Use of a Secondary Database to Capture Recruitment Rates in the Enhanced Recovery In Children Undergoing Surgery (ENRICH-US) Trial

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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)

Hospital	Eligible Patients		Recruitment Rate
	ENRICH-US	PHIS	
A	4	11	36.4%
B	5	20	25.0%
C	6	19	31.6%
D	15	25	60.0%
E	23	50	46.0%
F	27	46	58.7%
G	30	35	85.7%
H	38	42	90.5%
I	38	52	73.1%
J	43	44	97.7%

Figure 1.

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

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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