Annual Household Income

- > $150,000
- $100-150,000
- $90-99,999
- $80-89,000
- $70-79,999
- $60-69,999
- $50-59,999
- $40-49,999
- $30-39,999
- $20-29,999
- $10-19,999
- < $10,000

Chart Title

- Previous Participation in Health Research
- Previous Planning/Conduct of Health Research

- No
- Yes
Appendix O: Data Coding Dictionary

**Effective Methods for Engagement:** Methods for engaging individuals at various places in the research process, ways of executing the key elements or themes. This is the “how.” Methods relating to stakeholder selection should NOT be coded here. Example: “For the type of work you’re doing a technique called joint fact finding might work. This is a process you use when you are generating research and you want to make sure all the stakeholders are going to believe and trust the outcomes.”
- Patient training (specific elements, the need for it)
- Goals and objectives for involving stakeholders and of certain methods

**Issues with Patient Engagement:** Methods used for engaging individuals throughout the research process that may not be appropriate for a given population, stakeholder group, or for other reasons. This theme is exclusive from “Effective methods for engagement.” This is “how not to.” Example: “One of the problems with initiatives like citizens juries is that they come from the government down rather than grassroots up. The issue is how to acculturate people and make them different when they become involved in ongoing developments, but the government doesn’t feel that citizens juries are problematic.”
- What is needed, expected, desired from patients

**Appropriate Engagement:** Circumstances when it is appropriate to engage stakeholders. This is “When and where.” Example: “My belief is that there is no place in which it is inappropriate to engage the public.”

**Inappropriate Engagement:** Circumstances where it may not be appropriate to engage stakeholders. This is “when and where not to.” Example: “Certainly if a decision has already been made, it might not be appropriate to engage. You don’t want to do this just because the grant or the funder says they want to do it.”

**Key Themes of Engagement:** Supporting evidence for a key theme. Includes both mentioning the theme as well as examples (but NOT methods) demonstrating the theme. Example: “Engagement to me, by definition, is a two way dialogue in which both parties are informed by the other. That is fundamental, if it’s not that, it’s not engagement.”
- See list of themes in draft report.

**Stakeholder Category Definitions:** The differentiation, distinction, and definition of different stakeholder groups (e.g., surrogates, advocates, patients, clinicians, researchers) and what those voices represent. Example: “A collective patient perspective is when an individual has knowledge of multiple disease experiences and conveys this rather than their own personal experience.”
• Everyone is a patient

**Stakeholder Selection:** The roles of differing stakeholder groups, selecting individuals within those groups, when individuals from different groups should be used, and methods relating to selection. Include quotes illustrating these roles. Example: “For most people who represent ‘patients’ for research activities the researchers don’t know who to go to. They go to advocacy organizations and say we need someone to represent the patients perspective and what you get is a mix of people who are far more knowledgeable about the condition;” “I get the chance to say things other people are thinking but they can’t because they’re researchers.”

• Who is or should be around the table

**Synthesizing and Integrating Stakeholder Input:** Incorporating and synthesizing the voices of various stakeholders, evaluation or process feedback. Example: “The HTA program tended to involve service users at the very beginning in a pilot project, and we said people join us, try this out, and tell us how it was. On the basis of that we modified the procedures, increased the numbers and got more structured feedback. There were cycles of development and integration.”

**Systemic Issues:** Systemic elements such as institutional, social, and cultural norms that impact successful patient engagement within the research and medical community. Descriptions or explanations of the existing system. Example: “Another big challenge is you have a group of researchers and they all know each other and until you get to be part of that community and people know who you are you’re not considered a colleague.”

**Knowledge Gaps** Areas identified as having little available information, or little development in the health field. Example: “The idea is to ask a patient what they think, but I don’t think we have a foundational theory from the perspective of ‘patient’ and how that changes the interaction.”

**Underrepresented Populations:** Any comments related to engaging underrepresented, minority, or other special populations, even if example is very specific to a certain population. Cross-tag this content with other relevant codes (e.g., methods, stakeholder selection, etc.). Example: “If you’re going to walk into a minority group and ask them to do whatever and you have not engaged that community or leadership you are not going to be successful.”

**Experience/Background:** Background information about the interviewee.
Appendix P: Annotated Bibliography

Books


Web Resources and Resource Complications


Links to several documents include a description AHRQs involvement processes, educational materials for stakeholders, learning modules for researchers, basics of meeting facilitation, and resulting documents of several workshops and webcasts.

Aligning forces for Quality (AF4Q). [http://www.qualitycarenow.org](http://www.qualitycarenow.org)

The primary content is in the Quality Tool Box including consumer engagement tools such as recruitment and educational materials for community members, orientation and resources on public reporting and performance measurement. Links to regional community alliances are also accessible.

Center for Collaborative Policy. [http://www.csus.edu/ccp/](http://www.csus.edu/ccp/)

Content on the website includes educational resources about collaborative policy making and collaborative public involvement; a bibliography and list of publications; learning programs through the Center; and descriptions of current and past Center projects.


A handbook with a wide variety of types of resources. The best books, guides, manuals, and articles are listed. Additional examples of successful collaborations, online engagement projects, types of engagement processes, and specific case-studies are also included.
Theory


Improving community capacity to solve problems is argued as an appropriate ultimate goal of deliberative practice which builds on itself to achieve six proposed goals of deliberation, discussed in detail: issue learning, improved democratic attitudes, improved democratic skills, individual/community action, improved institutional decision making, and ultimately improved community problem solving.


A model of stakeholder engagement and the moral treatment of stakeholders is described and presented as an alternative to the traditional idea of ‘more is better’ with stakeholder engagement. The model considers the levels of stakeholder engagement and stakeholder agency.


Due to traditional differences in power between stakeholders and organizations, a construct of organizational trustworthiness is presented as a possible solution. Although it does not create an obligation or duty between the two, it may result in stakeholders who lack power being treated fairly.


Ten proposed theories of needed elements for effective collaboration are broken out by how people learn, innovate, and negotiate in groups; how people decide whether the process is fair; and how people decide whether the process is worthwhile. Each theoroid includes a postulate and implication.


A consideration of how participatory research may be an appropriate method for family physicians. The training, established partnerships with patients and communities, comfort with uncertainty, and pragmatic response to questions arising from patients are


Different types of public communication are examined for the purpose of expanding civic engagement. Dialogue and deliberation are connected with community organizing to establish a number of principles for successful public engagement including the use of multiple forms of speech and communication, connecting with personal experience with public issues, and encouraging analysis and reasoned argument.
Research and Evidence on Involvement


A Delphi method was used to determine whether there was consensus around evaluating the impact of public involvement. It was determined feasible in 5 of 16 impact issues: identifying and prioritizing topics, disseminating findings, and key stakeholders.

