

# CMSS-NHC Primer

## Enhancing Patient Partnerships

How Patient Organizations and Medical Societies  
Can Enhance Patient Engagement in Clinical  
Registries and Research



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## Background and Purpose

Patient and family engagement is increasingly acknowledged as a key component of a complete approach to achieving high quality and affordability in health care. Today, massive amounts of data are collected in electronic health records, patient registries, and other data sources for multiple purposes, including quality reporting, paying for care, accreditation, and patient safety. These data can help us learn what works best, for which people, and under which circumstances. But what often is missing is the patient voice, essential to meeting the important goals of improving treatment, experiences with care, and patient outcomes, and perhaps most importantly, ensuring care is aligned with patients' goals, values, and preferences. Finally, the patient perspective is important to identify the research questions of importance to patients and to provide research results in a manner that patients, families, and caregivers can understand and use in their own care and decision making.

One mechanism to gather patient input, specifically information on patients' views, experiences, and outcomes, is for specialty societies to engage patients in their clinical registries. Specialty society registries are driving to be more patient-centered by collecting data from patients on outcomes, especially patient-reported outcomes (PROs) of value to both clinicians and patients in order to better assess the value of care and treatments provided. To be successful in these endeavors, specialty societies need to learn how to effectively engage patients in registries, including, but not limited to, activities such as quality initiatives and development of tools and resources to facilitate and motivate patient and family engagement as these capabilities emerge.

Toward this end, the Council of Medical Specialty Societies (CMSS) produced in 2019 the *Engaging Patients in Clinical Registries* primer,<sup>i</sup> directed toward medical specialty society staff and members, especially registry developers. It is intended to provide background on key principles of effective patient engagement, identify opportunities for increased engagement, and provide tools and resources for advancing patient-centric approaches. The 2019 primer focus was on sharing promising practices and pathways to further capture the patient voice in the selection of patient outcomes to be measured and to identify research questions of interest and benefit to patients that could be incorporated into registries.

This companion primer for patient organizations was developed to complement the CMSS *Engaging Patients in Clinical Registries* primer aimed at specialty specialties. This primer is not intended to be exhaustive. Rather, it is an introduction to the many aspects of registries sponsored by specialty societies, why they are important in the U.S. health system, and how the role of patients, families, and caregivers is essential in registries to expand the movement toward patient-centeredness.

The goal of these companion primers is to enhance collaborations and partnership among specialty societies and patient organizations so that new and evolving registries become more patient-centered. In addition, continued engagement will help to address questions relevant to patients. To that end, we include a case study that highlights an existing partnership between a patient group and specialty society on a clinical registry, the relationship they have developed, how they collaborate, and lessons learned.

## Understanding Clinical Registries: What are they? How are they used in the U.S. health system?

A **clinical registry** is a database that compiles information regarding the real-world experience of a treatment. The objective is to increase patient safety, improve patient outcomes, foster research, and promote best clinical practices. Many kinds of registries exist, and some patient groups have their own registries. Many specialty societies have been gathering and analyzing clinical data in a variety of specialty areas through clinical data registries (CDRs) for more than 40 years. Initially, most registries started with manual chart abstraction, and while this method is still employed, technology has evolved, allowing more automated abstraction from electronic health records, patient data portals, payment systems (claims data), and public health systems. CDRs continue to play an important role in the health care system by providing longitudinal data on patients, monitoring and informing the quality of medical care and generating new clinical knowledge that can lead to improved patient care and outcomes.

