Council of Medical Specialty Societies

ENGAGING PATIENTS IN CLINICAL REGISTRIES

November 2019

CMSS Primer for Specialty Societies and Organizations Developing and Advancing Clinical Data Registries

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INTRODUCTION

In 2018, the Council of Medical Specialty Societies (CMSS) was awarded a Patient-Centered Outcomes Research Institute (PCORI) Engagement Award focused on Engaging Patients in Clinical Registries. As an organization that represents 46 of the nation's specialty societies, representing more than 800,000 U.S. physician members, CMSS is positioned to identify innovative approaches to capturing the patient voice and develop best practices for organizations to effectively incorporate the patient voice into clinical data registries. The majority of our members support clinical registries as engines for research, evidence generation, discovery, and improvement. This project was designed to provide actionable opportunities for greater engagement with patients on clinical outcomes and research. This 2019 primer, *Engaging Patients in Clinical Registries*, is intended to share promising practices and pathways to further capture the patient voice in the selection of patient outcomes to be measured, particularly patient-reported outcome (PRO) selection, and to identify research questions of interest to patients that could be incorporated into registries. This primer identifies and presents effective approaches and tools for patient engagement in specialty society registries. This current specialty society edition will be followed by a companion primer with materials to share with patients, and an education and training series to continue building tools and resources for your use.

As we embarked on this project, we did so with the knowledge that CMSS members have begun to incorporate PROs into registries. With value-based payment models on the horizon, specialty society registries will increasingly shift toward more outcomes and PROs in their registries. CMSS members have expressed interest in learning how to effectively engage patients in quality initiatives and in the development of tools and resources to facilitate and motivate patient and family engagement as these capabilities emerge.

We hope this primer will advance knowledge of why patient engagement is critical to continue advancement of patient-centered care in any quality initiative, including clinical registries. In addition, we provide examples of tools and resources to support your efforts to incorporate best practices into evolving and future initiatives.

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OVERVIEW AND PURPOSE

Patient and family engagement is increasingly acknowledged as a key component of a comprehensive strategy to achieve a high-quality, affordable health system. Health care providers are collecting massive amounts of data in electronic health records, patient registries, and other data sources for multiple purposes, including quality reporting, value-based purchasing, outcomes-based contracting, accreditation, and patient safety. While these real-world data can help us learn what works best, for which people, and under which circumstances, what is often missing from these data is the patient voice, which is needed to inform shared decision-making by patients and clinicians to ensure that care is aligned with patients' goals, values, and preferences.

A top priority for CMSS is to drive quality through value and quality assessment, including clinical registries, innovative care delivery models, and achieving equity in health care. In 2016, the organization released the *CMSS Primer for the Development and Maturation of Specialty Society Clinical Data Registries*.[i] The registry primer was developed to serve as background and as a resource guide for those who are new to the area and for organizations interested in remaining current on new and emerging issues. Since 2016, the U.S. health care system has been continuously evolving, with advances in medicine and treatment, movement toward value-based payment, and a much stronger emphasis on patient-centered care.

In 2017, the Centers for Medicare & Medicaid Services (CMS) launched the Meaningful Measures initiative, which identifies the highest priorities for quality measurement and improvement. At the core of Meaningful Measures is the intent to focus health care quality efforts on what is really important to patients, families, and caregivers, including making informed decisions about their care, aligning care with the patient's goals and preferences, and improving quality of life and patient outcomes.[ii] CMS' focus on meaningful measures and empowering patients and providers requires input and the ongoing involvement of health care stakeholders. Perhaps the most important stakeholders are patients, families, and caregivers. To ensure and promote patient-centricity, stimulating, motivating, and catalyzing patient engagement in the process of care is essential in our evolving health system.

This *Engaging Patients in Clinical Registries* primer is intended to provide background on key principles of effective patient engagement, identify opportunities for increased patient engagement in specialty society quality initiatives, and provide tools and resources for specialty societies and other organizations interested in advancing patient-centric approaches to improving quality.

BACKGROUND ON CLINICAL REGISTRIES AND PATIENT ENGAGEMENT

The Importance of Registries for Medical Specialty Societies

Specialty society clinical data registries (CDRs) have been gathering and analyzing clinical data in a variety of specialty areas for more than 40 years. Initially, registry data population started with manual chart abstraction, and while this method is still used, our health information technology data infrastructure has evolved, allowing interoperability and automatic abstraction from electronic health records (EHRs), patient data portals, payment systems, and public health systems. CDRs continue to play an important role in the health care system by monitoring and informing the quality of medical care and generating new clinical knowledge that can lead to improved patient care and outcomes.

Clinical registries have been a major investment for specialty societies in evidence generation, discovery and quality improvement:

- Aggregate investment of approximately $500 million over five years;
- Hundreds of peer-reviewed scientific papers have been developed using the registry data;
- Registries contributed to informing clinical and health policy;
- Registries generated new knowledge and best practices; and
- Registries served as a major component of society value propositions for members.

Societies continue to use registries for a variety of quality initiatives, including benchmarking, drill-down reports, quality improvement training, collaborative quality projects, and quality improvement toolkits. From annual CMSS registry surveys, we can track the degree of engagement with patients and use of PROs. While there are significant opportunities for improvement, many registries have begun to incorporate the patient voice and PROs into their registries:

- 36% of the registries reported having engaged patients or patient groups.
- 24% of the registries reported having incorporated patient-reported outcomes into registry data.

Understanding the incorporation of the patient voice in registry design, development, and use is of growing importance in an era in which the health care system is striving for patient-centeredness and increasing value through initiatives such as CMS' Meaningful Measures.

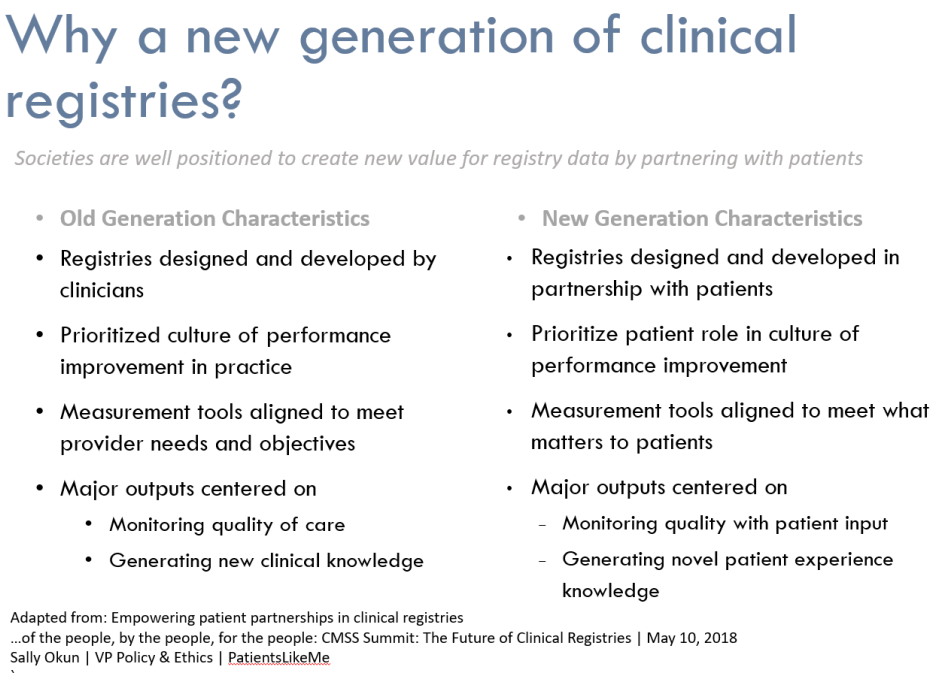
What is a Clinical Registry?
A clinical data registry records information about the health status of patients and the health care they receive over varying periods of time. Clinical data registries typically focus on patients who share a common reason for needing health care. They allow health care professionals and others to see what treatments are available, and how patients with different characteristics respond to various treatments. This information can be used to inform patients and their health care professionals as they decide the best course of treatment and to improve care for patients in the future. Information from registries may also be used to compare the performance of healthcare providers with regard to their outcomes and resource use.[iii]

Specialty society registries present evolving value propositions for physicians, societies, the profession, and populations through the following:

- Improving quality of care
- Quality reporting under MACRA (MIPS)
- Generating new science/evidence
- Informing health policy decisions
- Enhancing society value to members
- Interfacing analytics from EHRs and other data sources:
    - Imaging systems
    - Patient-reported outcome tools
    - Genetics data sets
    - Claims management

In addition, 45% of the specialty society registries indicated conducting research or analytics with registry data to assess quality of care and provider performance, which drives momentum for understanding the patient perspective.

