A Mixed-method Approach to Generate and Deliver Rapid-cycle Evaluation Feedback
Lessons learned from a multicenter implementation trial in pediatric surgery

Salva Balbale, PhD
10.16.2023
Acknowledgements

Disclosures / Conflicts of Interest
• None

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Disclaimer
• Views expressed in this presentation are those of the authors and do not necessarily represent the views of the NIH
Objectives today

Provide an overview
  • A little bit about me and our team
  • The ENRICH-US trial

Share our recent publication on rapid-cycle evaluation feedback in ENRICH-US

What we did

What we see as lessons learned

Get your thoughts on it!

• How can we make this process better

• Have you used similar approaches?
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• Have you used similar approaches?
A little about me

• Health services researcher. Educator / mentor. Team scientist.

• Assistant Professor
  – GI Division, Dept of Medicine and Surgery
  – Center for Health Services & Outcomes Research (CHSOR), IPHAM
  – Northwestern Quality Improvement, Research, & Education in Surgery (NQUIRES)

• Research Health Scientist
  – Hines VA HSR&D Center of Innovation

As a health services and outcomes researcher, my focus is on making healthcare safer, better coordinated, and more equitable for people with chronic illnesses, such as inflammatory bowel disease.
Challenges in optimizing pediatric surgery

• In the flurry of activity before and after pediatric surgery, a lot needs to happen all at once!

• Equipment prepped, patients and families coached, staff briefed, medication administered and monitored

• Incorporating new techniques into that process, even when they improve patient care, is often a challenge

• Especially noticeable when it comes to enhanced recovery protocols (ERPs)

• ERPs = a set of short procedures performed before, during, and after surgery that improve care, cutting hospitalization time, reducing cost, and improving patients’ recovery

• But many pediatric surgery centers don’t adopt them
Implementation science + pediatric surgery

• It can sometimes take up to seventeen years for patients to see the benefit.

• Pediatric surgery is complex
  – children = diverse population with age-specific needs
  – Those complexities not always accounted for in new strategies to improve care

• Some surgeons also resist altering long-standing practices
  – partly due to misperceptions
  – lack of knowledge about recent research
The ENhanced Recovery In CHildren Undergoing Surgery (ENRICH-US)

Prospective, pragmatic multicenter implementation trial

Evaluate the effect of an evidence-based ERP adapted specifically for pediatric surgical patients undergoing elective gastrointestinal surgery

Enhanced Recovery = Getting better sooner
More on ENRICH-US

- Type II hybrid stepped-wedge, cluster-randomized study with 3 clusters of 6 pediatric surgical centers
- Data primarily gathered from existing data sources including electronic health records during three phases: baseline, implementation (12 months), and sustainment.
- Key outcomes of interest are length of hospital stay and, for the implementation evaluation, adoption, fidelity, and sustainability
- To support team engagement → site principal investigators (PIs) and research coordinators at each center created a center implementation team
- Center implementation teams participated in monthly ERP learning collaborative sessions during the 12-month implementation period
  - Practical guidance and benchmarking of predetermined implementation milestones
  - Center-specific quarterly data reports tracking patient-level ERP compliance
  - Benchmarking against peer performance
Implementation Team

- Surgeon Champion
- Anesthesia Champion
- Patient Advocate Liaison (PAL)
- QI Leader
- Data Abstractor
- Project Coordinator
Team roles

ENRICH-US Implementation Team
Enhanced Recovery In Children Undergoing Surgery

- **Surgeon Champion**
  - Implementation leader for surgery
  - Secures leadership and colleague support
  - Develops the ENRICH-US Protocol with Anesthesia and Nursing Champions

- **Anesthesia Champion**
  - Develops anesthetic protocols for implementation
  - Secures leadership and colleague support for ENRICH-US Protocol implementation
  - Develops the ENRICH-US Protocol with Surgeon and Nursing Champions

- **Patient Advocate Liaison**
  - Ensures that the Local Implementation Team considers the integration of patient-centeredness
  - Advocates for the patient "voice" in ENRICH-US Protocol implementation
  - Represents Patients Undergoing GI Surgery

