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Executive Summary

Meaningful patient engagement is a central tenet of patient-centered outcomes research (PCOR), yet there is no expert consensus on best practices (Clancy & Collins, 2010). In August, 2011, the Patient Centered Outcomes Research Institute (PCORI) Methodology Committee issued a request for proposals to conduct a series of expert interviews to identify effective methods and best practices in patient engagement. The Center for Evidence-based Policy (the Center) at Oregon Health & Science University (OHSU) was contracted to conduct the expert interviews in November 2011.

Methods
The Center designed a multi-faceted approach that included convening a representative Advisory Panel to consult on all phases of the project. Project and contracted staff conducted interviews with 87 national and international experts representing diverse stakeholder groups and fields of expertise, and arranged and attended 12 facilitated discussions with 123 patients, caregivers, and members of the public in six regions of the US. Interviews were conducted between December 12, 2011 and February 15, 2012, and discussions were conducted between January 11 and February 9, 2012.

Findings

Practical Methods for Engagement
Patient engagement in research is carried out along a continuum of involvement points. The methods used at any given point of involvement may differ based on several factors: the project’s goals and objectives, the point of engagement in the process, the specific populations or communities engaged, and the existence of a formal structure for patient engagement. Interviewed experts and facilitated discussion participants identified eight categories of methods and best practices for eliciting the patient perspective. These are:

1. **Planning for Patient Engagement**: Developing a written framework that includes six key elements:
   a) Well-defined project goals,
   b) Understanding of patient and community needs,
   c) Defined rationale for engagement,
   d) Defined points of engagement,
   e) Transparency throughout engagement processes and
   f) Ease of participation and fair compensation for stakeholder time and contribution.
2. **Stakeholder Identification and Selection**: Developing clear processes for stakeholder selection to help build trust and transparency.

3. **Eliciting Stakeholder Perspectives**: Matching the method of engagement with the purpose and patient.

4. **Stakeholder Preparation**: Preparing patients through orientation, training and general support.

5. **Evaluation, Feedback, and Dissemination**: Providing information, implications, and impact of research to engaged patients and the broader stakeholder community.

6. **Sustainability**: Developing ongoing relationships with patients and their communities.

7. **Communication**: Using clear and respectful communication.

8. **Resource Considerations**: Providing appropriate resources including funding, staffing, and infrastructure.

**Key Themes**

The findings outlined above represent three key themes that emerged across expert interviews and facilitated discussions:

1. **Respect**
   
   Respect is generated by acknowledging the value of patient involvement, taking the time to build trusting relationships through transparent engagement, committing time and resources to ensure meaningful engagement, and recognizing that all participants possess expertise.

2. **Communication**
   
   Knowledge exchange between stakeholders and researchers provides information that neither party has access to alone. Careful listening and flexibility demonstrated through adaptation to patient perspectives and needs can help build trusting relationships.

3. **Dedicated Resources**
   
   Patient involvement is resource intensive. Necessary resources include adequate time, staffing, support, and funding.

**Recommendations**

Experts widely recognized the need for published standards and tools for patient engagement. In addition, the PCORI Methodology Committee has called for the development of standards. Based on the findings outlined in this report, the following six standards are recommended:

1. **Patient Involvement Across the Spectrum of Research Activities**
   
   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 should be clearly articulated in all research projects.

2. **Dedicated Resources for Patient & Other Stakeholder Involvement**
Provide dedicated resources to support patient involvement activities, including staff, budget, patient incentives, and other support considerations.

3. **Stakeholder Identification & Selection**
   Develop systematic and formal processes to identify, recruit, and select patients and other stakeholders.

4. **Support for Patient Engagement**
   Provide institutional and organizational processes that support researchers, patients, and other stakeholders in all phases of research including orientation and training for patients and other stakeholders, and engagement training for researchers.

5. **Communication with Patients & Other Stakeholders**
   Support patient-centered communication styles and modes, including but not limited to consideration of culturally appropriate language, interpersonal communication styles, and the use of skilled facilitators.

6. **Transparent Involvement Processes**
   Provide clear and complete information on the purpose, goals, policies, timeline, and processes to engage patients and other stakeholders. Also include clear and complete information on researcher, patient, and other stakeholder roles and expectations, as well as descriptions of decision making processes and dissemination plans. Information regarding data use, management and ownership should be disclosed.
Background

Over the past two decades patient involvement in health and social science research has become an increasingly frequent and important activity. Meaningful patient involvement in research processes is a central tenet of patient-centered outcomes research (PCOR), yet, there are few models beyond community-based participatory research (CBPR) with demonstrated success for both the research enterprise and patient experience. Historically, biomedical and social science research in the United States has focused on questions and outcomes of interest to investigators and funders (Minkler, 2005). Until recently, funders rarely required stakeholder or community engagement as part of their grant-making decisions, and investigator-initiated research projects seldom engaged patients, caregivers, members of the public, patient surrogates, or other lay individuals in the design or conduct of medical outcomes research (Ahmed & Palermo, 2010). When patients and other lay stakeholders have been included in research activities, their voices have often been muted, partially the result of investigator attitudes about lay stakeholder abilities to make meaningful contributions and lay stakeholder insecurities about the same (Ahmed & Palermo, 2010).

Based on published literature, it is clear that even acknowledged experts are uncertain about which engagement methods work best for which patients, and under what circumstances. A key problem in synthesizing effective engagement methods has been inconsistent and poor quality reporting in the literature on patient involvement activities (Staniszewska, et al., 2011). Without consistent reporting standards it is difficult to know the impact of patient engagement or specific methods on research quality, relevance, or implementation. In addition, short of anecdotal evidence, little is known about the impact on patients who participate in these activities. Due to the minimal evidence-base there is currently no expert consensus on best practices for patient engagement in research processes (Clancy & Collins, 2010). Although groups such as the EQUATOR Network in the United Kingdom are attempting to develop guidance for reporting patient and public involvement, the evidence-base remains limited. Investigators, however, require guidance to effectively integrate patient voices in PCOR activities, and to facilitate successful engagement of stakeholders across research processes.