Faulkner, A. (2010). *Changing our worlds: Examples of user-controlled research in action.* Eastleigh, UK: INVOLVE.

Seven examples of service user-controlled research explore the rationale, methods of implementing research, benefits, challenges, and the impact of research on outcomes when research is user-controlled.


A literature review sought knowledge on the evidence of the impact of public involvement in health research. The impacts of involvement varied and the type of involvement affected whether a difference was made. Evidence on impact is limited and there are a number of gaps in current evidence.


Applications at INVOLVE were reviewed to determine the extent of public involvement in health research. Less than 20% indicated intention to involve patients, 43% misunderstood the meaning of public involvement, and 38% had no plans for involvement. Responses are broken out by types of study and types of involvement activities.

Case Studies and Examples


A series of options, examples, and lessons learned are presented within the categories of online collaborative platforms, product development challenges, online communities, grassroots community organizing, collaborative research. Four broad tasks were identified to effectively engage patients, and are described in detail: outreach, support, managing relationships with researchers, partnering to disseminate products.


As part of the Community Forum project, an advisory panel was convened to discuss patient and consumer involvement in the effective Health Care Program.

The general approach of CHSRF in supporting and engaging citizens is described followed by an overview of implementation in key programs and activities. These activities include 10 patient engagement projects, policy dialogues, and mass media efforts.


A training/orientation document used to describe research processes and types to patients in lay language.


A checklist for determining areas where further research is needed. Five key stages, initiation, consultation, collation, prioritization, and reporting and refining each include specific requirements regarding process and goals.


A flyer announcing a priority setting workshop related to Type 1 diabetes research. A description of the objectives of the workshop, expectations of participation, and notification of financial assistance are included. The second page is an application form for individuals wishing to attend.


A pilot program working with community partnerships seeking to change knowledge, attitudes, and behaviors to increase patient awareness of and participation in cancer clinical trials particularly among minority groups. An evaluation of outcomes from the program is included.


A sample process for using the community-based participatory research approach in cancer clinical trials is described. Out of the project emerged seven recommendations for community engagement in Phase III cancer clinical trials.


The findings from an earlier phase of the project around the input of service user perspective on outcomes were implemented in partnership with four local groups of service users. Lessons learned and common themes such as respect for service users, mobility and access, across the projects are presented. Descriptions of the four individual projects are also included.

The concept of patient-based evidence is presented as a compliment to clinical and economic evidence. One demonstration project of operationalizing the concept is discussed.

**Tools and Methods**


The use of netnography is described as a means to understand the language, meanings, rituals, and practices of consumer tribes. Challenges of the method are described and an example is used to demonstrate the cultural nuance required for netnographic interpretation.


A description of netnography as an ethnographic method adapted to the study of online communities. Benefits of use over traditional ethnography are described and the types of information that can be gathered such as the symbolism, meanings, and consumption patterns of online consumer groups.


Proposes questions to guide the development of policy briefs to support evidence-informed policymaking. These include consideration of whether the issue is high-priority; the use of systematic methods; inclusion of applicability and equity into account in discussion; and review for scientific quality and system relevance.


Proposes questions to guide the use of policy dialogues to support evidence-informed policymaking. These include consideration of whether the issue is a high-priority; if there are opportunities to thoroughly discuss the problem; fair representation; use facilitation; outputs produced and follow-up undertaken.


Key issues relating to patient and public involvement were identified to inform the development of the Guidance for Reporting Involvement of Patients and Public (GRIPP) checklist to improve reporting of patient and public involvement. Key issues included poor quality of methods reporting, little formal evaluation of quality of involvement, and limited focus on negative impacts.

A qualitative study sought to explore how patients express evaluations of quality of their care. The authors found that patients are reluctant to offer negative criticisms, and that patient evaluation is more complex than routinely acknowledged. Recommendations for standardized approaches that are more sensitive to this complexity are presented.

**General Principles and Frameworks for Involvement**


The National Institutes of Health Director’s Council of Public representatives developed definitions and operating principles of “community engagement” and “public participation;” guidelines for educating researchers and the lay public about community engagement; and criteria and guidance that peer-review panels can use to gauge community engagement.


Seven principles for public engagement are presented, each with a description of the principle, what it might look like in high quality engagement and what to avoid. The principles are planning and preparation; inclusion and demographic diversity; collaboration and shared purpose; openness and learning; transparency and trust; impact and action; and sustained engagement and participatory culture.


The five steps assessment/planning, organizational, educational, negotiation/resolution, and implementation, are presented with specific tasks and challenges relevant to each step.


Underlying democratic theory provides the rationale for public involvement in the form of public communication (advertisements, websites), public consultation (opinion polls, public hearings), and public participation (citizens juries, scenario workshops). Key conditions for successful involvement include representativeness, early involvement, and influencing policy decisions. Options for integrating involvement into the Canadian health system are discussed.


A background paper describes the characteristics and forms of deliberative public engagement then outlines nine principles for effective execution. These are the type of process used, transparency,
integrity, process specific to circumstances, the right number and types of people are involved, participants are treated with respect, participant discussion prioritized, process is reviewed and evaluated to improve practice, participants are kept informed.


Community-based participatory research is presented as a potential paradigm to apply to clinical and health services research. Twelve guiding principles such as co-planning research activities, following community values and time frames, and developing social capital in the community are described. The implementation of CBPR in these settings is described the three stages: vision, valley, and victory.


This logic model provides one approach to stakeholder dialogues including the inputs, activities, outputs, outcomes, and health outcomes with specific steps and opportunities within each.


Five types of engagement streams (exploration, conflict transformation, decision-making, and collaborative action) are described including when use is appropriate, sample issues, and key considerations. Descriptions and the types of engagement used for 19 well-known dialogue and deliberation processes are included.


Lora Church (starts at 66 min) discusses engaging American Indian communities in efforts to improve health outcomes. Topics include tribal IRB, tribal approval, flexible timelines, approval for publication, principles of engagement.


This update includes nine broad principles such as a clear goal for engagement, necessity of partnering with the community, flexibility in response to community needs, and a commitment to long-term collaboration. Twelve case studies in community engagement are presented. Includes some implementation considerations such as managing organizational support and program evaluation.


A literature search and qualitative interviews and discussion were undertaken to establish a definition and operation of user controlled research. Key characteristics of user controlled research are presented along with principles for good practice, and the benefits and barriers of this approach. Recommendations for developing user controlled research are included.

The history and purposes of involving patients in research is presented followed by the expertise and skills needed for panels to be successful such as experiential knowledge of panel members, facilitators, and historical experience. An overview of currently available guidance for involving patients is included.


The definition of “research” is considered in the context of community-based participatory research. Discussion includes relevance of research to communities, equal value of community and academic partners, and openness to diverse perspectives.

