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BACKGROUND
- Inadequate patient recruitment is the most common cause of pediatric clinical trial discontinuation
- Recruitment of eligible patients was lagging in our ongoing stepped-wedge, cluster randomized, pediatric clinical trial, ENhanced Recovery In Children Undergoing Surgery (ENRICH-US), to investigate the effect of enhanced recovery protocols on surgical outcomes in children after elective gastrointestinal surgery.

RESEARCH OBJECTIVES
- Determine the recruitment rate of potentially eligible patients into the ENRICH-US trial, using a secondary dataset

METHODS
- A retrospective cross-sectional analysis was performed using the Pediatric Health Information System (PHIS) administrative dataset to identify potentially eligible patients for the ENRICH-US trial at 10 Children’s Hospitals that are current ENRICH-US study sites, between 07/01/20 to 06/24/22
- Eligible patients were defined as children, ages 10 to 18, who underwent an elective gastrointestinal procedure, as defined by 76 procedural codes from International Classification of Diseases, 10th Revision (ICD-10)
- The number of potentially eligible patients identified in the PHIS data were compared to actual ENRICH-US recruited patients at each site to calculate recruitment rates (Figure 1)

RESULTS
- A total of 229 patients were enrolled in ENRICH-US across the 10 sites compared to 344 potentially eligible patients identified in the PHIS dataset during the study period, yielding an overall recruitment rate of 66.6%
- Recruitment rates varied considerably by site, ranging from 25.0% to 97.7%
- Overall, the three sites with the lowest number of potentially eligible patients identified in the PHIS dataset were also low enrollment sites

LIMITATIONS
- Identifying potentially eligible patients in the PHIS database using ICD-10 codes alone may not capture other factors such changes in patient’s clinical status, surgical clinical judgement, or a patient’s and/or family’s refusal to participate that may disqualify a patient from trial enrollment
- Not all ENRICH-US trial sites participated in the PHIS database limiting comparative analysis

CONCLUSIONS
- Novel data-driven approaches must be adapted to monitor, identify, and enroll all eligible patients in clinical trials
- Using a secondary dataset to ascertain potentially eligible patients can be a relatively easy way to assess and monitor recruitment rates for clinical trials

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Figure 1.

<table>
<thead>
<tr>
<th>Hospital</th>
<th>ENRICH-US</th>
<th>PHIS</th>
<th>Recruitment Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>4</td>
<td>11</td>
<td>36.4%</td>
</tr>
<tr>
<td>B</td>
<td>5</td>
<td>20</td>
<td>25.0%</td>
</tr>
<tr>
<td>C</td>
<td>6</td>
<td>19</td>
<td>31.6%</td>
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</tr>
<tr>
<td>E</td>
<td>23</td>
<td>50</td>
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</tr>
<tr>
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<td>46</td>
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</tr>
<tr>
<td>G</td>
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<tr>
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<td>52</td>
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</tr>
<tr>
<td>J</td>
<td>43</td>
<td>44</td>
<td>97.7%</td>
</tr>
</tbody>
</table>

Qualitative data from the ENRICH-US trial suggested high-enrollment sites had more surgeon champion engagement with many of the elective gastrointestinal surgeries being performed by a single surgeon or a small cohort of surgeons

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