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Implementation and Effectiveness of an Enhanced Recovery Protocol for Children Undergoing Surgery

The ENRICH-US Stepped-Wedge Cluster-Randomized Trial

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IMPORTANCE Despite evidence that enhanced recovery protocols (ERPs) improve outcomes in adults undergoing surgery, adoption for pediatric populations has lagged.

OBJECTIVE To assess the implementation and clinical effectiveness of a consensus-based ERP for pediatric patients undergoing elective gastrointestinal (GI) surgery.

DESIGN, SETTING, AND PARTICIPANTS A prospective type 2 hybrid implementation-effectiveness, stepped-wedge, cluster-randomized by entry date into implementation phase, trial of pediatrics patients, 10 to 18 years of age, undergoing elective GI surgery at 18 US sites from September 2019 to June 2024.

INTERVENTIONS Sites were randomized into 3 groups, each spending at least 9 months in a control phase, with usual care, followed by an implementation phase at 6-month intervals that included a 21-element ERP supported by a structured Implementation Toolkit, based on 5 Active Implementation Frameworks (5AIFs), and a sustainment phase (12-24 months). Implementation was facilitated by a 1-year, group-based Learning Collaborative curriculum, a repository of tools, ERP adherence feedback, and implementation report cards.

MAIN OUTCOMES AND MEASURES Site-level scores were created based on 5AIFs domains. ERP adherence was assessed by ERP elements delivered at patient and site level. The primary effectiveness outcome, postoperative length of stay (LOS), and secondary effectiveness outcomes (including opioid use, time to regular diet, complications, readmission, and patient-reported health-related quality of life [HRQOL]) were evaluated across study phases (baseline, implementation, and sustainability). Correlations between site-level implementation scores and fidelity were estimated.

RESULTS Of the 597 enrolled pediatric patients (median [IQR] age, 15 [13-17] years; 274 [45.9%] female; 323 [54.1%] male), 433 (72.5%) had inflammatory bowel disease. No significant differences were found by study phase in LOS or secondary outcomes, except shorter time to regular diet and decreased opioid use during hospitalization. Patients who received at least 13 ERP elements had shorter median LOS (−1.14 days [95% CI −2.01 to −0.27]) and fewer complications (adjusted odds ratio, 0.48 [95% CI, 0.28-0.82]). Patient-level adherence increased by study phase (number of ERPs: 11 [10-13], 14 [12-15], and 14 [13-15], [$P < .001$]). ERP integration into order sets and site culture were moderately correlated with fidelity.

CONCLUSIONS AND RELEVANCE This stepped-wedge cluster-randomized trial found that despite multifaceted implementation strategies, a pediatric GI surgery ERP did not significantly reduce LOS. However, when accounting for implementation fidelity at the patient level, it resulted in significantly lower LOS and complications.

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Enhanced recovery protocols (ERPs) for surgical patients, which incorporate evidence-based elements (eg, minimally invasive surgery, early oral feeds after surgery), improve clinical outcomes in adults including reduced hospital length of stay (LOS), decrease opioid use, and lower costs.[1-5] Since their introduction in the late 1990s, ERPs have been adapted for and used in a wide range of surgical populations.[6-14] However, adoption in pediatric surgery has been more gradual, with limited evidence, mostly from single centers.[15,16]

In a prior study, while most pediatric surgeons endorsed use of an ERP for children undergoing gastrointestinal (GI) surgery,[17] modifications to the adult ERPs were deemed necessary, leading to the creation of a Pediatric GI Surgery ERP.[18] A pilot test of the Pediatric GI Surgery ERP demonstrated improved outcomes,[19] prompting many pediatric surgeons and hospitals to implement selected elements of the ERP. However, pediatric surgeons identified substantial barriers to implementation of some elements, particularly those that required coordination across multiple clinical teams and organizational levels.[20] This study sought to assess the effect of multifaceted implementation strategies to implement a 21-element Pediatric Surgery ERP at 18 sites on length of stay (LOS) by study phase (primary clinical outcome); number of patient-level ERP elements delivered or implementation fidelity (primary implementation outcome); and the association between implementation fidelity and LOS, opioid use, and complications. The study hypothesized that the Pediatric Surgery ERP would reduce LOS. To this end, we designed a multicenter, stepped-wedge, cluster-randomized clinical trial of pediatric patients undergoing elective GI surgery, The Enhancing Recovery In Children Undergoing Surgery (ENRICH-US) Study, using a type 2 hybrid study design with equal focus on both evaluating the effectiveness and implementation of the Pediatric GI Surgery ERP, hereafter referred to as the ENRICH-US Protocol.[21-24] A stepped-wedge design was selected to ensure that all sites received the ERP intervention with randomization at the site-level to facilitate engagement and implementation.[25,26] To select implementation strategies addressing site-specific implementation needs and to guide our implementation evaluation, we used the National Implementation Research Network's 5 Active Implementation Frameworks (AIFs), a commonly used implementation science framework that organizes strategies within 5 domains (usable innovations, teams, drivers, stages, innovation cycles).[27] Learning Collaboratives, based on the Institute for Healthcare Improvement's Breakthrough Series Learning Collaborative, were created to promote shared experience and learning between clinicians, staff, patient advocates, and quality improvement (QI) leaders from all participating sites.[28]

Key Points

Question Can enhanced recovery protocols (ERPs) improve outcomes for pediatric patients undergoing elective gastrointestinal surgery?