**Specific Engagement Guides**


The results of a workgroup tasked with determining how to effectively and consistently engage advocates in the research process designated four distinct roles and descriptions for advocates. Seven steps from recruitment to promotion provide a framework for involving advocates. Additional implementation considerations such as establishing an ongoing application process and online training sources are discussed.


A step by step guide for local Alliances to establish a consumer advisory council. Steps include getting buy-in from leadership and board, determining roles and responsibilities for advisory council including a written document, orient stakeholders to the goals of the advisory council, and dedicate staff to support and maintenance.


Three key principles for engagement are described including the goal, outcomes, and a spotlight on one local Alliance project and how they are implementing the principle. The principles are provide consumer support, make participation meaningful, and optimize the community organizations’ trusted voice.

Canadian Institutes of Health Research (CIHR). (n.d.). *Citizen engagement handbook.* Ottowa, Canada: CIHR.
A continuum of involvement ranging from listening/informing through to collaboration is described. A decision tree model with five key questions about involving citizens includes considerations for why, when, who, what, and how. Techniques for involvement at each stage in the continuum such as interviews, study circles, and advisory groups are discussed in terms of when they are most appropriate to use as well as benefits and drawbacks.


Public involvement in assessing and updating the Essential Health Benefits under the Affordable Care Act is discussed in terms of the role of citizens and the need for citizen input. Steps in the deliberation process are outlined, specific examples are highlighted, and a summary of guidelines for participation specific to reviewing EHBs are included.


A draft version of the NICE process for developing healthcare quality standards out for consultation. The process includes the groups and types of stakeholders involved; processes for drafting, developing, reviewing, and publishing materials; and general information about how stakeholders can be involved.


An overview of participatory research and its context within CIHR is presented followed by a process for engaging in participatory research. Steps include identifying partners, identifying barriers and facilitators, establishing a governance structure, and actually conducting research. A number of resources are also included.


A description of community-led action research and rationale for utilizing the approach leads into the specific theoretical and practical steps for implementing this type of research. Specific methods (e.g., questionnaires, photographs, focus groups) and sample tools are included.
# Appendix Q: Standards

## Patient Involvement Across the Spectrum of Research Activities

<table>
<thead>
<tr>
<th>Identification and background of the proposed standard</th>
<th>Description of standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCOR should strategically and systematically involve patients and other stakeholders in all stages of planning, conducting and implementing research*. The goals, objectives and level of patient involvement at each phase will depend on the needs of the project and should be clearly articulated in all research projects. A written plan delineating all aspects of patient involvement will be submitted as a required component of all proposals. Possible points of engagement are listed below. PCOR projects that do not include patient and stakeholder involvement should provide rationale for exclusion. Research projects should report on all involvement activities including an evaluation of methods used. Research processes appropriate and feasible to include patients and other stakeholder include:</td>
<td></td>
</tr>
</tbody>
</table>
| **a.** Writing Proposals  
**b.** Priority Setting  
**c.** Topic Identification  
**d.** Topic Refinement  
**e.** Determining Research Methods  
**f.** Reviewing Research Conduct  
**g.** Interpretation of Findings  
**h.** Dissemination of Information  
**i.** Implementation  
**j.** Evaluation |

* See attached diagram of patient-centered engagement

## Implementation Strategy

Options for determining whether this standard has been met could be based on a patient engagement plan including consideration of the following aspects. (Not every strategy will be relevant for all PCOR processes)

- **Specific project aims and goals**
  - Description of how project aims were developed including patient and other stakeholder involvement
  - Description of desired project outcomes
  - Description of expected research products

- **Understanding patient and community needs**
  - Discussion of how aims align with needs of specific patient populations and/or...
Patient Involvement Across the Spectrum of Research Activities

- communities
  - Discussion of impact of outcomes on patients
  - Description of how researchers understand or plan to gain knowledge of the culture, structure, processes and communication styles of patients and their communities

- Determining and providing rationale for points of engagement (see attached diagram)
  - Prioritization (clinical areas, funding allocations, designing and reviewing RFPs)
  - Topic identification (stakeholders serving as co-applicant)
  - Topic refinement (determining outcomes of importance, what questions are asked)
  - Research methods (study design, recruitment methods, instrument design)
  - Research conduct (carrying out research plan, recruit participants, data collection)
  - Translation (reviewing report drafts, interpreting findings)
  - Dissemination (determining who needs information, how it is communicated, drafting and reviewing publications)
  - Action and evaluation (implementation of the findings, using the results)

- Project process
  - Description of project processes and key stakeholders for each phase
  - Description of project decision-making process
  - Designated staff for central point of contact for patients and other stakeholder participants

- Patient and other stakeholder process elements
  - Description of patient selection process
  - Description of patient orientation and training
  - Description of patient support
  - Description of follow-up with patients and other stakeholders after end of project

- Patient involvement resources
  - Budget with dedicated involvement resources included

- Description of Evaluation Plan

Current Practice or Examples from Qualitative Data

The importance of patient and other stakeholder involvement in research is widely recognized and acknowledged by experts in the field. However, the literature base on best practices is very limited. Current practice consists of multiple approaches to involvement depending on the topic area, goals and objectives of the research being conducted. Involvement ranges from one-time
Patient Involvement Across the Spectrum of Research Activities

<table>
<thead>
<tr>
<th>MC Key Criteria: Rationale for and against adoption of the proposed standard</th>
<th>Contribution to Patient Centeredness</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Involving patients and other stakeholders across the spectrum of research activities contributes to patient centeredness in the following ways:</td>
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<tr>
<td></td>
<td>- Increases the relevance, application, and dissemination of the research findings by identifying and addressing the information needs and outcomes of importance to end users</td>
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<td></td>
<td>- Accesses knowledge and expertise that may be otherwise untapped and inaccessible (even to content experts and experienced investigators)</td>
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<tr>
<td></td>
<td>- Assists with identification of values and preferences important to end users where clear clinical evidence is not available/complex issues or topics are involved</td>
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<tr>
<td></td>
<td>- Helps to ensure that research focuses on the needs of specific groups or communities such as traditionally underrepresented groups</td>
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<tr>
<td></td>
<td>- Helps to ensure that research conduct and protocols are culturally and linguistically sensitive and appropriate</td>
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<td></td>
<td>- Facilitates development of trust between researchers, patients and other stakeholders through knowledge exchange and sustained relationship building Contributes to the development of evidence and ‘just in time’ information that clinicians need in order to assist patients with decision-making at point of care</td>
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<tr>
<td></td>
<td>- Contributes to the development of evidence that policymakers need to make defensible coverage decisions</td>
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<td></td>
<td>- Helps to ensure funding is allocated to areas which patients and other stakeholders have identified as higher priority</td>
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<tr>
<td></td>
<td>- Builds trust and facilitates relationship building especially in traditionally</td>
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</tbody>
</table>
# Patient Involvement Across the Spectrum of Research Activities

- Underrepresented, stigmatized or marginalized groups
- Requires researchers to clearly articulate the goals, objectives and expectations of participants, roles and responsibilities for all participants involved in the processes
- Has the potential to recognize and address past indiscretions or oversights that have led to patient mistrust or suspicion
- Increases credibility with all stakeholder audiences
- Increased credibility may facilitate increased uptake and implementation which may then lead to greater interest and participation

## Contribution to Scientific Rigor

Since little is known about how patient and other stakeholder involvement contributes to scientific rigor, PCORI is uniquely positioned to lead the development of new standards and measurements in this area. Patient involvement across the spectrum of research activities also allows continued development in two key areas: 1) the collection of evidence on the impact of patient and public involvement; and 2) development of processes and methods to evaluate the successes and limitations of patient involvement.

