

THE FIRST PCORnet® STUDY

Which Aspirin Dose is Best to Protect Patients with Heart Disease?

Every day in doctors' offices across the country, more patients joins the ranks of the estimated 15.4 million Americans diagnosed with heart disease. Many of them will be told at some point to start taking a daily dose of aspirin to prevent a heart attack or stroke, a prescription offered for the past 40 years. And yet, although we know this most common of drugs is effective for this purpose, research has yet to definitively determine the dose that works best for these patients while minimizing potentially serious side effects, such as internal bleeding. It's time we figured this out.

THE QUESTION:

Clinicians often prescribe aspirin to prevent strokes and heart attacks in people living with heart disease. Research has yet to determine the best dose to use, since aspirin can cause serious side effects—like bleeding—in some people.

To answer that question, PCORI has announced a three-year, \$14 million clinical trial comparing the benefits and risk for side effects of two commonly used doses of aspirin—low-dose 81 mg (“baby aspirin”) and regular strength 325 mg—in preventing heart attacks and strokes in people with heart disease.

This is important on its own, but it's especially exciting because it's the first study to be conducted through PCORnet, the National Patient-Centered Clinical Research Network. This collaborative collection of individual clinical research networks seeks to harness the power of data to conduct research that will answer important healthcare questions—like the one about aspirin—more efficiently and quickly, at lower cost, than would be possible otherwise.

The study, called ADAPTABLE (Aspirin Dosing: A Patient-centric Trial Assessing Benefits and Long-Term Effectiveness), aims to enroll and follow as many as 20,000 patients with heart disease quickly and efficiently using PCORnet's resources.

The trial will be led by researchers at Duke University and involve researchers, clinicians and patients seven PCORnet partner networks. Six of them are Clinical Data Research Networks (CDRNs), based in large health systems, and one is a Patient-Powered Research Network (PPRN), operated by a patient-led group. Patients, clinicians, and other healthcare stakeholders are part of the research team and will help to design and conduct the study and be involved at every stage.

The ADAPTABLE trial will compare two common aspirin dosages.



81 mg

The study will be large and will involve patients across the U.S.

20,000
patients living with heart disease will use a daily aspirin dosage of either 325 mg or 81 mg

ADAPTABLE will use PCORnet to conduct the study and disseminate results. Patients will be partners at every stage of the trial, which will collect data using tools with state-of-the-art security.

Patients who have heart disease and are at high risk of having a heart attack or stroke will be randomly assigned to use low- or regular-strength aspirin and followed up to 30 months. Researchers will look at benefits and side effects not just overall, but also by gender, age, ethnicity, and race, as well as in patients with medical conditions in addition to heart disease, such as diabetes. It's a far cry from traditional studies that assess what works for the “average” patient.

In addition, the study will be conducted in a variety of clinical settings. This also makes ADAPTABLE different from traditional clinical trial, which often take place in specialized centers and require a great deal of time, money, and effort to conduct.

As the first study to be conducted through PCORnet, ADAPTABLE will give us a sense as to whether the emerging research network has the capacity to fulfill its substantial promise. That researchers would test this potentially transformative research resource by studying one of the oldest drugs around may seem a bit surprising. But the question they seek to answer is extremely important.

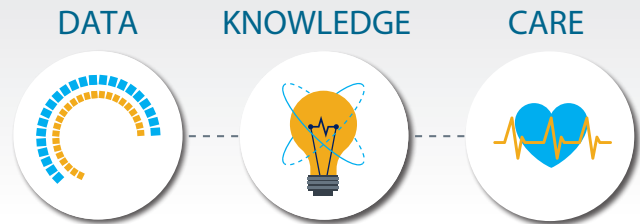
Heart disease causes one in four deaths in the U.S., more than 800,000 in 2014 alone, making it this country's leading killer. It is a disease that places enormous burdens not only on patients and their families but on the nation and its healthcare system as a whole. That alone is reason enough to seek a clear answer to the question of how to best use a common drug to prevent heart attacks and strokes in these patients and makes it a fitting demonstration study for PCORnet.

We hope that what we learn from the ADAPTABLE study will improve care and outcomes for patients with heart disease. But we're also excited by the prospect that this study will be a major step forward in the effort to leverage data to conduct the kind of research that can help us answer many other health and healthcare questions that patients—and their clinicians—face every day.

Results of this study will help patients and their caregivers answer questions like:

- How much aspirin should I take each day to reduce my risk of another heart attack or stroke?
- Do the benefits of taking aspirin every day differ based on the dose?
- Do the risks differ based on the dose?
- Based on my health, age, and other circumstances, what's the best dose to protect my health?

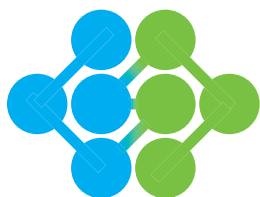
This study will use the power of PCORnet to seek answers to these questions and improve patient care and outcomes.



Identifying the aspirin dose that works best could prevent as many as

[88,000]

deaths per year worldwide.



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The National Patient-Centered
Clinical Research Network

PCORnet is an initiative of the Patient-Centered Outcomes Research Institute.