7. Communication

Overall strength of evidence: Strong

Concerns about awareness and application of general communication principles were discussed by experts and in all of the facilitated discussions. Experts, patients, and other stakeholders felt strongly that clear and respectful communication was essential to successful patient engagement. Many of the methods and principles discussed below emerged as overall key themes of this project. Communication, for the purposes of this section, is divided into three types—external, interpersonal, and facilitation.

A) External

Facilitated discussion participants voiced strong concerns about the use of technical language when describing and discussing research. Experts also identified the need for language about research to be appropriate and accessible by patients and the public. The largest area of discussion was the need for simple, understandable, plain language materials and methods that employ examples and scenarios from the patient perspective. Written and verbal communication should be appropriate in terms of language and cultural referents. A small number of experts explicitly expressed the importance of not “dumbing” down information or leaving out technical aspects of research, but instead describing research in a way that was understandable. Experts, patients and caregivers also frequently mentioned the power of using personal stories, videos, quotes, anecdotes, and testimonials to effectively communicate information and demonstrate knowledge about the patient perspective.

B) Interpersonal

The importance of skillful interpersonal communication was discussed in all of the facilitated discussions and among a third of experts who mentioned communication. Experts stressed listening to and hearing patients, their needs, and perspective. Experts also suggested allowing opportunities for patients to tell their stories and for researchers to listen openly and learn from this process. From the patient and other stakeholder perspective, researchers need to be willing to listen and be engaged, come with empathy, compassion, and respect, be non-judgmental, honest and treat patients with dignity.

C) Facilitation Skills

The need for strong facilitation skills were brought up in both the discussion groups and expert interviews. Of the experts who discussed communication, a third emphasized the need for good facilitators and facilitation. Experts offered examples of skills that effective facilitators use to elicit the
patient voice in research environments. A small number of experts discussed the need to develop a level of comfort in the group and that each person should be helped to feel that their perspective and thoughts have value. Experts suggested rotating chairs or seating configurations to encourage equal voices at the table, discouraging the use of obscure language, using easel note taking so that all participants can see progress, repeating back information to confirm that the patient perspective is accurately captured, encouraging people to talk with each other about their perspectives to develop a more comprehensive understanding of the issues, and debriefing with patients after the experience to discuss what could have been improved.

Discussions of effective facilitation for successful patient engagement focused on the need for a skilled facilitator, potentially in the chair position, and to build in space and time for patients to express their perspective. Experts suggested developing a facilitation-training program for researchers, clinical committees, and guideline and committee chairs, where they could be coached about the importance of the patient role, the need for understandable language use, and creating space in a meeting where patients could express themselves. One expert recommended building into each meeting agenda, specific questions for patient representatives.

8. Resource Considerations

*Overall strength of evidence: Moderate*

Experts discussed organizational resource issues even though this was not an area of direct inquiry. Some experts discussed aspects of funding or research oversight to aid successful patient engagement while others brought up staffing considerations.

Experts discussed different aspects of funding to support successful patient engagement ranging from the perspective of the funder and what questions to include on funding applications, to the perspective of researchers applying for funding. A small number of experts commented on the need to focus a portion of funding applications on if and how patients and/or communities had been involved in the development of the proposal and were designed into the research process. Several experts also expressed concern about requiring patient engagement in the research process as it might lead, without proper guidance and oversight, to tokenism and ineffective patient engagement. Experts also discussed the need to explain why it is important to engage patients in research and to provide guidance and information on how to do this successfully. Experts suggested incorporating funding for patient honorariums, indirect costs incurred by
community partners and for dissemination of results back to the community. Participants in facilitated discussions also suggested the latter.

Some experts discussed the importance of adequate staffing for conducting successful patient engagement. These experts stressed that teams need to be diverse, skilled at cross-cultural communication, have the ability to bring organizations together, and be dedicated to meaningful patient engagement. Several experts also commented on the benefits and challenges of a “team approach,” such as the difficulty posed by large teams, the need for neutral team members, or the importance of respect within a team.

**Summary**

Experts agreed that meaningful engagement is a process that does not happen at a single point in time. They overwhelmingly agreed that there are a number of “steps” to successful patient engagement as well as overarching systemic considerations that can help aid the process. Integrating five critical steps (Planning for Patient Engagement, Patient Identification and Selection, Patient Training and Support, Conduct for Eliciting Stakeholder Perspective, and Evaluation and Dissemination) into patient engagement efforts can help ensure meaningful engagement on behalf of all stakeholders. Figure 5 has been developed to summarize the steps and specific systemic considerations emerging from these findings, as well as to present a logical sequencing of these steps.
B) Methods for Accurately Determining Patient Perspective

Use of the Surrogate Voice

Overall strength of evidence: Moderate

Expert opinion varied widely on the topic of whether or not surrogates could accurately reflect the patient perspective. Most experts noted that in almost all cases, it is possible and feasible to elicit the voice of the patient. However, experts generally acknowledged that in limited circumstances it might be necessary to speak with patient surrogates. Some circumstances when this might be necessary included when the patients are unconscious, have severe cognitive impairments or are children. Most experts noted that surrogates have interests, values and perspectives that are valid and useful in their own right but may not accurately reflect the patient voice. In addition, many of the experts who discussed special circumstances when surrogates might be considered, also cited successful engagement in similar situations, including past projects with children and
cognitively impaired adults, noting that while difficult and resource intensive to elicit, patient perspectives should be represented by patients whenever possible and that ‘surrogates’ such as caregivers, parents, family members or patient advocates should be considered adjunct perspectives rather than being substitutes for the patient voice. However, experts also observed that in some underrepresented populations, surrogates and patients are considered a “family unit” when determining treatment options, so to exclude these “surrogates” would be culturally inappropriate.

