

THEMES/BEST PRACTICES

Best Practices Identification

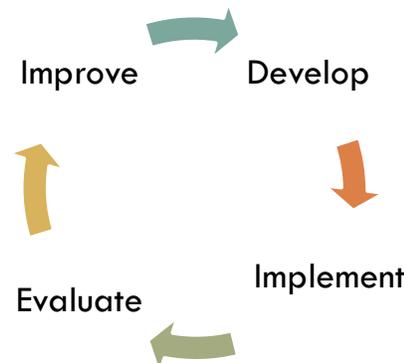
To identify promising practices and examples of strategies and tools being used to foster and promote patient engagement, the CMSS project team worked with an Engagement Advisory Committee (see Appendix 1). The team sought to identify experts who could share lessons learned and resources from patient-powered research networks (online platforms run by patients, patient partners, and other stakeholders such as patient advocacy groups), guideline and measure development, state and federal agencies, and clinical trials. Identified stakeholders were provided a discussion guide prior to a scheduled conversation, and dialogues evolved and were customized based on the key informant's subject area of expertise. Often, these conversations led to additional resources, which are captured in the Resource List section of this primer.

Key Components of Comprehensive Patient Engagement Strategy

Several important themes resonated and were prioritized, from both the patient engagement literature and discussions with experts, that cut across understanding patient engagement and how to integrate patients into a quality improvement strategy.

1. While nomenclature is important, there was no clear preference in the use of terms such as “patients,” “persons,” “advisors,” “consumers,” etc. There was consensus that when saying “patient engagement,” we are really talking about patients, families, and caregivers and those with lived experience with the area of focus—whether that be a condition, a procedure, or a service. Throughout this primer, we use the term “patient,” and that is intended to incorporate the broader perspective of families and caregivers.
2. Engaged patients prefer interactions to be bidirectional and inclusive throughout the initiative. Patients welcome the opportunity to share and contribute information and hope that their input is valued. Patients want to see the initiative through and see how their information is used. Patients are also interested in helping to convey learnings and experiences back to their respective communities.
3. Recruitment and sustainability for meaningful patient engagement are challenging, especially in diverse populations, rare diseases, and rural communities. Specific challenges for recruitment and sustainability should be identified early, and strategies should be developed to mitigate and overcome obstacles.
4. There are numerous approaches to attracting, engaging, and supporting patients, which will often need to be customized for the population. Strategies include providing training and orientation, offering stipends or honoraria, and supporting childcare and transportation to meetings. Understanding complex medical terminology and interpretation of abbreviations and acronyms were cited as common barriers to level-setting and educating patient participants.

The following sections of this primer summarize key and consistent themes discovered during the environmental scan on patient engagement approaches, input from the CMSS Engagement Advisory Committee, experiences and expertise gleaned from the key informant interviews, and resources on promoting patient engagement in health care. Improving patient engagement can be construed as a goal for a continuous quality improvement model depicted as:



When modeling a patient engagement strategy for implementation in an organization, there are a variety of best practices that are recommended by stakeholders and experts in the field. The following tables describe these best practices and key activities grouped into the steps for continuous quality improvement: 1) Develop, 2) Implement, and 3) Evaluate to lead to improvement.

| 1. Develop Plans for Engaging Early and Often |
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| <p>Incorporating patients into initial project design and development builds trust by exhibiting the inclusion of the patient perspective as important. This “Spirit of Co-Creation” should begin as early as possible in the design phase of a new research study, program, or other initiative and have a goal of aligning research questions, objectives, and outcomes with patient needs. Incorporating patient preferences, values, priorities, and concerns early in the design phase can lead to enhancement in research efficiency.</p> <p>Meaningfully engage patients as co-developers to inform:</p> <ul style="list-style-type: none"> ▶ Activity or programmatic intent. Are we addressing something patients care about? ▶ Optimizing recruitment and retention strategies ▶ Selecting the questionnaire or mode of administration of patient-reported outcome measures used |
| Opportunities for Patient Collaboration |
| <ul style="list-style-type: none"> ▶ Setting objectives: Address questions, outcomes, and areas of interest that are high priority for and relevant to patients, families, and caregivers. ▶ Define roles, responsibilities, and expectations: Be inclusive of all advisory members to create an atmosphere of sharing and respect for the patient voice. <ul style="list-style-type: none"> ○ Set participation criteria and be transparent: Typically, a key selection requirement for a patient representative is to have lived experience with a condition or treatment, whether that be as a patient, family member, or caregiver, in order to provide the patient perspective. Knowing general or representative information about conditions and patient perspective does not replace lived experience. In contrast, a patient group representative provides information about the population of patients’ experiences rather than individual experience. ○ Concept of patient partners: “Patient partners” include patients (those with lived experience), family members, caregivers, and organizations that are representative of the population of interest in a particular study. Patient partners are members of the research team and are involved in the planning, conduct, and dissemination of the research. Patient partners can help in developing and facilitating the |

Engaging Patients in Clinical Registries

recruitment and retention strategy. They are better positioned to understand potential barriers from the patient perspective and, as trusted members of their respective communities, they can ensure recruitment procedures are sensitive to the needs of the patients.

