

PCORnet[®] Playbook

CASE STUDIES

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Using the Power of PCORnet® for Patient-Centered Health Research

This module includes examples of how research teams have used the PCORnet® infrastructure to accelerate evidence generation and translate healthcare innovations into population health benefits.

[PCORnet® Studies](#) span a range of sizes, designs, therapeutic areas, populations, and funding sources, including the Patient-Centered Outcomes Research Institute® (PCORI®), the National Institutes of Health (NIH), and industry sponsors. More than 300 research projects have used the PCORnet infrastructure to conduct patient-centered health research that helps patients, caregivers, clinicians, health systems, and policymakers make better-informed decisions to improve health and healthcare.



Overview of the PCORnet® Infrastructure

The PCORnet infrastructure enables insights from high-quality health data, patient partnership, and research expertise to deliver fast, trustworthy answers that advance health outcomes. The case studies in this module illustrate how PCORnet® Study teams successfully leverage these assets — individually and in combination — to improve their research.

The robust infrastructure of PCORnet, and particularly the PCORnet® Common Data Model that unites millions of disparate data points so they are usable and meaningful for research, gave us a significant head start in our search for answers.



— Mark Pletcher, Principal Investigator for the BP Control Laboratory, a PCORnet® Study



PCORnet® COMMON DATA MODEL (CDM)

Standardized, high-quality data enables national-scale research

Every PCORnet® Clinical Research Network (CRN) operates under a shared [PCORnet® CDM](#), so you can ask the same question across millions of patients simultaneously and receive a clear answer, even across disparate systems. This capability of the network is especially beneficial in research on health conditions, like rare diseases, that can be challenging to study because of their rarity and variability.

Data experts on the PCORnet® Front Door team can help you complete a [Data Network Request](#) to determine if sites participating in PCORnet have the population of patients you need to achieve your research goals.

The PCORnet® CDM can be used to link EHR data to insurance claims, patient registries, death records, and other data sources to collect and validate baseline, outcomes, and safety data.





AN ENGAGED, RESEARCH-READY COMMUNITY

Patients and other community partners ensure endpoints are meaningful and enhance trust

[Patient Partners](#), clinicians, health system representatives, insurers, and policymakers are all vital participants in the [PCORnet community](#).

Some research teams leverage existing partnerships while others work with the [PCORnet® Front Door team](#) to connect with the team's extensive network of experienced community partners and engagement resources.

Check out [Module 4](#) to learn more about how engaging patients in research early and often can drive actionable changes to improve health.



RESEARCH EXPERTISE

Experienced partners across the nation support users of the network to improve the rigor of their research

With built-in national collaboration, the PCORnet infrastructure supports a learning health system that helps researchers generate answers to advance health outcomes. [PCORnet® Clinical Research Networks \(CRNs\)](#) include the nation's leading clinical researchers whose collective knowledge and experiences can empower and support you throughout all phases of your study. Research experts across the network and in the [Coordinating Center for PCORnet®](#) can help you implement contracts, trial and data use agreements, and single IRB processes.

The PCORnet® Front Door team can help you identify sites across the PCORnet® CRNs through a [Network Collaborator Request](#) or you may partner with sites you select through your own connections, including sites that are not participating in PCORnet.

[PCORnet Tools for Study Startup](#), like the [PCORnet® Data Sharing Agreement](#) and the [Clinical Research Collaboration Agreement](#), can uniquely position you to conduct patient-centered studies more efficiently by addressing some of the most time-consuming, costly, and difficult aspects of study start-up.



Overview of Case Studies

The table below provides general information about each study included in this module. This is a small sample of the wide range of [research activities supported by the PCORnet infrastructure](#). These examples include some of the largest clinical research studies conducted in the U.S. for specific populations or conditions.