Experts also raised the issue that all stakeholder groups – patients, caregivers, family members, etc. – have unique perspectives and interests and therefore inclusive engagement is necessary to gain a comprehensive understanding of contextual factors. For example, a mental health patient and his or her family member or caregiver may not be in agreement regarding outcomes of importance for any given treatment course. Both are valid, yet the ethical treatment of patients and maintaining patient autonomy may require hearing both perspectives when determining patient-centered outcomes of importance.

Facilitated discussion participants varied widely on their opinions of whether or not they would want anyone to speak for them, as well as whether or not they would want to speak on behalf of another person. Participants were reluctant to endorse either activity for the most part, and leaned heavily toward only utilizing surrogates in cases where patients were unable to speak for themselves. Discussion participants declared their discomfort with surrogacy even though they acknowledged that they acted in this role with their own children or elderly family members.

**C) Methods for Synthesizing Findings & Accounting for Heterogeneity**

*Overall strength of evidence: Weak*

Experts and participants in facilitated discussions offered little discussion and few methods for accounting for heterogeneity when synthesizing findings. Suggested strategies included triangulation of findings by employing traditional and emerging methods, use of formative methods with diverse patients in group interview settings, and testing findings with small groups of patients using in-depth, semi-structured interviews. Several non-traditional techniques were suggested including the use of netnography (the ethnography of online internet communities), and comprehensive efforts to gain representative patient voices. This may occur through multiple methods of gathering feedback from broad cross sections of the population to collecting in-depth information from carefully selected individuals. This is the opposite of tokenistic participation that both experts and facilitated discussion participants identified as ineffective engagement.

**D) Systemic Issues**

Throughout the interviews, experts identified challenges to patient engagement rooted within the existing research enterprise. These systemic issues were cited as significant barriers to effective patient engagement
with direct impact on the relationships between researchers and patients and/or other stakeholders, and implications for the strategic design of engagement processes. Experts discussed issues within several primary categories: cultural differences between researchers and patients, asymmetry of power between researchers and patients, a lack of commitment to meaningful engagement, patient perceptions about research and researchers, and scientific methods not being designed to engage patients or incorporate their perspectives. Similar systemic issues were discussed in facilitated discussions with patients, caregivers and members of the public.

### 1. Cultural Differences

One of the primary systemic issues identified by experts is the difference between research and patient cultures. One expert asserted there are often clashes between these cultures, which may in part be due to misperceptions and difficulty communicating as a result of ‘not speaking the same language.’ Others described the gulfs between priorities and motivations of researchers and patients, the use of vernacular communication, and the use of highly specialized research language and discourse among researchers. Similarly, many of the topics addressed by health services research are inextricably fraught with emotion for patients, while the research culture often attempts to address the same topics with a rational, scientific approach, divorced from the emotional context. Differences in the methods used by both cultures are evident in struggles to effectively communicate. Although researchers and patients may speak the same language in the strict sense of the word, shared meaning may be difficult to achieve without adjustments in both directions. A high level of cultural competency is required for multiple stakeholder groups to effectively interact and engage with each other.

### 2. Asymmetry of Power

In addition to cultural differences, experts identified the inherent institutional and historical asymmetry of power between researchers and patients as a challenge to successful engagement. The imbalance in dynamics can be influenced by asymmetry of information, equal numbers of patient and researcher representatives, and perceptions of power. Patients may be intimidated by researchers due to their grasp of specialized knowledge and training. However, as one expert highlighted, solely providing patients more

*It can be overwhelming to have a culture where there is civility, and walk into a scientific conversation where there isn’t that same level of civility, and there is a robust academic conversation that can feel aggressive.*

(Government)

*You need to be concerned with power and status dynamics within the group. Just because a group is demographically representative, doesn’t mean that the low-income person who doesn’t speak English well will have the same force in a room with an MD who says “this is how we do it.”*

(Researcher – Non-Health)
information will not bolster their ability to participate as equals. The idea that “information is power” neglects the many contextual factors that can empower patients to be engaged in research processes, despite a lack of specialized scientific training. Throughout interviews, experts across disciplines stated that “we are all patients.” However, there was less recognition that “lay patients” are experts in their own disease experience, and that this experience is different than that of a “clinician patient.” Experts and patient advocates repeatedly voiced the need to empower patients to fully participate in research processes, including helping to decrease the information asymmetry through training and support. A notable exception to this finding is the perspective of community-based participatory research (CBPR) experts who expressed that the notion that patients need to be empowered comes from an assumption that they are without power. These experts articulated that patients have inherent power, but it is often not recognized by the research enterprise.

Thus, empowerment of patients requires more than a supply of information. It necessitates providing the right information at the right time, to the right people, and in the right way. One expert suggested that as a research community “we have kept our patients illiterate,” by “dumbing down” materials and concepts, further asserting that this maintains the power imbalance between researchers and patients.

In addition to the asymmetry of information and knowledge, patients and researchers may perceive an asymmetry of power through disproportionate presences in the research process. One expert noted that the research community is “small” and has not traditionally been inclusive of external stakeholders, vesting control of research agendas within a limited group of individuals. When patients are invited to participate it is usually in limited numbers and at limited points. The physical underrepresentation of patients in research processes creates an immediate power imbalance. Participants in facilitated discussions and expert often cited the need to address the “number imbalance,” and one expert suggested there should always be equal numbers of patients and researchers – if there are five researchers participating in a process, there should be five patients as well. One patient advocate noted that projects with less than equal numbers of patients cannot claim to be “patient-centered.”