## Contribution to Transparency

NA

## Empirical Evidence and Theoretical Basis

This finding is one of the strongest ones to come out of the PCORI Expert Interviews Project. There was near consensus of experts interviewed for this project that strategic and systematic involvement of patients and other stakeholders be employed across all phases and stages of the research process. Findings from the facilitated discussions supported the opinions of the experts.

Some established involvement programs have well-developed policies, procedures and guiding principles to conduct this work. However, the evidence base for what methods work best under which circumstances and with which audiences is not robust.

*Overall Strength of Evidence: Strong*

## Implementation Issues

Implementation of systematic and strategic involvement of patients and other stakeholders represents significant challenges for many institutions and researchers. These include:

- The resource intensive nature of successful and meaningful involvement including funding to support sustainable involvement efforts
### Patient Involvement Across the Spectrum of Research Activities

- The need to develop involvement infrastructure within research organizations/institutions
- The need for a cultural shift within the research community that addresses hesitation or unwillingness to alter accustomed practices (research conducted without meaningful patient involvement)
- The need for policy change/management structures within organizations
- Supplementary patient involvement standards, including operational guidance, criteria, and evidence of implementation
- Additional guidance to address uncertainty about when, how and who should be engaged
- Additional standards that incorporate criteria for and evidence of implementation including standards that require reporting on patient involvement activities
- The need to develop and use clear methodologies to collect information on patient views and experiences

### Other Considerations

In order to appropriately implement this standard it is also critical to consider the following:

- Ensuring there are dedicated resources to support involvement
- Ensuring transparency throughout involvement
- Developing organizational policies and procedures supporting involvement
- Using appropriate methods of patient-centered communication
- Systematic methods of identifying and selecting stakeholders
# Dedicated Resources for Patient and Other Stakeholder Involvement

<table>
<thead>
<tr>
<th>Identification and background of the proposed standard</th>
<th>Description of standard</th>
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<tr>
<td></td>
<td>PCOR should provide evidence of dedicated resources to support patient involvement activities in the conduct of research, including a stand-alone description of dedicated resources such as staff, budget, patient incentives and other items. Specific resources will vary depending on the particular research project and the level and depth of involvement. PCOR projects that do not include dedicated resources for patient involvement should provide rationale for exclusion. Research projects should evaluate and report on the use of these resources.</td>
</tr>
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</table>

## Implementation suggestions

Options for determining whether this standard has been met could be based on documented inclusion and successful description of the following aspects. (Not every strategy will be relevant for all PCOR processes)

- **Patient participation**: description of activity, time estimate and compensation for
  - Writing and reviewing grant applications
  - Participation in orientation, training and/or other briefing activities
  - Participation in research methods, meetings and support activities (e.g., research activities, peer groups)
  - Contributing to translation and dissemination of research findings

- **Researcher participation**: description of activity, time estimate and compensation for
  - Participation in researcher orientation, training and/or other briefing activities on patient involvement
  - Meeting with and supporting patients over the course of the project
  - Participation in translation and dissemination as relates to patient involvement
  - Developing relationships in the community

- **Materials**: resources required to produce and distribute materials for patient-related activities including translation and dissemination of research findings

- **Staff support**: resources required for identification, selection, coordination and support of patient involvement in research projects

- **Logistical components**: parking, travel, child care, and other requirements

- **Specific assistance**: for research with non-English speakers, children, and people with disabilities
### Dedicated Resources for Patient and Other Stakeholder Involvement

**Current Practice or Examples from Qualitative Data**

There was strong evidence from experts regarding the resource-intensive nature of patient involvement in research and the need for dedicated funding. In general, processes can take longer when patients are involved and the time required for effective planning and completion of activities may increase. Researcher and staff time makes up one of the largest investments for patient but this is rarely fully quantified or taken into account, especially when initiating patient involvement in agencies with intense workloads.

In addition, developing relationships and establishing trust is time and resource intensive. Experts in Community-based Participatory Research (CBPR) note that it can take up to 1-2 years to establish trusting relationships that facilitate representative involvement. This was echoed by patient and consumer advocates and other researchers. If the community or population of interest is traditionally underrepresented or from a group that has been exploited or harmed by research activities, the time to develop effective working relationships may be even longer. Cultural differences also may impact research timelines as community norms and values are not always harmonious with those of academic research or funding institutions. In academic research, researcher incentives are publication in academic journals; however there is little funding or academic reward for making research meaningful and accessible to patients in ways they can use.

Although resources required for patient involvement such as coordination, staff support, and travel costs are generally well-recognized, experts observe that patient involvement is resource intensive in less obvious ways. To date in the US, little funding is specifically devoted to patient involvement in research or to its effective dissemination to the public. One exception to this is the field of CBPR which may serve as a model for PCOR activities moving forward. In addition, it is unusual to financially support patient involvement in grant development, an area that experts and participants in the facilitated discussions both noted was important.

In England and Wales, the NICE Patient and Public Involvement Program provides training days to new guidance development chairs and patient and caregiver representatives. Initial briefings are provided to each new guidance development group with a 6-month follow-up workshop for patient and caregiver representatives during the guidance development period. In addition, a designated team supports patients, carers, and guidance developers on an as-needed basis. All of this work is supported by dedicated resources and would likely not be feasible without this explicit and planned support.