Additional Resources

- ▶ National Health Council (NHC):
 - Online Educational Series: Increasing Patient-Community Capacity to Engage on Quality of Health Care (<http://www.nationalhealthcouncil.org/nhc-educational-program-quality>)
 - NHC Patient Engagement Rubric (http://www.nationalhealthcouncil.org/sites/default/files/National_Health_Council_Patient_Engagement_Rubric.pdf)
 - Glossary of Patient Engagement Terms (<http://www.nationalhealthcouncil.org/resources/glossary-patient-engagement-terms>)
- ▶ U.S. Food and Drug Administration (FDA): Charter of the Patient Engagement Advisory Committee to the Food and Drug Administration (<https://www.fda.gov/advisory-committees/patient-engagement-advisory-committee/charter-patient-engagement-advisory-committee-food-and-drug-administration>)
- ▶ Northern Nevada Medical Center: The Patient and Family Advisory Council (PFAC) Charter (<https://www.nnmc.com/events-programs/pfac-charter>)
- ▶ patientslikeme: *Best Practices Guide for Online Researchers* (http://patientslikeme_mkting.s3.amazonaws.com/Best%20Practices%20Guide.pdf)
- ▶ Oregon Health Authority: *Community Advisory Councils, Recruiting and Engaging Oregon Health Plan Members: Best Practices Handbook* (<https://www.oregon.gov/oha/HPA/dsi-tc/Resources/CAC%20Best%20Practices%20for%20OHP%20Members%20Handbook.docx>)
- ▶ Canadian Patient Safety Institute: *Engaging Patients in Patient Safety – a Canadian Guide, Chapter 3: “Partners at organizational and system levels.”* This chapter offers guidance, tools, and practice examples that support patient and family partners to take on roles in safety and quality, helping organizations prevent, respond to, make improvements after, and learn from patient safety incidents. (<https://www.patientsafetyinstitute.ca/en/toolsResources/Patient-Engagement-in-Patient-Safety-Guide/Partners-in-Building-Safe-Care/Pages/default.aspx>)
 - Example 1 provides examples of patient engagement in primary care practices. Some of these examples are also used in other settings, as they can be adapted from one health care setting to another.^{xv}

Example 1: Potential Patient Roles and Responsibilities

| Examples of patient partner roles in primary care practices ¹³¹ | | | |
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| Strategy | Description | Advantages | Limitations |
| Complete patient surveys | One-time surveys given to patients to assess experience of care or components of care delivery | Quick, low cost | Unidirectional, may not capture the right data, limited response |
| Use the suggestion box | Comment boxes in waiting rooms or exam rooms to collect ideas for practice improvement projects | Ongoing, can help to generate new practice improvement ideas | Typically, low participation, needs upkeep to maintain and collect responses |
| Be a secret shopper | Patients gather experiential feedback from trial phone calls to clinic or gathering step-by-step feedback on each step of clinic visit | Quick, low cost, can feed into patient experience efforts | Hard to recruit patient volunteers, data may not be representative |
| Attend a town hall | Large-scale forum to gather community feedback on clinic initiative | Modest cost, if participation is high gains a large pool of feedback, patients can interact/discuss with each other at meeting | One-time feedback, may be challenging to facilitate |
| Be a partner on a quality improvement (QI) team | Patients are QI or practice improvement team members | Project driven, aligned with clinic QI efforts | Patient is minority among staff, may not feel supported in participating, not necessarily representative feedback |
| Join providers at conferences/workshops | Patients accompany staff/clinicians to academic or practice-based meetings to share experiences | Provides visibility to patient partners, patients may have unique insights to inform organizational priorities | Limited amount of patient representation, may not have clear follow-up for clinic operational improvements |
| Become a member of a patient advisory council | Representative group of seven to 15 patients who meet monthly or quarterly to discuss practice improvement | Bi-directional feedback, project driven, can recruit diverse/ representative council, can integrate with QI efforts at the clinic | Time-intensive, higher cost, require staff time, can be hard commitment for patients |
| Assist in training providers | Patients participate in onboarding and training new clinical staff, particularly in-patient communication | Demonstrates importance of patient perspective to new hires, builds awareness for patient experience of care | Patient partners need support and role clarity within training |
| Participate in a virtual advisory board/social media opportunity | Use online message boards and social media to collect patient feedback, project-oriented patient working groups that exist for shorter term | Nimble, more action-oriented, may access harder-to-reach patients, such as teens or younger working families | Less tested, some concerns about online security |