STUDY NAME	DESIGN	POPULATION	THERAPEUTIC AREA	FUNDER
Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-Term Effectiveness (ADAPTABLE)	Intervention Trial	15,076 adults aged 18+	Cardiovascular	PCORI
Blood Pressure (BP) Control Laboratory	Retrospective Observational Study & Intervention Trials	Observational study: 1,737,995 adults aged 18 to 85 Intervention trials: 24 clinics; 2,101 adults aged 18+	Cardiovascular	PCORI
Comparing Two Ways to Promote Healthy Weight Gain and Prevent Obesity in Early Childhood (Greenlight Plus)	Intervention Trial	900 English- and Spanish-speaking parent-infant pairs	Metabolic Disorders	PCORI
Medications and Weight Gain in PCORnet: The MedWeight Study	Prospective Observational Study	Separate analyses include 52,309 to 1,074,314 adults aged 20 to 84 and 74,005 children aged 10 to 19 years	Metabolic Disorders	NIH
Neuroendocrine Tumors – Patient Reported Outcomes (NET-PRO)	Prospective Observational Study	2,539 adults aged 18+	Oncology; Rare Diseases	PCORI
Pediatric KIDney Stone (PKIDS) Care Improvement Network	Prospective Observational Study	1,290 youth aged 8 to 21 years	Nephrology	PCORI
Pragmatic Evaluation of Events and Benefits of Lipid-lowering in Older Adults (PREVENTABLE)	Intervention Trial	Up to 20,000 older adults aged 75+	Cardiovascular	NIH
Provider-Targeted Behavioral Interventions to Prevent Unsafe Opioid Prescribing for Acute Non-Cancer Pain in Primary Care	Intervention Trial	22,616 adults aged 18+	Opioid use and pain	PCORI

Case Study Details

Learn more about each study's goals, design, results, and how the research teams used the PCORnet infrastructure to successfully conduct their studies.

Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-Term Effectiveness (ADAPTABLE) – Intervention Trial





[ADAPTABLE](#) was the first PCORnet® Study to be conducted as an intervention trial and is the largest study to date to look at the appropriate aspirin dose for patients with heart disease.

Research Questions

- Which dose of aspirin—81 mg or 325 mg—offers the right balance of preventing problems from heart disease while limiting the risk of bleeding from taking the medicine?
- Can PCORnet be used to find the answer using a clinical trial model wherein patients are drivers of engagement?

PCORnet® Study Results

The 81 mg and 325 mg doses of aspirin did not differ in safety and effectiveness when used to prevent heart-related health problems.

-  Study results were published in the [New England Journal of Medicine](#) and the study was named a Top 10 Clinical Research Achievement for 2022 by the [Clinical Research Forum](#).
-  [Read the final research report.](#)

How the Research Team Used the Power of PCORnet®



PCORnet® Common Data Model

- Ran a cohort identification query (computable phenotype) to identify potential participants and enrolled **15,076 participants** in **38 months**
- Ran a query to obtain participants' baseline clinical characteristics and medical history, reducing the study burden on sites and participants
- Determined nonfatal endpoints using standardized EHR data from across 40 sites and a health plan as the primary source
- Linked EHR data to supplemental data sources—including patient-reported outcomes, private health plans, and Medicare claims—to assess study end points



An Engaged, Research-Ready Community

Patient and clinician engagement was a priority throughout all phases of ADAPTABLE.

- **Nine patient partners**

- Served on study leadership committees
- Advised on the study design, the consent form, and recruitment efforts
- Helped develop and disseminate study information to participants

- **Clinical champions**

- Raised awareness about the importance of the study
- Helped tailor recruitment efforts to their site's processes and clinician preferences
- Provided training and administrative support



Read ADAPTABLE's [Evaluation of Stakeholder Engagement](#) (p.19-31) to learn more.



Research Expertise

- Partnered with a health plan and **40 sites** across **9 PCORnet® CRNs** to enroll **15,076 participants** with heart disease
- Developed and distributed a guidance document to proactively address IRB concerns about eConsent and avoid delays in review processes



Blood Pressure (BP) Control Laboratory – Retrospective Observational Study & Intervention Trials

The [BP Control Lab](#) research team conducted three studies:



BP Track

BP Track, a retrospective observational study, established a BP control surveillance system to conduct large, patient-centered research studies.