3. Commitment to Engaging Patients
Many experts cited the tendency of research processes to include patients in token roles, and a lack of commitment to meaningful engagement processes. Patient engagement was described by the majority of experts as a process, not an event or series of events. Commitment to effective engagement requires strategic and thoughtful

In order for us to really do patient-centered outcomes research and engage communities it requires humility on the part of institutions. It is easy for us to have token representation, or semi-transparent processes, or somewhat consistent approaches, and think that it is enough. (Advocate)
design of appropriate processes. However, as one expert stated, “we have skipped steps by assuming we researchers know what is best for patients.” Another expert further suggested that researchers may be “afraid they won’t have the final say” if patients are engaged. To this end, when researchers do engage patients they are often treated as objects in research rather than potential end-users, stakeholders, colleagues or partners. The needs and context of the patient experience may be overlooked, or not adequately integrated into the process. All of these factors contribute to creating a perception of patient “tokenism” rather than true engagement.

As previously noted, effective engagement is resource intensive, and requires a strong commitment to process. While there is general consensus about the rationale for engaging patients, there is often tension resulting from expectations for how that process should be shaped and evolve. Some experts note that significant resistance to engage patients still exists in some parts of the research community. Experts also note that this resistance stems from the perception that patients are misinformed, uneducated, biased, or counterproductive to efficient research process.

4. Patient Perceptions
In addition to researcher perceptions of patients impacting the design of engagement processes, patient perceptions can have equally detrimental impacts on participation. Several experts cited negative perceptions of researchers and the research enterprise as barriers to effective engagement of patients. Experts cited examples when patients thought that researchers were condescending or hostile as illustrations of this. In addition, they noted that engagement processes may appear to be (or in some cases, may actually be) tokenistic or for meeting funding obligations only, and that patients are not actually welcome at the table. Participants in facilitated discussions were more apt to express concern about the motivations for conducting research, with specific concern for profit-motivated research. Additionally, experts and participants in facilitated discussions cited mistrust of research, particularly from underrepresented populations, due to historical experiences of abuse or researcher misconduct. Individuals speaking to this point often cited the Tuskegee syphilis study and more recent experiences of the Havasupai tribe in Arizona.

5. System Not Designed to Incorporate Patient Perspective
One of the greatest barriers to incorporating the patient perspective is that current research systems and methods are not designed to incorporate the patient perspective. One element of this mismatch is the reward system researchers operate within. There are few rewards or positive reinforcements for many of the essential elements identified by experts as crucial for effective engagement. Researchers are rewarded for receiving grants and publishing research results. Therefore, the system is
competitively designed to answer questions or complete projects, not produce processes or products to effectively involve patients. While researchers have become better at communicating information to patient communities, there is still little reward for providing feedback loops, which is significantly more engaging than limiting contact to communicating results at the end of a study. Further, as one expert highlighted, by the time patients are typically involved, a series of decisions have already been made for them. The interests and decisions of the research community have already shaped their involvement experience. Several experts insisted that patient interests are divergent from what is being addressed in clinical settings, or what the scientific method can attend to in most circumstances.

E) Key Themes
The findings outlined above support several key themes that emerged across expert interviews and facilitated discussions. Themes were subsumed into the three broad categories:

- Respect
- Communication
- Dedicated Resources

Eleven additional subthemes are included within these broad categories. Each theme summarized below is defined as it emerged from interview and group data, described, and accompanied by quotes to illustrate the theme. Practical examples are included when provided by experts or facilitated discussion participants. Many experts submitted materials to substantiate the information provided during interviews, and these are summarized included in an annotated bibliography (Appendix P)

1. Respect
_Treating patients as equal colleagues, respecting their views, background, and experience as valid and valuable._

Respecting patients is critical to effective engagement. Respect includes communicating the value of patient involvement, demonstrating how patient input will be used, and recognizing and understanding individual needs, perspectives, and values in relation to the conduct of research and outcomes of importance to patients. While this finding may seem self-evident to many and too obvious to state, “respect” was such an oft repeated
suggestion, along with many reported anecdotes of poor treatment of patients and other lay stakeholders at the hands of less skillful professionals, that the research team concluded it was necessary to make this basic element of interpersonal interaction explicit. Patient, caregiver, and public participants in facilitated discussions expressed strong feelings about the importance of being treated respectfully, being provided full and clear information, and being treated as “equals.” Many experts suggested using a written code of ethics that explicitly calls for respect for the patient and his/her community to ensure that all participants recognize the importance of this basic element of research.

A) Trust
The expectation that researchers are communicating in a clear and open way about their interests and intentions.

Trust was seen as closely connected to respect. Patients clearly expressed that trust (with an individual researcher, institution, or other entity) is a necessary prerequisite for engaging in research, and transparency is a core component of building trust. In contrast, experts described trust as a result of patient engagement. Patients described their lack of trust in the research enterprise stemming from experiences where they did not feel respected. They particularly labeled top-down approaches to medicine occurring within a profit driven model and limited opportunities to contribute meaningful feedback as contributing to lack of trust. Both experts and patients cited mutual trust as a source of future benefits, particularly from well established relationships. As one researcher noted, “you can’t just go out and get some.” It takes time to develop trust.

B) Commitment to Meaningful Engagement
A conscious commitment to include and support patients in decision-making processes for the value they bring, and setting appropriate conditions for presenting their views so that they can make an impact.
Meaningful engagement results from a genuine respect for patients and the perspectives they bring. A broad range of experts emphasized the need to commit to meaningful patient engagement, and to move beyond involving patients simply to fulfill funding or other requirements. Experts and patients alike provided multiple examples in which patients were involved to “check the box” and were seen as a token in the research exchange. Both called for involvement that was purposeful, significant and resulted in important inputs or outcomes. Additionally, experts and patients alike expressed that the research culture must become more accepting and supportive of patient involvement, and that meaningful involvement means engaging patients throughout the range of research activities (from identifying priorities, to funding allocation, and disseminating findings).