In an effort to bolster PCOR activities in the United States, Congress passed the 2010 Patient Protection and Affordable Care Act, which includes legislation establishing the Patient-Centered Outcomes Research Institute (PCORI). One of PCORI’s goals is to ensure patient voices are central in all of its funded research activities. PCORI’s authorizing legislation tasked its Methodology Committee with identifying and developing methodological standards to incorporate patient perspectives into three key areas of research: 1) development and prioritization of research questions; 2) design and study components; and 3) processes of clinical decision-making/care delivery. Because much of what is known about eliciting
patients’ perspectives in PCOR is likely not captured in the published literature, PCORI issued a request for proposals to conduct expert interviews to identify effective methods and best practices in patient engagement. The Center for Evidence-based Policy (the Center) at Oregon Health & Science University (OHSU) was contracted to perform these interviews using a multifaceted approach (see Methods section) that included:

- A representative Advisory Panel of 11 individuals to consult on all phases of the project,
- Qualitative interviews with national and international experts representing diverse stakeholder groups and fields of expertise,
- A series of patient, public and caregiver facilitated discussions conducted in six geographically diverse sites, and
- Regular guidance from PCORI’s Patient Centeredness Workgroup.
Introduction

As noted, there is currently no consensus on which engagement models should be considered evidence-based or “best practices.” This knowledge gap leads to wide variation in engagement practices and a lack of clarity about which methods should be used with which stakeholders and under what circumstances. This lack of consensus became evident through expert interviews. When asked about methods of engagement considered to be “best practice” the experts’ most common response was “it depends.” They noted that “best practices” vary based on the purpose, goals, and objectives of engagement, the type of stakeholders involved, and the scope and topic of research.

In lieu of recognized best practices, frameworks to guide involvement activities have been developed by organizations in the United Kingdom, Canada, and the United States that regularly engage patients in research activities. These frameworks demonstrate varying levels of involvement across research phases such as general outreach, consulting with patients, creating partnerships, and collaboration and shared leadership. Figures 1-3 provide context for the methods of engagement discussed by experts in this project. These frameworks demonstrate the role of patients or other members of the general public at different points of involvement, and illustrate the importance of differentiating levels of involvement as part of best practices. Regardless of their breadth or depth of involvement, these frameworks represent continuums of involvement, with the optimum including knowledge exchange and shared action. In addition, each framework highlights issues raised in expert interviews and facilitated discussions.

**Figure 1. Community Engagement Continuum.** Adapted from “Principles of Community Engagement,” by National Institutes of Health (2011).
**Figure 2. Continuum of Engagement.** Adapted from “Citizen Engagement Handbook,” by Canadian Institutes of Health Research (n.d.).

**Figure 3. Three Levels of Involvement.** Adapted from “Primer on Public Involvement,” by F.-P. Gauvin and J. Abelson (2006).

There is also wide variation in the terminology used in both the literature, and by engagement professionals and researchers interviewed as part of this project. Experts identified multiple definitions and varying levels of acceptance for terms such as *patient, stakeholder, involvement,* and *engagement.* Many experts urged PCORI to be clear and consistent in the use of terminology and to create transparent definitions. To assist with data analysis and intra-project consistency, the Center, in conjunction with guidance from the Advisory Panel, developed stakeholder definitions specific to this project (Appendix A). Appendix A also includes the distribution of experts interviewed according to these definitions.

In addition, the term *engagement* varies based on the discipline, field, or community. It is a broad term inclusive of outreach, involvement, advocacy, support, treatment, and other related actions. For the purposes of this project stakeholder engagement was defined as an iterative, bi-directional exchange between stakeholders and researchers that results in:

- Reciprocal understanding,
- Improved mutual trust,
- Inclusion of stakeholder values and preferences,
- Increased relevancy of research,
- Increased transparency and credibility of research, and
- Uptake and implementation of findings
Research Methods

The Expert Interviews Project was conducted using a multifaceted approach (Figure 4). At the outset, an Advisory Panel (AP), representing a diverse range of stakeholders, was convened to provide guidance to the project. The Center collected evidence in two overlapping phases. Research staff: 1) identified and recruited experts and conducted qualitative interview telephone interviews; and 2) organized and attended 12 facilitated group discussion sessions with patients, caregivers, and members of the general public in six national regions. Analysis of expert interviews began as soon as data collection was underway. Analysis of facilitated discussion group data began when approximately two-thirds of groups were completed. High-level data analysis was competed after both interviews and discussions were completed. PCORI and the OHSU IRB approved all protocols and study materials. In addition, the PCORI Patient Centeredness Workgroup and interested PCORI staff were provided bi-monthly updates and regular calls on project methods and progress.

Figure 4. Multifaceted Approach

Advisory Panel

As part of the project design, an Advisory Panel (AP) of diverse stakeholder representatives was convened to provide guidance and input on project processes and materials. An initial list of 15 potential members was identified by the Center with representatives for each of the key stakeholder groups identified in the Request for Proposal. The list was approved by PCORI and recruitment began in November 2011. Of the 15 individuals contacted, 13 accepted the invitation to serve and 11 completed their service; two members were unable to continue due to scheduling conflicts (Appendix B contains a list of AP members). AP members were not compensated for their time, and all members submitted PCORI-required conflict of interest forms. No AP members reported conflicts of interest.
The AP met by web-enabled conference calls five times between December 2011 and March 2012. Between meetings the Center also e-mailed materials for review and provided a monthly newsletter with status updates (Appendix C). AP members provided input and guidance on:

- Identification and prioritization of experts,
- Expert interview guide,
- Facilitated discussion guide and patient information materials,
- Stakeholder category definitions,
- Emerging themes from data,
- Draft report,
- Draft standards, and
- Prioritization of knowledge gaps.

**Expert Interviews**

**Identification**

**Professional Networks**
The Center used its existing professional contacts to create an initial list of experts for potential interviews. Selection was based on prior work in the fields of patient and stakeholder engagement and national and international expertise in diverse fields, with a variety of perspectives. The initial list included 74 individuals from the fields of health, consumer advocacy, policy, and corrections.

**Environmental Scan**
To complement the initial list of 74 potential interviewees, an environmental scan of the literature was conducted to ensure comprehensiveness and national and international representation across fields of expertise/practice as well as categories of stakeholders. The scan included targeted searches of identified sources and the MEDLINE database. Search strategies for the environmental scan processes are discussed in Appendix D.

Relevant references were compiled in an Excel spreadsheet listing first, second and last authors for each reference, full reference citation, source where the reference was identified, and applicable field of research (e.g., health, education, corrections, social services, mental health, or environment). Citations were organized by field topic (e.g., business, civic engagement, corrections, education, environment, health, mental health, and social services) and ranked based on relevance to the research questions. Citations were ranked with a 1, 2, or 3, with a “1” ranking indicating highly relevant, “2” somewhat relevant, and “3” tangentially relevant.

The environmental scan identified 198 unique citations yielding 402 unique names. Citations ranked as highly relevant were reviewed and prioritized based on the following criteria:
- Individuals whose names appeared on both the Center professional network and environmental scan lists
- Individuals from the environmental scan known to the investigators, PCORI, or the AP
- Individuals representing multi-disciplinary fields and international perspectives
- Individuals with more recent citations or citations most relevant to the research questions, when other criteria were not applicable

Additionally, individuals whose names appeared more than once were included, regardless of how the individual citations were ranked. In cases of multiple citations with the same multiple authors, the first author was selected unless specific knowledge or relationships supported the selection of the second or last author. When contact information could not be found for the selected author, citations were reviewed to identify and select an appropriate alternative key informant. A total of 43 individuals were prioritized from the environmental scan, including 11 individuals who were also identified through the Center’s professional networks.