BP MAP

BP MAP, a cluster randomized trial, compared the effectiveness of two versions of a clinic-level program to improve the quality of BP care.



BP Home

BP Home, a decentralized randomized controlled trial, compared the effectiveness of home BP monitoring with and without a smartphone app.

Research Questions

- How well are clinics and patients controlling BP?
- Would new programs or technologies help improve BP control?

PCORnet® Study Results

The research team found

- Inconsistent BP control metrics across health systems, racial/ethnic disparities in BP control (especially among Black patients), and significant opportunities to improve the quality of care for patients with hypertension (BP Track)
- Coaching for a clinic-level quality improvement program did not improve BP control more than the program without coaching (BP MAP)
- Reductions in BP were the same for participants with high BP who used home BP monitoring with and without a smartphone app (BP Home)



The development of the novel platform was featured in [Circulation: Cardiovascular and Quality Outcomes](#).



Results from BP Track were published in the [Journal of the American Heart Association](#) and results from BP Home were featured in [JAMA Internal Medicine](#).



[Read the final research report.](#)

How the Research Team Used the Power of PCORnet®



PCORnet® Common Data Model

- **BP Track:** Standardized BP control metrics for **1,737,995 patients** and ran queries across **25 health systems** to measure BP control outcomes
- **BP MAP:** Used BP Track metrics to compare the effectiveness of two versions of a clinic-level quality improvement program at **24 clinics** across **9 health systems**
- **BP Home:**
 - Ran eligibility screening queries across sites
 - Assessed baseline data including comorbidities, smoking, and medication use
 - Analyzed BP outcomes of **2,101 participants** with uncontrolled BP



Engaged, Research-Ready Community

The BP Control Laboratory was developed in partnership with the American Heart Association (AHA), the American Medical Association (AMA), researchers and patients in the PCORnet Cardiovascular Health Collaborative Research Group, the Heart Research Alliance, the Coordinating Center for PCORnet® and a Patient Advisory Board.

The **Patient Advisory Board**

- Helped design the study and a web portal for study information and consent
- Advised the research team on all decisions that affected the participant experience
- Reviewed all patient-facing materials



Research Expertise

- Partnered with **25 health systems** across **7 PCORnet® CRNs** to analyze data from **1,737,995 patients** with hypertension
 - Utilized [PCORnet Tools for Study Startup](#) to streamline processes for running queries and obtaining data from each site
- Leveraged network connections to establish a reusable, national BP control surveillance platform to
 - Conduct future patient-centered health research
 - Reduce burden on patients and investigators
 - Streamline evidence generation around new programs or technologies to improve BP control

Comparing Two Ways to Promote Healthy Weight Gain and Prevent Obesity in Early Childhood (Greenlight Plus) – Intervention Trial

The [Greenlight Plus](#) randomized controlled trial compared strategies to promote healthy weight gain for children during their first two years of life.

Research Questions

- Does text messaging in addition to clinic-based health behavior counseling improve healthy weight trajectories, or growth patterns, compared to health behavior counseling alone?
- How do the digital and counseling-only interventions compare in promoting healthy weight gain for different groups based on language, race, ethnicity, and health literacy?

PCORnet® Study Results

The digital intervention group showed a significant reduction in early obesity markers compared to the counseling-only group. Specifically, the children who received the digital intervention achieved:

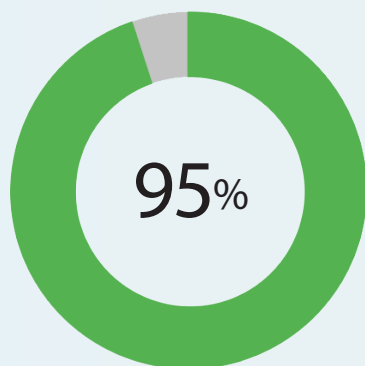
- Lower average weight-for-length trajectory
- 41% lower obesity rate (7.4% vs. 12.7% in the counseling-only group)

The intervention was effective across a racially and ethnically diverse population that included participants who had a higher risk for childhood obesity.