2. Implement Engagement Activities

A systematic, integrated approach helps encourage long-term, meaningful participation by patients and caregivers and mitigates the pitfall of a “check-the-box exercise” (i.e., patients invited only to validate a pre-determined concept).

- ▶ To engage patients in the team in a meaningful way, make sure that they are well prepared to fully contribute to the team’s discussions and decisions.
- ▶ Professional participants (e.g., physicians, clinical staff, other experts) must be prepared to accept and accommodate patient engagement as essential to success.
- ▶ It is important to make sure professional researchers understand how to best communicate about the research in language understood by patients and convey the essential role patients play in conducting all phases of the work.

Opportunities for Patient Collaboration

- ▶ Creating a positive user experience: Data collection efforts and platforms must be user-oriented and provide some incentive for engagement and participation over time. For longitudinal registries, it is especially imperative to build in education, support, and/or other community resources. Patients are key stakeholders in identifying the tools and resources needed to create this positive experience.
- ▶ Elevate patient voices by having patients provide opening remarks at research team meetings or on conference calls.
- ▶ Obtaining patient input requires active communication techniques and prompts; do not leave participation to chance. Provide meeting structures where there are prompts to contribute or round-robins where everyone is called on to provide input. Avoid domination of conversation by any specific participant.
- ▶ Patient roles can include preparing or reviewing patient outreach materials, identifying more effective methods to increase awareness of the study in the community of patients, and developing new methods to recruit difficult-to-reach patients.
- ▶ Areas of training and education may include enhancing understanding of the scientific method, research design, skilled communication, how to tell a story, how to use a personal story to reinforce a larger point, and unfamiliar language or abbreviations/acronyms. Other stakeholders, such as providers or regulatory bodies, must also receive training in how best to work with patient advisors.

Additional Resources

- ▶ FDA Patient-Focused Drug Development Meetings: From 2012 to 2017, under the fifth authorization of PDUFA (PDUFA V), FDA conducted 24 disease-specific patient-focused drug development (PFDD) meetings to more systematically obtain the patient perspective on specific diseases and their treatments. PFDD meetings provided key stakeholders, including FDA, patient advocates, researchers, drug developers, health care providers, and others, an opportunity to hear the patient’s voice. For more information on the program and examples of meeting agendas, discussion questions, and reports, see <https://www.fda.gov/drugs/development-approval-process-drugs/cder-patient-focused-drug-development>.
 - Example 2 provides the framework for the FDA PFDD meetings and how the organization prioritizes patient involvement. Executive Summary for the Patient Engagement Advisory Committee and Connected and Empowered Patients: e Platforms Potentially Expanding the Definition of Scientific Evidence (<https://www.fda.gov/media/122887/download>)
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Example 2: Engaging Patients in the Process and Tapping Their Experience and Expertise

Externally Led Patient-Focused Drug Development Meetings (adapted from:

<https://www.fda.gov/industry/prescription-drug-user-fee-amendments/externally-led-patient-focused-drug-development-meetings>)

Collaboration: The success of an externally led PFDD meeting requires a joint, aligned effort by multiple patient organizations associated with the disease area and other interested stakeholders. This effort helps to ensure awareness and increased participation in the meeting by the patient community, enhancing the value of the meeting as an opportunity to hear from the community. FDA encourages multiple patient groups and other stakeholders in a disease space to collaborate in planning, executing, and developing deliverables from the meeting.

Agenda and Meeting Format: FDA believes that the process, materials, and deliverables of its FDA-led PFDD meetings can serve as a model for engaging patients in a way that is useful within the drug regulatory context. Patient organizations can explore different mechanisms to organize and host these meetings (e.g., public meetings, web-only meetings, and other possible mechanisms to collect public input).

- ▶ The FDA PFDD meetings conducted to date have covered a spectrum of disease areas (e.g., fibromyalgia, lung cancer, sickle cell disease) that have tested and support the applicability of this design across a wide range of diseases and related considerations. FDA recommends reviewing the meeting materials and discussion questions for a variety of the PFDD meetings when planning the design for your meeting.