- **Study Coordinator**
  - Organizes regular Local Implementation Team meetings and takes minutes
  - Partners with Champions and all project constituents to help identify key stakeholders
  - Manages the project and completes all deliverables in a timely manner

- **Nurse Champions**
  - Creates nursing-specific ENRICH-US Protocols that span all phases of patient care (e.g., pre-operative, recovery, and floor representation).
  - Co-leads implementation with the Surgeon and Anesthesia Champions

- **Child Life Specialist**
  - Coaches pediatric patients and families on mindfulness and deep breathing techniques to help with relaxation and pain control
  - Utilizes ENRICH-US Protocol to help patients with pain management

- **Hospital Level QI Leader**
  - Plans and conducts rapid cycle improvements
  - Helps the implementation team navigate system level changes (e.g., order sets, patient education materials)
  - Works with the Study Coordinator to organize Local Implementation Team meetings

- **Executive Sponsors**
  - Approves project charter and reviews project progress
  - Provides overall guidance and accountability for the project
  - Mobilizes resources for the Implementation Team
The ENRICH-US trial: Pragmatic clinical trial

Strong evidence that interventions take 20 years to get from bench to bedside

Many effective surgical interventions from clinical trials and health services research ultimately fail to be translated into clinical practice
Enhanced Recovery Protocol

Focus is on IMPLEMENTATION of an Enhanced Recovery Protocol – across the entire perioperative period

**PREADMISSION**
- Nutritional support
- Medical optimization
- Education and counseling
- Selective bowel preparation (oral antibiotics)
- Setting patient/family expectations
- Activate/notify the team

**PREOPERATIVE**
- Avoid prolonged fasting and load with clear carbohydrate drink
- Begin non-narcotic analgesic medications
- Prevention of postoperative nausea and vomiting
- Mindfulness training

**INTRAOPERATIVE**
- Goal directed fluid resuscitation
- Local/regional blocks
- Venous thromboembolism prophylaxis
- Minimally invasive surgical techniques
- Avoid drains and tubes
- Hypothermia prevention
- Closing bundles to minimize infection

**POSTOPERATIVE**
- Early removal of catheters/drains
- Advance diet
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- Early and frequent ambulation
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- Engaged patients/families
- Audit compliance and outcomes
What’s an example of an ERP?

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Individual ERPs are relatively simple, but …

…Together, their combination (i.e. bundle) requires contextually adapted, coordinated efforts across multiple clinical care teams at each stage of surgery.
The ENRICH-US trial: Study sites

1. Seattle Children's Hospital
2. Oregon Health & Science University (Doernbecher Children's Hospital)
3. Children's Hospital of Los Angeles
4. University of Utah (Primary Children's Hospital)
5. UT Southwestern Medical Center at Dallas (Dallas Children's Hospital)
6. University of Texas HSC at Houston (Children's Memorial Hermann Hospital)
7. Baylor College of Medicine (Texas Children's Hospital)
8. University of Tennessee HSC (LeBonheur Children's Hospital)
9. Ann and Robert H. Lurie Children's Hospital of Chicago
10. Indiana University Purdue University Indianapolis (Riley Children's Hospital)
11. University of Florida (Shands Children's Hospital)
12. Medical University of South Carolina (MUSC Children's Hospital)
13. Duke University (Duke University Children's Hospital and Health Center)
14. Virginia Commonwealth University (Children's Hospital of Richmond at VCU)
15. State University of NY at Buffalo (John R. Oishei Children's Hospital)
16. Feinberg Institute for Medical Research (Cohen Children's Medical Center)
17. Alfred I. duPont Hospital for Children
18. Children's Hospital Boston
ENRICH-US: Stepped wedge design
Assessing effectiveness and implementation of a perioperative enhanced recovery protocol for children undergoing surgery: study protocol for a prospective, stepped-wedge, cluster, randomized, controlled clinical trial

Mehul V. Raval, Erin Wymore, Martha-Conley E. Ingram, Yao Tian, Julie K. Johnson, and Jane L. Holl

Age- and Sex-Specific Needs for Children Undergoing Inflammatory Bowel Disease Surgery: A Qualitative Study