As the use of registries expands and the health care system's focus on meaningful measures and patient-centric care evolves, the impetus for broad stakeholder input, including that from patients and families, is also growing. Patients, families, and caregivers are now playing an essential role in helping to identify and prioritize aspects of care that are important to them.



With the health system's growing emphasis on patient-centric care and the acknowledgment that the patient voice (and that of the family and caregiver) is essential to achieving better outcomes, patient engagement in specialty society quality activities, particularly registries, is essential.

The Importance of Patient Engagement

Before providing a summary of best practices, tools, and resources that can support registry initiatives to integrate the patient voice into activities, it's imperative to understand concepts in patient-centeredness and patient engagement.

> **Patients are living longer with chronic conditions due to [advances in medicine], and their role in health care is shifting from that of a passive recipient of medical care to an active participant in clinical decision-making.**
>
> **—*21st Century Patient Registries* (Agency for Healthcare Research and Quality)[iv]**

Active, meaningful patient engagement provides a connection between the health care provider and the patient, which is needed to identify what is most important to patients in both the process and outcomes of care. This connection can align care goals and promote mutual understanding. While patient input into the clinical process is essential to drive improvements in quality and to ensure alignment of goals, there is also a need for information to come back to the patient in a feedback loop. Patients want to know how their input into the system ultimately impacts them. They want to know how their experience and care trajectory is similar to or different from that of others.

A comprehensive patient engagement strategy requires an atmosphere of active, sustainable, and bidirectional collaboration that encompasses providers, patients, families, and caregivers to understand and meet the diverse health needs of the population of interest. There is a spectrum of opportunities to engage patients in the medical process, from gathering input through surveys and focus groups to patient advisory meetings, inclusion on governing committees and boards, or giving patients leadership roles to ensure capture of the patient's voice.

How Are Specialty Societies Currently Engaging Patients and Families?

Nearly half of the specialty societies that responded to the 2019 CMSS Registry Survey reported the engagement of patients in their registry initiatives. A variety of mechanisms are employed by specialty societies to garner input from patients, family, and caregivers, including:

- Focus groups
- Seats on advisory committees
- Guideline and measure development panel membership
- Meetings with patient groups
- Registry public advisory boards

While these are examples of active patient engagement by societies, they are not specific to registry development and use. However, societies have indicated interest in understanding how to both start engaging patients (for those that haven't yet) and strengthen and broaden areas of opportunity to include the patient voice, including in registry initiatives. Following are examples of how specialty societies and clinically focused registries are starting to include the patient voice in registry and research initiatives:

American Urological Association

At the 2019 CMSS Registry Summit held in Chicago in May 2019, the American Urological Association (AUA) described the development and implementation of the AQUA Quality Registry and indicated that

the overarching goal for adding patient-reported outcomes to the registry is to: "Gather information, from the patient's perspective, on the impact of a medical condition/treatment on functional status, symptom management, and quality of life." The AUA indicated that the uses of data are intended to include:

- Patient and provider monitoring of health care outcomes over time
- Determining comparative effectiveness of treatments
- Informing shared decision-making discussions
- Benchmarking the performance of health care providers

American Academy of Orthopaedic Surgeons

The American Academy of Orthopaedic Surgeons Registry Program's mission is to improve orthopaedic care through the collection, analysis, and reporting of actionable data. By collecting and reporting data, the American Joint Replacement Registry (AJRR) provides actionable information to guide physician and patient decision-making to improve care.[v] Recognizing the importance of public participation in the AJRR, the governing board recommended convening a formal Public Advisory Board for the registry. The mission of the Public Advisory Board is to enhance the value of the AJRR by ensuring a public voice in the registry's data collection, reporting, and utilization activities. The Public Advisory Board consists of 12 members who are representatives of patient/consumer groups, people with joint replacements, or other important public stakeholders. The board is an important component of engaging relevant stakeholders, including patients and families, in contributing to the efforts of the registry.

The AJRR Public Advisory Board objectives include:

- Bring the voice of people with joint replacements, their caregivers, and key stakeholders to the oversight of the AJRR and ensure that the AJRR addresses concerns of individuals with or considering joint replacements and the general public
- Provide guidance to the AJRR Board of Directors and staff on issues such as:
    - Adequacy, quality, and accessibility of data
    - Information security
    - Research activities using data from the AJRR
    - Policy issues
    - Communication to the public and interested stakeholder groups including:
        - Information about AJRR and joint replacements for consumers
        - Public reports from AJRR

Many specialty societies with registries are on the path toward incorporating the voice of the patient by integrating patients in a continuous learning cycle, which will be of interest to others in the registry space. A growing body of evidence demonstrates that patients who are more actively involved in their health care experience better health outcomes and incur lower costs.[vi] As a result, many public and private health care organizations are employing strategies to better engage patients, such as educating patients about their conditions and involving them more fully in making decisions about their care.

KEY CONCEPTS IN PATIENT-CENTEREDNESS, PATIENT ENGAGEMENT, AND PATIENT-REPORTED OUTCOMES

In June 2019, the National Health Council (NHC) released *The National Health Council Rubric to Capture the Patient Voice: A Guide to Incorporating the Patient Voice into the Health Ecosystem.*[vii] The rubric may be useful to registry staff as it includes useful definitions and sections on Meaningful Patient Engagement Processes and General Patient-Centeredness Considerations. The NHC defines "patient-centered" as "any process, program, or decision focused on patients in which patients play an active role as meaningfully engaged participants, and the central focus is on optimizing use of patient-provided information."[viii]

There are varying definitions of patient engagement, as well as varying levels of patient engagement in our health care system. Some levels of patient engagement are more clinically focused and could be considered a partnership between the patient and the clinical team. At another level, patients could be engaged in the broader health care process. The following definition is intended to focus on patient engagement more holistically, at the patient to clinical team level:

- **Patient Engagement:** Partnering with clinicians and the broader care team in exploring, decision-making, and planning health care. Patients can also be engaged in the clinical system through research, registries, quality improvement, etc., which could be separate activities from health care decisions.

Additional concepts in patient engagement and patient-centeredness include:

- **Patient Activation:** refers to a patient's knowledge, skills, ability, and willingness to manage his or her own health and care.[ix]
- **People First:** People-first language is used to speak appropriately and respectfully about an individual with a disability or condition. People-first language emphasizes the person first, not the disability. For example, when referring to a person with a disability, refer to the person first by using phrases such as "a person who …," "a person with …," or "a person who has … ."[x]
- **Shared Decision-Making (SDM):** A process of communication in which clinicians and patients work together to make optimal health care decisions that align with what matters most to patients. SDM requires three components:
    - Clear, accurate, and unbiased medical evidence about reasonable alternatives—including no intervention—and the risks and benefits of each;
    - Clinician expertise in communicating and tailoring that evidence for individual patients; and
    - Patient values, goals, informed preferences, and concerns, which may include treatment burdens.[xi]

The NHC rubric is paired with a glossary intended to help patients, patient advocates, and other health care stakeholders understand what common terms mean and ensure that everyone collaborating to make health care more patient-centric is speaking the same language. Following are excerpts from the glossary that are important for distinguishing terms and meanings in patient-centeredness and patient engagement.

Key Concept Definitions (Adapted from: https://www.nationalhealthcouncil.org/resources/glossary-patient-engagement-terms)

Meaningful Engagement: direct relationships and partnerships that are bidirectional, reciprocal, and continuous. Communications are open, honest, and clear. Engagement goals, participants, methods, desired impacts, and actual impacts are clearly outlined and transparent.

Patient: someone having or at risk of having a medical condition(s), whether or not they currently receive medicines or vaccines to prevent or treat a disease. They are dependent on the health care system after the diagnosis of a medical condition or disability. A patient relies on the health care system to feel better and to have a longer, healthier, and more robust life. An individual patient's views on health issues, such as the benefit and risk of new treatments, will vary depending on the severity of his or her condition and personal circumstances.