Findings This stepped-wedge cluster-randomized trial of 597 pediatric patients found that multifaceted implementation strategies did not reduce overall length of stay. However, when accounting for higher implementation fidelity at the patient level, length of stay and complications were significantly reduced.

Meaning This study's findings highlight the importance of also assessing implementation outcomes when evaluating the clinical effectiveness of a multicomponent intervention.

Methods

Study Design

The stepped-wedge, cluster-randomized clinical trial, ENRICH-US, evaluated the implementation and effectiveness of the 21-element ENRICH-US Protocol for pediatric patients, aged 10 through 18 years, undergoing elective GI surgery.[24] The study was conducted at 18 pediatric surgery sites across the US. The study was registered with ClinicalTrials.gov, and the trial protocol (Supplement 1) was approved by Advarra Inc (Columbia, Maryland), which served as the central institutional review board (IRB) for all study sites. The full protocol has been published previously.[24] Northwestern University was the data coordinating center. All eligible pediatric patients undergoing GI surgery were recruited, thus fulfilling most of the requirements of a pragmatic study aimed at understanding the performance of the ENRICH-US Protocol in actual clinical settings.[29] The stepped-wedge approach enabled sequential rollout of the same intervention (ENRICH-US protocol) with the same implementation strategies, while documenting and evaluating outcomes and site-specific contextual adaptations over time.[30] The 2025 Consolidated Standards of Reporting Trials (CONSORT) reporting structure was used.[31]

Setting and Randomization

Sites participating in the Pediatric Surgery Research Collaborative were purposefully selected to represent all geographic regions of the United States and a range of pediatric GI surgery volumes. A total of 18 sites were selected and randomly assigned, using SAS version 9.4 (SAS Institute), to 1 of 3 groups with each group then randomly allocated to an implementation start period by the central study team.[32] Site randomization was stratified such that each group contained 2 lower-volume and 4 higher-volume sites. The stepped-wedge design eased the practical challenges of concurrently providing implementation strategies and data collection training across the 18 sites.[30,33] Allocation was revealed to sites 8 weeks before their implementation start date, to provide time for preparation and assembly of the implementation team. All sites had at least a 9-month control phase during which baseline data were collected. Then, each group had a 12-month implementation phase followed by a sustainability phase of 1 to 2 years, depending on the group implementation start date, during which post-implementation data were collected (eFigure 1 in Supplement 2).

Study Populations

The study involved 2 study populations, (1) pediatric patients, ages 10 to 18 years, undergoing elective GI surgery, and

their legal guardian, family member, and/or caregiver and (2) all clinicians and staff involved in the care of pediatric patients undergoing elective GI surgery, patient advocates, and QI leaders. Elective GI surgery included ileocecectomy, segmental bowel resection, ostomy closures, stricturoplasty, proctocolectomy with or without intestinal J-pouch creation, and total abdominal colectomy with or without ostomy creation. Pediatric patients requiring emergent GI surgery and caregivers who could not read and/or write English or Spanish were excluded. Trained, authorized study team members obtained informed consent from patients and their caregivers as well as all clinicians, staff, patient-stakeholders and QI leaders, using an IRB-approved consent. For patients and caregivers, informed consent was written. For clinicians, staff, patient-stakeholders, and QI leaders, informed consent was electronic.

Intervention and Implementation Support

During the control phase, sites administered standard care. During the implementation phase, sites received support, guided by 3 key domains of the 5AIFs[27] (eFigure 2 in Supplement 2), including (1) creation of 12-monthly, 60-minute, group-level learning collaboratives, for all members of the site-level multidisciplinary implementation teams, with 12-monthly learning collaborative sessions to deliver the implementation curriculum and promote shared learning during the implementation phase; (2) creation of a site-level multidisciplinary (clinicians, QI experts, and patient advocate liaisons [PALs]) implementation team at each site; and (3) provision of group-level quarterly data reports and site-level implementation report cards,[34] based on the results of site-level quantitative surveys and qualitative interviews with each site's implementation team. The learning collaborative curriculum included information and strategies to change organizational culture, engage leaders, synergize anesthesia and pain service practices with surgical care, and incorporate patient and family perspectives into ERP elements. Further, the learning collaborative curriculum outlined key milestones for sites, including formation of an implementation team with scheduled team meetings, preparation of a project charter, development of anesthesia protocols, guidance on embedding ERP elements into electronic health record (EHR) systems (eg, order sets), and creation of a sustainability monitoring plan. Existing (eg, opioid order set) and new (eg, early nutrition protocol) resources and materials, developed by sites were posted to a study website, with sites gaining access to the website only when their group entered the implementation phase. More resources and materials were posted by sites as more groups entered the implementation phase. These included handouts for engaging stakeholders, order sets, elevator pitches for leadership, and study-specific videos tailored to patients and/or families as well as clinicians. Beginning during the implementation phase, sites received quarterly data feedback reports focused on ERP adherence as a measure of implementation fidelity and LOS. Following site-specific focus groups, implementation report cards were created at 6- and 12-month postimplementation and summarized and graded each site's progress in implementing the ENRICH-US Protocol.[34]