### **What Is a Clinical Data 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 data on treatments is 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 health care providers with regard to their outcomes and resource use.<sup>ii</sup>

A **medical society or association** is an organization representing a particular group of medical professionals. Medical societies perform a number of important functions for members, including education and advocacy. They also help set standards for excellence in the profession. Medical societies help inform members about new research and developments in the field, and they assist doctors and other professionals in protecting the interests of their patients. Societies keep their members informed through newsletters, websites, email, and conferences. What this all means for patients is that if your physician belongs to a medical society, they are he or she is tapped into a broader professional network whose mission is to inform members about the newest, best practices.<sup>iii</sup>

A **patient registry** is a collection of information about people who have a specific disease or condition. Some patient registries seek participants of varying health status who may be willing to participate in research about a particular disease. Individuals provide information about themselves to these registries on a voluntary basis. Registries can be sponsored by a government agency, nonprofit organization, health care

facility, or private company.<sup>iv</sup> The use of “patient” in patient registries is often used to distinguish the focus of the data set on health information.

### **What Is a Patient Registry?**

The purposes for patient registries can range widely. According to the National Institutes of Health, “Registries can be used to recruit patients for clinical trials; to learn about a particular disease or condition; to develop therapeutics or to learn about population behavior patterns and their association with disease development; developing research hypotheses; or for improving and monitoring the quality of health care.” Patient registries can also be used to monitor outcomes and study best practices in care or treatment.<sup>v</sup>

### Roles of Registries

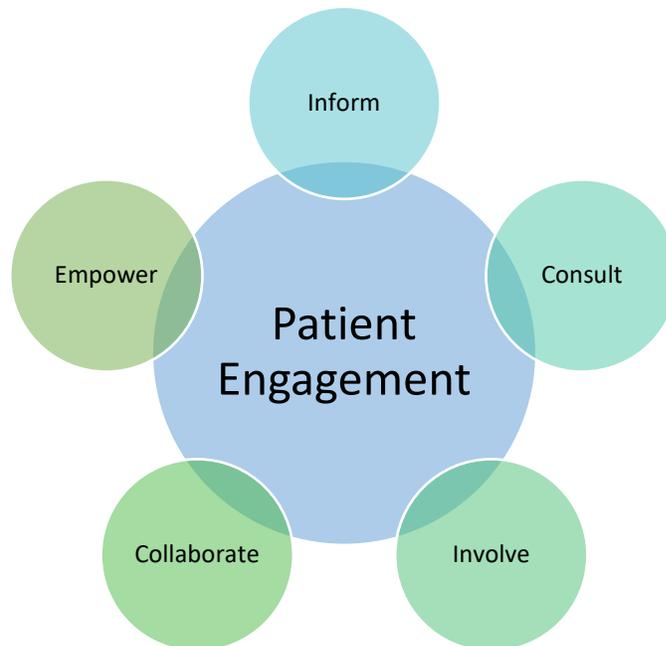
Registries have been started by medical societies for many reasons, and the roles of those registries have evolved over time. The roles include, but are not limited to:

1. Stimulating the research ecosystem to advance care and treatments for individuals and informing the development of hypothesis-driven research.
2. Improving clinical outcomes and quality of life for those with a condition.
3. Promoting understanding of the natural history of an illness and how it is treated, informing understanding of variability, progression, and current treatment practices.
4. Setting clinical benchmarks and observing practice patterns to establish standards and norms for quality assessment.
5. Assessing provider quality of care and easing compliance with Medicare and other payer quality reporting requirements.
6. Improving care through the collection, analysis, and reporting of longitudinal and actionable data.

While each of these roles is critical to improving patient care through advancing research, increasing knowledge, and improving clinical practice, increasing the patient voice and engagement in the development and implementation of clinical registries should provide relevant information that patients, families, and caregivers can use to support their decision making. Achieving patient engagement in clinical registries and research is analogous to the importance of community engagement in population health improvement: **Community engagement** is based on the idea that everyone who is affected by an issue that impacts their community should have a say in the decision making around it. For organizations, it’s about working with, and listening to, communities (or patients and caregivers) to build long-term relationships and develop meaningful solutions to complex issues.<sup>vi</sup>

*Engagement seeks to connect with the community (or patient population) to achieve sustainable outcomes, promote equitable decision-making processes, and deepen relationships and trust between organizations and communities.*

The following diagram depicts the spectrum of patient engagement, ranging from little to none to fully empowered patients who are strong contributors to the process.