C) **Everyone Possesses Expertise**

*The recognition and appreciation that patients bring a level of expertise based on their lived experience of a disease or services.*

Patient perspectives are anchored in experience, and within personally built frames of reference that should not be assumed, but taken into account and given attention. One concrete expression of respect is acknowledgement that patients are experts in their own right. Experts observed that a challenge to effective collaboration with patients is making the conceptual shift from “doctor-patient” or “researcher-subject” to “expert-expert.” Effective collaboration is fostered when everyone is valued and respected for their unique contribution and expertise. The experience of living with a particular condition such as diabetes or cancer confers expertise in its own right. This may include strategies for coping with symptoms, direct experience with treatment side effects, and differing values such as placing more emphasis on quality of life issues versus longevity. Patients’ views and values are based on their own experiences, which often differ from researchers or clinicians. Successful patient engagement programs are designed to effectively incorporate all forms of expertise. This may entail obtaining a range of patient perspectives in order to assure the patient voice is represented, and incorporating qualitative approaches into traditional quantitative or evidence synthesis methods.
2. Communication

*Actively communicating with patients in a variety of modes to keep them informed about research processes, progress, and outcomes, while developing sustainable relationships.*

Patients who participated in facilitated discussions highlighted the need for clear and consistent information before, during, and after research. One weakness of research that was cited by experts and facilitated discussion participants alike was the failure to provide results and implications to patients who had participated. Communicating with patients throughout the process, from topic identification through publication and dissemination of results, was seen as critical for transparency and building trust. Experts noted that researchers tend not to communicate with patients past a certain point in the project because they are often not funded or resourced to do so.

*Facilitated Discussion Participant, Nebraska*

**I think everyone wants to feel like their input makes a difference. I think that’s a major thing for researchers. I think the researchers need to treat us like people. We want to know why you’re researching this, what you hope to gain from this, and how what I say is going to help you.**

A) Knowledge Exchange

*An iterative, two-way exchange between researchers and patients, in which each is informed and affected by the others’ perspective.*

Patients and experts clearly called for two-way communication that goes beyond mere consultation of the public. Discussion of “knowledge exchange” described a process that depicted the ideal of long-term relationships in which patients, or patient communities, were seen as co-owners of the information produced (see also Introduction section, Figures 1-3). Knowledge exchange seeks to create new knowledge that neither party had before, nor that would have been possible without the exchange. It can also help align disparate patient and researcher interests within a single topic area. Achieving knowledge exchange requires setting up conditions that allow people to interact and learn from each other. For research taking place in traditionally underrepresented communities, it implies becoming familiar with the community itself, including governance and service delivery structures, available resources and community dynamics. Both experts and facilitated discussion participants expressed that people learn in the context of relationships, and in situations designed to spark interaction.

*Researcher – Health*

**We’ve observed the influence between patients and professionals goes both ways. As a result of their deliberation patients influence health professionals and the influence goes the other way. In the end you have common priorities that are seen by the stakeholder groups as being credible, important, and feasible which has been a concern expressed in the literature.**
B) Listening to Patients: Keeping the Patient Perspective in Mind
Paying careful attention to patient descriptions of experience and allowing them time to answer questions, to speak, and utilizing techniques that acknowledge that patients may not be able to directly answer the questions researchers ask.

Listening to patients is key to good communication, and to understanding the patient experience. While this may appear self-evident, the task is complex. Listening involves not only paying attention to what is said, but also recognizing underlying agendas or influencing contextual factors, synthesizing the information, and resistance on the part of researchers from imposing their own personal perspectives on the processes. As one expert stated, listening to patients may require a change in “the way we ask questions.” Listening may also necessitate innovative and nontraditional ways of obtaining information.

C) Flexibility
Adapting decisions, decision-making, and research methods in response to patient characteristics or context.

Flexibility demonstrates the capacity to communicate effectively with patients. Most experts asserted there is no single engagement approach that will work for all patients or members of the public. What is important is being adaptive to patient perspectives and needs, and having a variety of communication tools to match them. Flexibility is particularly important when working with some populations and cultures, especially those with a “community-minded” orientation. In these cases in particular, traditional research methods need to be adapted. Flexibility may involve analyzing goals and expectations, tasks to be carried out, contributions that are best obtained from patients, and selection criteria for the types of individuals with the appropriate experience and knowledge to contribute to each task.

D) Transparency
Explicit definition and honest communication about relevant aspects of the research and research process, including what will not be addressed.
The need for explicit communication was almost universally discussed. Participants across all facilitated discussions were extremely concerned with transparency – requesting full disclosure of intent, purpose, funding sources, use of findings, and process. Negative experiences with research were cited in each facilitated discussion, including historical abuses such as the Tuskegee study. Transparency was also the theme most frequently arising from expert interviews. Experts cited historical abuses such as the Havasupai study, or other examples of researchers collecting data, and not returning to the community, misusing findings, or not acknowledging patient contributions. Experts and patient participants alike explained the importance of making research activities clear and explicit, including the purpose and reason for the study, how patient participation will be conducted and used in decision-making, expectations for involvement, the scientific methods used, limitations of the process, analysis and expected outcomes, impact and expectations about the patient and public role.

**E) Two-Way Training & Capacity Building**

*Providing guidance, training, and support to both patients and researchers in effective communication with the goal of increasing knowledge exchange.*

Patient involvement in research shares similarities to cross-cultural communication. Individuals from different backgrounds and frames of reference endeavor to communicate across their different perspectives. In order to effectively communicate and engage patients in research activities, people need to span a divide, which was conceptualized by some experts as “boundary spanning,” “two-way capacity building,” “developing interactional expertise,” and “finding a way to level the playing field.” The most cited practices for “boundary spanning” included appropriate selection of patients and researchers, training for both patients and researchers working with one another, and other activities to form joint expertise such as steering groups.