**Published Guidance**

NA for this project

**MC Key Criteria: Rationale for and Contribution to Patient Centeredness**

Addressing the logistical and practical needs of patients and researchers has the potential to...
### Dedicated Resources for Patient and Other Stakeholder Involvement

| against adoption of the proposed standard | facilitate better representation of populations of interest. The ability of patients and other stakeholders to participate in research in a meaningful way may improve when patient involvement is supported with dedicated funding. Identifying, documenting, and supporting the tangible and intangible costs of patient-centered research will provide a better understanding of resources required to develop an institutional and research culture that is patient centered. |
| **Contribution to Scientific Rigor** | NA |
| **Contribution to Transparency** | Providing clear estimates and reports of resources for patient involvement increases accountability. Collection of evidence on the costs incurred in patient involvement will also provide baseline data and a realistic understanding of resources required in three key areas: (1) patient involvement research; (2) capacity-building to ensure the sustainability of research on patient involvement; and (3) tools and resources needed to further develop the field of PCOR. |
| **Empirical Evidence and Theoretical Basis** | National and international experts across multiple disciplines cited the need for dedicated resources in order to involve patients and other stakeholders in a meaningful and effective way. This finding was mirrored by participants in facilitated discussion groups who called for fair and equitable compensation for their time and contributions to research activities. Internationally, research infrastructures have been developed to support patient involvement in research. In England, INVOLVE, a national advisory group on patient involvement in research provides research, programs, and tools for identifying, tracking, and estimating the costs and benefits of patient and stakeholder involvement. |
| **Overall Strength of Evidence: Strong** | |

<table>
<thead>
<tr>
<th>Additional considerations</th>
<th>Implementation Issues</th>
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<tbody>
<tr>
<td>Below are issues for consideration to institutions and researchers.</td>
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<tr>
<td>▪ Adding an additional layer of documentation to research</td>
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<tr>
<td>▪ The potential to require and incorporate additional auditing capacity within research organizations/institutions</td>
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<tr>
<td>▪ The need for a cultural shift in the funding community to address any hesitation to alter accustomed practices for which there is very little funding, such as developing relationships in a community or reimbursing patients in collaborating on grant development.</td>
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<tr>
<td>▪ The need for policy change/management structures within organizations to support</td>
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<tr>
<td>Dedicated Resources for Patient and Other Stakeholder Involvement</td>
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<td>funding for sustainable involvement once relationships have been established with communities.</td>
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**Other Considerations**

In order to appropriately implement this standard it is also important to consider:

- Developing organizational policies and procedures supporting involvement
- Involving patients and other stakeholders across the spectrum of research activities
- Using appropriate methods of patient-centered communication
- Identifying and selecting stakeholders
- Transparent involvement processes
### Stakeholder Identification and Selection

<table>
<thead>
<tr>
<th>Identification and background of the proposed standard</th>
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<tbody>
<tr>
<td></td>
<td>PCOR should demonstrate systematic and formal processes by which to identify, recruit, screen and select patients and other stakeholders to participate in PCOR activities. In addition, researchers will identify the range of stakeholder perspectives needed as well as the scope and purpose of engagement. Research projects should evaluate and report methods for selecting patients and other stakeholders.</td>
</tr>
</tbody>
</table>

### Implementation Strategies

Options for determining whether this standard has been met could be based on documented inclusion and successful description of the following aspects. (Not every strategy will be relevant for all PCOR processes)

- **Identification**
  - Determine goals and purpose of involvement
  - Identify range of stakeholder perspectives necessary to achieve research aims including minimum and maximum number of participants

- **Recruitment**
  - Develop a recruitment plan
    - Modes of communication
    - Dedicated staff and resources
    - Community partners
    - Involvement of patients and other stakeholders in recruitment, screening and selection efforts
    - Develop screening criteria, including types of stakeholder needed and clearly defined “match” with project needs
  - Identify likely sources for desired stakeholder categories. These may include any of the following as well as other sources:
    - Online or community bulletin boards
    - Community centers
    - Faith-based organizations
    - Community organizations
    - Consumer or patient advocacy organizations
    - Professional associations
    - Social media
Stakeholder Identification and Selection

- Professional or personal networks
  - Develop and distribute recruitment information materials including:
    - Purpose of the project
    - Role of participants
    - Responsibilities/expectations/selection criteria
    - Time commitment required
    - Available support/compensation for participation

- Screening
  - Determine team members for screening and selection
  - Apply screening criteria and select candidates for participation

- Selection
  - Screen applicants for skills, knowledge, perspective required in selection criteria
  - Communicate selection and rationale to stakeholders
  - Orient and support patients and other stakeholders selected for participation throughout the process

Current Practice or Examples from Qualitative Data

The importance of selecting the appropriate stakeholder for participation in PCOR activities was identified by a broad and diverse group of engagement experts, both national and international. Many of these experts advocated for formal selection processes that allow researchers to screen patients and other stakeholders to determine the optimal “match” of stakeholder with the purpose and need of the project. Screening and selection processes also help ensure that a concern raised by experts is addressed: that of ensuring broad perspectives as well as that of individual patient experience are included (caregiver, advocate, general public, frontline clinicians, etc.).

Organizations with well established patient involvement programs, such as the NICE Patient and Public Involvement Program, INVOLVE and the FDA, approach stakeholder selection through a formal and systematic process which some experts liken to hiring an employee. Interested stakeholders apply for positions on steering committees, advisory panels, or as individual informants and go through formal screening and orientation processes.

Experts who work in organizations with less established patient involvement programs described recruitment and selection methods that used word of mouth or contacts known through personal or professional networks. However, the majority of experts identified the latter practice as problematic as it may limit diversity of opinion and perspectives represented. Participants who are identified in this way are more likely to represent ‘professional patient’ or
## Stakeholder Identification and Selection

‘junior researcher’ perspectives than that of the actual lay patient who may not have extensive previous experience participating in research processes. The lack of lay patient perspective may contribute to research that is less focused on patient centered outcomes. However, experts noted that depending on the project needs, this may be a suitable selection process.

### Published Guidance

NA for this project

<table>
<thead>
<tr>
<th>MC Key Criteria: Rationale for and against adoption of the proposed standard</th>
<th>Contribution to Patient Centeredness</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Formal and systematic selection processes increase the likelihood of effective and meaningful engagement for researchers, patients and other stakeholders. Creating and implementing formal processes makes stakeholder selection more transparent and therefore increases trust, credibility and accountability with the public, funders and other stakeholders. Formal processes also help to ensure the identification and selection of appropriate patients and other stakeholders, given the unique requirements of each project or phase of research. Adhering to systematic and transparent selection processes increases the credibility of those who are conducting research as well and simultaneously builds trust among stakeholder groups. Greater trust and transparency can increase uptake of findings to improve patient centered outcomes and thereby contributes to patient centeredness.</td>
</tr>
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</table>

### Contribution to Scientific Rigor

Formal and systematic selection processes increase the likelihood that appropriate candidates will be identified and therefore may minimize bias. Requiring funded researchers to report on these processes may increase replicability. Formal and transparent processes make stakeholder selection more transparent and accountable.

### Contribution to Transparency

NA

### Empirical Evidence and Theoretical Basis

There was strong support from both national and international experts across all disciplines for transparent and systematic patient and stakeholder selection processes.