Together, the lists of individuals identified through the environmental scan and the Center professional network resulted in a total of 133 potential experts.

**Selection**

PCORI staff and members of the Patient Centered Work Group, as well as the AP, reviewed the list of 133 individuals. PCORI suggested 21 additional individuals and organizations, and the AP suggested an additional 19 for a total of 173 potential experts to interview. Of these 173, the Center identified 96 “high priority” experts for initial recruitment. The prioritization criteria included:

- Individuals who were identified by more than one source (such as by the Center, through Advisory Panel and PCORI, or through the environmental scan)
- Individuals from the environmental scan known to the Center, PCORI, or the Advisory Panel
- Individuals representing non-health fields and international perspectives

The expert list, including “high priority” experts, was presented to PCORI and the AP for finalization. Further refinements were made to ensure geographic diversity and to include additional individuals practicing community based participatory research (CBPR).
Additional experts were identified through a snowballing technique in which interviewed experts were asked to suggest other potential informants. Snowballing, combined with experts identified through the Center’s professional network, the environmental scan, PCORI staff and workgroup members, and the AP resulted in a total of 299 potential experts.

Recruitment
Center staff contacted potential interviewees from the “high priority” expert list via phone and email with a request for an interview. Experts were first contacted by phone and then sent a follow-up email with information about the project and the purpose of the interviews. Experts were contacted up to three times by phone and email. Of the 299 identified experts, 128 were contacted for participation. Of these 128 experts, 21 did not respond to recruitment requests, 10 declined the invitation, and six accepted an interview but did not complete scheduling. When experts declined the invitation, research staff then asked them to provide referrals for alternative individuals representing similar expertise.

Conducting Expert Interviews
A total of 87 interviews were conducted between December 12, 2011 and February 15, 2012. The stakeholder categories and fields of expertise represented by interviewed experts are included in Appendix A.

A standardized interview guide for health engagement experts was developed with consultation from PCORI and the AP. Questions were then adapted for each stakeholder category to best capture their experience. Interview questions focused on experiences with patient and public engagement, best practices in engagement, practical strategies for eliciting patient perspectives, identification and recruitment of patients (including use of surrogates), and circumstances of patient engagement (including informing patients about research processes and accounting for heterogeneity). The complete interview guide is included in Appendix E.

After conducting the first few interviews, the guide was adapted to improve conversational flow and to account for expert preferences. For example, all of the experts spontaneously requested to give background information about their work and field of expertise prior to answering the first interview question. Although background information had not been included in the interview guide due to time constraints, it became clear that this was an important conversational element for the informants and therefore was incorporated into the standardized guide. In addition, experts were reluctant to answer specific questions about “best practices” or effective methods outside the context of specific projects. Open-ended questions were asked first, followed by more specific probes when necessary.

One of four Center interviewers was assigned as the lead interviewer for each expert interview. Before each interview the lead interviewer emailed the expert a summary of interview questions and a brief
description of the project. Most interviews (n=84) were conducted by telephone; three were completed in person. The first ten interviews were conducted by one lead interviewer while other team members observed and took notes. Immediately following each interview the team discussed relevant findings and areas where the interview instrument should be adjusted. Subsequent interviews were conducted with one lead interviewer and at least one note-taker. An independent interviewer was contracted to conduct interviews with experts who had close personal or professional ties to the Center. Interviews were digitally recorded with verbal consent, and recordings used to verify content as necessary. Interviews were between 30 and 60 minutes in length, depending on how much time and input experts offered. Data from expert interviews were entered into a HIPAA compliant survey tool for analysis (Zoomerang, 2012).

Facilitated Discussions
To gather additional information from patients and lay stakeholders, 12 facilitated discussions were held with patients, caregivers, and other stakeholders including members of the general public in six regions of the US. The Center contracted with the Policy Consensus Initiative (PCI) and the University Network for Collaborative Governance (UNCG) for skilled, university-based facilitators. UNCG facilitators participated in a series of web-enabled conference calls during December 2011 to discuss the project, the role of UNCG and its facilitators, the facilitation guide, recruitment, logistics, the execution of the discussion groups, data management, and data analysis.

Identification, Recruitment & Selection
Each site determined the appropriate dates, times, locations, and recruitment methods for their local context and culture. Recruitment methods used at the sites included:

- Community centers and bulletin boards,
- Community housing centers,
- Community organizations (Salvation Army, Veterans Affairs, Big Brothers Big Sisters),
- Email via listservs (professionals in health and human services, young professionals organizations),
- Grocery store bulletin boards,
- Local clinics and hospitals (both private and safety net clinics),
- Outreach to community organizations,
- Press releases to radio, newspaper, newsletters,
- Social media (Facebook, Twitter), and
- University academic departments (UNCG centers and other academic departments).

Individuals interested in participating responded by either phone or email. Potential participants were notified about the intent to audio record discussions, and screened to ensure minimum age requirements (19 years in Nebraska, 18 years in all other states) and that they met the definition of patient, caregiver, or member of the public (refer to stakeholder definitions in Appendix A).
Conducting Facilitated Discussions
Initially, two facilitated discussions each were planned in California, Oregon, Georgia, Massachusetts, Nebraska, and Arizona to ensure diverse geographic representation. The two groups in Arizona were intended to focus on tribal populations. However, the project’s limited timeframe did not allow adequate time for, appropriate relationship development, Indian Health Services and individual tribal IRB processes, or collaboration with the communities. In lieu of the Arizona groups, two auxiliary groups were organized and conducted in Texas. A total of 12 facilitated discussions were conducted between January 11 and February 9, 2012 in:

- Los Angeles, California
- Portland, Oregon
- Athens, Georgia
- Boston, Massachusetts
- Omaha, Nebraska
- Austin, Texas

A standardized interview guide was developed with consultation from PCORI and the Advisory Panel (Appendix F). Questions were written to correspond with the questions being asked of experts to the extent possible. The first two groups held in Los Angeles, California, served as pilot groups for the discussion guide and materials. As a result, changes were made in the facilitation guide to 1) limit technical language and provide more plain language and contextual examples; and 2) broaden the scope of research experience to include participation outside of biomedical and health services research. Subsequent discussions benefited from the early revisions, although it remained an iterative process with shared learning between sites, and feedback incorporated from participants.

Discussion participants were provided an optional demographic form, voluntary consent form, IRB information sheet about the research project, and information about PCORI and PCOR (Appendixes G-J), as well as a $50 Visa gift card for their time. Facilitators utilized the discussion guide and three standard posters (Appendixes K-M) featuring ground rules and discussion objectives, example research process, and example opportunities for patient involvement in research. A total of 123 individuals participated in facilitated discussions across the six sites (demographic characteristics are provided in aggregate in Appendix N). Facilitated discussions explored participants’ experiences with research involvement, opinions about appropriate engagement, and effective approaches to engagement.