*One of the challenges is the notion of transparency. One of the best ways to provide meaningful transparency is to outline an operation process that is defined, on an annual basis (or some period of time), where people know when and how to engage, and what to expect from that engagement.*

*(Advocate)*

*In the literature about the spread of ideas they talk about “boundary spanners” – people who can work in different areas and other areas – talk about people with cross-cultural skills. It’s that sort of thing that’s absolutely vital to get user involvement off the ground.*

*(Researcher – Health)*
3. Dedicated Resources

The recognition that patient involvement requires committed resources to seek, involve, orient and support participants, and to incorporate and evaluate the impact of patient input.

Patient involvement is resource intensive. To date, in the United States, little funding or other dedicated resources have been specifically devoted to patient engagement in research. Important aspects of the resource dedication include adequate time, staffing, support, and funding. Identifying and recruiting patients for engagement is time intensive, and many research processes may initially take longer when patients are involved. Planning for the resources required in personnel, skills, time, and funding to effectively complete processes is critical. Most experts agreed that the investment of dedicated time and resources has the potential to result in a greater impact, and that research with populations having special needs may require unique resources.

A) Engagement Plan

Defined procedures and methods for engaging patients in research, including clear roles, responsibilities, and expected outcomes.

Experts and participants in facilitated discussions described the need for a transparent plan that explains the process that will be used for patient engagement and how it will be operationalized. Development and implementation of such a plan requires resources not typically dedicated to research projects. Experts noted the importance of recognizing engagement as a process, not a onetime event, requiring clearly defined and transparent purpose, methods, roles and responsibilities, appropriate conduct, and expected outcomes. Patients participating in facilitated discussions described the need for researchers to be clear and transparent about the process and outcomes of research, and make efforts to ensure that patients can comprehend the research process and outcomes. A patient involvement plan should clearly articulate goals and purpose; steps taken to understand patient needs; when, why and how patients will be involved; communication tools and techniques; and how participation will be evaluated and improved.
B) Skilled Facilitation
The use of skilled individuals who understand group processes, and are dedicated to direct engagement with patients.

Those consulted agreed on the importance of dedicating resources to providing a skilled facilitator. Skilled facilitation enhances communication, particularly in situations with diverse cultures, backgrounds, perspectives, or values. Effective facilitation can encourage patients, while cautioning professionals to use accessible language and spend adequate time presenting research in a way that patients understand. One expert specifically noted the benefits of having neutral or external facilitators to ensure attention to process, rather than content. Experts highlighted facilitation as a necessary component of patient engagement, and further described the unique skills required for effective facilitation. Effective facilitators promote meaningful communication between researchers and patients, utilize techniques that actively encourage patient contributions, validate the importance of patient perspectives, and promote patient understanding of research.

C) Funding & Financial Support
Recognition that patient involvement requires adequate funding and support to be established and sustained.

Experts noted the importance of explicit funding for patient engagement, and described three main issues related to this financial support: 1) lack of funding to include patients in proposal creation, 2) limited funding for incentives and reimbursement of patient time, 3) increased time, and lack of incentives for researchers to engage patients, and 4) limited funding or incentive for translation of research findings, or “reporting back.”

At the beginning phases of research, such as writing grant proposals, responding to RFPs, or designing projects, there is generally no funding for those outside of the research organization (such as patients) to be involved. Experts noted the challenge of including patients or other stakeholders in these early phases, and noted the particular difficulty in managing expectations around acceptance/funding and timelines.
During the conduct of research, there is also generally limited funding to support patient participation, including reimbursement for time, travel, or childcare expenses. Facilitated discussion participants echoed the importance of incentives and financial support for participation, noting that the $50 gift card for their participation was highly motivating, and for many, helped offset costs for participation, such as parking, transportation, and childcare. Of similar concern is the sustainability of the limited funding that does exist. Since many research projects are funded on project-specific, limited time bases it can be hard to devote adequate time to do the groundwork and planning necessary to establish and maintain trusting relationships. Most experts viewed long term funding and financial support as a crucial element to engaging patients and also expressed frustration that little funding is available for translating research results into accessible, user-friendly products. Publishing articles in peer-reviewed journals is a primary research goal and grant funding rarely includes translation for lay audiences, with few professional incentives for researchers to do so.
Knowledge & Evidence Gaps

Although experts were not specifically asked to identify evidence gaps as part of this process, clear gaps emerged throughout the interviews. These gaps were either explicitly identified by experts, or emerged through the process of analyzing multiple discussions or interviews. Potential knowledge gaps generated from the data were discussed with the project Advisory Panel. As a result of AP guidance and these project findings, four primary knowledge gaps have been identified:

1. The lack of evidence of effectiveness of patient engagement methods. There is wide-spread belief that engaging patients in research will improve research process and outcomes as well as patient centered outcomes. While there are anecdotal data to support this assertion, these data are difficult to categorize and publish. There is need for systematic evidence generation on the effectiveness and comparative effectiveness of specific engagement methods and their results.

2. The related lack of evidence for the impact of engaging patients in research. While the rationale for and theory of patient and stakeholder engagement in research processes is clear, there have been few studies of the impact of their engagement, and no systematic reviews. More evidence highlighting the results of patient engagement is necessary to better understand the implications for future research processes and to develop systematic methods and best practices.

3. The lack of standard language and definitions in the field of patient engagement. Experts used a range of terminology to describe engagement processes including involvement, participation, and engagement. For each expert these terms had varied meanings and uses. There is need for a standard set of definitions and consistent application guidance.