This is standard practice in organizations with well established patient and public involvement programs such as the NICE Patient and Public Involvement Program, the James Lind Alliance and INVOLVE. These organizations have established selection processes that were developed with input from stakeholders over many years. Much of this information is publically available on websites or in other program materials.
## Stakeholder Identification and Selection

<table>
<thead>
<tr>
<th>Additional considerations</th>
<th>Implementation Issues</th>
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<tbody>
<tr>
<td></td>
<td>Initial efforts to establish systematic and formal selection processes will be resource intensive. Once systems are in place, continued resources will be needed to staff and evaluate selection processes. Researchers may need technical assistance setting up systematic selection processes. Current models exist (NICE Patient and Public Involvement Program, UK NHS INVOLVE, etc.) and this may help with implementation if new systems borrow elements and piggyback from lessons learned by well-established programs.</td>
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<table>
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<tr>
<th>Other Considerations</th>
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</table>
In order to appropriately implement this standard it is also critical to consider the following:
- Developing organizational policies and procedures supporting involvement
- Involving patients and other stakeholders across the spectrum of research activities
- Ensuring there are dedicated resources to support involvement
- Ensuring transparency throughout involvement
- Using appropriate methods of patient-centered communication
# Support for Patient Engagement

<table>
<thead>
<tr>
<th>Identification and background of the proposed standard</th>
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<tbody>
<tr>
<td>PCOR should have processes in place that support patients and other stakeholders involved in all phases of research. Processes should be broad enough to allow researchers flexibility in designing patient engagement activities and substantially directive enough to avoid tokenistic patient involvement. Institutional and organizational processes should provide direction on appropriate orientation, training, and general support for researchers, patients, and other stakeholders engaged in research.</td>
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</table>

## Implementation Strategies

Options for determining whether this standard has been met could be based on documented inclusion and successful description of the following aspects. (Not every strategy will be relevant for all PCOR processes)

- **Orientation for participants and investigators, including:**
  - Rationale for and value of engaging patients in research
  - Defined roles for each member of the project (e.g., researchers, patients and other stakeholders)
  - Defined engagement requirements for patients (e.g., time, travel, meetings, commitment, timeframe, etc.)
  - Description of how materials and information will be communicated to patients (e.g., written document in written in simple and easy to understand lay language)
  - Specific scientific and research process content relevant for the project

- **Training**
  - Goals of training (e.g., basic science education, group communication skills, research process)
  - Training agenda and activities
  - Training logistics (webinar, in-person, workshop, phone, 2-day etc)
  - Training evaluation

- **Patient engagement – General support**
  - Dedicated contact person for patient engagement
  - Patient only Q & A sessions
  - Opportunities for patients to discuss/speak with each other
  - Length of support
Support for Patient Engagement

- Logistics of support (e.g., in person meetings, phone, etc)
  
  **Patient engagement - Follow up support**
  
  - Mode of follow up (e.g., newsletter, email, workshops, etc)
  - Process for follow up (e.g., patients need to contact researchers, researchers reach out, ongoing work group, etc)
  - How patients can help shape and develop new research projects
  - How patients can be more involved in research (e.g., mentor, training other patients, further education)
  - Patient involvement in evaluating the process and their contribution

- Organizational policies and procedures
  
  - Documentation or evidence of organizational policies and procedures that confirm these, and other aspects, of supporting patient and other stakeholder involvement

Current Practice or Examples from Qualitative Data

The importance of patient and other stakeholder involvement in research has strong support by experts in the field. While some funders require patient engagement as a condition of funding, few institutions and organizations have taken it upon themselves to develop their own patient and other stakeholder support processes. Experts stress the need for appropriate orientation, training and support of patients and other stakeholders engaged in research processes and for researchers to be trained in appropriate patient engagement methods. Facilitated discussion participants and experts expressed a need for appropriate communication by the research community that includes respect, compassion, time and integrity.

Among experts, there was broad agreement that the following components should be minimally included as orientation and training components:

- Emphasis in the value of the patient and other stakeholder perspective in the entire research process
- A clear description of roles and expectations for all participants including researchers
- Goals, objectives and design for the project including patient engagement
- Any relevant tools or information needed to understand the conversation and meaningfully participate (e.g., topic information, evaluation tools, research process description, methods, etc.)

Support for patients and other stakeholders is critical for meaningful patient engagement in research. Support activities can vary from providing program support contact information to
## Support for Patient Engagement

Answering any questions or concerns, developing a peer-directed support group, and creating separate meeting times for patients to share their experiences. General support, including compensation for time, travel expenses, and other participation costs, for patients and other stakeholders needs to be ongoing throughout the research process.

Support processes should reflect the concepts and elements of appropriate orientation, training and general support described above. The development of these organizational processes should include patients and their perspectives in the process.

### Published Guidance

NA for this project

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<th>MC Key Criteria: Rationale for and against adoption of the proposed standard</th>
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<td>Requiring applicants to develop and implement individual processes on support of patients and other stakeholders will help shift the current culture of research to be more patient centered. Providing training and support for researchers in how to meaningfully engage patients and other stakeholders may facilitate further cultural shift. These processes go beyond simple “check the box” patient engagement and work to develop an institutional and organizational culture to support patients throughout engagement in research. Providing orientation and training to patients and other stakeholders engaged in research, so they understand the project goals and objectives, enables stronger and more meaningful participation and contributions from patients and other stakeholders. Ongoing support for patients is a pathway for developing relationships and for encouraging confidence and assurance that the patient voice is central to the research process. Patient and other stakeholder involvement may improve the application, relevance and quality of research. Involvement also necessitates the development and use of clear methodologies to collect information on patient views and experiences. Established support processes may encourage and further enable patients to have a stronger and more meaningful voice in the development of effective methodologies for eliciting the patient perspective and successfully engaging patients in research.</td>
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</table>

### Contribution to Scientific Rigor

Requiring applicants to develop and document processes supporting patients and other stakeholders may help contribute to the creation of further evidence on patient engagement and therefore may lead to stronger methodological best practices.

### Contribution to Transparency

Documenting and implementing support processes builds the groundwork for incorporating patients and their values into the research process. Patients and other stakeholders with an
Support for Patient Engagement

Understanding of the project and engagement processes can then provide input throughout the research process. Involvement throughout the process ensures that conclusions are linked to the data and accurately reflect patient and other stakeholder interpretation. These processes also improve the opportunity for users to access and assess findings.

**Empirical Evidence and Theoretical Basis**

Experts across multiple disciplines both nationally and internationally emphasized the need for training and support of patients throughout involvement processes. Participants in facilitated discussions expressed a strong desire to be treated with compassion, respect, and dignity by researchers and the research community – as evidenced by initial and ongoing support for their involvement. Providing training and support of patients in research can lead to the development of trusting relationships and more meaningful contributions. Additionally, training researchers on how to appropriately engage patients and other stakeholders leads to more meaningful participation and respect of patient and other stakeholder roles.