Patient Outreach: The key to an insightful, robust, and informative externally led PFDD meeting is active community outreach to ensure a representative group of patient perspectives.

Resources: It is at the patient organization's discretion to determine its capabilities and resources for planning an externally led PFDD meeting. The planning of an externally led PFDD meeting can be done without being resource intensive (e.g., FDA does not encourage enlisting event planners, consultants, scientific writers, or other external resources on your team, especially when resources may be limited). The key is to begin planning early. FDA does encourage patient organizations to consider including externally led PFDD sessions as part of annual meetings or symposiums to help maximize resources.

- ▶ A patient organization may seek financial sponsors (e.g., medical product developers, larger patient organizations) for their externally led PFDD meeting. To facilitate transparency, the patient organization should identify any financial sponsors in their Letter of Intent and any subsequent meeting materials and deliverables. The patient organization and any other meeting planning team members and collaborators are also encouraged to disclose any interactions (financial and non-financial) that could be considered relevant to the planning and conduct of the meeting. All decision-making related to the externally led PFDD meeting (e.g., development of agenda, discussion/polling questions, selection of patient panelists) should be done independent of medical product sponsor input.

3. Evaluate Efforts to Ensure Ongoing Engagement

Organizations can enlist patients to provide perspectives on what’s important to meet their needs and expectations, how investigators can best engage with them, how to best collect required data, and how a registry or other initiative can provide additional value beyond data collection. Patients have preferences for how they want to engage with the health system and other organization, as well as how they want to see data or information about themselves and others. Continuously assess how patients want to communicate and use that information to improve ongoing interactions.

- ▶ Ensure that patients have the necessary information to make informed decisions about the health care choices available to them, linked to health outcomes that are important to them. Understanding how an organization’s patient engagement strategy contributes to this objective is essential for success.
- ▶ Continuously assess barriers to engagement in your organization and identify opportunities to overcome them.

Opportunities for Patient Collaboration

- ▶ To respond to requests for more frequent contact, one organization established a newsletter for enrolled registry patients to keep them abreast of initiative activities, as well as reminders closer to an annual follow-up period to encourage continued participation. A newsletter or periodic email updates can also be used to keep patients abreast of research progress and encourage bidirectional communication.
- ▶ Patient advocacy groups can provide support and opportunities for integration and sustainability, building a sense of community around registry data collection and research studies. Methods include providing a forum for engagement about research priorities; social media interactions sharing information about the study through the enrollment, implementation, and dissemination phases; in-person and virtual social support; virtual “research club” interactions to review and discuss relevant peer-reviewed publications; authoring and distributing literature on care and management and the patient experience; and regional support groups.
- ▶ Feedback to patients during research or implementation—and, when complete, on how their contributions made an impact—enhances sustainability, especially where change was being sought.
- ▶ Patient partners can assist in interpreting study findings, describing results in a way that is meaningful to patients, suggesting additional analytic questions, and communicating results in patient-friendly language.

Additional Resources

- ▶ Planetree International is an organization focused on promoting and implementing patient-centered care. The organization offers a variety of tools and resources, speakers, conferences, and consulting services to organizations, providers, patients and families, and health care staff.
 - Example 3 is an example of a resource developed and offered by Planetree to help organizations identify patient engagement barriers and strategies to overcome them: Planetree: Barriers to Engagement in Research & Ways to Overcome Them (<https://resources.planetree.org/barriers-to-engagement-in-research-ways-to-overcome-them/>)

Example 3: Barriers to Patient Engagement and Strategies to Overcome Them



Barriers to Engagement in Research & Ways to Overcome Them

What We Learned From PFACs About Barriers to Engagement in Research:

In 2015, [Planetree International](#) received a Eugene Washington PCORI Engagement Award from the Patient-Centered Outcomes Research Institute (PCORI; www.pcori.org) to support our understanding of how Patient-Family Advisory Councils (PFACs) engage in research; (read more here: <http://bit.ly/2tQLUaT>). Between January 2016 and July 2016, we conducted focus groups, also known as group interviews, with 21 PFACs around the country in a variety of settings, such as hospitals, rehabilitation centers, out-patient surgery centers, and behavioral health communities. Below is a summary of PFAC responses to questions about barriers to engaging in research with suggestions for ways to overcome them. THANK YOU to all participating PFACs for your time & ideas!