4. Beyond the need for more knowledge generation around methods and definitions, there is a need to develop understanding for how to translate and “scale” successful local engagement processes. Many experts have been successful at engaging local communities, and numerous “best practices” are the result of local engagement strategies. Some organizations have developed methods to activate national advocacy efforts. However, experts were unclear about how to translate methods that are successful in engaging local populations to a national scale.
Summary

This study provides an overview of best practices in patient involvement in research as described by 87 national and international experts in patient and stakeholder involvement and by 123 patients, caregivers and members of the public in 12 facilitated discussions across the country. Analysis of findings led to: 1) practical methods for engaging patients in research and 2) key overarching themes for engaging patients in research, involving respect, communication and dedicated resources. This study adds to a growing body of work on how best to involve patients and other stakeholders in patient centered outcomes research projects.

With feedback from the project Advisory Panel, the Center developed a diagram illustrating findings from this study. Figure 6 illustrates potential points of engagement, as well as the patient-centered rationale described by many experts and facilitated discussion participants about when and why to engage. It also demonstrates the iterative nature of the process. Research, and engaging patients in it, is an interconnected series of steps, rather than a linear or circular set of activities. While the “on the ground” process of engaging patients is complicated, and involves a frequently changing cast of players, the diagram illustrates important points and questions for involvement, as well as the iterative nature of engagement.
In addition to the concrete opportunities for patient engagement represented in the diagram, patient involvement requires respect, communication, and dedicated resources to carry out the research. Respect is demonstrated by treating patients as equal colleagues and by accepting their views, background, and experience as both valid and valuable. Key components of respect are trust, a commitment to carrying out meaningful engagement, and the recognition that patients possess expertise. Key components of effective communication for patient engagement purposes include bi-directional knowledge exchange, listening to patients, demonstrating flexibility in methods, transparency about processes, and two-way training and capacity building. Dedicated resources are also necessary to support patient involvement and should include appropriate processes, facilitation, funding and financial support.
Patient engagement is a process, not an event or series of events. Specific methods depend on the circumstances, goals, priorities, and context of each research project. Patient engagement can be viewed along a continuum, where different methods are more applicable at various points, or with specific populations and communities. Methods and best practices for eliciting the patient perspective can be summarized by a five step approach (summarized in Figure 5 above) that includes 1) planning, 2) identification and selection of participants, 3) training and support of patients and researchers, 4) the conduct of research, and 5) evaluation and dissemination. These steps should be supported by sustained investment of funding, staff, outreach and education, and effective communication.
Recommendations

Standards

A few experts discussed the need for published standards for public engagement and a general guide or toolkit for patient engagement in research. In addition, the PCORI Methodology Committee has called for the development of standards for patient engagement. Based on the findings outlined in this report, six inter-related standards have been reviewed by the AP, and are recommended for the Methodology Committee’s consideration (complete versions contained in Appendix Q):

- Patient Involvement Across the Spectrum of Research Activities
- Dedicated Resources for Patient & Other Stakeholder Involvement
- Stakeholder Identification & Selection
- Support for Patient Engagement
- Communication with Patients & Other Stakeholders
- Transparent Involvement Processes

1. Patient Involvement across the Spectrum of Research Activities

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 and include an evaluation of methods used. Research processes appropriate and feasible to include patients and other stakeholder include:

- Writing Proposals
- Priority Setting
- Topic Identification
- Topic Refinement
- Determining Research Methods
- Reviewing Research Conduct
- Interpretation of Findings
- Dissemination of Information
- Implementation
- Evaluation

2. Dedicated Resources for Patient & Other Stakeholder Involvement

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 their exclusion. Research projects should evaluate and report on the use of these resources.

3. **Stakeholder Identification & Selection**
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 should 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.

4. **Support for Patient Engagement**
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.

5. **Communication with Patients & Other Stakeholders**
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.

PCORI funded research should demonstrate patient-centered communication styles, take into account participant culture, language background and the impact of differing interpersonal communication styles, and consider the use of facilitators skilled at enabling balanced and collaborative communication.

6. **Transparent Involvement Processes**
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 for engaging 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.

Materials intended for use by patients and other stakeholders should be written in plain language and comply 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:

- **Purpose of research and project goals:** 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.

- **Policies, processes and standards for engagement:** 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.

- **Roles and expectations of participants:** Clear descriptions of the roles, expectations (including time commitment), and depth of involvement that patients and other stakeholders are expected to fill.

- **Intended use and dissemination of results:** Plans and processes for the analysis, interpretation and communication of research results.

**Other Recommendations**

In addition to the Standards above, based on the strong findings from this project and with input from the AP, the research team recommends PCORI consider the following actions:

1. Pilot projects to compare the effectiveness of face-to-face versus other strategies for engagement. Data from this effort will be important to inform the knowledge gap about how to “scale” successful and locally-based engagement strategies (which are often face-to-face) in a national effort with a large and diverse geography and limited resources.

2. Launch demonstration projects to map the themes emerging from the data in this project to the points of engagement in research, and specific methods for engaging patients. Data from this effort can help address questions such as, “Which methods are most effective for which points of involvement and under which circumstances?”

3. Generate evidence regarding the use of surrogates versus patients. Experts had divergent opinions about whether and under what circumstances surrogates (including advocates, family members, and caregivers) are suitable substitutions for the patient voice. Data is needed about the differences in voice and resulting impact on both research process and outcome so that intentional decisions can be made about when which type of voice is needed and/or the appropriateness of using ‘surrogates at all.

4. Sponsor “mini research schools” for patients and “mini engagement schools” for investigators. As demonstrated in this study, successful engagement depends on respect, communication, good facilitation and common understanding. The provision of training and support for these foundational skills, at least initially, should be integrated at a regional or national level. Data from this effort would
enable PCORI to determine which support strategies are effective and therefore, which strategies they will support or require at a local level.