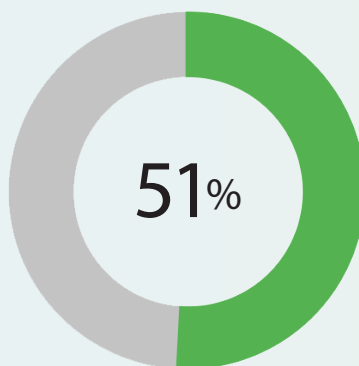
 Study results were published in [JAMA](#).

 [Read the final research report.](#)

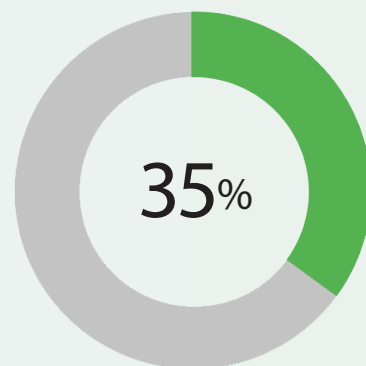
Parents in the Greenlight Study are:



Mothers



Not born in the U.S.



Spanish primary language

How the Research Team Used the Power of PCORnet®



PCORnet® Common Data Model

The Greenlight Plus research team used the PCORnet® CDM to ensure the generalizability of study findings by comparing baseline data from **900 parent-infant pairs** enrolled in the study to the general clinic population across **6 U.S. medical centers**.



Engaged, Research-Ready Community

The Greenlight Plus **Stakeholder Advisory Board**, including parents, medical professionals, language interpreters, and clinic staff from each participating site:

- Informed the design, implementation, evaluation, and dissemination of the study
- Helped develop study booklets and health information text messages
- Advised on health communication training for all primary care providers participating in the study



Research Expertise

The Greenlight Plus research team partnered with **6 primary care clinics** across **3 PCORnet® CRNs** to enroll **900 parent-infant pairs**.



Medications and Weight Gain in PCORnet: The MedWeight Study – Prospective Observational Study

The [MedWeight Study](#) is the most comprehensive study to date of how the long-term use of commonly prescribed medications affects weight gain, which is an outcome that matters to patients and a common reason for medication discontinuation. The research team is examining the electronic health records (EHRs) of children and adults for up to 2 years after they started treatment with a common medication to compare how different medications affect different people over time.

The results of the study available so far provide important information for patients and their health care providers to make better-informed decisions about medications.

Research Question

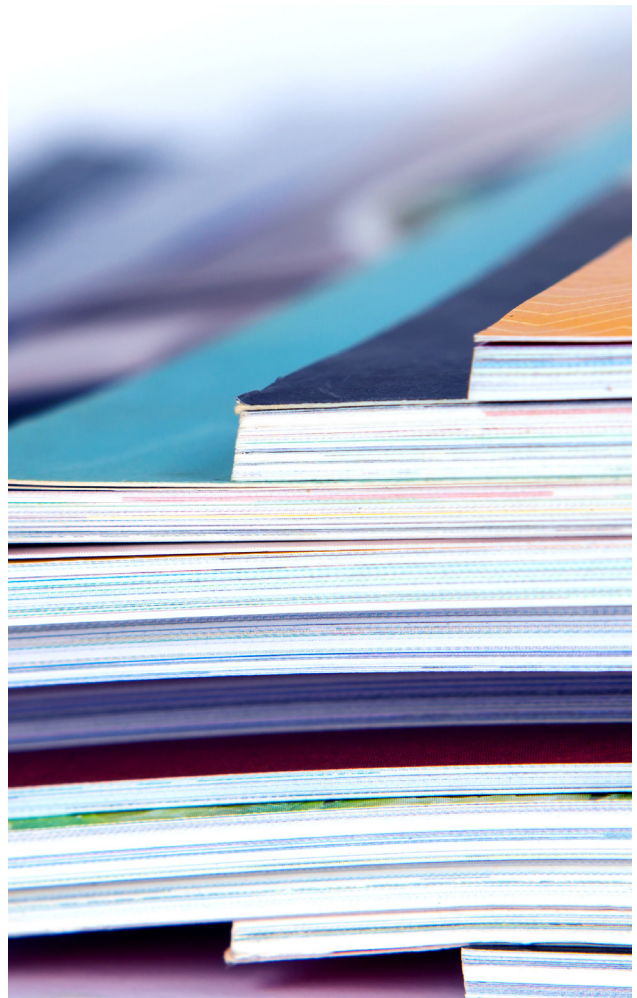
How do five classes of commonly prescribed medications influence weight, risk for diabetes, and cholesterol over time?