Patient-Centered Health Care: care that is respectful of and responsive to individual patient preferences, needs, and values in context of their own social worlds. Patient-centeredness is created by engaging, informing, and actively listening to people with chronic conditions at every point of contact—from the research bench to the bedside and everywhere in between.

Patient Community: broadly encompasses individual patients, family caregivers, and the organizations that represent them. The patient community is heterogeneous and brings to the value discussion different perspectives that have been informed by their experiences, trajectory or stage of disease, level of expertise, and many other factors.

Patient Engagement in Research: refers to "the active, meaningful, authentic, and collaborative interaction between patients and researchers across all stages of the research process, where research decision-making is guided by patients' contributions as partners, recognizing their unique experiences, values, and expertise."* While this definition refers specifically to research, it is also applicable across stakeholders and engagement activities (e.g., participation in an interview, focus group).

Patient-Generated Health Data: health-related data created, recorded, or gathered by or from patients (or family members or other caregivers) to help address a health concern.

Patient-Reported Outcome (PRO): a subset of Patient Provided Information (PPIn); an outcome measure based on a report that comes directly from the patient (e.g., study subject) about the status of the patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else. A PRO can be measured by self-report or by interview, provided that the interviewer records only the patient's responses.

Patient Information: broadly means all information regarding a patient from any source, such as patient-provided information as well as other medical information about a patient, including but not limited to: test results (e.g., genetic, pathology, imaging), identifying information, family history, provider opinion, and any other information in a patient's medical records.

* ISPOR Patient-Centered SIG. Defining Patient Centeredness and Engagement in HEOR: Proposed Definition and Stakeholder Response. Published May 21, 2018. Accessed April 15, 2019. https://www.ispor.org/docs/default-source/presentations/1388.pdf?sfvrsn=ccb5658d_1.

Integration of Patient-Reported Outcomes

Collecting patient-reported outcomes (PROs) and other patient-provided information (PPIn) is often a goal or objective of patient engagement activities. The National Health Council definitions, provided above, offer important differentiations for registries to consider in the development and integration of PROs. It is essential to engage patients, families, and caregivers in projects and activities for identifying outcomes of importance, interest, and meaningfulness to patient stakeholders. However, merely including a PRO questionnaire that fits the needs of an organization and including it in registry data collection does not equal patient-centeredness or ensure that patients are engaged in the registry. According to an article in *Value in Health* titled "Assuring the patient-centeredness of patient-reported outcomes: content validity in medical product development and comparative effectiveness research," not all patient-reported outcomes are patient-centered and not all patient-centered outcomes are patient-reported. The authors state:

> *The essential characteristic of a patient-centered approach to outcome measurement is that it assesses concepts (i.e., health-related phenomena) that are considered most important by members of a given target population, based on direct input from representatives of that population. Concepts for measurement should not be selected based solely on convenience or interest to investigators.*
>
> *Key items for investigators who are developing a new PRO measure, or selecting an existing measure for use in a new study, are to 1) describe all of the concepts reported as important by patients in the target population or in a closely related population, and 2) provide a rationale for which concepts were included or excluded. … It is critical to remember that research to inform care of patients – and to be understood and interpreted by patients – is one of the targets of Comparative Effectiveness Research; hence patient-centered PRO measures need to be consistently understandable and meaningful to patients themselves, and this generally requires patient input up front.*[xii]

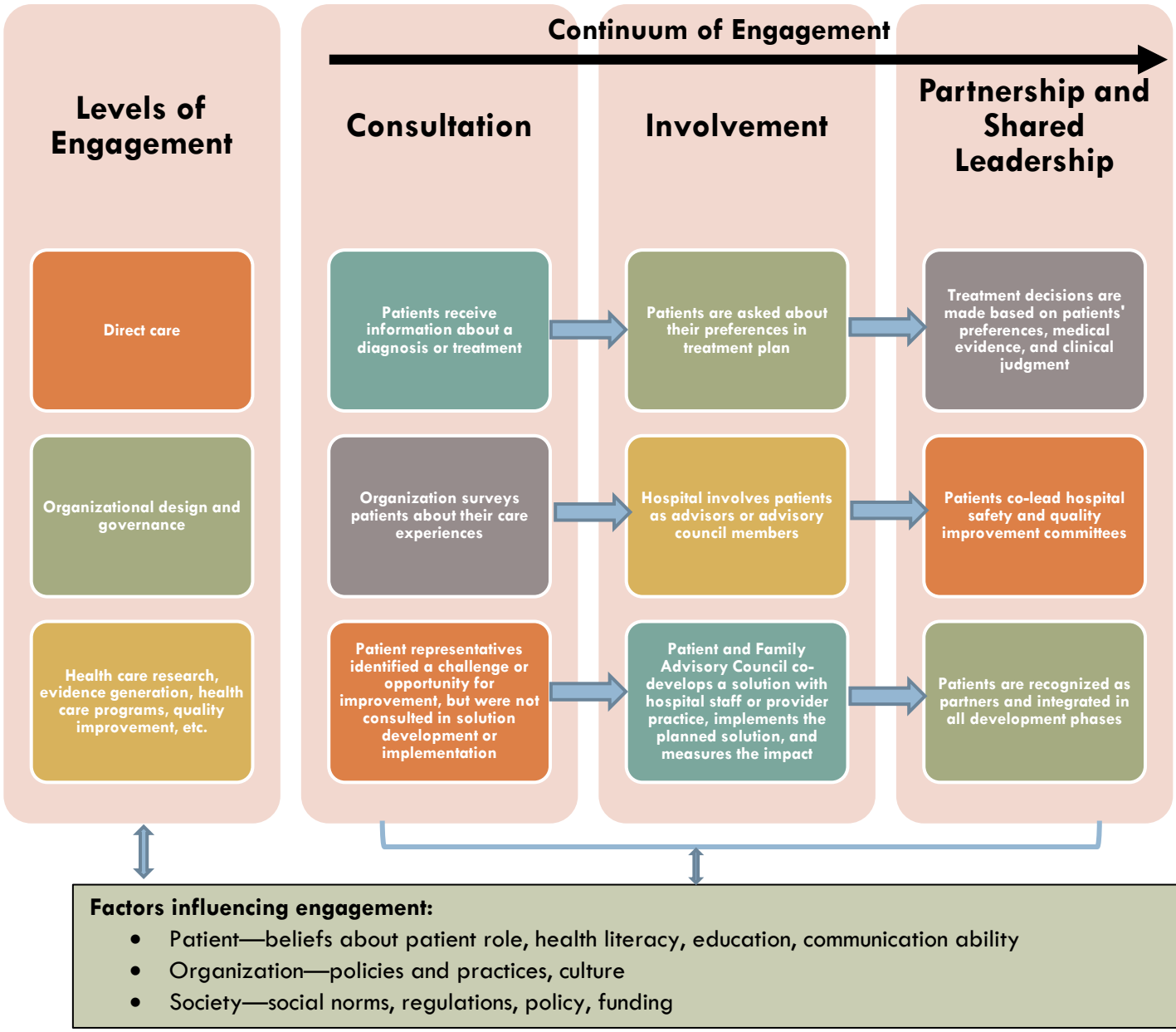
This guidance aligns with the qualitative information from key stakeholders gathered during this project; the best practices suggested include:

1. Prior to PRO implementation, involve patients in PRO selection and implementation decisions
2. Assess how the process of including patients and capturing data is working periodically, not just when issues arise
3. Use various patient-generated data collection methods (e.g., tablet input in office, online survey or questionnaire)
4. Identify how data will be shared with patients and providers, with patient input on how they want to receive information

Patient Engagement Framework

There are many aspects to meaningful patient engagement that are useful to consider when designing approaches to patient inclusion, as well as understanding opportunities for involvement. Figure 1 suggests a framework for patient engagement in their own health and health care in the broader sense.