All facilitated discussions were audio recorded with participant consent. Skilled facilitators led the discussion groups, and most used backup note-takers. At least one staff member from the Center attended

1 In addition, some tribes in Arizona have had negative experiences with research and this historical context required additional resources and relationship development not possible with the time and resource constraints of this project.
each group to take additional notes, answer contextual questions, and provide other assistance as required. Facilitators were responsible for collecting data and performing initial thematic analysis. Summaries of data and initial analysis were entered into a HIPAA compliant Zoomerang survey tool for further analysis and synthesis by the Center (Zoomerang, 2012).

Analysis
Thematic analysis of expert interview data began upon completion of the first four interviews. A list of preliminary codes was developed with emphasis on content of importance for the final report, as outlined in PCORI’s Request for Proposals (RFP). Four Center team members coded initial interviews as a group until agreement was reached on codes and operational definitions. Three interviews were then coded individually to assess inter-coder reliability. Results were compared and discussed until reliability reached 80%. Individuals coded remaining interviews and data from the facilitated discussions in the same manner. The coding team met weekly to discuss changes, clarifications, and other concerns with the process. Codes and code definitions were continually revised as additional interviews were conducted and coded (final coding dictionary included in Appendix O).

A thematic snowballing technique was used for key theme identification and selection. Topics identified by more than one expert were captured and subsequently amended as additional experts discussed the topic, provided practical examples, or submitted related supplemental material. Themes identified or reinforced by facilitated discussions were captured utilizing the same technique. The coding team focused on topics raised spontaneously during expert interviews and facilitated discussions, and analyzed coded data as a group over the course of five meetings with each meeting dedicated to specific coded topic areas. Analysis of the complete data set elicited additional key themes that were reviewed and confirmed by the principal investigators. Due to the time constraints of the project, only high-level themes were identified for the purposes of this report. Additional analysis may provide more detailed and nuanced findings.

Strength of Evidence
To assess the “strength” of evidence for findings of the qualitative data presented below, the research team applied the evidence scale defined in Table 1.
**Table 1. Strength of Evidence**

<table>
<thead>
<tr>
<th>Evidence Scale</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Strong</strong></td>
<td>Finding was consistently reported by experts from three or more disciplines, regions or countries, and/or participants from a majority of facilitated discussion groups. Practice or method is widely viewed as significantly contributing to successful engagement of stakeholders, and is broadly accepted as a best practice; or conversely, is widely viewed as ineffective and should not be used in engagement activities. Strong evidence may also include unique practices or methods that have deep support within two or fewer disciplines, regions or countries, and are based on extensive cumulative expert experience (e.g., engagement professionals have successfully employed the practice over several years).</td>
</tr>
<tr>
<td><strong>Moderate</strong></td>
<td>Finding was regularly reported or recommended by experts from more than one but fewer than three disciplines, regions or countries, and/or participants in several facilitated discussion groups; or conversely, is widely viewed as ineffective and should not be used in engagement activities. Moderate strength of evidence may also include deep support within one discipline or region/country.</td>
</tr>
<tr>
<td><strong>Weak</strong></td>
<td>Finding was supported by one or more experts but was not widely identified or used either within or across disciplines, regions, or countries, and participants in two or fewer facilitated discussion groups. Practices or methods with weak evidence may include new or innovative approaches to engagement where there is promise, but variation in application or experience.</td>
</tr>
<tr>
<td><strong>Insufficient</strong></td>
<td>Finding was only identified by one or a few engagement experts or facilitated discussion participants and may be new to practice.</td>
</tr>
</tbody>
</table>
Findings

This section addresses questions outlined in the original RFP, including practical methods for engaging patients in research activities, identification and selection of patients and stakeholders, eliciting patient perspectives, informing patients about research processes, and accounting for heterogeneity. In addition, this section discusses ineffective methods, systemic challenges, and other considerations identified in the expert interviews and facilitated discussions. Many experts submitted materials to substantiate the information provided during interviews. These are summarized as an annotated bibliography in Appendix P. Finally, key themes that emerged from expert interviews and facilitated discussions are also defined and discussed in this section.

A) Practical Methods for Engaging Patients in Research

The field of patient engagement in research is continuing to evolve, with limited consensus on best practices for engaging patients and other stakeholders. There are multiple paradigms developing about how patients and other stakeholders should be involved in research processes, and multiple terminologies are used to describe both patients and the processes for involving them. As noted in the Methods section, experts use disparate terminology and definitions of patient, public, advocate, consumer, engagement, involvement, and participation. There is no clear consensus on common language in the field of patient and other stakeholder engagement. Experts advised PCORI to be clear regarding definitions for different stakeholder categories, and to recognize the different roles each plays in engagement processes. For the purposes of consistency in this project, a taxonomy of stakeholder definitions was developed and used (Appendix A).

With differing paradigms of patient and community involvement in research, the use of specific methods to engage patients and other stakeholders depends on the circumstances, goals, priorities, and context of each research project. Patient engagement can be viewed along a continuum as outlined in the Introduction, where different methods are more applicable to specific points, or with specific populations and communities. Methods may also be selected based on whether there is already a formal structure for patient engagement in place, or if patient engagement is integral to the development of a new research process or structure. The methods and best practices identified by experts and facilitated discussion participants for eliciting the patient perspective fall into eight categories:

1. Planning for Patient Engagement
2. Stakeholder Identification and Selection
3. Eliciting Stakeholder Perspectives
4. Stakeholder Preparation
5. Evaluation, Feedback, and Dissemination
6.  Sustainability
7.  Communication
8.  Resource Considerations

Categories 1, 2, 3, and 7 address the questions of what practical methods are effective in engaging patients: a) identifying and prioritizing research questions; b) identifying outcomes that are meaningful to patients; c) identifying comparators/interventions that are meaningful to patients; and d) methods appropriate for underrepresented populations. Categories 4, 5, and 6 address the question of what methods are effective in ensuring that participants understand the pertinent clinical and research issues so that results can meaningfully inform decision-making.