PCORnet® Study Results



Results from the study's analysis of

- **Anticonvulsant mood stabilizers** and risk of type 2 diabetes in children and adults were published in [JAMA Network Open](#).
- **Antiseizure medications** and weight change in adults were published in [Obesity](#) and in children were published in the [Journal of the American Academy of Child and Adolescent Psychiatry](#).
- **Antidepressants** and weight change in adults were published in the [Annals of Internal Medicine](#).
- **Antihypertensives** and weight change in adults were published in the [Journal of General Internal Medicine](#).
- Trends in the prescription of **antihypertensives** after the 2017 change in clinical practice guidelines for hypertension were published in the [Journal of the American Heart Association](#).



How the Research Team Used the Power of PCORnet®



PCORnet® Common Data Model

- Used a target trial emulation approach and data from 2010 to 2019 across **8 health systems** to compare weight change for
 - Six common antiseizure medications in 52,309 adults aged 20 to 64 years
 - Eight first-line antidepressants in 183,118 adults aged 20 to 80 years
 - Five commonly prescribed antidepressants in 67,039 children aged 5 to 19.5 years
 - Seven antihypertensives in 141,260 adults aged 20 to 80 years
- Queried standardized EHR data from **1,074,314 adults** aged 20 to 84 years to examine trends in prescriptions for medications to treat high blood pressure after the 2017 change in clinical practice guidelines for hypertension.



Engaged, Research-Ready Community

- **Patient partners** from previous research in obesity advocated for the MedWeight Study.
- Patient partners from each participating PCORnet® CRN serve on the study leadership team, co-authored manuscripts, and have been engaged in decision making throughout all phases of the project.
- Patient partners are actively involved in planning dissemination to make sure the results of the study can help patients and their health care providers make better-informed decisions when choosing medications.



Research Expertise

- Partnered with **15 sites** across **3 PCORnet® CRNs** to conduct multiple analyses including children and adults
- Leveraged the curation and analyses of data from prior observational PCORnet® Studies to accelerate the MedWeight Study
- Utilized the PCORnet® Data Sharing Agreement to facilitate data queries and the PCORnet® CDM to analyze data across sites

Neuroendocrine Tumors – Patient Reported Outcomes (NET-PRO) – Prospective Observational Study



[NET-PRO](#) is the largest ever prospective cohort study to date of patients in the U.S. with neuroendocrine tumors (NET). This comparative clinical effectiveness research project aims to use patient-reported outcomes (PROs) in combination with clinical data to identify the most effective therapies for neuroendocrine tumors and the best order of treatments to reduce negative side effects, improve health-related quality of life outcomes, and increase survival.

The patient-centered design of this study and the NET-PRO patient health record system (PHR) serve as a model for future research on rare conditions.

Research Questions

Which care options work best, for whom, and under which circumstances to improve symptom management, treatment outcomes, and quality of life among patients with neuroendocrine tumors?

The NET-PRO study will examine PRO and EHR data to learn more about the

- Effects of common treatment combinations on disease symptoms and quality of life
- Best order of treatments to improve patient outcomes and survival
- Impact of patient traits and tumor characteristics on treatment choice and survival

PCORnet® Study Results

The research team and patient partners co-developed surveys to collect PROs and co-designed a PHR system for patients with neuroendocrine tumors. Participants can use the NET-PRO PHR system to learn more about their condition and track symptoms. These features and personalized data visualizations help patients monitor their health over time, facilitating shared decision-making with their health care providers. The system also serves as the study portal for consent and enrollment, enabling longitudinal clinical research on neuroendocrine tumors.

