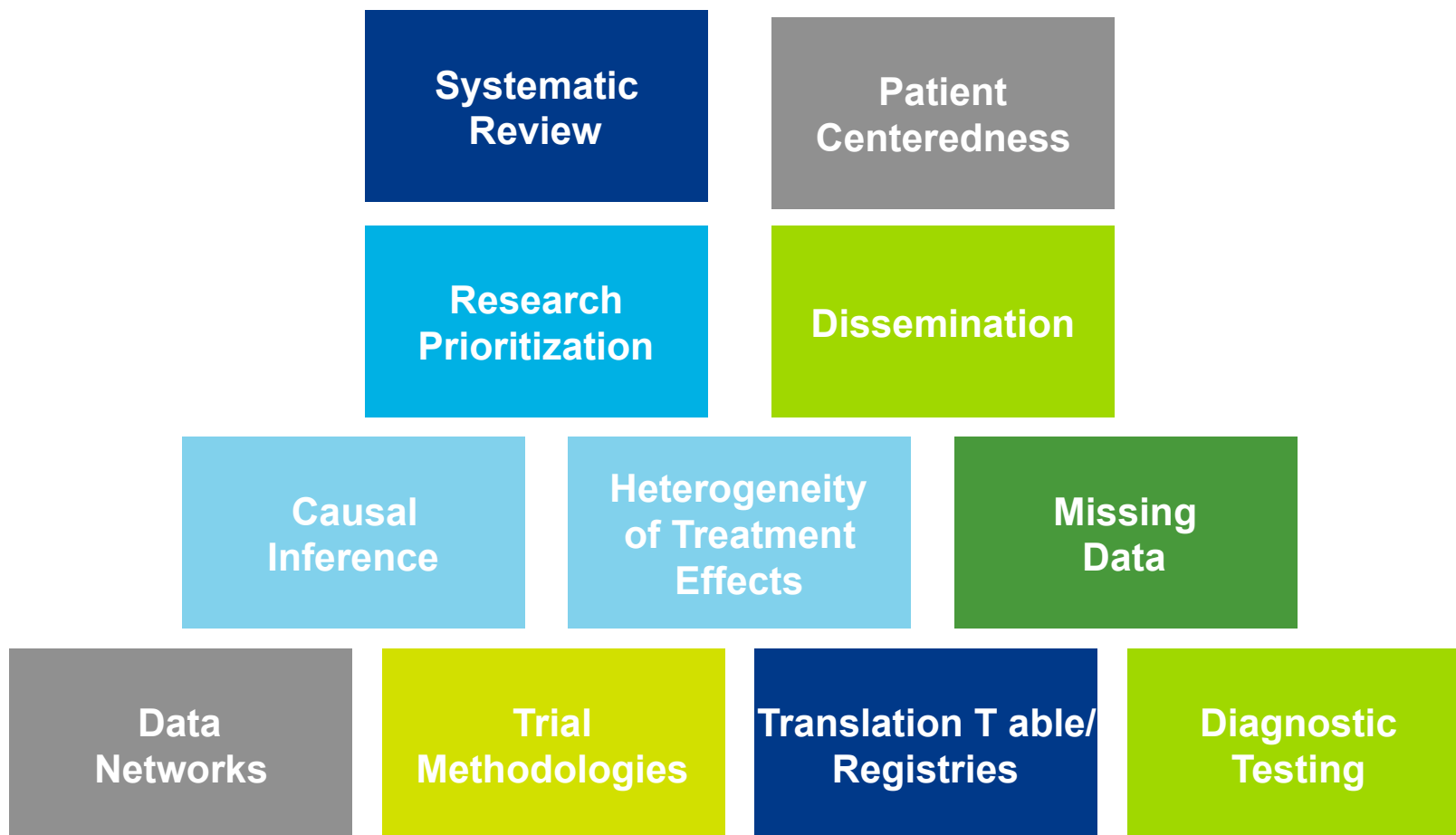
METHODOLOGY COMMITTEE

- Review and Revisions of Standards/Recommended Actions
- Future Directions

Review and Revision of Standards



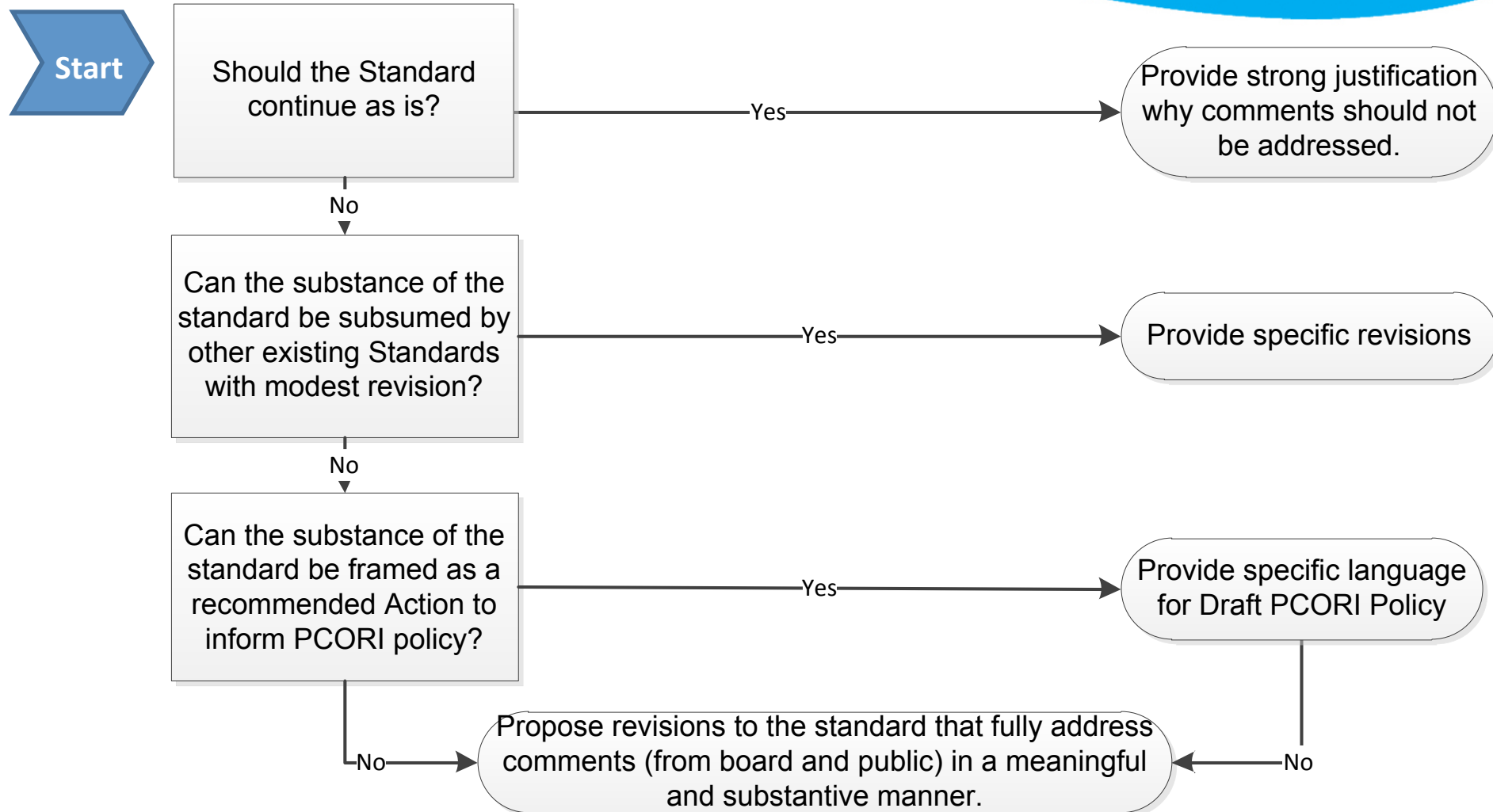
The MC will provide revisions to methodologic standards and recommended actions across each of the eleven research domains



Methodology Committee Goals

1. Propose revisions to the standards and recommended actions based on public and Board comments (with justification)
2. Provide summary of MC responses to public and Board comments
3. Offer additional suggestions for methodological research gaps gleaned from public and board comment