1. Planning for Patient Engagement

*Overall strength of evidence: Strong*

Experts and facilitated discussion participants emphasized the importance of understanding patient and community needs in designing research. Experts stressed the importance of matching research priorities and goals to the needs of patients and their communities. They cited the need to develop an in-depth understanding of patient and community needs, and to develop a written plan that allows meaningful patient involvement. This document should provide an explicit framework for developing and carrying out patient engagement that will be significant for all participants. Findings from interviews and facilitated discussions coalesced around nine key elements of a patient engagement plan, including:

A) Define Project Goals

Experts expressed an explicit requirement for a plain-language, written description of project goals that can be shared with patients and communities. This was echoed in the facilitated discussions. Project goals should:

- Be “upfront” about the interests of the project, investigators, and funders
- Describe the expected outcomes and impact
- Describe the expected research products (e.g. reports, presentations, partnerships, agreements, papers)
B) Understand Patient & Community Needs

Most commonly, experts and participants in facilitated discussions described the need for researchers to learn about the culture, structure, processes, and communication styles of a community. This knowledge can be aided by an understanding of community history and structure, governance and decision-making structures, economic conditions, demographic trends, norms and values, developed social networks, along with previous experience working with outside groups. Experts working with underrepresented populations cautioned that overlooking the contextual factors associated with a community’s history and culture could be detrimental to relationship building and ultimately to the success of engagement activities. Additionally, knowledge of cultural expectations and traditions helps researchers design appropriate methods for engagement. For example, working with tribal populations may require larger meeting spaces to accommodate extended family members who are viewed as integral to the health experience. Specific methods for understanding patient and community needs include learning about the community before approaching representatives for participation, and asking for input throughout the process.

C) Determine Why to Engage

Besides points of engagement along the continuum of research, experts also suggested the types of topics or circumstances for which engagement would be most appropriate. Determining engagement methods and their timing is highly contextual, and creating an appropriate mix of engagement points and depth of engagement opportunities within each point is important. The engagement plan should be responsive to the intended purpose of engagement at each point. Determining when to engage stakeholders requires strategic planning and early identification of goals and intended purposes. Experts agreed that it is most critical to involve patients when there is no clear course of action from the existing evidence, or when there are tradeoffs in risks and value considerations. Experts also provided the caveats that when topics are “highly politicized” or where “cultural values are so embedded that no facts will change anything,” involvement is not advised. In addition, involving patients or other stakeholders should only occur when their input can have an effect on decision-making, or when outcomes or decisions will affect individuals, families or their communities.
D) Determine the Points of Engagement
An important part of planning for patient engagement is determining at which points in the research process to involve stakeholders. Experts nationally and internationally, from health and non-health disciplines, as well as discussion participants recognized the importance of involving stakeholders throughout the research process. Depending on the project’s purpose and intended outcomes, the scope of patient involvement should be determined early in the planning process. Nearly half of all experts interviewed indicated that stakeholders should be involved early and across all stages of research.

Experts working with underrepresented populations stressed the particular importance of including these groups at the beginning phases of research including the initial agenda setting, topic identification and ongoing engagement throughout and between research projects. Involving underrepresented communities in the planning and development of research helps to ensure that communities will be invested in the research process and products, as well as allows communities an opportunity to guide research to fit their unique needs. In addition, it is important to work with the community on the selection of data for dissemination, and how it should be shared, including working with community members to draft papers for publication, design posters for display at conferences, and develop presentations for community and academic audiences.

Within the facilitated discussion groups, a strong majority of participants expressed that patients should have some level of involvement throughout the entire research process. Participants saw an important role for patients in identifying and refining topics, in the design and conduct of research, translation and dissemination. Patients and other stakeholders asserted that they have valuable and unique input to guide research and that this perspective should be represented throughout the process.

E) Create Transparency
Ensuring transparency in research projects was one of the most frequently identified elements of effective engagement in both expert interviews and facilitated discussions. This finding was unanimous across all 12 facilitated discussion groups. Providing clarity about project processes was described as a particular requirement, and five areas were highlighted for explicit definitions and communication:
1. **Rationale for Engaging Patients**
Experts stressed the need to describe to patients the rationale for engaging them in the research process. Patients and other stakeholders want a clear rationale about why they are being asked to engage in the research process; this can also assist them to understand the value of their participation and input.

2. **Impact on Patients & Community**
Patients and other stakeholders, as well as experts, described the importance of informing patients about how research will affect patients and their communities. For underrepresented populations this is particularly salient. Experts working with these populations cited the need to convey the value of the research to the community (such as family, church, neighborhood) as well as the individual, and to state the expected immediate and future impacts. Understanding the expected difference the research will make in terms of quality of care or health outcomes, as well as the expected timing of these impacts, can motivate participation. Understanding the impacts can also help frame the research process and provide context for engagement activities.

3. **Engagement Design**
Experts who discussed the importance of transparency described the need to explain *how patients* would be involved in the research process including which methods will be employed. Participants in the facilitated discussions echoed the need for a clear and well-articulated patient engagement design. Experts also discussed the importance of clearly and explicitly stating roles, time commitment, risks and benefits, and skills needed for participation. Experts working with underrepresented populations asserted that, whenever possible, research protocols and engagement designs should be adapted to processes already existing within communities. Many communities have existing infrastructure and processes that have developed organically over time and are suited for the needs and culture of the community. An example of this would be using existing meeting times, places and styles. Additionally, using meeting locations that are culturally central (such as faith-based organizations) and sharing rituals (such as a meal together) may also be important.

4. **Timeline**
Patients and other stakeholders discussed the importance of a well defined timeframe for the research project and the expected commitment necessary for engagement. Experts identified this as a key element to achieve transparency. When working with some populations, particularly with tribal communities, experts cited the need for flexible timeframes. Building culturally sensitive relationships may require researchers to adapt their time frame to match that of the community and when working with communities, researchers need to understand that processes will occur at a pace set by the community. One expert described
the imposition of tight timelines as “time oppression” for communities with disparate concepts of time and schedule, and that it may be necessary to “take off your watch and bring a book” if working with groups such as tribal councils. Maintaining flexibility in timelines for underrepresented communities communicates respect and builds trust.

5. Dissemination of Results
Patients and other stakeholders across facilitated discussions were very interested in the results of research and whether or how they would receive those results. Experts who discussed transparency also stressed the importance of disseminating results. Experts and facilitated discussion participants highlighted the importance of:

- Being clear about how results will be translated into action
- Describing how findings will be discussed both within the community and external to the community
- Identifying who will “own” the data
- The types of research products to be available to patients and community members
- Timelines for dissemination
- Transparency and accountability for when results will be shared
- Using plain language without oversimplifying findings
- Communicating in modes that are important to the community (e.g. meetings with community members or key leaders to discuss results)

F) Enable Ease of Participation & Fair Compensation
Compensation for time, travel, and lodging expenses coupled with incentives for participation was one of the most frequent recommendations from all of the facilitated discussions. Three quarters of experts who discussed the need for compensation and incentives for patient participation thought it should be monetary. Patients and other stakeholders strongly supported this suggestion in the facilitated discussions and suggested that monetary incentives would be the strongest form of incentive, further citing the effectiveness of the $50 gift card for their participation in this project. Other forms of incentives could include food, childcare, door prizes, extra medical care, or attendance at an event. Many patients and caregivers in the facilitated discussions also expressed “benefiting the greater good” as an incentive.