Data Collection

Data were collected from 3 sources. First, trained data collectors prospectively entered patient-level data from EHRs into a REDCap database[35] including demographics (age, sex, race or ethnicity, height, weight, primary insurance source), surgical procedure details, clinical outcomes, and implementation fidelity (measured by ERP adherence). Body mass index (BMI) categories were calculated based on the guideline published by the Centers for Disease Control and Prevention.[36] Second, online parent and patient surveys were administered preoperatively, 2 days after surgery, and 2 to 4 weeks after surgery. Lastly, interviews with site implementation team members (3 per site) were conducted by video conference, the monthly learning collaborative sessions (12 per group) were transcribed and coded, and online site surveys at 6- and 12-month postimplementation were administered to capture implementation contextual adaptations and outcomes.

Implementation Assessment

Patient-level implementation fidelity was calculated from the EHR-abstracted REDCap data by ascertaining the number of the ENRICH-US Protocol elements delivered to an individual patient (maximum = 17, given that some elements were at the site-level) for patients during all 3 study phases. Each adhered-to element was assigned one point, resulting in a possible score ranging from 0 to 17 per patient. Site-level implementation fidelity was then calculated by calculating the number of ERP elements delivered to eligible patients during the implementation and sustainability phases at the site divided by the number of possible ERP elements that could have been delivered during the implementation and sustainability phases. Site-level implementation scores were calculated using subscores (0-1) for each of the 5AIFs domains: (1) integration of ERP elements into EHR order sets, (2) commitment and consistency of each site's implementation team, (3) site culture and attitudes toward ERPs, (4) process for monitoring patient eligibility, and (5) total number of patients enrolled per site. To assign the scores, we used data collected during the implementation and sustainability phases. Quantitative data from the REDCap database were scored by a single researcher (W.S.). Qualitative data from site surveys, site interviews, and the learning collaborative transcripts (eTable 1 in Supplement 2) were scored by dyads of researchers (W.S., S.C.), using computer-assisted qualitative data analysis software (MAXQDA, VERBI Software, 2025), with the scores being verified by a third researcher (M.P.).

Clinical Effectiveness Outcomes

The primary effectiveness outcome was postoperative hospital LOS. We also constructed a binary outcome, prolonged LOS (defined as ≥7 days).[19] Secondary clinical outcomes include days to regular diet, average morphine milligram equivalents (MME) per day during hospitalization, 30-day composite measure of postoperative complications (yes/no), opioid prescription at discharge (yes/no), 30-day readmission (yes/no), and Patient-Reported Outcomes Measurement Information System (PROMIS) Pediatric Global Health and Pain Interference T-scores to assess patient-reported health-related quality

of life (HRQOL) prior to surgery as well as 2 days and 4 weeks after surgery.[37-41] A dichotomous composite measure of postoperative complications was used that included surgical complications (anastomotic leak, bowel obstruction, bleeding, and ileus), infectious complications (superficial site infection, deep space infection, wound dehiscence, need for percutaneous drainage of intra-abdominal or pelvic abscess, postoperative antibiotics use longer than 4 days, pneumonia, and urinary tract infection), pulmonary complications (respiratory compromise, failure of extubation requiring reintubation, pneumothorax), vascular complications (eg, deep vein thrombosis [DVT], thromboembolic stroke, heart attack, pulmonary embolism), neurologic events (peripheral nerve injury, cerebral-vascular accident, coma, and altered mental status), and kidney complications (acute kidney injury, oliguria, acute tubular necrosis, and onset of acute kidney failure requiring initiation of hemodialysis).

Adverse Events and Complications

During the study period, the ENRICH-US Data Safety Monitoring Board met virtually via video conference every 6 to 9 months to review any reported adverse events and interim results. No clinically significant complications were attributable to the intervention.

