

Stakeholder involvement in clinical trial design leads to greater recruitment, retention

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By seeking the advice of patients, families and other stakeholders in designing a clinical trial investigating pediatric appendicitis, researchers at Nationwide Children's Hospital found a way to significantly increase the number of people recruited and retained in the trial.

Recruitment of patients increased by 30 percent after changes were made to the wording of the enrollment script, and retention of patients increased by 27 percent after an email/online option was offered for completing follow-up questionnaires, preferred times of contact were attained and reminder letters were sent out about the follow-ups.

The changes were made at the recommendation of a group of 20 individuals who are stakeholders on the research team, including children 7 to 17 years old, their families, physicians, nurses, patient educators and payers. The stakeholders have provided advice about all phases of an ongoing clinical trial on the use of an app called PAT (Patient Activation Tool) to help patients and their families and doctors make decisions concerning uncomplicated pediatric appendicitis.

After the stakeholders' recommended changes were adopted into the study, the study's enrollment rate increased from 65 percent to 95 percent and the retention rate increased from 58 percent to 85 percent.

"Honestly I didn't expect it to have such a large effect," said Katherine J. Deans, MD, who led the study published online in *JAMA Surgery* with Peter C. Minneci, MD. Drs. Deans and Minneci are co-directors of the

Center for Surgical Outcomes Research and principal investigators in the Center for Innovation in Pediatric Practice in The Research Institute at Nationwide Children's.

"This is our bias as researchers," explained Dr. Deans. "Often, we think we know best. We think we know how to do it the right way. We are trained to do it. We have degrees in doing it. We were told by this group of people to change wording and to then change the bend of the content. I didn't put a lot of stock in it right away. But it clearly had an effect. This is why we have our stakeholder group, so that we can incorporate their input into all phases of the study. In this situation, it was critical to the success of our project."

Typically, recruiting patients for clinical trials, particularly those involving surgery in the urgent care or emergency room, is challenging. Recruitment rates for pediatric clinical trials are usually under 50 percent, according to Dr. Deans.

"There are a lot of people who don't want to be part of research. There's another group of people who are afraid of research. They feel like they're going to be guinea pigs. So it's important to approach them in a way so that they understand why it's important and why the results would be important to them or to patients just like them," Dr. Minneci said.

Retaining those patients who do agree to enroll in a clinical trial is difficult as well because it can be time-consuming for patients and their families to fill out the often lengthy and highly detailed follow-up questionnaires. The families of patients treated for appendicitis typically are cured or feel better after treatment, so there may be little incentive to take the time to fill out the questionnaires.

"If they don't feel sick any more, people don't necessarily want to be bothered," Dr. Minneci said.

The resulting jump in recruitment and retention rates from this study underscores the value of involving [patients](#), families and other healthcare professionals when designing and performing [clinical trials](#).

"These are tangible statistics that show that this process of involving the stakeholders can improve the study," Dr. Minneci said.

Both researchers are also assistant professors of surgery and pediatrics in The Ohio State University College of Medicine.

More information: Minneci PC, Nacion KM, Lodwick DL, Cooper JN, Deans KJ. Improving Surgical Research by Involving Stakeholders. *JAMA Surgery*. 2016 Feb. [Epub ahead of print]

Provided by Nationwide Children's Hospital

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