The need to “go to the community” was discussed by experts as well as patients and other stakeholders. The location of engagement activities convenient to community participants can have a positive impact on participation. As one expert asserted, in order to build trust and transparency, it must be “easy to participate.” Examples of convenient community locations for recruitment and participation included community-based organizations, religious institutions, clubs, community meeting venues, schools, neighborhoods, churches, food co-ops, parish nurse programs, and libraries. In addition, geographic location, time of day, physical accessibility, font size and readability of
meeting materials, pace of agenda, and language were all mentioned as important logistical considerations for effective engagement.

Going to the community versus expecting the community to come to researchers was identified as particularly important when working with underrepresented populations. This is considered to be a basic demonstration of respect. Reasons offered by experts in favor of this practice ranged from basic logistics such as limited or complicated transportation options and difficulty arranging childcare to historical and current power imbalances between groups. Experts also highlighted the need to build time into agendas and to set an appropriate pace to accommodate accessibility concerns, such as extra time for interpretation, reflection, or to confirm accurate understanding of the patient perspective.

2. Patient Identification & Selection

*Overall strength of evidence: Strong*

Identification and selection of appropriate stakeholder representatives was identified by experts and facilitated discussion participants as another category of importance. In general, selection involves identifying the types of stakeholders to include, the most appropriate methods and locations for finding them, and defining a clear process for their selection. Clearly defined and transparent selection processes can help lead to productive patient engagement in research as well as build trust with the public.

Recruitment and selection processes are time consuming and resource intensive but many experts agreed that a formal application and screening process with dedicated staff is necessary. Experts observed that less rigorous methods of identification and selection can be problematic and can introduce bias. Some common identification and recruitment methods such as word of mouth or referrals from personal networks lead to the same individuals being engaged over multiple projects and topics. This continuity may be helpful for particular types of projects (such as highly technical study sections), but experts warned that it can lead to less overall involvement and may introduce problematic personal bias.

A) Identification

Patients, caregivers, and experts identified a variety of methods, locations, tools and general principles of identification of individuals to participate in research projects. Methods for finding patients were broad and diverse but most focused on outreach through community-based organizations such as faith-based organizations, community centers, and libraries. Other potential locations included barbershops, health fairs, health clubs, talks, schools, parks/picnics, conferences, meetings and medical clinics, although some facilitated discussion participants expressed mistrust and frustration with being approached in public places such as a mall or grocery store. Both experts and facilitated discussion participants suggested partnering with trusted community entities, working with respected members of the community, using medical registries, magazine subscribers, claims data, or paying
survey companies to locate people, along with developing a cadre of interested and available patients who could self-identify for participation in specific projects.

Patients and caregivers in all of the facilitated discussions emphasized the need to be approached by a trusted source, and expressed strong support for using clinics and clinic contacts as a method of identifying patients. In contrast, among experts, the use of medical clinics to identify patients for engagement was controversial, as this could result in problems such as conflicts of interest, perceived coercion of patients, or other ethical considerations.

Experts working with underrepresented populations suggested using community “gatekeepers,” or individuals who are highly respected in the community, to identify potential participants. These individuals can assist with the identification of appropriate participants as well as facilitate community trust, buy-in, and participation.

B) Recruitment
Similar to the identification of participants, experts and facilitated discussion participants provided many examples of how patients and other stakeholders could be recruited for research activities. Of the experts who mentioned stakeholder identification and selection, approximately half discussed contacting patients through existing stakeholder groups or networks such as patient groups, coalitions, advocacy groups, community groups, networks, unions, or disease societies. About two in five experts recommended snowballing techniques with stakeholder representatives to recruit additional potential participants. A small number of experts also suggested advertising patient engagement opportunities on organizational websites, and discussing ways to be engaged in research on organizational homepages.

Experts and facilitated discussion participants suggested several modes of communication to reach patients, with email and social media the most frequently mentioned, although many cautioned that these may not be applicable to all demographics, and that the trustworthiness of the source was still highly important. Other suggested modes of communication included newsletters, events, online chat rooms, text messages, press releases, mass media, newspapers, flyers, community forums, in-person, and by phone. Experts also mentioned asking patients about their preferred mode of communication and how they would like to receive information.
C) Selection
Three quarters of experts interviewed agreed that an essential element to effective patient engagement is the appropriate selection of participants. This finding was true for US and international experts. However, they observed that many researchers in the US lack resources or knowledge of how or where to locate such individuals. As a result, the most accessible candidates – trained patient advocates – are frequently chosen. This practice may actually undermine the representativeness that is sought in efforts to integrate the patient voice. Half of the experts who discussed stakeholder selection expressed the need for representativeness of the patient population or community including traditionally underrepresented and/or hard to reach populations.

You have to be humble about the fact that one or two patients are supposed to represent the universe of patients, and it is possible that most patients who could benefit from your activities might not participate because you didn’t invite them.

(Engagement Professional – Health)

Recruiting, selecting, and engaging appropriate patients and their surrogates are recognized as significant challenges by most experts interviewed regardless of the phase of research. This was true even among organizations that had well developed and long standing recruitment and selection processes such as NICE in the United Kingdom and the FDA in the United States. Many experts raised concerns about selection bias and lack of representativeness in those who are selected through convenience samples or other less rigorous methods. To assist with this, experts suggested the use of formal applications or registration processes, transparent recruitment processes, conflict of interest forms, and informed consent processes.

D) Matching Patients with Points of Engagement
Almost all experts agreed that the type of individual appropriate for involvement was context dependent and that researchers need clarity about project needs and expectations as well as participant roles. Thinking through the task at hand and who may best assist in achieving the goal is a crucial aspect of the planning phase. For example, a large, national process that entails televised public meetings of controversial or high profile topics will require a sophisticated and well-seasoned participant, whereas smaller, local projects that are less publicized or of less interest to broad audiences may be well served by minimally trained patients whose purpose is to report on their individual experiences. Experts working with underrepresented populations stressed that communities need to self-identify their own representatives. These experts further asserted the need for researchers to work harder to identify representative participants and to provide these individuals with more support, if necessary, throughout the process. Otherwise, they cautioned, participants will continue to be the “usual suspects” of higher income, well-educated middle class individuals who are well versed in research.
E) Patients vs. Advocates
A clear division emerged between some experts who stated that only research savvy or trained patients should be engaged in research processes, and those who said that patients without special training or knowledge in research are appropriate and necessary candidates for eliciting the patient voice. This division appeared to be more consistent among advocates and researchers in the US than those in Europe, Canada or the UK. Some experts suggested only trained patient advocates should be involved due to their ability to represent a broader patient experience. Others identified concerns with engagement of “professional patients” or advocates who had been participating in research activities for so long that they were more likely to represent a “junior researcher” perspective than a patient experience. These respondents suggested that patients bring an immediacy of experience from which trained advocates are more removed. Most experts agreed that in order to gain a comprehensive view of the topic, a mixture of perspectives is important and that both patients and advocates have valuable, but different, contributions to make in research activities.