Adapted From: <https://www.bangthetable.com/what-is-community-engagement/>, accessed online February 29, 2020.

## How can patients be engaged in clinical registries and how can they benefit from participation?

### Patient engagement to aid in registry development and implementation

Patient input can have significant impact on registry design, development, and use. Patient engagement in the design of the registry impacts what data are collected, how the data are collected, and by whom they are collected from. Patient engagement draws attention to the research questions patients care about and helps researchers refine their questions. It can help ensure that the questions studied are the right questions and that the right study designs are aligned with those questions. In addition, patients can influence how findings from registry clinical research—that have the potential to impact patient care and patient and family experience—are translated in a way that will be useful and understandable to patients, families, and caregivers.

### Patient Engagement to ensure *patient-centered*, patient-reported outcomes (PROs) are collected in registries

While many would assume that all PROs are patient-centered because the patient is reporting the information, this is not always the case. It is important to collect in registries the PROs that are patient centered. Patient engagement helps to ensure the right PRO measures are developed and included in registries, and to support the necessary data collection.

**Patient-reported outcome (PRO):** A PRO is an aspect of health, how a person feels or functions, that is self-reported by the patient and that can be self-reported by the patient only and no one else. For example, only a patient can report on their own level of pain. Others, such as doctors or family members, can only report their observation of a person with pain and their view of how that patient is experiencing pain or how it may be interfering with daily life. The tools used to collect this information are called PRO measures or PROMs, and they are often questionnaires, instruments, or surveys.

**Patient-centered outcome:** The outcomes that patients report are important to them.

**Patient-centered PRO:** An outcome that patients report as important to them that only a patient can report on (e.g., an aspect of how a person feels or functions that is important to the patient).

Example: Patient-Centered Versus Patient-Reported Outcomes (PROs) (next page)

For more information see: National Health Council Clinical Outcome Assessment (COA) Webinar Series (<https://nationalhealthcouncil.org/the-nhcs-clinical-outcome-assessment-webinar-series-is-now-the-patient-focused-medical-product-development-webinar-series/>).

It also is important to understand the credibility of the PRO questionnaire(s) (also called measures, tools, or instruments) chosen to be included in the registry. The questionnaires must be of sound quality and “fit-for-purpose.” This means that the tool was designed and tested properly and was found to be valid for the intended use in a registry. Not all PRO questionnaires are “plug-and-play.” Keep in mind that there is no PRO measure in existence that is considered valid for every possible setting and use. So, when someone uses the term “validated” to refer to a PRO tool, be sure the psychometric testing that was conducted is aligned with the use you have in mind. Of course, a registry can be an ideal opportunity to conduct the validation studies needed when developing a new tool and those data collection opportunities should be leveraged when possible.

Patient-reported outcomes are increasingly important in both patient and clinical registries; however, obtaining patient-centered and -reported outcomes can be difficult when the registry focuses on a disease that includes vulnerable populations and young children. Challenges such as progressive, disabling, and cognitive impairments make it more difficult to obtain relevant, valid, and reliable information about the patients’ experiences with their condition and the treatment under consideration. Although the collection of PROs may be desired, it may not always be practical. If patients are unable to self-report on their disease experience, it will be necessary to collect information regarding treatment benefit indirectly from clinicians, parents, or others who have direct knowledge about patient condition-related behavior, signs and symptoms, or functional status. In such cases, indirect measures of treatment benefit may be required on the basis of patient observation, that is, **observer-reported outcomes (ObsROs) or clinician-reported outcomes (ClinROs)**.<sup>vii</sup>