*Overall Strength of Evidence: Strong*

<table>
<thead>
<tr>
<th>Additional considerations</th>
<th>Degree of Implementation Issues</th>
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<tbody>
<tr>
<td></td>
<td>Requiring the development and adoption of patient and other stakeholder engagement support processes represents a cultural shift for many institutions and researchers. Applicants will need to first define their requirements for support processes and how to operationalize the requirements through specific procedures and direction. It is thus critical to include all relevant stakeholders in the development of such processes in order to maximize stakeholder buy-in.</td>
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**Other Considerations**

In order to appropriately implement this standard it is also critical to consider the following:

- Involving patients and other stakeholders across the spectrum of research activities
- Ensuring there are dedicated resources to support involvement
- Ensuring transparency throughout involvement
- Using appropriate methods of patient-centered communication
- Identifying and selecting stakeholders
# Communication with Patients and Other Stakeholders

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<td></td>
<td>PCOR should demonstrate patient-centered communication styles and modes, including but not limited to consideration of culturally appropriate language, impact of different interpersonal communication styles and use of facilitators skilled at eliciting patient perspectives.</td>
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<td></td>
<td>PCORI research should demonstrate an awareness of patient-centered communication styles, take into account participant culture, language background and the impact of differing interpersonal communication styles, and facilitate balanced and collaborative communication.</td>
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</tbody>
</table>

### Implementation Strategies

Options for determining whether this standard has been met could be based on documented inclusion and successful demonstration of the following aspects. (Not every strategy will be relevant for all PCOR processes).

- **Key personnel**
  - Facilitation experience
  - Communication styles and group communication training
  - Researcher training sessions on working with patients

- **Project communication**
  - How materials and information will be communicated to patients (e.g., documents written in plain language for lay audiences)
  - Use of language and cultural references appropriate to the targeted patient and community populations (including descriptions of project aims, research processes, and patient engagement)

- **Facilitation**
  - Plan for using effective facilitation techniques in research project (e.g., logistics [e.g., easel, voting mechanisms, etc.], room set up and seating arrangements, etc.)
  - Elements to ensure successful facilitation (e.g., setting ground rules, processes that ensure all perspectives are included and add value)

### Current Practice or Examples from Qualitative Data

The importance of patient and other stakeholder involvement in research is widely recognized and acknowledged by experts in the field. Experts acknowledged the style and methods used to communicate with patients and other stakeholders are essential to effective engagement activities. Experts agreed on the need for researchers who are able to exhibit effective interpersonal communication, including listening carefully to and hearing what is important to patients. In
Communication with Patients and Other Stakeholders

addition, researchers need to be able to effectively acknowledge and address concerns raised by patients and other stakeholders, even if project parameters are not able to accommodate these concerns.

Facilitated discussion participants expressed a strong desire for researchers to engage them using communication styles that exhibit respect and empathy. Awareness of body language and tone of voice were of particular note as well as attention to the use of technical language or scientific jargon that may act as a barrier to open exchange and mutual understanding. Some participants and experts even suggested that how researchers dress when participating in engagement activities may demonstrate an understanding of community, and this in turn can affect how forthcoming patients and other stakeholders are in sharing their perspectives.

Experts agreed that the style and level of verbal and written language should meet the needs of patients, other stakeholders, and the community. Language should be simple and easy to understand. Technical material should not be “dumbed” down but should be communicated in plain language. The use of personal stories, quotes, vignettes, and scenarios can help communicate information to patients and other stakeholders. Investigators should use the language that the community speaks, taking into account verbiage, ethnic style, vocabulary, concepts and approaches. Language should also be culturally and socially appropriate.

Use of a neutral facilitator was supported by experts. Facilitators should have strong skills and be able to demonstrate that all participant voices are of value. Facilitators need to be able to create a safe environment for patients and other stakeholders to share their perspective. Experts noted that lead researchers often facilitate meeting discussions and therefore, facilitation training programs may be beneficial for researchers. In addition to training, process design can also assist with effective information exchange. Integrating specific agenda items for eliciting perspectives from patients and other stakeholders can help to ensure active participation.

<table>
<thead>
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<tr>
<td>NA for this project</td>
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<tr>
<td><strong>Contribution to Patient Centeredness</strong></td>
</tr>
<tr>
<td>Culturally appropriate use of language and communication with patients and other stakeholders can create environments where patients feel heard and supported in their participation. Creating an environment within a meeting where patients feel that their participation and insights are valued can lead to greater and more in depth sharing of the patient perspective. Patients and other stakeholders who feel listened to and respected are more likely to share their perspectives and participate fully in meaningful discussions. Additionally, culturally appropriate language coupled with listening to and respecting the patient and other stakeholder perspectives, can create the basis for trusting relationships.</td>
</tr>
</tbody>
</table>
## Communication with Patients and Other Stakeholders

### Contribution to Scientific Rigor

Plain language that is culturally appropriate can lead to a greater comprehension of project goals and processes on behalf of patients and other stakeholders. This can lead to greater participation and the sharing of patient and other stakeholder perspectives. Including the patient and other stakeholder perspective can enhance the conversation and lead to a reduction of bias.

### Contribution to Transparency

Communicating in a way that is understandable and approachable by patients and other stakeholders will allow for more effective communication and exchange of information between the research project and patient and other stakeholders. Culturally appropriate communication may enhance the uptake of information and lead to a greater understanding by patients and other stakeholders about all aspects of the research process.

### Empirical Evidence and Theoretical Basis

A strong majority of experts and facilitated discussion participants expressed a need to communicate with patients and other stakeholders in a way that is respectful, sensitive, culturally appropriate and easy to understand. Additionally, there was moderate evidence that information and concepts should not be oversimplified but that time and resources be taken for the assurance of clear communication and mutual understanding. Experts suggested that effective facilitation is often required to acknowledge the value of the patient and other stakeholder’s perspectives and to create a “safe” environment where patients and other stakeholders feel comfortable sharing their views.

*Overall Strength of Evidence: Strong*

### Additional Considerations

#### Degree of Implementation Issues

Trainings in communication methods, techniques and facilitation are not commonly held for researchers, patients, or other stakeholders. While effective communication is integral to the research process, discussion of successful communication techniques might not be viewed as valuable to some researchers and institutions. Implementing effective communication techniques will require dedicated resources and in some instances, a cultural shift in how researchers and research institutions interact with patients and other stakeholders.