Figure 1: Framework for Patient Engagement in Health and Health Care[xiii,xiv]



THEMES/BEST PRACTICES

Best Practices Identification

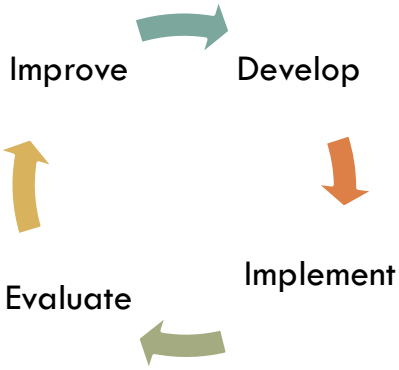
To identify promising practices and examples of strategies and tools being used to foster and promote patient engagement, the CMSS project team worked with an Engagement Advisory Committee (see Appendix 1). The team sought to identify experts who could share lessons learned and resources from patient-powered 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
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. Meaningfully engage patients as co-developers to inform: ▸ 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
▸ 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. ○ 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

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]			
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)
  -

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

PLANETREE

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:**
*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.*	*Our hospital **gives PFAC members institutional email addresses** so that we can access library resources, such as journal subscriptions.*
*Research is hard for the average person to read. It is full of **jargon and complex statistics.***	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).
*As a PFAC member, I don't have additional **time** to participate in the council and research. We are un-paid volunteers.*	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/j/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.

Example 4: Engaging Patients Throughout Research

PLANETREE

II. Review, Design and Conduct of Research: How PFAs are Engaged

Meaningful engagement means that PFA involvement is ongoing, and not isolated to one activity or event on the study. Here are some examples of engagement in review, design and conduct of research:

1. Influencing Study Design and Data Collection

It is important that PFAs be engaged as early as possible in the research process—preferably before a proposal is submitted-- so that they can steer agendas and outcomes and provide a values context, which will improve study design and applicability, ensure a relevant perspective and prevent them from being relegated only to review of established protocols.[viii]

Even if research aims are established before PFAs are engaged in research, it is critical that they remain broad at the outset so advisor input can revise specific aims to include aims that are meaningful in patient lives. For example, in one study at a Massachusetts hospital[ix], additional aims were added to a study to measure the ability of the patient to return to work and decreasing the extent to which patients reported feeling like a burden to family and other caregivers. Researchers and PFAs also refined the study intervention, methods and measures to allow for optimal interactions with patients. For example, they

- gave input on specific components of the intervention, such as 'Who would you want to be told to call with questions/concerns after discharge and what is the best way to present this information in the discharge summary?'
- provided feedback on clarity and presentation of patient-facing documents
- refined tools created for clinicians involved in the intervention
- refined proposed survey content
- added new focus area for evaluation: PFAs felt that it was important to assess which piece of the intervention patients liked most, rather than solely assessing the most effective component, as proposed by researchers. This new perspective led the team to add a focus group to assess which intervention component patients liked most.

2. Influencing Study Implementation

At one Massachusetts hospital[x], PFAs met with a Research Assistant who enrolled patients in a study who performed a mock intake interview; the PFAs then discussed and provided feedback to the Research Assistant on patient-friendly language and behaviors. Throughout the study, PFAs also reviewed enrollment progress, troubleshooting intervention challenges and monitoring input from patient participants.

3. Influencing Study Dissemination

At one Massachusetts hospital[xi], PFAs practiced reading preliminary results and discussing their interpretations in preparation for the final stages of the study.

Example 5: Learning Network

IMPROVECARENOW™

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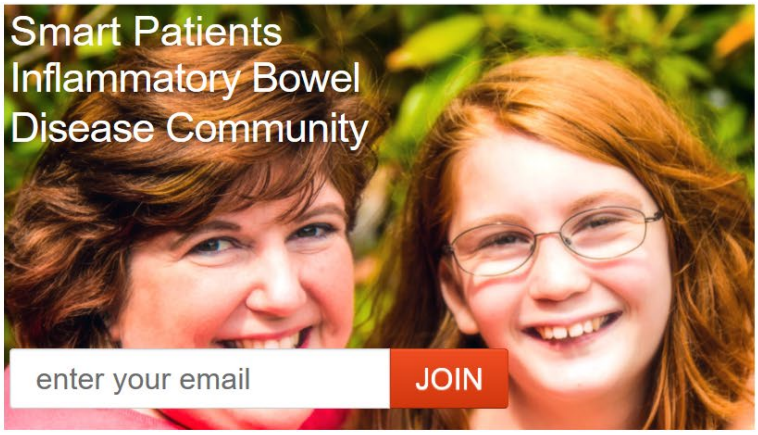
Smart Patients

Parents and caregivers, as well as patients 18 years and older, are invited to join the Smart Patients IBD Community!

There are many social networks and online communities for Crohn's disease and ulcerative colitis (Inflammatory Bowel Disease or IBD). The Smart Patients team has built custom, disease-specific forums, which offer a truly safe, warm and engaging online community experience.

Smart Patients introduces features like conversation tagging and a clinical trials search into a culture and a space for generous, information-rich sharing. Smart Patients gives people living with chronic illnesses like IBD a safe place to learn and share, and to help each other.



SHARE THIS: EMAIL | FACEBOOK | TWITTER

Sign up. Speak out.
Join our CIRCLE community.

Email

We're social!
Follow us to get the latest.

TOOLS FOR LIVING WITH IBD

GET INVOLVED

Stay in the LOOP
Updates from the ICN Blog

Our involvement with ICN has been a family affair
POSTED NOVEMBER 05

Opportunities for Improvement

The preceding section highlights successes and recommendations from initiatives that have prioritized the patient role in research, registries, or other quality programs. Here we will describe engagement process failures that provide helpful lessons learned:

1. Tokenism: Initial forays into patient inclusion on committees and panels were often a "token" act: When only one or two patients were appointed, participation was dominated by clinicians. While there may not be a "magic number," including more than two or three patients invites more of a community culture, facilitates new ideas on what can be changed and improved, and seems to accelerate participation and engagement. The National Health Council promotes a policy that is truly patient-centric: At least half of panel or committee members should be patients (including family, patient groups, etc.).
2. Rubber Stamp: Inviting patients late into initiatives that have already been formulated compromises trust and creativity. Allow the patient group to define what it is that they want to see changed and can be changed, and give them the ability to see the initiative through to the end. Patient panels need some structure, but they also need some autonomy.
3. Bottom-up versus top-down approach: A culture that values patient engagement is essential to success. It takes culture change to transform the role of a health system into that of a facilitator that aims to prevent harm, yet instills confidence in patients to do the right thing. This strategy allows patients opportunities to do what matters to them and helps with sustainability and recruitment.

Areas for Further Exploration

The field of patient engagement is evolving, including ongoing development of best strategies and approaches to be successful. The primary goal of this primer is to provide tools, resources, and best practices to integrate patient engagement activities into specialty society registries. Many topics in patient engagement that arose during our research require further exploration and understanding. We will touch on some of these areas in the upcoming patient-focused companion primer:

- Harnessing social media (see FDA resources below)
- Information technology issues and emerging initiatives: MyChart messaging, natural language processing, apps, etc.
- Challenges associated with representativeness and recruitment of diverse populations
- Identifying and using truly patient-centered, patient-reported outcomes (PROs), patient-reported outcome measures (PROMs), and patient-reported outcome performance measures (PRO-PMs).

RESOURCE LIST

Agency for Healthcare Research and Quality (AHRQ): Research White Paper: Patient- or Participant-Generated Registries: Addendum to Registries for Evaluating Patient Outcomes: A User's Guide, Third Edition

https://effectivehealthcare.ahrq.gov/products/registries-guide-4th-edition/white-paper-2016

Resource Overview	This white paper from AHRQ describes how patient registries can contribute to real-world evidence and be used by patients, consumers, and providers, as well as regulatory agencies and payers. The document provides foundational definitions, discussion on challenges and limitations to patient- or participant-generated registries, and planning and design considerations that may be useful in the design and development stages of registries or research projects where patients will be a key data source.
Citation	Terry S, Runkle D, Wicks P. *Patient- or Participant-Generated Registries*. Addendum to *Registries for Evaluating Patient Outcomes: A User's Guide, Third Edition*. AHRQ Publication No. 17(18)-EHC017-EF (Rockville, MD: Agency for Healthcare Research and Quality; February 2018). https://effectivehealthcare.ahrq.gov/products/registries-guide-4th-edition/white-paper-2016.