**Patient-Centered Versus Patient-Reported Outcomes (PROs):**

**An Example Based on the Psoriasis Voice of the Patient Report Findings in 2016**

<b>Outcomes reported in the Psoriasis Voice of the Patient Report</b>	<b>Patient-Centered Outcomes:</b> Patients Reported as Important to Them	<b>Patient-Reported Outcomes:</b> Can <i>Only</i> be Reported by Patients
1. Itching	<b>X</b>	<b>X</b>
2. Stinging, burning pain	<b>X</b>	<b>X</b>
3. Joint pain, stiffness and swelling (for psoriatic arthritis)	<b>X</b>	<b>X</b>
4. Headaches (as a result of scalp psoriasis)	<b>X</b>	<b>X</b>
5. Constant fatigue	<b>X</b>	<b>X</b>
6. Quality of life	<b>X</b>	<b>X</b>
7. Limitations on activities	<b>X</b>	Could be measured as a PRO, ClinRO, ObsRO, or PerfO
8. Embarrassment*	<b>X</b>	<b>X</b>
9. Stigma*	<b>X</b>	<b>X</b>
10. Social discrimination*	<b>X</b>	<b>X</b>
11. Skin appearance: Flaking and scaling skin; dry, cracked skin that may bleed; skin rash inflamed, red skin covered with silvery white scales; small, red spots on the skin; bright red, shiny lesions that appear in skin folds; widespread, fiery skin that appears burned	<b>X</b>	Could be measured as a PRO, ClinRO, ObsRO, or PerfO (e.g., skin plaque size or percentage of body covered) Typical measures used are more granular than patient concerns (e.g., patients do not differentiate between 70% or 80% of body coverage)
12. Issues with ridged or pitted nails	<b>X</b>	Could be measured as a PRO, ClinRO, ObsRO, or PerfO
13. Concerns about treatment impact on fertility	Not an outcome patients mentioned spontaneously. Patients were asked about it, and reported low concern. Could be an artifact of the sample responding, hesitation to talk publicly about the topic, or other factors.	<b>X</b>

\*Noted as a priority for patients but not captured often enough in PRO measures.

Adapted from data reported in: U.S. Food and Drug Administration. The Voice of the Patient: A series of reports from the U.S. Food and Drug Administration's (FDA's) Patient-Focused Drug Development Initiative-Psoriasis. <https://www.fda.gov/media/101758/download>. Published November 2016.

## How do patients benefit from engagement in registries?

Given the multiple uses of registries by medical societies, patient organizations, and researchers, registry developers and patient groups should consider the value proposition for patient involvement. In a review of patient organization registry websites, here are some of the ways that patients may benefit from participating in a registry:

- Make a difference in their own lives and in the lives of millions of individuals and families who, like them, are suffering from an illness.
- Contribute directly to research for new treatments and a cure.
- Be part of a community helping to inform research.
- Connect with investigators at institutions nationwide to learn about and participate in clinical trials.
- Use for personal/family medical record-keeping.
- Share experiences to guide and enhance educational and awareness programs, lead to better care and research about the disease, and help improve the health of future generations.
- Compare individual experiences to the experiences of others.
- Demonstrate the seriousness of the disease.
- Demonstrate where patients need more information and pinpoint what additional resources would be helpful.
- Contribute to programs that are most useful to patients and caregivers.
- Contribute to increased awareness of their own care by patients and their health care providers. This awareness may promote more individualized care.

## How do medical societies and patient organizations benefit from patient engagement in registries?

A health system that promotes patient-centered care and involves patients, families, and caregivers for both care delivery and operations can also benefit medical societies and health-related organizations. Emphasis on the lived experience of patients and their broader community promotes productive, durable change through deliberative dialogue. Patient engagement provides participants with information they need to engage in a meaningful way with their providers and other health care professionals about what matters to them. Specialty societies can benefit from patient engagement in ways similar to patients, but changing the foci to providers:

- ▶ Increased patient knowledge and understanding encourages active engagement in health, well-being, and health care choices, which can help patients be more adherent to care plans and reduce health care utilization.
- ▶ Improved shared decision making; providers can make better decisions regarding a patient's health, improving the patient-provider relationship and overall patient retention by understanding what is important to patients from patients.
- ▶ Changing the way providers interact with their patients, helping health care experts develop new treatment plans, and helping patients feel like an important partner in care.