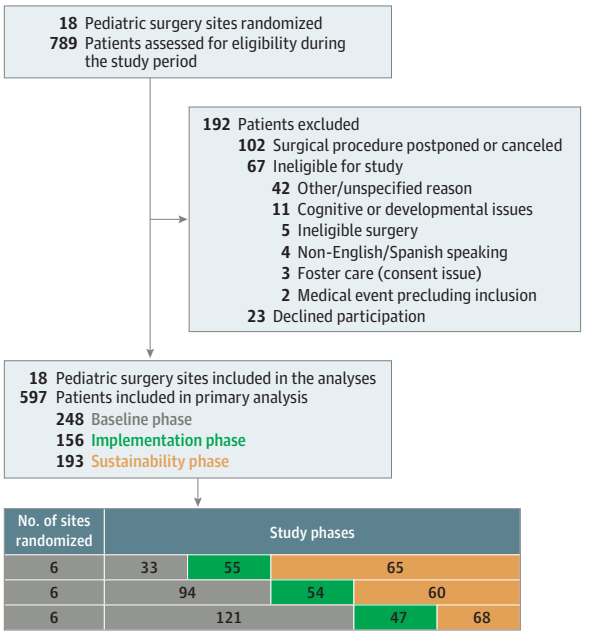
Statistical Analysis

Initial sample size estimates indicated that 20 patients per site were necessary to provide greater than 80% power to detect a difference in hospital LOS of at least 1.25 days at the .05 significance level.[19] Descriptive statistics were used to summarize patient characteristics. Kendall rank correlation coefficient was used to examine the correlation between the domain scores and site-level implementation fidelity.

In our primary analysis, we constructed generalized linear mixed models to examine the effect of the ENRICH-US Protocol by comparing differences in outcomes between study phases (implementation vs baseline and sustainability vs baseline). We included time and group as fixed effects and accounted for within-site correlation and repeated surgeries by patient using random effects. We prespecified that all analyses would adjust for patient age, sex, race or ethnicity, payer categories, BMI categories, American Society of Anesthesiologists (ASA) classification, indicator of surgery, and categories of surgical procedures. For LOS, we used linear quantile mixed models to test the difference in medians. For other continuous outcomes with a right-skewed distribution (eg, average MME per day), we conducted a log-transformation. For binary and count outcomes, we used logistic or negative binomial mixed models with similar adjustments to the primary outcome. We also performed subgroup analyses by key patient characteristics, including age, primary insurance source, indication of surgery, and surgical procedures, as post hoc analyses.

In a sensitivity analysis, we examined the association of patient-level implementation fidelity (high vs low) with clinical effectiveness. A threshold of fidelity was determined by its empirical distribution. The analyses were conducted using SAS verson 9.4 (SAS Institute) and R version 3.2.2 (R Project for Statistical Computing) and the statistical significance level was set at 2-sided $P < .05$.

Figure 1. CONSORT Diagram With Patient Enrollment by Study Phase



CONSORT indicates Consolidated Standards of Reporting Trials.

Results

Study Population Characteristics

A total of 597 patients were enrolled, with 248 (41.5%) in the control phase, 156 (26.1%) in the implementation phase, and 193 (32.3%) in the sustainability phase (**Figure 1**). **Table 1** shows patient demographics and characteristics by study phase. No significant differences were noted, with the exception of the number of privately insured patients enrolled in the control phase being significantly lower than in subsequent phases ($\chi^2_4 = 11.35$; $P = .02$). The most common indication for surgery was inflammatory bowel disease (IBD) (n = 433, 72.5%); procedures included bowel resection or ileocecectomy (n = 204, 34.2%), ostomy closure or stricturoplasty (n = 160, 26.8%), J-pouch creation (n = 120, 20.1%), and total abdominal colectomy with ileostomy (n = 113, 18.9%). The distribution of surgical procedures differed across the three study phases ($\chi^2_6 = 27.93$; $P < .001$). However, no significant differences were observed for other clinical characteristics by study phase.

Implementation Assessment

Table 2 shows patient-level implementation fidelity and clinical outcomes by study phase. Implementation fidelity increased from a median (IQR) number of ERPs of 11 (10-13) during the baseline phase to 14 (12-15) during the implementation phase and remained stable at 14 (13-15) during the sustainability phase ($P < .01$). Site-level implementation scores ranged