AHRQ: 21st Century Patient Registries

https://effectivehealthcare.ahrq.gov/sites/default/files/registries-guide-3rd-ed-addendum-research-2018.pdf

Resource Overview	An online resource that recognizes the critical role of the patient perspective and patient-reported outcomes is the *21st Century Patient Registries* report. This report is an e-book addendum to AHRQ's *Registries for Evaluating Patient Outcomes: A User's Guide*. Its chapters focus on engaging with patients throughout the design and conduct of registries; methodological considerations for using digital health technologies in registries; designing direct-to-patient and other patient-centric studies; and building registry networks that allow greater use and sharing of information.
Citation	Gliklich RE, Dreyer NA, Leavy MB, Christian JB (eds). *21st Century Patient Registries*. E-book addendum to *Registries for Evaluating Patient Outcomes: A User's Guide, 3rd Edition*. AHRQ Publication No. 17(18)-EHC013-EF (Rockville, MD: Agency for Healthcare Research and Quality; February 2018). https://effectivehealthcare.ahrq.gov/sites/default/files/registries-guide-3rd-ed-addendum-research-2018.pdf.

American College of Physicians: Position Paper: Principles for Patient and Family Partnership in Care
https://annals.org/aim/fullarticle/2716698/principles-patient-family-partnership-care-american-college-physicians-position-paper

Resource Overview	This is an American College of Physicians (ACP) position paper that explores patient and family partnerships in care and reviews outcomes associated with patient engagement in the care process. Also included are a discussion on challenges associated with implementing patient- and family-centered models of care and a set of principles that form the foundation for authentic patient and family partnership in care.
Citation	Nickel WK, Weinberger SE, Guze PA, for the Patient Partnership in Healthcare Committee of the American College of Physicians. Principles for patient and family partnership in care: an American College of Physicians position paper. *Ann Intern Med*. 2018;169(11):796–799. https://annals.org/aim/fullarticle/2716698/principles-patient-family-partnership-care-american-college-physicians-position-paper.

American Institutes for Research: Principles for Making Health Care Measurement Patient-Centered
https://aircpce.org/sites/default/files/PCM%20Principles_April182017_FINAL.pdf

Resource Overview	American Institutes for Research published a set of principles providing a vision of patient-centered measurement that may assist the industry in transforming measurement to reflect meaningful and important perspectives from patients.
Citation	American Institutes for Research (AIR). *Principles for Making Health Care Measurement Patient-Centered* (Washington, DC: AIR; April 2017). https://aircpce.org/sites/default/files/PCM%20Principles_April182017_FINAL.pdf. Funded in part by the Robert Wood Johnson Foundation, the Gordon and Betty Moore Foundation, and the California HealthCare Foundation. The project team for this effort was led by the American Institutes for Research, with contributions from the Integrated Healthcare Association and Patients' View Institute. 2017.

American Medical Association: AMA STEPS Forward: Forming a Patient and Family Advisory Council
https://edhub.ama-assn.org/steps-forward/module/2702594

Resource Overview	The AMA STEPS Forward program is a series of modules developed as practice improvement strategies. This specific module focuses on how to form a Patient and Family Advisory Council and includes the following resources: • Six STEPS to form a Patient and Family Advisory Council (PFAC) • Answers to frequently asked questions about PFACs • Tools and resources to help you and your team advance patient and family engagement strategies
Citation	Forming a Patient and Family Advisory Council (PFAC). American Medical Association AMA STEPS Forward: https://edhub.ama-assn.org/steps-forward/module/2702594.

Recommendations for Patient Engagement in Guideline Development Panels: A Qualitative Focus Group Study of Guideline-Naïve Patients

https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0174329

Resource Overview	This is a peer-reviewed article that explores patient perspectives related to participation in guideline development panels. The paper provides analysis and summaries for how patients recommend organizations pursue engagement strategies and considerations for implementation and maximizing patient inclusion.
Citation	Armstrong MJ, Mullins CD, Gronseth GS, Gagliardi AR. Recommendations for patient engagement in guideline development panels: A qualitative focus group study of guideline-naïve patients. *PloS One*. 2017 March 20;12(3):e0174329. https://doi.org/10.1371/journal.pone.0174329.

British Columbia Patient Safety and Quality Council (BCPSQC): Engaging People in Quality (EPIQ)

https://bcpsqc.ca/resources/engaging-people-in-quality-epiq/

Resource Overview	This resource was designed to increase understanding of quality improvement and engagement in health care. The module provides tools and resources on quality improvement principles and methods. There are four modules within the EPIQ teaching toolkit, each with a different focus for learning. Each module contains foundational information for learning about quality improvement, as well as a variety of activities, discussion topics, and additional resources to support its content.
Citation	Engaging People in Quality (EPIQ). BC Patient Safety & Quality Council. https://bcpsqc.ca/resources/engaging-people-in-quality-epiq/.

BSPSQC: The Patient Voice on What Matters

https://bcpsqc.ca/resource/the-patient-voice-on-what-matters/

Resource Overview	This links to an hour-long webinar featuring three different presentations on the importance of patient participation in quality improvement: • Patient Partner Compensation in Research And Quality Improvement: Tips From The Patient Perspective • Patient Journey Mapping: A Valuable Tool for Quality Improvement Projects • Why Aren't We Listening? Prenatal Ultrasounds: How Every Voice Matters
Citation	The Patient Voice on What Matters [video]. BC Patient Safety & Quality Council. March 5, 2019. https://bcpsqc.ca/resource/the-patient-voice-on-what-matters/.

BSPSQC: Patient Engagement Learning Series

https://patientvoicesbc.ca/resources/patient-engagement-learning-series/

Resource Overview	This webinar series provides education and training to develop skills for authentic patient engagement; the series is designed to strengthen the partnerships between patients and health care providers. • Primary Care Networks: What are they and how do they work? • Building Authentic Patient Engagement: Why and how you should work together • Communication 101: Tips for effective communication for great partnerships
Citation	Patient Engagement Learning Series. Patient Voices Network. https://patientvoicesbc.ca/resources/patient-engagement-learning-series/.

BSPSQC: The Patient Voices Network (PVN)

https://bcpsqc.ca/advance-the-patient-voice/patient-voices-network/

Resource Overview	The PVN is a community of patients, families, and caregivers working together with health care partners to improve BC's health care system. This resource is the PVN webpage, including the PVN Strategic Plan, which may be useful for organizations

	embarking on a patient engagement initiative and in the goal-setting process. The Strategic Plan may be found at https://patientvoicesbc.ca/about-us/pvn-strategic-plan-2017-2020/.
Citation	Patient Voices Network. BC Patient Safety & Quality Council. https://bcpsqc.ca/advance-the-patient-voice/patient-voices-network/.

CMSS Primer for the Development and Maturation of Specialty Society Clinical Data Registries: For Specialty Societies and Organizations Developing and Advancing Clinical Data Registries
https://cmss.org/wp-content/uploads/2016/02/CMSS_Registry_Primer_1.2.pdf

Resource Overview	This Registry Primer was developed to educate practicing physicians, leaders and staff of specialty societies, national medical boards, registry organizations, and other organizations with current information on: • Special issues for specialty societies about CDRs; • Business case for CDRs; • Brief descriptions of the key players in CDRs; • Overview of data standards for CDRs; and • Overview of quality measures and quality improvement in registries. The Registry Primer is intended to serve as background and a resource guide on clinical registry development and implementation for those that are new to this area and those organizations that are interested in remaining current on new and emerging issues.
Citation	Council of Medical Specialty Societies. *Primer for the Development and Maturation of Specialty Society Clinical Data Registries: For Specialty Societies and Organizations Developing and Advancing Clinical Data Registries*. 1st ed. (Chicago, IL; CMSS: January 2016). https://cmss.org/wp-content/uploads/2016/02/CMSS_Registry_Primer_1.2.pdf.

European Patients' Academy: Webinars
https://www.eupati.eu/category/webinar/

Resource Overview	This link provides access to a series of webinars with topics including: • The Impact of GDPR (General Data Protection Regulation) on Clinical Trials • Community Advisory Boards • Registries • Experience with Patient Involvement in Health Technology Assessment (HTA) Processes
Citation	Articles Listed Under: Webinar. European Patients' Academy. https://www.eupati.eu/category/webinar/.

FasterCures: Patient-Perspective Value Framework (PPVF) Version 1.0
https://www.fastercures.org/assets/Uploads/PPVF-Version-1.0-Methodology-Report-Final.pdf

Resource Overview	The Avalere-FasterCures Patient Perspective Value Framework is a resource describing a model and methodology designed to assess the patient perspective on value and change the value conversation in health care to being more patient-centric.
Citation	Avalere Health and FasterCures. *Patient-Perspective Value Framework (PPVF) Version 1.0* (Washington, DC; Avalere Health and FasterCures: May 2017). https://www.fastercures.org/assets/Uploads/PPVF-Version-1.0-Methodology-Report-Final.pdf.