- ▶ By supporting patient-generated health data collection, providers are able to better the health care industry by helping build a wealth of information clinicians, researchers, and patients can all use.

## Examples of Patient-Focused Registry Messaging

The following table provides examples of patient organizations with active registries, the respective links, and how the specific registry phrases messaging to patients about the purpose of the registry and how patients can benefit or be involved.

Registry/Organization	Messaging Examples
Parent Project Muscular Dystrophy  Registry link: <a href="https://www.duchenneregistry.org/">https://www.duchenneregistry.org/</a>	<ul style="list-style-type: none"> <li>• The Duchenne Registry and your data will help fuel the fight to end Duchenne. We share your anonymous Registry data with researchers to speed development of new therapies</li> <li>• 12-year-old network of patient-powered data that will be used to improve care for people living with Duchenne and increase our understanding of the disorder. By sharing your data, you become a citizen scientist by contributing to real scientific research.</li> </ul>
Hydrocephalus Association  Registry link: <a href="https://www.hydroassoc.org/happier/">https://www.hydroassoc.org/happier/</a>	<ul style="list-style-type: none"> <li>• HAPPIER is an online database created for our community to share your experience living with hydrocephalus.</li> <li>• By sharing your experience, you're giving researchers access to important data that can lead to discoveries in underlying causes of the condition, intervention strategies for preventing the condition, improvements in diagnosis, and/or alternative treatments.</li> </ul>
National Osteoporosis Foundation  Registry link: <a href="https://www.nof.org/hbfl/">https://www.nof.org/hbfl/</a>	<ul style="list-style-type: none"> <li>• A first of its kind tool in the osteoporosis field, the Healthy Bones, Build Them for Life® Patient Registry surveys patient and caregivers about how osteoporosis and osteopenia impact their lives.</li> </ul>

	<ul style="list-style-type: none"> <li>This patient-reported information is collected anonymously, combined, and analyzed by the National Osteoporosis Foundation (NOF) to map out the patient journey. This map will show NOF and the broader bone health community what patients need and want most.</li> </ul>
<p>The ALS Association</p> <p>Registry link: <a href="http://www.alsa.org/advocacy/als-registry/">http://www.alsa.org/advocacy/als-registry/</a></p>	<p>The Registry is collecting critical information about the disease that will improve care for people with ALS and help us learn what causes the disease, how it can be treated and even prevented.</p>
<p>Immune Deficiency Foundation</p> <p>Registry link: <a href="https://primaryimmune.org/programs/usidnet-patient-registry">https://primaryimmune.org/programs/usidnet-patient-registry</a></p>	<p>When your experiences and those of other patients are examined collectively, common findings can help advance vital research and help improve the quality of life for the entire primary immunodeficiency community. The more patients registered the more data researchers have to further their work.</p>
<p>National Psoriasis Foundation: Corrona Psoriasis Registry</p> <p>Registry link: <a href="https://www.psoriasis.org/psoriasis-registry">https://www.psoriasis.org/psoriasis-registry</a></p>	<p>The questionnaires you complete provide your doctor with additional important data which may not otherwise be collected during a typical clinic visit. This helps your health care provider to better understand you and your disease and possibly result in better care provided to you. With your help, findings from the Corrona Registries will help doctors treat these diseases. Patients, like you, who participate in the registry will directly contribute to the health and well-being of others being treated for an immune-mediated disease like psoriasis.</p>

## How can a patient group take action?

### FINDING THE WIN-WIN: WHAT DOES A PARTNERSHIP LOOK LIKE BETWEEN A MEDICAL SOCIETY AND A PATIENT ORGANIZATION?

#### CASE EXAMPLE

##### A Specialty-Society and Patient-Group Registry Partnership

###### Who are the partners?

**Professional Association (CMSS member):** American Society for Reproductive Medicine (ASRM) and Society for Assisted Reproductive Technology (SART)

**Patient Advocacy Organization (NHC Member):** RESOLVE: The National Infertility Association

###### About the partnership:

RESOLVE has been working with SART/ASRM since it was formed in 1974. The SART Registry (aka SART CORS) is used to create clinically specific annual success reports, facilitate external questions and answers, collect treatment details, and provide data to federal and state governments for policy purposes. As a partner, RESOLVE provides patient input on the restructuring of data collection and public success reporting, facilitates patient focus groups, and provides advice regarding the SART Patient App. The SART Registry is an information tool for patients who may need IVF medical treatment. The Registry provides valuable information before a person seeks care, helps them frame questions to ask their medical team, and gives outcome data to help guide their own medical treatment plan.

