PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE
RESEARCH SUMMARY

PROJECT INFORMATION

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Understanding and Improving Informed Consent for Clinical Trials during Health Emergencies

Principal investigator
Neal Dickert, MD, PhD

Organization
Emory University

What was the project about?

Some research studies, called clinical trials, test treatments to see if they are safe and effective for patients. Before patients enroll in a trial, researchers ask patients for informed consent. In informed consent, a doctor or researcher explains what the trial is about and the benefits and risks of taking part. Patients then choose whether to enroll in the trial. If a patient is too sick to decide, a surrogate, such as a family member or friend, can decide on the patient's behalf.

Trials that test treatments in health emergencies, such as heart attack or stroke, may need a different informed consent process. Emergency situations can be stressful, and patients may have little time to learn about the trial.

In this study, the research team worked with patients and surrogates who had experience with informed consent for trials in health emergencies. They created a new informed consent process to use for trials about stroke and heart attack.

What did the research team do?

The study had two parts. In part one, 176 patients and surrogates took a survey about their experience enrolling in a trial; 48 percent had enrolled in a stroke trial and 52 percent in a heart attack trial. Of these, 64 percent were white, 26 percent were black, and 5 percent were Asian. The average age was 59, and 57 percent were men. The team also interviewed 27 patients and surrogates in depth, to learn more about their experiences.

In part two, the research team created the new process for getting informed consent. A group of five patients from part one, a patient panel, research ethics experts, and trial experts provided feedback.

What were the results?

Most patients taking the survey reported feeling respected during their informed consent process. But patients and surrogates had trouble recalling details about the trial they took part in. For example, 19 percent of patients in stroke trials and 44 percent of patients in heart attack trials didn't recall any trial details.

Interviews showed that the informed consent process should

- Avoid pressuring people to take part in the trial
- Clearly describe the trial's benefits and risks and what to expect
- Communicate with people after they enroll in the trial

The new informed consent process included

- Shorter consent forms with focused information about the trial, including risks and benefits that were important to patients

- Information sheets that people could look at during the trial
- A chance for people to ask questions about the trial after they enroll

What were the limits of the project?

On average, people took the survey about past experiences two years after their trial, which may have led to trouble recalling details. The research team and the advisory board creating the new process may not represent the backgrounds of all patients who have health emergencies.

Future studies could test the new informed consent process in clinical trials about emergency care.

How can people use the results?

Researchers can use the results when planning ways to get informed consent from patients enrolling in trials during health emergencies.

To learn more about this project, visit www.pcori.org/Dickert295.