The study is expected to be completed in 2027. Results will be provided on the [NET-PRO PCORnet® Study webpage](#), and a final research report will be available on the [PCORI project webpage](#).

In an article in [Cancer](#), the research team shares lessons learned and describes how the PCORnet infrastructure can support research on rare and common cancers.



How the Research Team Used the Power of PCORnet®



PCORnet® Common Data Model

To identify potential participants with neuroendocrine tumors, the research team developed and validated **3 computable phenotypes** to implement across **14 sites** participating in PCORnet.

As the study progresses, the research team will use the PCORnet® CDM to

- Link data from PROs to clinical data from chart reviews and EHRs to build a comprehensive dataset and assess study outcomes
- Create a framework to determine disease progression from real-world EHR data



Engaged, Research-Ready Community

Patients with neuroendocrine tumors, experienced clinicians, and **4 national patient advocacy organizations** partnered with the research team to co-design and conduct the NET-PRO study, ensuring that study questions, methods, and outputs are patient-centered, clinically relevant, and meaningful to the NET community.

- Patient partners collaborated in the development and refinement of PRO surveys and study materials.
- Patients were engaged throughout the design of the NET-PRO PHR system through focus groups, surveys, and usability testing.
- Dissemination activities are conducted in collaboration with patients and other community partners, including co-authored manuscripts and presentations, development of lay summaries, webinars, newsletters, and social media outreach, and return of study results to participants via the NET-PRO PHR portal.



In an article in [*JMIR Human Factors*](#), the research team shared their process for working with patient partners to design the NET-PRO PHR system.



Research Expertise

- Partnered with **14 sites** across **4 PCORnet® CRNs** to enroll more than **2,400 participants** in multiple regions of the United States
- Leveraged the PCORnet infrastructure to assess patient overlap and the PCORnet® CDM to analyze data across sites

Pediatric KIDney Stone (PKIDS) Care Improvement Network – Prospective Observational Study



The [PKIDS prospective observational study](#) looked at three different surgeries to see how well they cleared kidney stones and how patients felt after each type of surgery.

Research Question

What are the differences in kidney stone clearance and the lived experiences of youth following ureteroscopy, shock wave lithotripsy, and percutaneous nephrolithotomy for the removal of kidney and ureteral stones?

PCORnet® Study Results

Ureteroscopy and shockwave lithotripsy did not differ in stone clearance. Patients reported better experiences with shockwave lithotripsy than ureteroscopy one week after surgery. For patients with large kidney stones, percutaneous nephrolithotomy was more effective than ureteroscopy, and patients reported a better experience.

-  Research results were published as two articles in *JAMA Network Open*.
 - [Ureteroscopy vs Shockwave Lithotripsy](#)
 - [Percutaneous Nephrolithotomy vs Ureteroscopy](#)
-  [Read the final research report.](#)



The PKIDS study results were presented at the American Urological Association's annual meeting as "a paradigm-shifting, practice-changing plenary session." The study was also included as supporting evidence in the association's guidelines for the surgical management of patients with kidney and/or ureteral stones.

How the Research Team Used the Power of PCORnet®



PCORnet® Common Data Model

The PKIDS research team used the PCORnet® CDM to assess the generalizability of study findings by comparing the demographics and types of surgery received by **1,290 patients** aged 8 to 21 years who had kidney stone surgery.

PEDSnet, a pediatric PCORnet® CRN, created a longitudinal data resource that dates back to 2009, cutting across all pediatric diseases, and including all pediatric specialties.



Engaged, Research-Ready Community

The PKIDS research team met with a PCORnet engagement team member who provided insight into ways to deepen their engagement with patients, caregivers, and patient advocates. Throughout the study, the research team collaborated with an advisory council that included physicians specializing in urology, nephrology, and radiology; patients and caregivers; and health insurer and industry representatives.