We Asked: What challenges or barriers might limit you or your PFAC’s ability to engage in research?

| Challenges & Barriers: | Ways to Overcome Them: |
|---|---|
| <i>We have limited access to published research. Journal subscriptions are limited to professionals, organizations, and institutions. When we can access research articles, there is a purchasing or rental cost to read the full text that is difficult for consumers to pay.</i> | <i>Our hospital gives PFAC members institutional email addresses so that we can access library resources, such as journal subscriptions.</i> |
| <i>Research is hard for the average person to read. It is full of jargon and complex statistics.</i> | Some funders, like PCORI , require consumer-friendly summaries from researchers. Also, some journals, like the Journal of American College of Radiology (JACR) translate important research information into consumer-friendly explanations through their Twitter account (@JACR). |
| <i>As a PFAC member, I don’t have additional time to participate in the council <u>and</u> research. We are un-paid volunteers.</i> | Our research department includes compensation in their research project budget for PFAC members who participate in research. |

Improve Through Sharing and Dissemination

Dissemination of results and sharing of feedback and information about the initiative throughout the process and when complete were raised repeatedly as key components of sustaining patient involvement. This final table discusses key aspects of sharing and disseminating information with patient stakeholder groups. Recognize that patients, caregivers, clinicians, and other stakeholders may have diverse priorities for how their data are used, preferences about type and number of points of contact they receive to participate in meetings or information sharing (survey completing, etc.), and preferences about when and with whom their data is shared.

- ▶ A patient-centered approach can improve dissemination of research findings. Dissemination of research findings to health care providers and patients should be timely and transparent, and findings should be communicated in a manner that is clear and understandable to patients.

Opportunities for Patient Collaboration

- ▶ Ensure patients have an understanding of benefits of participation and how providing input and personal information may impact outcomes. Benefits are bidirectional. For clinicians, patient collaboration can promote efficacy in understanding patient goals and experience and reduce information imbalances by improving the flow of knowledge. Patients can better understand advances in treatment, participate in shared decision-making, and ensure their perspectives, needs, and values are incorporated into care planning.
- ▶ There are varying practices on compensation strategies for patients and families. The trending view is that patients should be offered compensation for time and expertise.
- ▶ Some organizations promote consistent or standardized levels of compensation across participants, where patients are paid the same as clinicians and other professional researchers. This may be dependent on the funding source for the project. Some organizations have clear policies on how external advisors are paid.
- ▶ Provide patients more direct control of where they fit in. Patients care about being part of the process, having an opportunity to tell their story, and being part of clinical input. This is an opportunity to integrate quality of life, shared decision-making, and other patient-reported outcomes of importance to patients.
- ▶ Patients want to receive longitudinal information on their own disease/treatment activity compared with other patients in the aggregate cohort.
- ▶ Once research is complete, it is important to compose a research summary document that is easily accessible and understandable to the general public. The summary document may include an overview of key findings and a fact sheet in non-scientific terms. This summary document can be sent to all research participants along with a letter thanking them for their participation. Once finalized, findings can be further disseminated through at least two broad channels:
 - Patient organizations provide many opportunities for dissemination of results to patient communities. Dissemination activities may include presenting study results to patients at face-to-face and online patient education events and webinars; through organization newsletter articles, blogs, press releases, and social media posts; and/or through conversations on Facebook, Instagram, Snapchat, Periscope, Twitter, and YouTube. These traditional and social media streams permit results to be disseminated repeatedly in a way that can enhance penetration into the patient community. Findings can also be shared via legislative advocacy and patient/provider mobilization activities.
 - In addition, scientific meetings and conferences provide opportunities to present results via project-related issue briefs, slide presentation sets, and printed materials. Data holders should prioritize dissemination in their data use agreements.

Additional Resources

- ▶ As noted above, Planetree International develops and makes available an array of tools and resources to promote patient and family engagement and patient-centered care.

- Example 4 is an additional resource from Planetree that describes how patient and family advocates (PFAs) can be involved in research throughout a project's continuum: Review, Design and Conduct of Research: How PFAs are Engaged (<https://resources.planetree.org/wp-content/uploads/2017/08/Lessons-from-the-Field-Promising-Practices-for-Meaningful-Consumer-Engagement.pdf> (see below))
- ▶ Cincinnati Children's James M. Anderson Center for Health Systems Excellence offers learning network programs to help to build and support sustainable collaborative networks that measurably improve health outcomes. The Learning Network Program offers expert training, tools, and services to help others start networks and to accelerate the pace of improvement in existing networks (<https://www.cincinnatichildrens.org/service/i/anderson-center/learning-networks>). An important feature of Learning Networks is engaging patients and families in the design, implementation, and sharing of the knowledge generated through the network.
 - Example 5 is an example from an active Learning Network: ImproveCareNow which focuses on inflammatory bowel disease and promoting opportunities for patients and families to share knowledge, challenges, and successes with others managing the condition.