3. Eliciting Stakeholder Perspectives

**Overall strength of evidence: Strong**
Experts and facilitated discussion participants identified multiple methods for eliciting patient perspectives, many of which are currently common practice. Although there was no consensus about a single “best” method, experts were clear regarding the need to “match” the method with the purpose of patient engagement, the level of involvement needed, and the type of stakeholder. The strength of evidence for a mixed methods approach (based on circumstances outlined above) is “strong.” Table 2 provides a summary of purpose and application considerations for methods discussed by experts.
<table>
<thead>
<tr>
<th>Method</th>
<th>Possible Purpose</th>
<th>Application Considerations</th>
<th>How to Enhance Participation</th>
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</thead>
</table>
| Focus Groups            | ▪ Determine research priorities  
▪ Define research questions  
▪ Discuss research direction  
▪ Discover key tension areas between stakeholders  
▪ Disseminate information  
▪ Gather information and advice  
▪ Introduce a program  
▪ Tool development          | ▪ Comfortable pace for patients to express their perspectives & values  
▪ Environment that encourages sharing  
▪ Group with shared experiences can instill confidence in participants  
▪ Not ideal for all contexts  
▪ Potential non-verbal pressure to participate or keep quiet  
▪ No designed for high conflict situations  
▪ Only provides limited amount of information                      | ▪ Patients as group facilitators  
▪ Expert facilitators  
▪ Locations that are easily accessible to participants  
▪ Fluid structure that allows for full expression of patient perspective  
▪ Designing focus group makeup around specific demographics  
▪ Prioritization exercises (e.g., writing topic on cards and having participants rank the value of each topic using dots) |
| Surveys & Questionnaires| ▪ Determine research priorities  
▪ Collect perspectives from a broad representation of stakeholders         | ▪ Difficult to capture depth of responses  
▪ Requires verbal and written skills  
▪ Relatively easy to conduct  
▪ Can reach large numbers of people  
▪ Administered by phone, mail, online, email, or in person  
▪ Responses may differ based on administration method  
▪ Tend to have a low response rate  
▪ Frustrating to participants if poorly designed                      | ▪ Use short, non-repetitious, easy to complete formats  
▪ Allow participants to complete survey on own timeframe and in own space  
▪ Use specific and open ended questions, allowing space for participants to explain their reasoning  
▪ Anonymity may increase participation                                  |
| Individual Interviews & One-on-One Conversations | ▪ Develop questions and approaches  
▪ Determine research priorities  
▪ Understand a topic context  
▪ Develop an understanding where there is a lack of evidence, experience or consensus | ▪ Can provide greater depth of information than surveys or focus groups  
▪ Option to direct patients back to topic or issue under discussion | ▪ Use specific and open ended questions, allowing time for participants to explain their reasoning  
▪ Send materials in advance  
▪ Call prior to interview to answer any questions  
▪ Be prepared to meet with individuals, families, and groups  
▪ Keep interviews brief  
▪ Avoid cold calling  
▪ Provide credentials and materials to verify legitimacy                  |
<table>
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<th>Method</th>
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</tr>
</thead>
</table>
| Groups, Committees & Boards | ▪ Participation in research process  
▪ Provide input and guidance for research process  
▪ Technical expert review  
▪ Peer review  
▪ Decision making  
▪ Topic identification  
▪ Topic development  
▪ Topic prioritization | ▪ Need diverse representation  
▪ Consider the numbers of patients and other stakeholders needed  
▪ Patients and other stakeholders can feel like outsiders if brought on to an existing group  
▪ Consider developing new working groups to involve all participants in developing partnership and working environment  
▪ Consider an independent patient and other stakeholder advisory group  
▪ May allow for broader representation of patients in the research process  
▪ Could create a forum for patients to discuss issues | ▪ Avoid patient and other stakeholder tokenism  
▪ Send out materials in advance  
▪ Call patients and other stakeholders to follow up on materials and discuss any questions  
▪ Consider electing a patient and/or member of the community as co-chair  
▪ Elect a chair to sit on main committee panel |
| Conferences, Meetings & Workshops | ▪ Determine research priorities  
▪ Discuss research opportunities  
▪ Create a forum for patients and other stakeholders to meet and discuss issues and experiences  
▪ Develop methods and objectives  
▪ Train patients and other stakeholders about research process, method and science  
▪ Develop excitement around a topic area  
▪ Introduce the beginning of a topic | ▪ Provides networking opportunities for patients, other stakeholders, and researchers  
▪ Provides opportunities to develop partnerships and relationships  
▪ Do not require written skills | ▪ Use a systematic and transparent methods of providing input  
▪ Design event with participants so that it is not viewed as “top down” |
| Websites & Online Fora | ▪ Understand perspectives, values and concerns of patients  
▪ Provide comment on research process or reports  
▪ Delphi process with | ▪ Consider using online discussion forums  
▪ Online portals for public comment  
▪ May only apply to specific demographics | ▪ Gives participants ability to participate in different environments  
▪ Allows patients and other stakeholders to participate in their own |
### 4. Patient Training & Support

**Overall strength of evidence: Moderate**

The PCORI Methodology Committee sought to identify effective approaches to patient engagement so that results are meaningful to decision makers. Patient preparation was the most commonly identified method discussed in expert interviews. Key aspects of preparation discussed by these experts included orientation, training, capacity building, mentoring, and general support. In contrast, preparation was seldom discussed among patients and caregivers in the facilitated discussions. This may be due to limited understanding or experience with the full breadth of research processes, or an historical lack of stakeholder preparation in the US research environment. Strength of evidence for individual findings in this section ranges from strong to weak, and can be summarized by six key methods.

#### A) Orientation

**Overall strength of evidence: Strong**

Experts indicated that orientation is an essential step for successful and meaningful patient engagement. Orientation should be done prior to beginning a research process, and allows researchers, staff, patients, and other stakeholders to discuss roles, expectations, accessibility needs, context, and other logistics. Orientation can help patients and other non-technical stakeholders feel more prepared and clear about why they are participating in the research process, see the value of their input, and establish project norms.

The way it gets talked about is that if you could just download the information and drop it like a mother bird into a baby bird’s beak, it would take—as if lack of information is the barrier. But we learn in the context of relationships that matter to us.

(Payer)
1. **Value in Participation**
As part of orientation, it is important to explain and emphasize the value of the patient voice and how the patient role is central to the research process. Experts suggested making participants as comfortable and involved as possible through strategies such as asking what they hope to get out of the process.