5. Create a “funding demonstration project” by issuing a request for proposal for plans for patient engagement, using the standards and guidance from this report. This effort will generate pragmatic data about the state of readiness and needs of organizations to engage patients in a meaningful way.

6. Provide opportunity for the research teams and advisory panels for this project and the patient panel at Mayo to “cross peer review” their findings.

7. Sponsor “end user” testing of proposed PCORI standards (including patients, investigator, organizational decision makers, etc.). This effort will create empirical data about what it will take to operationalize the standards at investigator and institutional levels, as well as with patients directly.

8. Sponsor projects to test specific facilitation or other engagement methods emerging from this data as best practices. Facilitation methods could be tested at specific points of involvement or with specific target populations of patients or other stakeholders.

9. Funded research should not be limited to the clinical question, but also include explicit objectives about the best methods to engage patients and other stakeholders. Funded research can be leveraged to provide evidence about the methods and outcomes of engagement.
Strengths & Limitations of Report

This report is a compilation of best practices and innovative methods for patient engagement in research as shared by experts and facilitated discussion participants. The ideas and methods for meaningful engagement reflected in the report stem from experts with extensive backgrounds and experience in health, business, social work, civic engagement, criminal justice, education, and the environment. These findings are based on real world experiences of these experts and facilitated discussion participants, and are grounded in a basic level of understanding of what has worked and what has not worked for involving stakeholders in research. While there are few standalone best practices, this report shows the breadth and depth of the collective experience that can be used to further refine and develop successful methods for patient engagement in research. This report and project was further strengthened by successfully employing the role of the Advisory Panel to review and comment on project processes, definitions, and end products. Additionally, the depth of input from patients, caregivers, and the public was strengthened by the use of neutral and independent facilitators with limited backgrounds in health services research or the health care field.

While this project has produced a substantial amount of data relevant to patient engagement, this report only includes high level reporting and initial analysis of findings. The brief timeline for the project did not allow time to interview all identified experts, nor did it allow for in-depth analysis and summary of the data collected. As a result, only high-level coding of the data was possible prior to writing this report. It is likely that additional key themes and methods for successfully engaging patients in research may emerge if more in-depth coding and analysis were performed. Additionally, while initial strong findings emerged from the data, the quantification of these findings is likely very conservative and underreported. The iterative nature of snowballing used to identify key themes did not likely capture the full strength of findings as discussed by experts and facilitated discussion participants. Further analysis and detailed coding may result a greater understanding of significant elements necessary to successfully engage patients in research.

The methods of this project were designed based on the deliverables described in the PCORI RFP. All tools (e.g., the expert interview guide, the facilitated discussion guide, and the coding terms and definitions) were designed based on the required content for the final report as outlined by the PCORI RFP. Again, due to project time limitations, the project team only coded data relevant to the final report questions. This specific coding process potentially left out significant sections of data that are likely to contain additional elements relevant to meaningful patient engagement. Moreover, project methods were not designed to address subsequent deliverables, such as the development of standards. Had all project deliverables been described in the RFP, it is likely that the methods would have been more representative.
of the ultimately desired end products. Due to time constraints, this report lacks any sub-analysis for experts based on geographic location and field of expertise, and geographic differences between facilitated discussion participants.

The facilitated discussions component of this project has specific limitations. In partnership with PCI/UNCG, the recruitment materials for and facilitation of the discussion groups were conducted in English and in urban settings. The project from this data is not representative of individuals living in rural communities or who do not feel comfortable conversing in English. Facilitated discussion participants self-selected to participate and the aggregate demographics of participants is not fully representative of the geographical, ethnic, racial, or socio-economic demographics of the national population. Specifically, there was limited representation of Latino and tribal perspectives in the facilitated discussions. This is possibly due to recruitment materials only being produced in English.

Finally, there is broad diversity among experts. The strategy employed by this project to identify experts (literature scan, use of knowledge of PCORI committee members and staff, the AP and research team, and snowballing) may not have identified all possible experts or authors on patient or public engagement. In particular, there is a wide range of patients and other stakeholders within specific clinical and/or disease areas. Based on limited time and resources, the project team was only able to interview a select number of patients, clinicians and other stakeholders within specific disease categories. While in aggregate the findings in this report are representative of key themes and patient engagement methods, it is possible that the nuanced details for engaging representatives in disease category is not fully captured.
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## Appendix A: Expert Interviews Project Definitions & Expert Professional Fields