Table 1. Patient Demographics and Characteristics by Study Phase

Characteristic	Baseline (n = 248)	Implementation (n = 156)	Sustainability (n = 193)
Age, median (IQR), y	15 (13-17)	15 (14-17)	15 (13-17)
Sex, No. (%)			
Female	101 (40.73)	79 (50.64)	94 (48.70)
Male	147 (59.27)	77 (49.36)	99 (51.30)
Race or ethnicity, No. (%)			
Black or African American	38 (15.32)	17 (10.90)	24 (12.44)
Hispanic	44 (17.74)	15 (9.62)	24 (12.44)
Non-Hispanic White	150 (60.48)	107 (68.59)	122 (63.21)
Other[a]	16 (6.45)	17 (10.90)	23 (11.92)
Insurance, No. (%)			
Private	124 (50.00)	104 (66.67)	112 (58.03)
Public	112 (45.16)	48 (30.77)	72 (37.31)
Others (not insured or unknown)	12 (4.84)	4 (2.56)	9 (4.66)
BMI category, No. (%)[b]			
Healthy weight	156 (62.90)	104 (66.67)	126 (65.28)
Underweight	39 (15.73)	21 (13.46)	22 (11.40)
Overweight	30 (12.10)	18 (11.54)	21 (10.88)
Obese	23 (9.27)	13 (8.33)	24 (12.44)
Indication for surgery			
IBD (Crohn, ulcerative colitis, mixed colitis)	172 (69.35)	117 (75.00)	144 (74.61)
History of trauma with prior bowel involvement	8 (3.23)	5 (3.21)	5 (2.59)
History of prior medical condition requiring bowel surgery	18 (7.26)	6 (3.85)	16 (8.29)
Familial adenomatous polyposis	28 (11.29)	21 (13.46)	12 (6.22)
Other (such as history of cancer)	22 (8.87)	7 (4.49)	16 (8.29)
Surgical procedure			
Ileocecectomy or segmental bowel resection	63 (25.40)	57 (36.54)	84 (43.52)
Ostomy closure or strictureplasty	78 (31.45)	37 (23.72)	45 (23.32)
Proctocolectomy (J-pouch creation)	63 (25.40)	21 (13.46)	36 (18.65)
Total abdominal colectomy with ileostomy	44 (17.74)	41 (26.28)	28 (14.51)
American Society of Anesthesiologists classification			
1 or 2	137 (55.24)	89 (57.05)	103 (53.37)
3 or 4	111 (44.76)	67 (42.95)	90 (46.63)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); IBD, inflammatory bowel disease.

[a] Other includes Asian, more than 1 race, and unknown.

[b] Assessed using the Child and Teen BMI Calculator published by US Center for Disease Control and Prevention.

from 0 to 1 (eTable 1 in Supplement 2; **Figure 2**). A significant correlation was found between site-level implementation fidelity and integration of the ERP into an EHR order set and with site culture and attitudes toward ERPs (Kendall correlation coefficients = 0.46 [95% CI, 0.15-0.69], P = .02 and 0.41 [95% CI, 0.09-0.65], P = .03, respectively), while no correlations were found with respect to the 3 other AIF domains.

Clinical Effectiveness Outcomes

Overall, no significant change by study phase was found for postoperative LOS or the secondary outcomes including HRQOL, except for time to regular diet and average MME per day (Table 2; eTable 2 in Supplement 2). The time to regular diet significantly decreased by 36.1% (95% CI, 5.91%-56.61%) between the control and sustainability phases. Similarly, the average MME per hospitalized day decreased significantly by 55.9% (95% CI, 11.4%-78.0%, P = .02).

In subgroup analyses, patients undergoing bowel resection or ileocecectomy experienced a 2.62-day (95% CI, 0.17-5.07) reduction in median LOS. Among patients who underwent total abdominal colectomy with ileostomy, average MME per day decreased by 89.96% (95% CI, 39.47%-98.33%), while those undergoing ostomy closure or stricturoplasty had an 80.18% (95% CI, 29.52%-94.43%) decrease (eTable 3 in Supplement 2).

Patient-Level Implementation Fidelity and Clinical Outcomes

Median implementation fidelity across all 3 phases was 13 elements (eFigure 3 in Supplement 2). Patient characteristics by low implementation fidelity (<13 elements) and high implementation fidelity (≥13 elements) are shown in eTable 4 in Supplement 2. The number of Hispanic or Latino patients who had a low implementation fidelity (<13 elements) was significantly higher than other racial and ethnic groups. Additionally, the number of bowel resection or ileocecectomy cases who had a high implementation fidelity was significantly higher than other surgical indications.