2. **Clear Roles & Expectations**
Experts who discussed stakeholder preparation indicated the need for clear and explicit roles and expectations of patients and other involved stakeholders. A clear description of the patient role including their level of involvement, required commitment, and expectations should be available and reviewed in written and verbal form. Role descriptions for all those involved should be used so all participants are clear about each other’s roles and involvement.

3. **Content**
In addition to emphasizing the value of the patient perspective and clearly articulating the roles and expectations of patients, experts suggested orienting participants to specific scientific and process content. Opinions on specific content varied among experts, and included introductions to the research process, specific regulations guiding the process, considerations of evidence, overall goals for the process, project timeline, and topic areas and issues.

4. **Logistics**
Experts offered different methods for conducting orientations such as by phone, in-person, or through web-based trainings. Experts suggested holding the orientation before the project begins, sending materials in advance, and allowing enough time for questions and discussion during orientation. Additionally, experts noted that it is helpful to provide a main point of contact for the entire process so that patients have a dedicated source to ask questions and seek support.

**B) Training**

**Overall strength of evidence: Strong**

Nearly two-thirds of experts who discussed the need for stakeholder preparation recommended that patients, researchers, and all other stakeholders be trained. Experts clearly expressed the need to “level the playing field” of knowledge between patients and researchers as a means for more successful and meaningful patient engagement, and that training is a key strategy for doing so. Some experts addressed the processes and context of when and how to train patients, others stressed the need to train researchers about how best to engage the public in research, and a small number of experts discussed training patients and researchers together.
Additionally, experts emphasized the potential positive impact of training patients as a form of capacity building.

1. Patients
Similar to findings for orientation methods, experts offered a diverse range of training structures and content. For training structures, there was no consensus on which model worked best. However, according to interviewed experts, the following models and techniques had demonstrated success: one day workshops, online courses, book clubs, using trainers with experience in adult education, experiential learning, using a combination of short presentations and exercises, and using experienced participants as teachers for new patient representatives. Regarding training content, experts expressed strong opinions that patients need tools and information about research processes and methods to participate meaningfully. Other content ideas included evaluation skills, the science of specific topics, the history of research, understanding proprietary information and conflict of interest, how to be prepared for a meeting, and general communication skills.

2. Researchers
Experts and participants in one facilitated discussion stressed the need to specifically train researchers on how to appropriately engage with members of the public. One expert suggested having informal conversations with researchers before meetings to brief them on effective engagement methods. Patients and caregivers raised the need to train researchers in empathy and in how to avoid being reactive to patients’ communication styles and perspectives.

3. All Stakeholders
Suggestions for combined training of patients and researchers were also provided by a small number of experts. Joint training was seen as a way to achieve mutual understanding of the others’ roles and to facilitate efforts to adopt use of shared language by each group. Content for this method included intercultural relationship building. One expert had successful experience building combined stakeholder training elements into research-related meetings.

C) Capacity Building

**Overall strength of evidence: Weak**
A small number of experts discussed the concept of capacity building through ongoing training and engagement experiences. Experts shared examples of patient experiences in research processes leading to better employment, further education, and general empowerment. As part of the patient engagement training process, experts suggested offering certificates of achievement that patients could add to their resumes/CVs. They also suggested that capacity building could be used to assist in motivating participants during recruitment.
D) General Support

**Overall strength of evidence: Moderate**

General support for patients during the engagement process helps mitigate the impact of information asymmetry between patients and other stakeholders. Many patients do not have access to professional networks or academic societies and resources like health libraries to gain knowledge about specific topics or research processes. Support, as discussed by experts, needs to be ongoing, accessible outside of meeting times, and able to “meet patients where they are.” Support can be in the form of an identified point person, structured methods to coordinate engagement activities, and the development of peer support groups.

E) Mentor Program

**Overall strength of evidence: Weak**

A small number of experts from different disciplines explicitly discussed developing a mentor program for new patients involved in research processes. In addition to providing general support, a mentor program allows participants opportunities to learn about each other’s experiences, discuss the process, and have their questions answered outside of involvement activities. One expert discussed mentor programs as another way to build capacity and as a possible incentive for participation.

5. Dissemination & Evaluation

**Overall strength of evidence: Strong**

The need for evaluation, dissemination, and feedback of research findings including patient engagement activities was expressed by both experts and facilitated discussion participants. At the end of the research process there is often discussion about results, how they impact further research, and how to disseminate the information to the broader research community and the public. Some research may include evaluation of the methodological processes and conduct of the project. Others research projects may use lessons learned as feedback to refine future research projects and engagement processes. It is essential for transparency and relationship building that findings be reported back to participants and that populations of interest are consulted on the use of findings and their wider dissemination.

Experts focused on the rationale, venues, and methods for disseminating information. Patients and caregivers across facilitated discussions expressed an unambiguous desire for results, information, and implications of research to be disseminated back to participants and their communities. Facilitated discussion participants stressed that dissemination helps validate their participation and affirms that their contributions were valued. Participants in one discussion group stated that not disseminating results would violate trust in the research process. Experts echoed these sentiments and suggested communities
can help craft messages that are scientifically accurate and culturally relevant, and help distribute information and results.

Experts and facilitated discussion participants had additional ideas about acceptable venues to disseminate information back to patients and community members. A small number of experts, as well as two facilitated discussion groups, suggested using community forums, such as movie theaters or conference rooms, to present findings and get feedback. Other experts suggested having a patient or community member co-author papers, publish video interviews and dialogue summaries online, and work with key patients and patient advocate groups to be community liaisons. Facilitated discussion participants suggested using the media for “hot” topics, but cautioned about the risk of “negative spin.”

Evaluation and the opportunity for feedback were mentioned in most facilitated discussions as other optimal ways for patients to be successfully engaged in research. Many experts also expressed the importance of feedback and evaluation. They suggested building in structural components, such as learning loops, to ensure that ongoing feedback was possible. Other suggestions included building evaluation into meeting agendas, and using direct feedback from the community to provide guidance on research protocols.

6. Sustainability

*Overall strength of evidence: Moderate*

Engaging patients in research is resource intensive, time consuming, and requires coordination and long term commitment to the communities involved. Experts cited the need to ensure sustainability of patient engagement and offered examples of activities such as holding monthly online journal clubs, having ongoing training engagement processes, hosting monthly webinars, conducting annual on-site workshops, using experienced patient representatives as leaders and teachers, providing regular communication, and discussing future research opportunities and upcoming projects. Experts working with underrepresented populations repeatedly noted that effective community engagement is resource intensive and requires sustainability in funding and relationships. One expert asserted that it is inappropriate to initiate a project if there are not enough resources – monetary, personnel, or other – to adequately sustain efforts. Additionally, if community input will not be incorporated or utilized in the final products, it is inappropriate to use participant time and resources – “don’t ask the question if you’re not going to use the answer” is how one expert described this concept.