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
<th># Interviewed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>Individuals who have health care conditions and/or receive health care services, including survivors of life-threatening conditions, but who may have no specialized training or experience in health advocacy/health research</td>
<td>5</td>
</tr>
<tr>
<td>Public</td>
<td>Individuals who are part of the general population, and who are not currently patients receiving care</td>
<td>Facilitated Discussions</td>
</tr>
<tr>
<td>Engagement Professional – Health</td>
<td>Individuals who have experience conducting engagement activities in the field of health/wellness/health care</td>
<td>9</td>
</tr>
<tr>
<td>Engagement Professional – Non-Health</td>
<td>Individuals who have experience conducting engagement activities in fields other than health including, but not limited to: business, education, transportation, criminal justice, environment, and civic engagement</td>
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</tr>
<tr>
<td>Health Care Provider</td>
<td>Individuals who provide health care or related services to patients, including, but not limited to: doctors, physicians assistants, nurse practitioners, nurses, behavioral health professionals, and oral health professionals</td>
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</tr>
<tr>
<td>Industry</td>
<td>Individuals representing organizations who sponsor, develop, market, and/or represent diagnostic, preventative, remedial, or therapeutic tools, devices, pharmaceuticals, or services</td>
<td>5</td>
</tr>
<tr>
<td>Government</td>
<td>Individuals employed by federal, state, or international government agencies (e.g. NIH, CDC, VA, and FDA)</td>
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<tr>
<td>Advocate/Community Organizer/ Consumer Group</td>
<td>Individuals or organizational representatives who have training or experience in advocacy, community organizing, or promotion activities, and who may represent collective patient voice.</td>
<td>14</td>
</tr>
<tr>
<td>Payer</td>
<td>Individuals representing of organizations that purchase health care through private or government programs, including integrated health care systems</td>
<td>3</td>
</tr>
<tr>
<td>Researcher – Health</td>
<td>Individuals who have experience conducting, writing, or synthesizing research in the area of health, including mental health</td>
<td>17</td>
</tr>
<tr>
<td>Researcher – Non-Health</td>
<td>Individuals who have experience conducting, writing, or synthesizing research in areas outside of health, including, but not limited to: business, education, transportation, criminal justice, environment, and civic engagement</td>
<td>9</td>
</tr>
</tbody>
</table>
| Caregiver                        | Individuals other than health care professionals who provide care to patients outside of the formal delivery of health care services. Caregivers may be:  
  ▶ Professional (in paid service)  
  ▶ Informal (such as parents, spouses/partners, family members)                                                                 | 2             |
Expert Professional Fields

- Health: 82%
- Mental Health: 5%
- Other: 1%
- Social Service: 1%
- Communication: 2%
- Civic Engagement: 2%
- Criminal Justice: 4%
- Environment: 1%
- Business: 2%
Appendix B: Advisory Panel Members

Stephen Bailous
Senior Vice President for Treatment and Advocacy and Community Affairs
National Association of People with AIDS

Maureen Corry, MPH
Executive Director
Childbirth Connection

Rachel Currans-Henry
Deputy Director, Bureau of Benefits Management
Division of Health Care Access and Accountability
Wisconsin Department of Health Services

Gwen Darien
Executive Director
Samuel Waxman Cancer Research Foundation

Jessie Gruman, PhD
President
Center for Advancing Health

Bryna Helfer, EdD
Director of Public Engagement
Office of the Secretary
US Department of Transportation

Kevin Manley
Patient Representative

William Phillips, MD, MPH
Theodore J. Phillips Professor in Family Medicine
Clinical Professor of Health Services
Department of Family Medicine
University of Washington

Alan Rosenberg, MD
Vice President of Medical and Clinical Pharmacy Policy
WellPoint, Inc.

Victoria Thomas
Associate Director, Patient and Public Involvement Programme
National Institute for Health and Clinical Excellence

Heath Young, PhD, RN, FAAN
Associate Vice Chancellor for Nursing Dean
Betty Irene Moore School of Nursing
University of California, Davis
Key Informant Interviews

The Center continues with recruitment and scheduling key informant interviews with expert stakeholders. To date, the team has completed 26 interviews. An additional 28 interviews have been scheduled, and 9 are in the process of scheduling. Interviewees are also being asked to identify additional experts as part of the “snowball” technique outlined in the proposal. Recruitment will continue until thematic saturation has been reached.

Initial key informant interviews have been conducted by a lead interviewer with additional team members observing and taking notes. Interviews are also digitally recorded after receiving verbal consent. Immediately following each interview, the team has discussed relevant findings and areas where the interview instrument could be adjusted for better flow and efficiency.

Interviews are on track to be completed by February 2, 2012.

Facilitated Discussions

National facilitated discussions with patients have been scheduled:
- Los Angeles, California: January 11 & 12
- Portland, Oregon: January 17
- Athens, Georgia: January 17 & 18
- Boston, Massachusetts: January 23 & 24
- Omaha, Nebraska: January 23 & 24
Advisory Panel
Guiding investigators in the work of the project

The Advisory Panel (AP) is a diverse group of experts with a broad range of experiences, background, and perspectives. The AP was convened to provide guidance in:
- Identification of experts for key informant interviews
- Framing key elements and concepts related to engaging patients in PCOR activities
- The development of interview guides and focus group design
- Identification and prioritization of knowledge gaps

The first Advisory Panel call occurred December 12, 2011. AP members provided a brief overview of the project objectives and processes as well as initial project materials. AP members were invited to provide feedback and suggestions on process, materials, and to help identify experts that should be contacted for key informant interviews.

Feedback and guidance from AP members has been invaluable in shaping the project to date. Continued support and guidance is greatly appreciated and the entire Expert Interviews team would like to thank members for their time and commitment to this work!

Data Analysis & Reporting
Collecting, synthesizing, and disseminating information from interviews and facilitated discussions

Data from the key informant interviews and facilitated discussions is being collected and stored in an online survey tool. An initial list of codes and definitions was created based on content needed for the final report. Emergent themes will also be coded as they are identified and included in final analysis of the total data set.

The team coded initial interviews as a group until agreement was reached on codes and operational definitions. Interviews will be coded individually and results will be compared and discussed as a team until inter-coder reliability consistently reaches 90%.

Data are too preliminary to reach conclusions, however, initial themes include:
- Field is in its infancy & methods are still evolving

Respondents do not consider themselves “experts”
- Effective methods cited are both traditional and non-traditional
- Problematic methods include small numbers of patients invited, or “tokenism”
- Adequate preparation of both researchers and patients is necessary for successful engagement

26 completed
28 scheduled
9 accepted

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www.ohsu.edu/policycenter

REMINDER!
Advisory Panel call on January 17, 2012

Pacific: 8-10 am
Mountain: 9-11 am
Central: 10 am - 12 pm
Eastern: 11 am - 1 pm
Greenwich Mean: 4-6 pm