RESEARCH LETTER

Improving Surgical Research by Involving Stakeholders

Enrolling patients in prospective surgical trials is difficult, especially in the urgent and/or emergent care setting. However, there is growing support for including patients, caregivers, and other health care stakeholders in all phases of research to assist with identifying and incorporating outcomes important to the public, developing strategies to improve enrollment and retention rates, and accelerating the dissemination and implementation of results.1-5 We report the effect of stakeholder involvement in an ongoing randomized clinical trial (RCT) (ClinicalTrials.gov, NCT02110485) of pediatric appendicitis.

Methods | A 20-member multidisciplinary stakeholder group has been engaged in all phases of the RCT described above, which is funded by the Patient-Centered Outcomes Research Institute and is investigating the effects of a patient activation tool in uncomplicated pediatric appendicitis. The stakeholder group began working with our research team at Nationwide Children's Hospital in Columbus, Ohio, in October 2012, and the RCT began enrolling patients on March 10, 2014. Patient activation involves providing families with the knowledge and skills they need to be willing, confident, and engaged participants in their child’s care.6 The patient activation tool is an interactive tablet-based application designed to improve shared decision making by educating and engaging families and helping them resolve decisional uncertainty. The stakeholder group consists of children aged 7 to 17 years and their families, community-based pediatricians, emergency medicine physicians, surgeons, nurses, patient educators, and payers. The stakeholders have participated in all phases of this project including trial design, intervention development, outcome selection, recruitment, and retention.

Collective stakeholder meetings occur semiannually, with additional quarterly email updates throughout the course of the project to discuss issues related to the current phase of the trial. Stakeholder suggestions are discussed to determine which can be reasonably implemented given financial, logistical, and ethical limitations. The 2 most recent meetings since the beginning of the trial have focused on approaches to enrollment and methods of retention. Several stakeholder recommendations have been implemented including changing the enrollment script, offering an online option via an emailed link (in lieu of a telephone interview) to complete follow-up questionnaires, asking for preferred times of contact, and mailing reminder letters about upcoming follow-up appointment. Enrollment and retention rates before and after the implementation of stakeholder recommendations were compared using χ² tests or Fisher exact tests as appropriate. The study was approved by the Nationwide Children's Hospital Institutional Review Board and written informed consent and assent for children 9 years of age and older was obtained from each participant and the participant’s parent or legal guardian.

Results | Participant enrollment and 30-day retention rates in the RCT of pediatric appendicitis improved significantly after the adoption of stakeholder recommendations. To improve enrollment, the enrollment script for the project was changed on the basis of stakeholder recommendations from stating that the RCT is investigating a tool designed to improve decision-making about appendicitis treatments to a script with a 2-part message. The first part states that the study was designed in conjunction with patients and families to improve the way in which the medical team communicates with families, and the second part explains to families that the study is testing a tool designed to improve both physician-patient communication and promote shared decision making about treatments for the patient’s appendicitis.

Following this change, enrollment in the RCT increased from 65% (22 of 34) to 95% (105 of 111 eligible participants enrolled; \( P < .001 \)). To improve retention, we began offering an online option via an emailed link for participants to complete follow-up questionnaires. This increased the rate of completed 30-day follow-up from 58% (14 of 24) to 85% (79 of 93) \( (P = .009, \text{ Table}) \) of participants enrolled for 30 days or longer. Further investigation revealed a significant increase in retention among participants who elected surgical therapy (7 of 17 vs 48 of 58; \( P = .002 \)) but not among those who elected medical management, as this subgroup already had a high reten-

<table>
<thead>
<tr>
<th>Stakeholder Recommendation</th>
<th>Surveys, No.</th>
<th>Complete</th>
<th>Incomplete</th>
<th>Completed, %</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Offer email/online option to complete follow up</td>
<td>Before implementation</td>
<td>14</td>
<td>10</td>
<td>58</td>
<td>.009</td>
</tr>
<tr>
<td></td>
<td>After implementation</td>
<td>79</td>
<td>14</td>
<td>85</td>
<td></td>
</tr>
<tr>
<td>Ask for preferred time of contact</td>
<td>Before implementation</td>
<td>53</td>
<td>17</td>
<td>76</td>
<td>.32</td>
</tr>
<tr>
<td></td>
<td>After implementation</td>
<td>40</td>
<td>7</td>
<td>85</td>
<td></td>
</tr>
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</table>
Discussion | The participation of a multidisciplinary stakeholder team provided unique perspectives that helped improve recruitment and retention rates in the RCT. Implementation of stakeholder recommendations on how to explain the purpose of the trial to eligible participants in the urgent emergency care setting significantly improved enrollment. The implementation of stakeholder recommendations for maximizing patient follow-up also significantly improved retention rates. We believe that our success in achieving these goals stems in part from involving stakeholders throughout the entirety of the project, building strong ongoing relationships, fostering open communication, and appreciating all opinions. This study demonstrates the potential value and effect of involving patients, families, and other health care stakeholders in the design and performance of surgical trials.

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Acquisition, analysis, or interpretation of data: Minneci, Nacion, Cooper.

Drafting of the manuscript: Minneci, Nacion, Cooper.

Critical revision of the manuscript for important intellectual content: Minneci, Lodwick, Cooper, Deans.

Statistical analysis: Minneci, Nacion, Cooper.

Obtained funding: Deans.

Administrative, technical, or material support: Nacion, Lodwick, Cooper.

Study supervision: Minneci, Deans.

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