Table 2. Summary of Implementation and Clinical Outcomes by Study Phase

Variable	Baseline (n = 248)	Implementation (n = 156)	Sustainability (n = 193)	Crude *P* value	Adjusted change (95% CI)	
					Implementation vs baseline	Sustainability vs baseline
Implementation outcomes						
Individual implementation fidelity						
Preadmission education	72 (29.03)	104 (66.67)	167 (86.53)	<.001	NA	NA
Optimize medical comorbidities	207 (83.47)	144 (92.31)	150 (77.72)	.001	NA	NA
Avoid prolonged fasting	43 (17.34)	71 (45.51)	118 (61.14)	<.001	NA	NA
Non-opioid analgesia	157 (63.31)	121 (77.56)	166 (86.01)	<.001	NA	NA
VTE prophylaxis	168 (67.74)	140 (89.74)	186 (96.37)	<.001	NA	NA
Antibiotic prophylaxis	225 (90.73)	148 (94.87)	174 (90.16)	.23	NA	NA
Minimally invasive procedure	168 (67.74)	112 (71.79)	143 (74.09)	.33	NA	NA
Intraop antiemetic	206 (83.06)	140 (89.74)	170 (88.08)	.12	NA	NA
NG tube avoidance	216 (87.10)	141 (90.38)	180 (93.26)	.10	NA	NA
Normothermia	210 (84.68)	123 (78.85)	174 (90.16)	.01	NA	NA
Intraabdominal drain avoidance	231 (93.15)	146 (93.59)	161 (83.42)	.001	NA	NA
Fluid management	46 (18.55)	62 (39.74)	90 (46.63)	<.001	NA	NA
Urinary drain avoidance	139 (56.05)	103 (66.03)	140 (72.54)	.001	NA	NA
Gut stimulation	154 (62.10)	110 (70.51)	163 (84.46)	<.001	NA	NA
Postoperative non-opioids	245 (98.79)	154 (98.72)	190 (98.45)	.95	NA	NA
Early oral nutrition	97 (39.11)	105 (67.31)	143 (74.09)	<.001	NA	NA
Early mobilization	230 (92.74)	143 (91.67)	186 (96.37)	.152	NA	NA
Patient-level No. of ERPs, median (IQR)	11 (10 to 13)	14 (12 to 15)	14 (13 to 15)	<.001	3.67 (−3.18 to 11.01)[a]	16.33 (6.08 to 27.58)[a]
Clinical effectiveness outcomes						
LOS, median (IQR)	4 (3 to 6)	4 (3 to 6)	4 (3 to 6)	.25	−1.10 (−3.23 to 1.03)[b]	0.24 (−2.51 to 2.99)[b]
Prolonged LOS (defined as ≥7 d), No. (%)	49 (19.76)	35 (22.44)	39 (20.21)	.80	0.83 (0.26 to 2.62)[c]	0.60 (0.11 to 3.33)[c]
Days between surgery and regular diet, median (IQR)	2 (1 to 3)	1 (1 to 2)	1 (1 to 2)	<.001	−13.77 (−35.11 to 14.59)[a]	−36.10 (−56.61 to −5.91)[a]
Any postoperative complication(s), No. (%)	50 (20.16)	37 (23.72)	37 (19.17)	.56	0.41 (0.12 to 1.39)[c]	0.63 (0.12 to 3.30)[c]
Average MME per day during a hospital stay, median (IQR)	24.08 (12.56 to 44.99)	22.75 (10.20 to 38.20)	14.90 (6.60 to 29.00)	<.001	−3.65 (−38.64 to 51.29)[a]	−55.86 (−78.01 to −11.39)[a]
Opioid at discharge, No. (%)	66 (26.61)	35 (22.44)	40 (20.73)	.33	0.28 (0.08 to 1.03)[c]	0.43 (0.06 to 2.94)[c]
30-d Readmission, No. (%)	28 (11.29)	16 (10.26)	23 (11.92)	.89	0.24 (0.05 to 1.23)[c]	0.57 (0.08 to 4.01)[c]

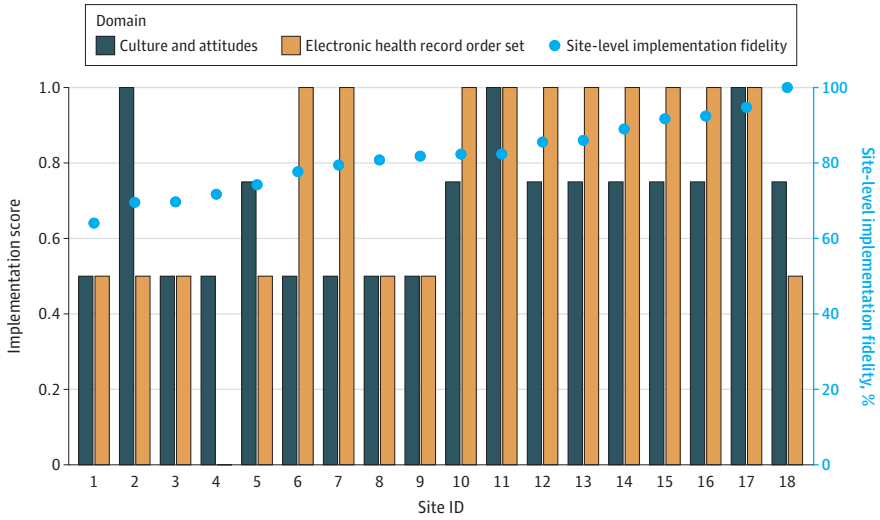
Abbreviations: ERPs, enhanced recovery protocols; LOS, length of stay; MME, morphine milligram equivalents; NA, not applicable; NG, nasogastric; VTE, venous thromboembolism.

[a] Adjusted change in percentage was estimated.

[b] Adjusted change in median was estimated.

[c] Adjusted odds ratio was estimated.