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

Resource Overview	This charter establishes authority and key parameters of the FDA Patient Engagement Advisory Committee and could be used by organizations as a template when organizing and establishing roles and responsibilities of patient and family advisors.
Citation	Charter of the Patient Engagement Advisory Committee to the Food and Drug Administration. Food and Drug Administration. Updated October 7, 2019. https://www.fda.gov/advisory-committees/patient-engagement-advisory-committee/charter-patient-engagement-advisory-committee-food-and-drug-administration.

FDA: The Voice of the Patient: A Series of Reports from FDA's Patient-Focused Drug Development Initiative

https://www.fda.gov/industry/prescription-drug-user-fee-amendments/voice-patient-series-reports-fdas-patient-focused-drug-development-initiative

Resource Overview	FDA has conducted 24 disease-specific patient-focused drug development (PFDD) meetings to more systematically gather patients' perspectives on their condition and available therapies to treat their condition. These Voice of the Patient reports summarize the input provided by patients and patient representatives at each of the public meetings.
Citation	The Voice of the Patient: A Series of Reports from FDAs Patient -Focused Drug Development Initiative. U.S. Food and Drug Administration. Updated May 1, 2019. https://www.fda.gov/industry/prescription-drug-user-fee-amendments/voice-patient-series-reports-fdas-patient-focused-drug-development-initiative.

FDA: Executive Summary for the Patient Engagement Advisory Committee Meeting

https://www.fda.gov/media/122887/download

Resource Overview	Summary of November 15, 2018, FDA Patient Advisory Committee meeting where discussions centered around "Connected and Empowered Patients: e Platforms Potentially Expanding the Definition of Scientific Evidence." The recommendations address how FDA can leverage patient-driven platforms, such as social media and registries, to better engage patients and consumers as empowered partners in the work of protecting public health and promoting responsible innovation.
Citation	*Executive Summary for the Patient Engagement Advisory Committee Meeting* (U.S. Food and Drug Administration; November 15, 2018). https://www.fda.gov/media/122887/download.

Institute for Patient- and Family-Centered Care (IPFCC): Advancing the Practice of Patient- and Family-Centered Care in Primary Care and Other Ambulatory Settings: How to Get Started …

http://www.ipfcc.org/resources/GettingStarted-AmbulatoryCare.pdf

Resource Overview	This resource, *Advancing the Practice of Patient- and Family-Centered Care in Primary Care and Other Ambulatory Settings: How to Get Started …*, was developed to provide background on the importance of patient-centered care, provide definitions, and explore potential impact when care is transformed.
Citation	Institute for Patient- and Family-Centered Care (IPFCC). *Advancing the Practice of Patient- and Family-Centered Care in Primary Care and Other Ambulatory Settings* (Bethesda, MD: IPFCC; 2016). https://www.ipfcc.org/resources/GettingStarted-AmbulatoryCare.pdf.

IPFCC: Better Together Toolkit

http://www.ipfcc.org/bestpractices/better-together-partnering.html

Resource Overview	The toolkit created by IPFCC for the Better Together campaign includes the following materials available to hospitals to download and use:
	• Strategies for Changing Policies
	  ○ Steps and models to use in the process of developing new policies
	• Strategies for Educating Staff
	  ○ Strategies and resources for bringing staff "on board" with new policies and practices
	• Guidance about Family Participation
	  ○ Practical ways to work ***TOGETHER*** as a team
	• Videos
	• Sample Website for Family Presence (Download)
	• Media Resources
	  ○ Strategies and materials to use in announcing new policies within a hospital's own community

Citation	Better Together Toolkit. Institute for Family- and Patient-Centered Care. https://www.ipfcc.org/bestpractices/better-together-partnering.html.

IPFCC: A Toolbox for Creating Sustainable Partnerships with Patients and Families in Research

www.ipfcc.org/bestpractices/sustainable-partnerships/index.html

Resource Overview	Offers strategies, tools, and lessons learned to guide others in creating and sustaining partnerships with patients and families in research.
Citation	A Toolbox for Creating Sustainable Partnerships with Patients and Families in Research. Institute for Family- and Patient-Centered Care. https://www.ipfcc.org/bestpractices/sustainable-partnerships/index.html.

IPFCC: Strategically Advancing Patient and Family Advisory Councils in New York State Hospitals

http://www.ipfcc.org/bestpractices/NYSHF_2018_PFAC_Online_v3.pdf

Resource Overview	The purpose of this project was to address gaps in knowledge about Patient and Family Advisory Council (PFAC) best practices. The best practices report shares the following information: • Prevalence of hospital-based PFACs in New York state. • Variation in hospital-based PFACs within New York state, including differences in characteristics such as composition, structure, resources, management, and functioning. • Assessment of the extent to which differences in hospital-based PFAC characteristics are related to selected outcomes, including safety and patient experience of care. • Best practices for PFACs. • Recommendations for policy and practice changes for New York state to facilitate the spread of effective PFACs and patient and family advisor roles in hospitals.
Citation	Institute for Family- and Patient-Centered Care. *Strategically Advancing Patient and Family Advisory Councils in New York State Hospitals* (NYS Health Foundation; June 2018). https://www.ipfcc.org/bestpractices/NYSHF_2018_PFAC_Online_v3.pdf.

IPFCC: Diverse Voices Matter: Improving Diversity in Patient and Family Advisory Councils

http://www.ipfcc.org/resources/Diverse-Voices-Matter.pdf

Resource Overview	Many hospitals and clinics struggle with building Patient and Family Advisory Councils (PFACs) that reflect the diversity of the communities they serve. Kendra Jones, a doctor of nursing practice student in health innovation and leadership at the University

	of Minnesota, developed this resource in collaboration with IPFCC and five PFACs across North America to provide strategies to increase and sustain diversity.
Citation	Institute for Family- and Patient-Centered Care. *Diverse Voices Matter: Improving Diversity in Patient and Family Advisory Councils* (IPFCC; January 2018). https://www.ipfcc.org/resources/Diverse-Voices-Matter.pdf.

IPFCC: Partnering with Patients and Families to Enhance Safety and Quality: A Mini Toolkit

http://www.ipfcc.org/resources/Patient-Safety-Toolkit-04.pdf

Resource Overview	This toolkit contains materials for use in partnering with patients and families to enhance safety and quality, including: • Patients and Families as Advisors in Enhancing Safety and Quality: Broadening Our Vision • Patient and Family Advisors Sample Application Form • Patient Safety Champions: Their Roles in Developing and Supporting Partnerships with Patients and Families • Tips for Group Leaders and Facilitators on Involving Patients and Families on Committees and Task Forces • Applying Patient- and Family-Centered Concepts to Rapid Response Teams • Selected Resources for Partnering with Patients and Families in Patient Safety
Citation	Institute for Patient- and Family-Centered Care. *Partnering with Patients and Families to Enhance Safety and Quality: A Mini Toolkit* (Bethesda, MD: IPFCC; February 2013). https://www.ipfcc.org/resources/Patient-Safety-Toolkit-04.pdf.

International Alliance of Patients' Organizations (IAPO)

www.iapo.org.uk

Resource Overview	IAPO is an organization that does the following: • Works with patients' organizations to build them up to be as effective as possible • Advocates internationally with a strong patients' voice on relevant aspects of health care policy • Builds cross-sector alliances and works collaboratively with like-minded medical and health professionals, policy makers, academics, researchers, and industry representatives IAPO offers a collection of resources developed to strengthen the advocacy efforts at https://www.iapo.org.uk/resources.
Citation	International Alliance of Patients' Organizations [homepage]. IAPO. Updated October 23, 2019. https://www.iapo.org.uk/.

Massachusetts General Hospital: Patient & Family Advisory Councils

https://www.massgeneral.org/patient-advisory-councils

Resource Overview	Patient and Family Advisory Councils (PFACs) bring together patients, family members, staff, and clinicians in an ongoing effort to improve care and the patient and family experience. This link provides an overview of Massachusetts General Hospital PFACs and ideas on how to promote patient involvement.
Citation	Patient & Family Advisory Councils. Massachusetts General Hospital. https://www.massgeneral.org/patient-advisory-councils.

