

Pragmatic Clinical Studies

Pragmatic clinical studies aim to provide research results that better reflect everyday health care and a wider range of patients. Traditionally, clinical studies test how well treatments or other care approaches work under ideal conditions with carefully selected patients. They are often conducted in specialized research centers. But everyday health care rarely takes place in such situations and settings. And many people differ from those in carefully selected study groups.

Pragmatic studies seek to produce results that can apply to a greater variety of patients and care situations. They are designed to take place during routine care in real-life practice settings, such as a typical hospital or clinic. They tend to include a broader range of patients with different circumstances and needs.

What Sorts of Pragmatic Clinical Studies Does PCORI Fund?

We fund comparative pragmatic studies designed to determine which of two or more healthcare options work best for different kinds of patients, given their preferences and circumstances. Studies we fund must involve clinician, patient, and other stakeholder groups as partners.

We are especially interested in topics that patients and other stakeholders prioritize as of greatest interest and concern. We also are interested in topics that the Institute of Medicine and the Agency for Healthcare Research and Quality have prioritized.

As of December 2018, PCORI has awarded

\$494 MILLION TO FUND **43**

pragmatic clinical studies.

CONDITIONS

Awarded projects are studying include:



CANCER



CARDIOVASCULAR
DISEASES



DIGESTIVE SYSTEM
DISEASES



INFECTIOUS
DISEASE



MENTAL/
BEHAVIORAL HEALTH



MULTIPLE/COMORBID
CHRONIC CONDITIONS



MUSCULAR/
SKELETAL DISORDERS



RARE DISEASES



RESPIRATORY
DISEASES



TRAUMA/INJURY

PCORI's Pragmatic Clinical Study Awards

Our Board of Governors has approved dozens of these studies to date. These large, patient-centered comparative clinical effectiveness research projects seek to answer critical questions on priority topics, including:

- Whether **breast cancer screening** tailored to women's individual risks and preferences detects cancer and minimizes "false alarms" as well or better than routine annual screening.
—*Laura J. Esserman, MD, MBA; University of California, San Francisco.*
- The comparative effectiveness of active surveillance of patients diagnosed with **ductal carcinoma in situ (DCIS)** versus immediate treatment with surgery or radiation.
—*Shelley Hwang, MD, MPH; The Alliance for Clinical Trials In Oncology Foundation.*
- The comparative safety and effectiveness of using antibiotics versus surgery to treat patients with uncomplicated **appendicitis**.
—*David Reed Flum, MD, MPH; University of Washington.*
- Whether regional anesthesia in the spine or general anesthesia results in better outcomes and fewer complications among **older adults undergoing hip fracture surgery**.
—*Mark D. Neuman, MD, MS; University of Pennsylvania.*
- The comparative effectiveness of more intensive versus less intensive surveillance via CT scanning to accurately detect **lung cancer** while minimizing potential harms in patients with potentially cancerous growths detected on their lungs.
—*Michael K. Gould, MD, MS; Kaiser Foundation Research Institute.*
- How various **breast cancer screening** methods—digital mammography alone or with tomosynthesis—compare based on the density of women's breast tissue and whether preoperative MRI imaging enhances evaluation of an initial cancer.
—*Diana Miglioretti, PhD; University of California, Davis.*
- Whether adding the diabetes drug metformin to a healthy lifestyle intervention is more effective than the lifestyle intervention alone in reducing weight gain and metabolic problems associated with certain antipsychotic medications used by **youth with bipolar disorders**.
—*Melissa P. DelBello, MD, MS; University of Cincinnati.*
- Whether **children with moderate to severe Crohn's disease** have better outcomes taking a biological therapy that targets tumor necrosis factor (anti-TNF) alone or taking a combination of anti-TNF plus a low dose of the drug methotrexate.
—*Michael Kappelman, MD, MPH; The University of North Carolina at Chapel Hill.*
- The effectiveness of different approaches involving community health workers and tailored clinician education to help **adults with serious mental illness quit smoking**.
—*Eden Evins, MD, MPH; Massachusetts General Hospital.*
- The effectiveness of **proton beam therapy versus conventional photon radiation therapy** in treating breast cancer and minimizing collateral damage to healthy organs and tissue.
—*Justin Bekelman, MD; University of Pennsylvania.*
- The comparative effectiveness of routine daily use versus symptom-based use of an **asthma** medication for reducing symptom exacerbations in African American and Hispanic adults.
—*Elliot Israel, MD; Brigham and Women's Hospital.*
- The comparative effectiveness of two approaches to help people manage their **chronic migraines** and reduce the risk of medication overuse.
—*Todd Schwedt, MD, MS; Mayo Clinic Arizona.*
- Whether a comprehensive package of transitional care and in-home support services is more effective than usual care at improving **stroke survivors' functional abilities** and preventing hospital readmissions.
—*Pamela Duncan, PhD, PT; Wake Forest University Health Sciences.*
- The comparative safety and effectiveness of three blood-thinning drugs commonly used to prevent potentially deadly blood clots in patients undergoing **hip and knee replacement**.
—*Vincent Domenic Pellegrini, MD; Medical University of South Carolina.*
- Whether use of a standing-order entry system advising physicians when to prescribe an infection prevention medication to patients with **breast, colorectal, or lung cancer** receiving chemotherapy reduces over- and underuse of this medication and reduces rates of potentially serious infections.
—*Scott D. Ramsey, MD, PhD; Fred Hutchinson Cancer Research Center.*
- The ability of an exercise coaching program versus usual care to prevent further injuries and improve health for **older adults who have experienced a low-impact fracture** as a result of a fall.
—*Christopher Sciamanna, MD, MPH; Pennsylvania State University Hershey Medical Center.*
- The comparative safety and effectiveness of blood-thinning drugs commonly used to prevent potentially deadly **blood clots in patients who have suffered broken bones**.
—*Robert O'Toole, MD, TRD; University of Maryland, Baltimore.*
- Whether increased integration of behavioral health and primary care services or the co-location of providers improve health and mental health outcomes for **patients with chronic conditions**.
—*Benjamin Littenberg, MD; University of Vermont and State Agricultural College.*
- Which intervention is more effective at preventing acute **low back pain** from progressing to chronic low back pain among at-risk patients: primary care based on clinical guidelines or primary care plus psychologically informed physical therapy.
—*Anthony Delitto, PhD, PT; University of Pittsburgh.*
- Which of two approaches involving telemedicine works best to manage **post traumatic stress disorder and bipolar disorder** in patients **in rural primary care settings**.
—*John C. Fortney, PhD; University of Washington.*

For more information about our Pragmatic Clinical Studies initiative and other funding opportunities, visit www.pcori.org/funding-opportunities, or contact us at info@pcori.org.

As with all PCORI projects, these studies were approved by our Board subject to a business and programmatic review by PCORI staff and completion of a final research contract.