Figure 2. Correlation Between Site-Level Implementation and Implementation Fidelity



Kendall correlation coefficients with site-level implementation fidelity: culture and attitudes: 0.41, $P = .03$; electronic health record order set: 0.46, $P = .02$.

Regardless of study phase, in a post hoc sensitivity analysis, patients who experienced high implementation fidelity had shorter median LOS compared with those with low implementation fidelity, with a reduction of 1.14 (95% CI, 0.27-2.01) days (**Figure 3**; eTable 5 in Supplement 2). Patients who benefitted from high fidelity had significantly lower complications with an adjusted OR of 0.48 (95% CI, 0.28-0.82). Patients who had bowel resection or ileocecectomy also experienced a significant decrease in median LOS, with a decrease of 1.76 (95% CI, 0.81-2.71) days.

Discussion

The ENRICH-US trial, although one of the largest pediatric surgery clinical trials conducted in the US to date, did not result in a significant decrease in overall LOS after implementation of the ENRICH-US Protocol. However, opioid use (during hospitalization) decreased significantly. Implementation fidelity increased during the implementation and sustainability phases compared with the baseline phase and, most notably, patients with higher implementation fidelity, regardless of phase, had significantly shorter median LOS, less prolonged LOS, and fewer 30-day complications.

Adoption of site-level implementation strategies varied by site. For example, while most sites were able to integrate some of the ENRICH-US Protocol elements into their EHR order set, this strategy was not universally feasible.[42] Sites with a more favorable organizational context (culture and attitudes toward ERPs) had higher implementation fidelity. Similar findings have been reported in adult ERP implementation studies, where culture and attitudes have been recognized as critical determinants of success.[43,44] In a recent study assessing implementation of ERPs in adults, strong staff buy-in and high organizational readiness for change enabled sites to overcome other barriers such as low surgical volume,[44] a common challenge in pediatric surgery centers, which was also experienced by some ENRICH-US sites.[45] Finally, while the value of order sets has also been emphasized in adult surgery, challenges, such as lengthy implementation timelines, are frequently reported.[43,46]

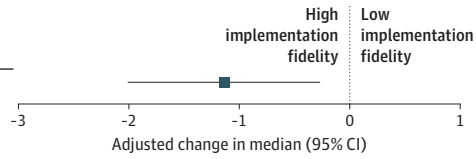
The literature suggests that use of standardized, multidisciplinary ERPs provides additive and often synergistic benefits compared with isolated interventions,[15] and that sustained implementation yields continued improvement, over time.[47] Certain ERP elements may contribute disproportionately to these effects. Early enteral feeding[48] and opioid-sparing multimodal analgesia are particularly impactful, expediting gastrointestinal recovery and reducing opioid-related adverse effects, respectively. Minimizing intravenous fluids and early catheter removal further support rapid mobilization and decrease morbidity.[19,47]

The ENRICH-US trial clinical effectiveness outcomes are consistent with several contemporary meta-analyses of predominantly retrospective data from single-centers, which demonstrate that ERPs in children are associated with shortened hospital LOS, reduced in-hospital costs, significantly lower intraoperative fluids, shortened the time to bowel return, first enteral nutrition, and oral intake, and decreased readmission rates.[15,16] However, unlike these prior studies, the ENRICH-US trial did not demonstrate a significant reduction in LOS. The modest decrease in hospital LOS observed in the ENRICH-US trial is most likely due to several factors. First, unlike the existing single center studies from the early 2000s to mid-2010s,[15,19,49] sites participating in the ENRICH-US study were already adhering to an average of 11 of the ENRICH-US Protocol elements during the baseline (preimplementation) phase, likely attenuating the potential effect size. Loganathan et al[15] concluded that hospital LOS was inversely proportional to the number of ERP elements delivered, suggesting limited room for improvement when baseline adherence is already high. Second, the procedure case mix differs between adult and pediatric colorectal surgical populations, with the adult literature that supports ERP

Figure 3. Association of Patient-Level Implementation Fidelity Level and Clinical Outcomes

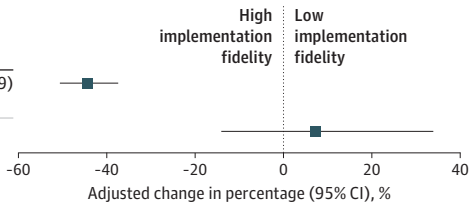
A Difference measures in median

Variable	Adjusted change in median (95% CI)
LOS	-1.14 (-2.01 to -0.27)



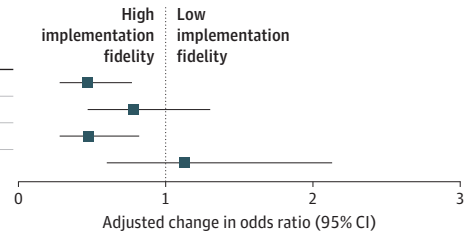
B Difference measures in percentage

Variable	Adjusted change in percentage (95% CI), %
Days between surgery and regular diet	-44.40 (-50.62 to -37.39)
Mean MME during a hospital stay	7.25 (-14.09 to 33.90)