<p><b>Question 1:</b> When and how did your registry partnership begin?</p> <p>What were your motivating factors in partnership?</p>	<p>RESOLVE has provided input to SART/ASRM on the Registry for many years through an annual face-to-face meeting for the National Coalition for the Oversight of ART. However, in 2013, SART/ASRM reached out to the RESOLVE CEO to seek patient input in several new features of the website for the registry data. Based on the success of these early interactions, RESOLVE has been asked to provide patient input on other areas, such as the SART Patient App and the formatting of the data for ease of use.</p>
<p><b>Question 2:</b> How would you describe your registry partnership?</p>	<p>It is very collaborative and transparent. There is a real desire from SART/ASRM for patient input.</p>
<p><b>Question 3:</b> What has made your registry partnership successful?</p>	<ul style="list-style-type: none"><li>• SART/ASRM and RESOLVE had an existing relationship and given that we have met face-to-face annually for many years, we have built respect and trust for one another. That existing relationship helped immensely</li></ul>

<p>What recommendations would you have for other organizations?</p>	<p>when SART/ASRM sought patient input more directly for the registry.</p> <ul style="list-style-type: none"> <li>• For other organizations, it is important to meet, at least annually, to discuss various issues and projects, and to build trust and a positive working relationship. This makes collaboration in many areas far more successful.</li> <li>• Genuinely seek and listen to patient input.</li> <li>• Support the development and invest in the future of patient advocacy organizations.</li> <li>• Start early investing in patient education and patient-oriented information, and engaging in patient partnerships.</li> <li>• “Never let a crisis go to waste.” In our case, we leveraged as much as possible governmental/regulatory pressure.</li> <li>• Ensure the clinical repository is outcomes-focused, relevant, and of important value to clinicians and patients (consumers).</li> </ul>
<p><b>Question 4:</b> What challenges have you encountered in your registry partnership?</p> <p>What suggestions would you have for other organizations to avoid or overcome these challenges?</p>	<ul style="list-style-type: none"> <li>• We have not encountered significant challenges in our partnership, while recognizing that two different organizations will always have some degree of difference in goals and mission.</li> <li>• We needed to develop systems and processes to address conflicts and differences in a collegial, productive manner.</li> <li>• It’s always a challenge to find the time to dedicate to building any partnership. You need to build in the time to work on relationship-building and maintenance.</li> <li>• Overcome challenges by building a relationship based on mutual respect and trust.</li> </ul>

<p><b>Question 5:</b> What advice do you have for medical specialty societies who have never worked with a patient organization before and who want to get started with such a partnership?</p>	<ul style="list-style-type: none"> <li>• <b>START YESTERDAY!</b> There are so many opportunities to partner and work together. But, if you don't have an existing relationship, it is hard to lean on each other in tough times. While relationships and trust can take time to build, you need to start now. Each organization will be better for the partnership. We like to say, "One plus one equals three!" We are all better working together.</li> <li>• Consider engaging a formal ongoing patient advocacy organization, rather than individual patients or an informal advocacy group, in the development and improvement of our registry.</li> </ul>
<p><b>Question 6:</b> What do you see for the future for your registry partnership?</p>	<ul style="list-style-type: none"> <li>• Continuing to refine the registry to meet the unique needs of patients. Making sure that the patient perspective is important to SART/ASRM even though there are several other goals of the registry.</li> <li>• Also, working together beyond the registry on other patient-centered initiatives.</li> </ul>

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