

## \$1.6 million study of appendicitis treatment could help children avoid surgery

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In the first study of its kind in the United States, researchers at Nationwide Children's Hospital will examine the effectiveness of antibiotic therapy alone to treat appendicitis in children, research that could allow patients to avoid a surgery many may not need. The \$1.6 million project also will explore the impact that involving children and their parents in medical decision-making may have on a child's response to treatment.

Appendicitis, caused by a [bacterial infection](#) in the appendix, is the most common reason for emergency [abdominal surgery](#) in children, sending more than 80,000 young people to the [operating room](#) each year. In as many as half of those cases, the condition may have been treatable with antibiotics alone, according to Katherine J. Deans, MD, MHSc, and Peter C. Minneci, MD, MHSc, co-directors of the Center for [Surgical Outcomes](#) Research at Nationwide Children's and leaders of this new study, which is funded by the nonprofit [Patient-Centered Outcomes Research Institute \(PCORI\)](#).

"The idea that surgery is the only treatment for appendicitis goes back to 50 or 60 years ago when high-resolution imaging studies were unavailable for early diagnosis and antibiotics were less effective in treating intra-abdominal infections," Dr. Deans says. "Surgery was established as the mainstay of therapy for appendicitis because of the risk of death that could occur if an intra-abdominal infection was not adequately treated." That's not the case today, thanks to access to [ultrasound](#) and CT scans and a wide range of antibiotics, allowing

physicians to more accurately diagnose and treat appendicitis early.

The new research will build on findings from a small [pilot study](#) Drs. Deans and Minneci launched last year. Preliminary data suggest that, when caught early, appendicitis can be treated with antibiotics, making surgery unnecessary. The results are similar to those from a series of European studies performed in adults that have found that in most cases, appendicitis doesn't require surgery at all.

For their study, Drs. Deans and Minneci will conduct a randomized controlled trial of a novel application that involves engaging patients and families as critical decision makers in choosing the therapy that is best for them. [Medical decision](#)-making in pediatrics involves not just the medical care team and the patient, but the patient's parents and family as well, says Dr. Deans, who along with Dr. Minneci is a principal investigator in The Research Institute at Nationwide Children's and an assistant professor of surgery and pediatrics at The Ohio State University College of Medicine.

"I love this study because it gets to the heart of what is needed in medical care right now—engaging the patient, and in this case, the parents and caregivers, in making decisions that are right for the family's own personal values," Dr. Deans says.

For this project, researchers will work with two Columbus-based companies, Soul Theatre and Clutch Interactive, to design an iPad app with an interactive tool that patients and parents can use to learn more about the causes of appendicitis, treatment options and what to expect during and after each kind of treatment. The app will feature versions for kids and adults.

Children who come to the emergency room and are diagnosed with appendicitis will be invited to participate in the study with their parents.

Participants will be randomly assigned to one of two groups—both will discuss appendicitis and treatment options with a physician, but one group will also get the information via the app on an iPad provided to them.

Once participants have received all the information, they will either opt for surgery or a course of IV [antibiotics](#) alone. Patients who choose [antibiotic therapy](#) alone will be admitted to the hospital for at least 24 to 48 hours, so that physicians can monitor whether the drugs are working. If their condition hasn't improved, they will have surgery to remove the appendix. Participants will be followed until 18 years of age to ensure that appendicitis does not recur in the group that chose antibiotic therapy.

"The study represents a groundbreaking investigation that will help determine whether children with [appendicitis](#) can be safely treated without undergoing [surgery](#) and brings the patient and family into the decision process as partners with the surgeon," says Nationwide Children's Surgeon-in-Chief Lawrence Moss, MD. "This underscores Nationwide Children's Hospital's commitment to family-centered care of every child."

Authorized by Congress in 2010, PCORI funds research that will provide patients, their caregivers and clinicians with the evidence-based information needed to make better-informed health care decisions. Of the 400 proposals considered, only 51—just 12 percent—were selected. All proposals have been approved pending the completion of a business and programmatic review by PCORI staff and completion of a formal award contract.

"The PCORI award to Dr. Deans and Dr. Minneci is an extraordinary achievement, given the intense national competition," says John Barnard, MD, president of The Research Institute at Nationwide Children's.

"Their expertise in clinical and outcomes research is an unique asset for Nationwide Children's Hospital, especially in the current environment of health care reform."

Provided by Nationwide Children's Hospital

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