C Difference measures in odds ratio

Variable	Adjusted change in odds ratio (95% CI)
Prolonged LOS	0.47 (0.28 to 0.77)
Opioid prescription at discharge	0.78 (0.47 to 1.30)
Any postoperative complications	0.48 (0.28 to 0.82)
30-d Readmission	1.13 (0.60 to 2.13)



Reference group: patients with low implementation fidelity (<13 enhanced recovery protocol elements). LOS indicates length of stay; MME, morphine milligram equivalents.

implementation in colorectal surgical populations being weighted heavily toward partial colectomies, primarily for cancer. In contrast, the majority of the ENRICH-US population included children with IBD. Prior studies have demonstrated patients with IBD have longer LOS than those undergoing surgery for colorectal cancer.[50] Finally, despite the support provided by ENRICH-US, many sites experienced other barriers to implementation including change of site principal investigator or study coordinator.

Across study phases, there was a significant decrease in opioid use. Opioid exposure can be harmful with immediate adverse effects including respiratory depression, delayed bowel motility, urinary retention, and unintentional overdose,[51] as well as long-term risks including increased risk of opioid use disorder, drug diversion, and future misuse.[52-54] Neurodevelopmental risk during adolescence may further heighten susceptibility to addiction and long-term neurobehavioral consequences.[55]

Patients who received at least 13 ERP elements, reflecting higher implementation fidelity, had a lower incidence of surgical complications, although no association with overall HRQOL was found. The significantly lower implementation fidelity among Hispanic or Latino patients across all phases is unclear but may relate to factors such as implicit bias or language barriers, despite translation of all patient facing materials into Spanish, and warrant further investigation. The absence of an association between complications and overall HRQOL aligns with prior work that shows no association on overall QOL of patients with no or minimal complications at 3 days, 6 weeks, or 1 year, following colorectal surgery.[56] These findings suggest that while higher fidelity reduces complications, the downstream effect on QOL may be limited especially when utilizing current HRQOL assessment tools such as PROMIS.

Limitations

The ENRICH-US trial has limitations. The trial was launched in early 2020 and initial enrollment was disrupted by the COVID-19 pandemic with several sites pausing all elective surgeries.[57] Even after surgery resumed, supply chain and work-force shortages slowed surgical volume and, consequently, study enrollment.[58,59] Simultaneously, the trial had to meet the Common Rule Revision (CRR) mandate for a single IRB for all US federally-funded, nonexempt, multisite, human participant research. Reliance agreement negotiations with the 18 sites significantly delayed trial initiation.[60] During the 3 years of patient recruitment, turnover of site PIs and/or study coordinators contributed to lower patient enrollment at some sites.[61]

A major challenge of the study was meaningful measurement of the quality of implementation. We used the 5AIFs to guide the implementation strategies and evaluation, which required specifying measures for each of the 5AIFs domains. However, this framework did not provide practical guidance regarding measurement. Generalizability of our findings to broader pediatric surgical populations may be limited. Given the lack of robust effectiveness data about ERPs in pediatric surgical patients, we elected to focus on an important surgi-

cal population: pediatric patients, 10 to 18 years old, undergoing elective GI surgery. Thus, the findings may not be applicable to newborns, infants, and younger children undergoing elective GI surgery. Furthermore, most of the study patients had surgery because of a diagnosis of IBD, yet many younger GI surgical patients have congenital diagnoses, such as imperforate anus or Hirschsprung's disease. Nonetheless, many of the ENRICH-US sites have already expanded the use of the ENRICH-US Protocol to younger surgical patient populations and our team is currently conducting a study to reach consensus on a Newborn/Infant GI surgery ERP.[62-65] Yet, the inclusion of 18 sites from across the US with a range of pediatric surgical volumes and diverse institutional characteristics (eg, free-standing children's hospitals and children's units nested within adult hospitals) and referral areas enhance the study's generalizability. Finally, insufficient sample size precluded interaction testing between study phase and subgroup indicators, limiting our ability to examine differential intervention effects across subgroup characteristics.

Conclusions

Despite multifaceted implementation strategies, a Pediatric GI Surgery ERP did not significantly reduce LOS. However, when accounting for implementation fidelity at the patient level, it resulted in significantly lower LOS, faster resumption of regular diet, and fewer complications. Future work is needed to assess whether ERPs will be effective for broader pediatric populations, including populations undergoing procedures beyond elective GI surgery, as well as in younger patients. As efforts to adopt ERPs in pediatric surgery advance, success will be contingent on the continued application of implementation science principles and evaluation of both clinical effectiveness and implementation outcomes.

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