PKIDS Patient and Family Partners were included as members of the research team and

- Helped plan the study, along with surgeons and health system representatives
- Informed decisions on the timing and choice of PROs, recruitment and retention efforts, and reporting of results
- Worked with PKIDS investigators to develop the Questionnaire for Urinary Issues—Kidney Stone Surgery (QUIKSS), a novel tool to measure patients’ symptoms after kidney stone surgery, including some symptoms (like hematuria) that aren’t captured in other validated urinary symptom scores



Research Expertise

The PKIDS research team partnered with **20 sites** across **5 PCORnet® CRNs** to enroll **1,290 participants** aged 8 to 21 years with kidney stones.

Pragmatic Evaluation of Events and Benefits of Lipid-lowering in Older Adults (PREVENTABLE) – Intervention Trial





[PREVENTABLE](#), the largest trial to date in people age 75+, has enrolled over 10,000 participants with a goal to include up to 20,000.

Research Question

Can a statin help older adults live well for longer by preventing dementia, disability, or heart disease, while not increasing risks of adverse health outcomes?

PCORnet® Study Results

This study is expected to last until 2031.

-  Learn more on the [study webpage](#).
-  View the [study design and rationale](#) published in the *Journal of the American Geriatrics Society*.

How the Research Team Used the Power of PCORnet®



PCORnet® Common Data Model

- Standardizing and linking existing data from EHRs, Medicare, and the National Death Index, plus data from phone surveys
- Running bi-annual queries of data to assess study outcomes



Engaged, Research-Ready Community

The **Participant Advisory Group**, called the PREVENTERS, includes community members who are 75 and older from study sites in urban and rural locations. The PREVENTERS

- Provide their input on study activities that involve participants
- Help inform recruitment strategies
- Review participant materials

A participant advisor and representatives from the Alzheimer’s Association serve on the PREVENTABLE Steering Committee.



Research Expertise

So far, **100 sites** across the national Veterans Affairs network and **6 PCORnet® CRNs** have enrolled more than **10,000 participants** age 75 and older, a population that can be challenging to recruit for clinical research studies.

Provider-Targeted Behavioral Interventions to Prevent Unsafe Opioid Prescribing for Acute Non-Cancer Pain in Primary Care – Intervention Trial

This [randomized controlled trial to prevent unsafe opioid prescribing](#) included **22,616 adults** diagnosed with acute non-cancer pain who had not used opioids before and **525 clinicians** who saw at least one of those patients during the study period.