National Academy of Medicine: Harnessing Evidence and Experience to Change Culture: A Guiding Framework for Patient and Family Engaged Care

https://nam.edu/harnessing-evidence-and-experience-to-change-culture-a-guiding-framework-for-patient-and-family-engaged-care/

Resource Overview	The National Academy of Medicine's (NAM's) Leadership Consortium for a Value & Science-Driven Health System convened a Scientific Advisory Panel to compile and disseminate important insights on culture change strategies to transform patient and family engagement. The focus of this document is on evidence-based strategies that facilitate patient and family engagement and are tied to research findings revealing improved patient care and outcomes.
Citation	Frampton SB, Guastello S, Hoy L, Naylor M, Sheridan S, Johnston-Fleece M. Harnessing evidence and experience to change culture: a guiding framework for patient and family engaged care. *NAM Perspectives*. January 31, 2017. https://nam.edu/harnessing-evidence-and-experience-to-change-culture-a-guiding-framework-for-patient-and-family-engaged-care/. doi:10.31478/201701f.

National Health Council (NHC): Increasing Patient-Community Capacity to Engage on Quality of Health Care

http://www.nationalhealthcouncil.org/nhc-educational-program-quality

Resource Overview	This educational series focuses on why quality is important in the health care environment and how patients and patient organizations can become strong advocates for and participate in advancing quality. Module topics include: • The Changing Health Care Environment and the Important Role of Quality • Why Quality Matters for Patients • Everything You Wanted to Know But Were Too Afraid to Ask • Where Do Quality Measures Come From? • The Role of Quality in Value-Based Payment • Turning What We've Learned into Practice
Citation	NHC Educational Program: Quality. National Health Council. 2016. http://www.nationalhealthcouncil.org/nhc-educational-program-quality.

NHC: The National Health Council Rubric to Capture the Patient Voice: A Guide to Incorporating the Patient Voice into the Health Ecosystem

https://www.nationalhealthcouncil.org/Patient-Engagement-Rubric

Resource Overview	The purpose of the NHC *Rubric to Capture the Patient Voice* is to provide a tool to evaluate attributes of patient-centeredness and to provide guidance on meaningful patient engagement.
Citation	National Health Council. *The National Health Council Rubric to Capture the Patient Voice: A Guide to Incorporating the Patient Voice into the Health Ecosystem* (Washington, DC: NHC; 2019). https://www.nationalhealthcouncil.org/sites/default/files/NHC_Patient_Engagement_Rubric.pdf.

NHC: Tackling Representativeness: A Roadmap and Rubric

http://www.nationalhealthcouncil.org/sites/default/files/Representativeness%20in%20Patient%20Engagement.pdf

Resource Overview	This white paper captures insights from an NHC-convened roundtable organized to address patient representativeness. The paper summarizes the roundtable discussion, providing stakeholders with a set of consensus-based recommendations and considerations on characteristics of "good" patient representativeness, and identifies gaps and barriers to be addressed in the future.

Citation	National Health Council. *Tackling Representativeness: A Roadmap and Rubric* (Washington, DC: NHC; 2017). http://www.nationalhealthcouncil.org/sites/default/files/Representativeness%20in%20Patient%20Engagement.pdf.

NHC: Webinar Clinical Outcome Assessments Series: What Are Clinician-Reported Outcomes (ClinROs)?
http://www.nationalhealthcouncil.org/resources/webinars

Resource Overview	This webinar provides an overview of ClinROs and how they are related to what patients report as being most important to them. Patient perception of importance is an essential goal in patient engagement and moving our health system toward patient-centered care.
Citation	Powers JH. COA Series: What Are Clinician-Reported Outcomes (ClinROs)? [video] National Health Council. September 12, 2019. http://www.nationalhealthcouncil.org/resources/webinars#10.

National Quality Forum (NQF): National Quality Partners (NQP) Shared Decision Making Action Brief
http://www.qualityforum.org/Publications/2017/10/NQP_Shared_Decision_Making_Action_Brief.aspx

Resource Overview	The NQP *Shared Decision Making* action brief is a playbook, or compilation of resources and guidance, for promoting and integrating shared decision-making principles into practice. In addition to providing guidance, the playbook integrates tools and resources to promote shared decision-making and ideas to overcome barriers and challenges to implementation.
Citation	National Quality Partners. *Shared Decision Making: A Standard of Care for All Patients* (National Quality Forum; October 2017). https://www.qualityforum.org/Publications/2017/10/NQP_Shared_Decision_Making_Action_Brief.aspx.

Oregon Health Authority: CAC Learning Community
https://www.oregon.gov/oha/HPA/dsi-tc/Pages/CAC-Learning-Community.aspx?wp5462=p:1

Resource Overview	The Oregon Health Authority (OHA) established a Transformation Center to guide the state in transforming the health care system. One mechanism the OHA uses is the establishment of Consumer Advisory Councils (CACs) to ensure the voice of patients or health care consumers is a part of the process. This site provides a variety of tools and resources for the establishment of CACs and covers topics such as recruitment and engagement of members.
Citation	CAC Learning Community. Oregon Health Authority Transformation Center. https://www.oregon.gov/oha/HPA/dsi-tc/Pages/CAC-Learning-Community.aspx?wp5462=p:1.

patientslikeme: Best Practices Guide for Online Researchers
http://patientslikeme_mkting.s3.amazonaws.com/Best%20Practices%20Guide.pdf

Resource Overview	With support from the Robert Wood Johnson Foundation, patientslikeme formed its first-ever patient-only Team of Advisors, which developed this guide. The guide outlines standards for how researchers can meaningfully engage patients in a virtual way throughout the research process. The guidelines approach how researchers can partner with patients from the beginning to the end as collaborators, reviewers, interpreters, translators, and disseminators.
Citation	patientslikeme. *Best Practices Guide for Online Researchers* (Cambridge, MA: patientslikeme; 2015). http://patientslikeme_mkting.s3.amazonaws.com/Best%20Practices%20Guide.pdf.

Patient-Centered Outcomes Research Institute (PCORI): Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records

https://www.pcori.org/sites/default/files/PCORI-JHU-Users-Guide-To-Integrating-Patient-Reported-Outcomes-in-Electronic-Health-Records.pdf

Resource Overview	This Users' Guide facilitates the inclusion of PROs in electronic health records (EHRs) and addresses 11 key questions that administrators, clinicians, researchers, and other professionals may have as they consider expansion of EHRs to include PROs: 1. What strategy will be used for integrating PROs in EHRs? 2. How will the PRO-EHR system be governed? 3. How can users be trained and engaged? 4. Which populations and patients are most suitable for collection and use of PRO data, and how can EHRs support identification of suitable patients? 5. Which outcomes are important to measure for a given population? 6. How should candidate PRO measures be evaluated? 7. How, where, and with what frequency will PROs be administered? 8. How will PRO data be displayed in the EHR? 9. How will PRO data be acted upon? 10. How can PRO data from multiple EHRs be pooled? 11. What are the ethical and legal issues?
Citation	Snyder C, Wu AW (eds). *Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records* (Baltimore, MD: Johns Hopkins University; 2017). https://www.pcori.org/document/users-guide-integrating-patient-reported-outcomes-electronic-health-records.

Planetree: Barriers to Engagement in Research & Ways to Overcome Them

https://resources.planetree.org/barriers-to-engagement-in-research-ways-to-overcome-them/

Resource Overview	This document summarizes common barriers and challenges Patient and Family Advisory Councils encounter when engaging in research and ways that have been found to overcome them.
Citation	Planetree. *Barriers to Engagement in Research & Ways to Overcome Them* (Planetree; 2017). https://resources.planetree.org/barriers-to-engagement-in-research-ways-to-overcome-them/.

PREFER Patient Preferences

https://www.imi-prefer.eu/about/

Resource Overview	PREFER is a public-private collaborative research project under the Innovative Medicines Initiative: Europe's Partnership for Health. PREFER is in the process of establishing recommendations to support development of guidelines for industry, regulatory authorities, and Health Technology Assessment bodies on how and when to include patient perspectives on benefits and risks of medicinal products. The PREFER website offers a list of publications documenting their research to date on patient preferences: https://www.imi-prefer.eu/publications/.
Citation	Including the patient perspective. PREFER Patient Preferences. https://www.imi-prefer.eu/about/.