Review and Revision of Standards

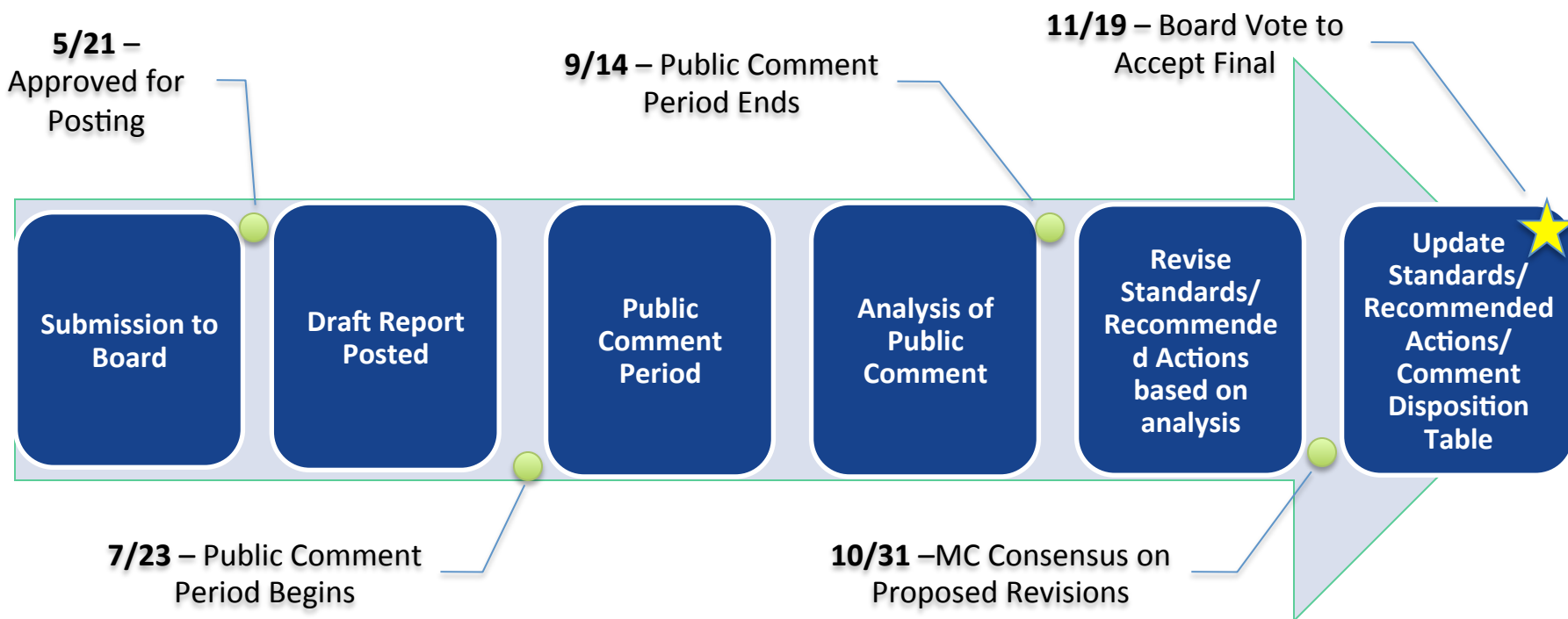


1. Review and propose responses and revisions to relevant Board and Public Comments. Include justification if no response/no change is recommended
2. Discuss and propose next steps for translation table.

Options include:

- No further changes. Maintain the translation table as it currently stands
- Propose RFP to develop v2 of Translation Tool which expands on current tool and creates additional versions for different audiences, e.g. Researchers, students, general public, policy makers etc.

Timeline



May-Jul 2012

Aug-Sep 2012

Oct-Nov 2012

Priorities

- Select Standards for further research in 2013
- Develop a detailed Standards implementation and dissemination plan
- Incorporate standards into PFAs
- Incorporate principles of research prioritization into evaluation of the impact of standards on improving research quality and advancing PCORI mission
- Enhance methods for use of patient-reported outcomes
- Create PCOR methods training programs for patients and other stakeholders

Methods Leadership

- Contribute to PCORI patient engagement workshop
- Contribute to PCORI methods workshop
- Participate in PFA development (subset of MC members)
- Advise on methods-relevant dissemination (subset of MC members)

Moving toward Standards 2.0

- Ongoing outreach planned for Standards following completion of revision in November 2012
- Further Standards development to be evaluated based on additional review by MC, Board, and patients and other stakeholders throughout the planned ongoing outreach and dissemination

To those who provided comment on the MC Standards and Report:

Thank you for your thoughtful input!

To the Methodology Committee:

Thank you for all your hard work in the development and revision of these document!