### Other Considerations

In order to appropriately implement this standard it is also critical to consider the following:

- Developing organizational policies and procedures supporting involvement
- Involving patients and other stakeholders across the spectrum of research activities
- Ensuring there are dedicated resources to support involvement
## Communication with Patients and Other Stakeholders

- Ensuring transparency throughout involvement
- Identifying and selecting stakeholders
## Transparent Involvement Processes

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<tbody>
<tr>
<td>PCOR should be conducted in an open and transparent manner. Research projects should provide clear and complete information regarding the purpose, goals, policies, timeline and processes by which they will engage patients and other stakeholders. PCOR projects should also provide clear and complete information regarding researcher, patient, and other stakeholder roles and expectations for participation, as well as a description of decision making processes and dissemination plans. Information on processes regarding data use, management and ownership should be disclosed.</td>
<td></td>
</tr>
<tr>
<td>Materials intended for use by patients and other stakeholders should be written in plain language and compliant with all relevant accessibility requirements. Tailoring materials to specific populations may include use of culturally sensitive language, translation into different languages and formats including written correspondence, electronic media, telephonic or in person communication. Transparency should be considered in, but is not limited to, four major areas which should be clearly communicated:</td>
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<tr>
<td>- <strong>Purpose of research and project goals</strong>: the reason for conducting research and the goals of the project. This should also include a description of the purpose and rationale for engaging patients, as well as a description of the expected impact on patients and their communities.</td>
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<tr>
<td>- <strong>Policies, processes and standards for engagement</strong>: provide clear descriptions of the overall research process, engagement design and how patients and stakeholders will interact with these processes. This should also include a description of how decisions will be made and conflicts resolved.</td>
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<tr>
<td>- <strong>Roles and expectations of participants</strong>: clear descriptions of the roles, expectations (including time commitment), and depth of involvement that patients and other stakeholders are expected to fill.</td>
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<tr>
<td>- <strong>Intended use and dissemination of results</strong>: plans and processes for the analysis, interpretation and communication of research results.</td>
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</tbody>
</table>

### Implementation Strategies

Options for determining whether this standard has been met could be based on documented inclusion and successful description of the following aspects. (Not every strategy will be relevant for all PCOR processes)

- **Purpose of research and project goals**
- Background, development, and goals of the project
  - Research design and methods
## Transparent Involvement Processes

- Desired outcome of research
- Purpose and rationale for patient involvement
- Desired outcome of participation (e.g., make research more relevant, selecting comparators, writing grant application)
- Expected impact on patients and their communities
- Prior involvement with the community and/or stakeholder groups relevant to the project
- Desired contribution from patients or other stakeholders and desired stakeholder perspective (e.g. patient, advocate, caregiver)

- **Policies, processes and standards for engagement**
  - How patient and other stakeholder input will be solicited
  - How patient and other stakeholder input will be integrated
  - How patient and other stakeholder input fits within broader research process
  - How decisions are made and implemented
  - How conflict or disagreement will be resolved
  - Descriptive timelines delineating opportunities for involvement

- **Roles and expectations of participants**
  - Roles and expectations of other stakeholders
  - Risks and benefits of participation (personal, professional, other)
  - Compensation offered (e.g., travel & lodging expenses, wages or incentives for participation, etc.)
  - Anticipated time commitment
  - Required or desired training/orientation
  - Resources available during the process
  - Expectations and opportunities for ongoing involvement

- **Intended use and dissemination of results**
  - Expected products (e.g., reports, meetings, papers, community gatherings)
  - Plans for dissemination
  - Plans for implementation
  - Opportunity for patient and other stakeholder review of findings and interpretation
  - Statement of data ownership or parameters of data sharing
# Transparent Involvement Processes

## Current Practice or Examples from Qualitative Data

Experts and facilitated discussion participants stressed the importance of transparency throughout the research process. Strong concerns about transparency in the conduct of research were expressed in relation to underrepresented communities. Past ethical breaches on the part of researchers were regularly mentioned, and points to the need for openness and clarity in all communications with patients and other stakeholders. Some experts suggested that transparency should begin with the earliest points of involvement and continue throughout. Experiences in which researchers failed to report back findings or used results without consent from the community were identified as poor practice by both experts and facilitated discussion participants. The need for open and honest communication of research processes, descriptions of participant roles, and intended uses of results was emphasized.

Many organizations that focus on patient and stakeholder participation in research (e.g., NICE, INVOLVE, the James Lind Alliance, and the Scottish Community Development Centre) have established policies, procedures, and role descriptions that have been developed with input from stakeholders over many years. These documents are publicly available and are used during orientation processes. Additionally, organizations in the civic engagement and public deliberation fields (e.g., National Coalition for Dialogue and Deliberation, Center for Collaborative Policy) have established processes and include transparency in their principles for engagement.

One expert stated that in the past, lack of transparency may have been due to organizers fear of addressing contentious topics or areas where there were conflicting values among stakeholders. However, well designed processes that are open and transparent to all participants, even when there is strong disagreement between stakeholders, can contribute to successful engagement activities by increasing trust.

## Published Guidance

NA for this project

## MC Key Criteria: Rationale for and against adoption of the proposed standard

### Contribution to Patient Centeredness

Increased transparency throughout the research process ensures patients and other stakeholders are fully informed of the scope of the project and of their participation at the start of involvement. It establishes realistic expectations, for participants and researcher alike, regarding what involvement entails. This allows patients and other stakeholders to assess opportunities for involvement and select the opportunity that best fits their desired involvement.

Transparency helps build trust between those conducting research and patients and other stakeholders. Involving patients and other stakeholders in the development of procedures and processes further improves trust. Greater trust may increase uptake of findings to improve clinical outcomes.
# Transparent Involvement Processes

Implementation of this standard also ensures that research conducted for PCORI accurately reflects patient preferences and concerns. Developing and implementing transparency throughout the research process demonstrates respect both for the individuals involved as well as their input and feedback.

## Contribution to Scientific Rigor

Transparency increases accountability. Increased accountability may lead to improved reporting if patients and other stakeholders are monitoring researcher activities thus improving reproducibility.

Implementation of this standard also will help further the evidence on patient engagement and may lead to stronger methodological best practices.

## Contribution to Transparency

NA

## Empirical Evidence and Theoretical Basis

There was robust support from national and international experts across all disciplines as well as from facilitated discussion participants regarding the need for transparency throughout the research process.

*Overall Strength of Evidence: Strong*

<table>
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<td>Achieving and communicating transparent research may require a culture shift for many individuals, institutions and organizations within the research enterprise. Traditional power structures and the established control and flow of information may be challenged. Transparent research may be more resource intensive and require increased staff time, dedicated funds or other forms of institutional support. Involving patients and other stakeholders in the development and implementation of these processes will require additional resources to solicit, synthesize and integrate feedback.</td>
</tr>
</tbody>
</table>

## Other Considerations

In order to appropriately implement this standard it is also critical to consider the following:

- Developing organizational policies and procedures supporting involvement
- Involving patients and other stakeholders across the spectrum of research activities
- Ensuring there are dedicated resources to support involvement
- Using appropriate methods of patient-centered communication
<table>
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<td>▪ Identifying and selecting stakeholders</td>
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