Research Question

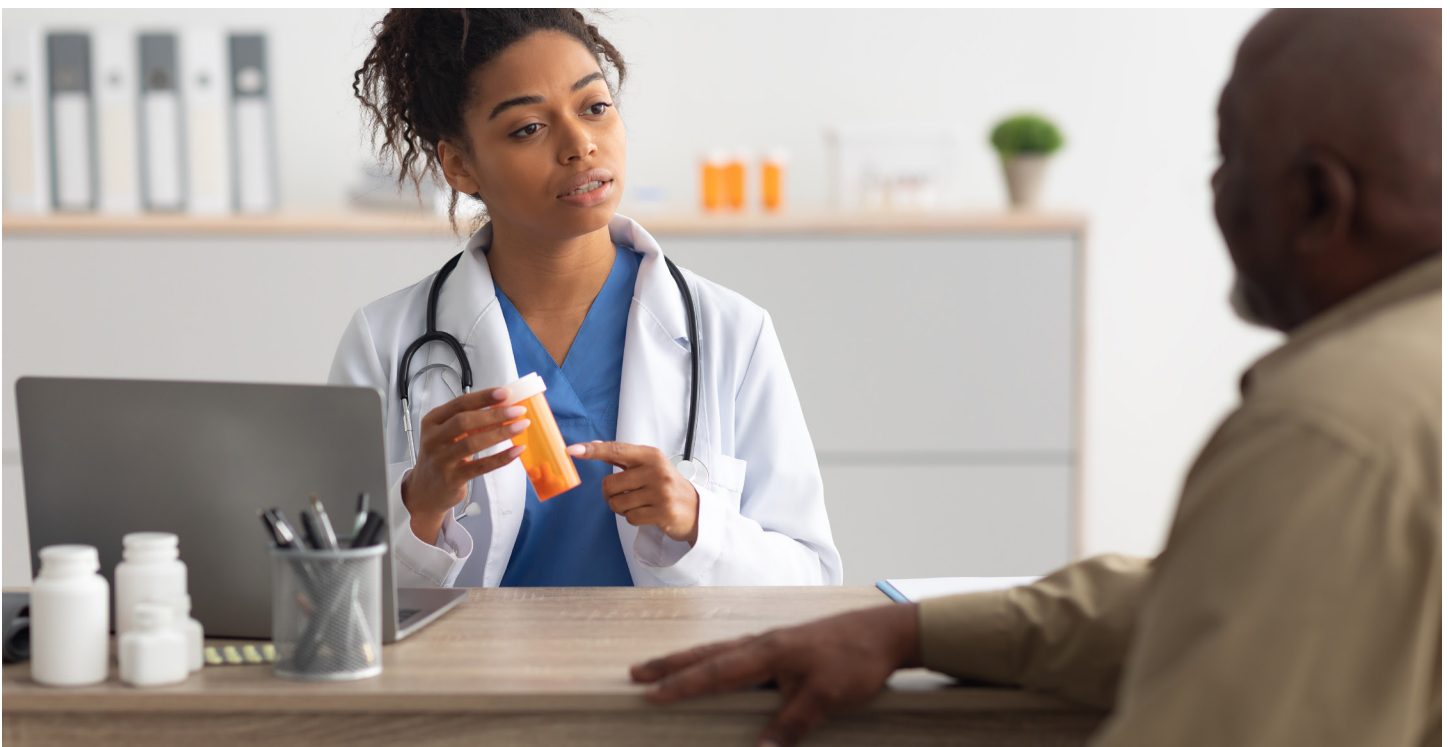
What is the comparative effectiveness of four different strategies to help primary care doctors increase safe opioid prescribing practices and improve patients' quality of life while reducing harm?

PCORnet® Study Results

Primary care providers who both entered a reason for prescribing an opioid and received personalized monthly emails with their prescribing rate had lower rates of prescribing opioids than providers who only received the clinical guideline.

 Study results were published in [Health Services Research and Managerial Epidemiology](#) and [JAMA Health Forum](#).

 [Read the final research report.](#)



How the Research Team Used the Power of PCORnet®



PCORnet® Common Data Model

- Queried standardized EHR data from **22,616 participants** at **48 clinics** across **3 health systems** to
 - Collect patient characteristics, health conditions, outpatient and inpatient visits, and medications
 - Track patient outcomes



Engaged, Research-Ready Community

The study's **Stakeholder Advisory Committee** included patients with a history of acute and chronic pain and opioid use, clinicians, representatives from an advocacy organization and a health system, and other subject matter experts.

The Advisory Committee

- Provided feedback on the EHR and email interventions before implementation
- Helped develop the script for qualitative interviews with clinicians in the study
- Informed the dissemination and implementation plan
- Identified partner organizations and opportunities for implementation and outreach beyond traditional methods



Research Expertise

- Partnered with **48 sites** in **2 PCORnet® CRNs** to enroll **22,616 adults** who had muscle pain or headaches
- Consulted with patients, primary care providers, health plan and medical center administrators, health information technology experts, policy representatives, and others to develop the project proposal

Get Started with PCORnet®



Looking for more inspiration? Check out the [PCORnet® Studies page](#) and [Module 1](#) to learn more about the wide range of research activities the PCORnet infrastructure can support.

All the research teams included in this module started with the same step: reaching out. When you are ready to get started, contact the [PCORnet® Front Door](#). Our team of experts will be happy to guide you in accessing PCORnet resources to achieve your study goals.

While it is best to contact the PCORnet® Front Door early in your study planning to make the most of PCORnet resources, such as assistance with community engagement, the PCORnet® Front Door team works with studies at any stage.