Twelve Lessons Learned for Effective Research Partnerships Between Patients, Caregivers, Clinicians, Academic Researchers, and Other Stakeholders

https://link.springer.com/content/pdf/10.1007%2Fs11606-017-4269-6.pdf

Resource Overview	This is a compilation of 12 lessons learned about how to ensure effective research partnerships that include patients, caregivers, clinicians, and other stakeholders.
Citation	Wittemann HO, Dansohko SC, Colquhoun H, et al. Twelve lessons learned for effective research partnerships between patients, caregivers, clinicians, academic researchers, and other stakeholders. *J Gen Intern Med.* 2017;33(4):558–562. https://link.springer.com/content/pdf/10.1007%2Fs11606-017-4269-6.pdf.

KEY INFORMANT/CONTRIBUTOR LIST

The following table contains the names and affiliations of each key informant included in the discovery of best practices and stakeholder interviews. The project team sought to identify experts with both broad and deep expertise in patient engagement. The links provided are for broader patient engagement documents not summarized in the Resource List. These links may be helpful for general research and further exploration of patient engagement initiatives.

Contact	Organization	Links
Gabriela Schmajuk, MD, Rheumatologist, Associate Professor of Medicine	University of California, San Francisco	https://healthit.ahrq.gov/ahrq-funded-projects/incorporating-pro-data-ra-clinical-encounters-using-health-it-pact
Teresa Bissenden, Director, Patient & Public Engagement	British Columbia Patient Safety and Quality Council	https://bcpsqc.ca/advance-the-patient-voice/
Evan Robert Myers, MD, and Barbara Lytle, Program Leader, Comparing Options for Treating Uterine Fibroids through a Patient Information Registry—The COMPARE-UF Study	Duke University School of Medicine, Department of Obstetrics and Gynecology	https://compare-uf.org/ Women with uterine fibroids and other stakeholders are a key part of the COMPARE-UF registry and participate at all points from study design to dissemination of results. Project summary: https://www.pcori.org/research-results/2014/comparing-options-treating-uterine-fibroids-through-patient-information
Nathan Glusenkamp, Director of Orthopaedic Registries	American Academy of Orthopaedic Surgeons	https://www.aaos.org/Quality/
Clifford Ko, Director of the Division of Research and Optimal Patient Care	American College of Surgeons	https://www.facs.org/quality-programs/about
Susan Edgman-Levitan, PA-C, Executive Director	John D. Stoeckle Center for Primary Care Innovation at Massachusetts General Hospital	https://www.pcpcc.org/profile/susan-edgman-levitan
Cynthia Grossman, PhD, Director, Science of Patient Input	FasterCures, a center of the Milken Institute	Advancing the Science of Patient Input in Medical Product R&D – Towards a Research Agenda: A Workshop: Landscape Analysis http://nationalacademies.org/hmd/~/media/Files/Activity%20Files/Research/DrugForum/2018-05-09-SPI/Draft-Landscape-Analysis.pdf?la=en Patient-Centric Initiatives: Focusing for Impact https://assets1b.milkeninstitute.org/assets/Publication/ResearchReport/PDF/Patient-Centric-Initiatives-Focusing-for-Impact-FINAL.pdf

Michael Seid, PhD, Director, Health Outcomes and Quality Care Research, Pulmonary Medicine	James M. Anderson Center for Health Systems Excellence	https://www.cincinnatichildrens.org/service/j/anderson-center/learning-networks
Gwen Darien, Executive Vice President for Patient Advocacy and Engagement	Patient Advocate Foundation (PAF)	The Roadmap to Consumer Clarity in Health Care Decision Making proposes actionable models to drive person-centered care at key decision points for people facing or living with serious illnesses. https://www.npaf.org/roadmap/
Brant Oliver, PhD, MS, MPH, FNP-BC, PMHNP-BC, Assistant Professor	The Dartmouth Institute	Oliver BJ, Nelson EC, Kerrigan CL. Turning feed-forward and feedback processes on patient-reported data into intelligent action and informed decision-making: case studies and principles. *Med Care*. 2019 May;57 Suppl 5 Suppl 1:S31–S37. https://www.ncbi.nlm.nih.gov/pubmed/30985594.
Susan B. Frampton, PhD	Planetree International	https://planetree.org/resources/6-steps-to-creating-a-culture-of-person-and-family-engagement-in-health-care/
Renée Markus Hodin, Deputy Director, Center for Consumer Engagement in Health Innovation	Community Catalyst	https://www.communitycatalyst.org/about/people/renee-markus-hodin
Bray Patrick-Lake	Former Director of Stakeholder Engagement, Clinical Trials Transformation Initiative (CTTI); Director, Patient Engagement, Duke Clinical and Translational Science Institute	DCRI Research Together https://dcri.org/insights/stakeholder-engagement/ Models of Engagement: Patients as Partners in Clinical Research http://www.appliedclinicaltrialsonline.com/models-engagement-patients-partners-clinical-research
Eugene Nelson, PhD, Professor and Director of Population Health and Measurement	Dartmouth Institute	https://sites.dartmouth.edu/patientadvisors/
Donna Cryer, JD President & CEO	Global Liver Institute	http://www.globalliver.org/donnacryerbio

APPENDIX 1

CMSS PCORI Engaging Patients in Clinical Registries Engagement Advisory Committee

Member	Title	Organization	Contribution to Advisory Committee
Judith Baumhauer, MD	Professor and Associate Academic Chair, Department of Orthopedics	University of Rochester	Research, patient-reported outcomes, and patient engagement
Carol Cronin	CEO	Informed Patient Institute	Patient engagement strategies
Donna Cryer, JD	Patient Advocate	Global Liver Institute; Board Member, People-Centered Research Foundation	Patient advocate, research expertise
Joyce Dubow	Consumer and Patient Advocate (formerly AARP Health Policy)	None	Breast cancer patient, consumer advocate, outcomes focus
Clifford Ko, MD	Director, Division of Research and Optimal Care	American College of Surgeons (ACS), UCLA	Registry expertise, leads ACS registries with focus on outcomes and research
Eugene Nelson, PhD	Professor and Director of Population Health and Measurement	Dartmouth Institute for Health Policy and Clinical Practice	Registry expertise, patient co-production
Sally Okun, RN	Vice President, Policy and Ethics	patientslikeme	Patient engagement, online communities, connection to FDA efforts
Bray Patrick-Lake	Patient Partner and Former Director, Director of Stakeholder Engagement	Clinical Trials Transformation Initiative (CTTI), Duke University	Patient engagement in clinical trials, connection to FDA efforts
Eleanor Perfetto, PhD	Senior Vice President, Strategic Initiatives	National Health Council	Patient engagement, PROs, research
William Rich, MD	Director, Health Policy	American Academy of Ophthalmology	Registry expertise, leads IRIS registry, focus on outcomes and PROs
Dan Solomon, MD	Professor of Medicine at Harvard Medical School and Chief of the Section of Clinical Sciences in Rheumatology	Harvard Medical School and Brigham and Women's Hospital	Research and registry expertise, including patient perceptions of registries

[i] Council of Medical Specialty Societies. Primer for the Development and Maturation of Specialty Society Clinical Data Registries: For Specialty Societies and Organizations Developing and Advancing Clinical Data Registries. 1st ed. (Chicago, IL; CMSS: January 2016).
[ii] Meaningful Measures Hub. Centers for Medicare & Medicaid Services (CMS). Updated September 10, 2019. Accessed June 2, 2019. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.
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[iv] Gliklich RE, Dreyer NA, Leavy MB, Christian JB (eds). *21st Century Patient Registries*. E-book addendum to *Registries for Evaluating Patient Outcomes: A User's Guide, 3rd Edition*. AHRQ Publication No. 17(18)-EHC013-EF (Rockville, MD: Agency for Healthcare Research and Quality; February 2018). https://effectivehealthcare.ahrq.gov/sites/default/files/registries-guide-3rd-ed-addendum-research-2018.pdf.
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[xi] National Quality Partners™ Action Brief: *Shared Decision Making: A Standard of Care for All Patients* (National Quality Forum; October 2017). http://www.qualityforum.org/NQP/Shared_Decision_Making_Action_Brief.aspx.
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[xv] Patient Engagement Action Team. *Engaging Patients in Patient Safety – a Canadian Guide* (Edmonton, AB: Canadian Patient Safety Institute; 2017). http://www.patientsafetyinstitute.ca/engagingpatients.