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A qualitative examination of barriers and facilitators of pediatric enhanced recovery protocol implementation among 18 pediatric surgery services

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(Abbreviations)
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METHODOLOGY

Open

Implementation Report Card
Enhancing Recovery in Children Undergoing Surgery

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Implementation Status Details

Excellent
- Bullet # 1
- Bullet # 2
- Bullet # 3

Needs Improvement
- Bullet # 1
- Bullet # 2
- Bullet # 3

Needs Significant Improvement
- Bullet # 1
- Bullet # 2
- Bullet # 3

NOTES
What does this report mean?
- This is a site specific report showing how your site is doing with implementation of the ENRICH-US protocol. We are using a simple traffic light approach to visualize the current status of implementation at your site.
- Quarterly data sharing reports tell you about how you’re doing with achieving patient-centered clinical outcomes related to EBP. This report card summary can show you how you’re doing in terms of ENRICH-US IMPACT.
- The report is intended to help team members at your site reflect on how implementation is going well and identify how it can be improved.

There are two versions:
- The ENRICH-US Implementation Team aggregated your site survey results and interview data and evaluated implementation outcomes and strategies used. This information was used to determine the extent to which you are implementing EBP according to the study protocol.

QUESTIONS? Email: enrich-us@northwestern.edu or visit the ENRICH-US study website

• How to speed up evaluation of bundled interventions implemented across facilities
• How to deliver evaluation feedback to facilities to iteratively improve implementation
Key attributes of this work

- **Timely, constructive feedback**
- **Collaborate within our team + with pediatric surgery centers**
- **Create and deliver feedback using report cards**
- **Improve surgical care delivery + outcomes**
We started with a problem
We started with a problem

- To improve surgical care for kids having GI surgery → pediatric surgery centers participating in ENRICH-US are implementing an enhanced recovery protocol

- We can learn many **valuable insights** when we **evaluate how that implementation process goes for each center**

- Insights that pediatric surgery centers + ENRICH-US coordinating center can benefit from
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• Except that evaluating implementation can take a really long time!

• We thought centers may also benefit from **more timely information on what’s going well and what can be better**
How can we support pediatric surgery centers with quick, practical feedback to promote iterative improvements as we get enhanced recovery protocols into practice?
Conduct interview / focus group

Team-based evaluation

Develop report card

Share report card with center

Conduct site survey
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Conduct interview / focus group

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Our approach

- Mixed-method sequential explanatory study (collect quantitative data → use that to inform qualitative data collection)
- Adapted previously established frameworks for rapid-cycle evaluation feedback from higher education and engineering
- Triangulated quantitative + qualitative data to generate and deliver center-specific implementation report cards
- Used “traffic light” ranking to visualize implementation status, strengths & opportunities for improvement
Our approach

**ENRICH-US Supports**
- Creation of center-wide implementation teams
- Monthly Learning Collaboratives to establish key implementation milestones
- Quarterly patient-level data reports on ERP compliance

**Rapid-cycle Feedback Process at 6- & 12-Months (led by ENRICH-US team)**
- Conduct site survey
- Conduct interview / focus group
- Share report card with center
- Develop report card
- Team-based evaluation

**Short-term Goals**
- ↑ Center implementation team engagement
- ↑ Iterative changes made to enhance center-wide ERP implementation
- ↑ Implementation adoption and fidelity

**Longer-term Outcomes**
- ↑ Sustained ERP use
- ↓ Length of stay

Expected During Implementation Period

Expected After Implementation Period
Our approach

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Mixed-method sequential explanatory design

QUANTITATIVE: SITE SURVEYS
Brief survey (15 multiple choice questions) administered at 6-months and then again at 12-months following the start of center’s implementation period

Sample: Site PIs or other representative of each center’s implementation team

QUALITATIVE: INTERVIEWS / FOCUS GROUPS
In-depth, semi-structured interviews / focus groups conducted as a follow-up to each center’s site survey results at 6-months and 12-months following the start of center’s implementation period

Sample: Members of each center’s implementation team (i.e. a pediatric surgeon / site PI; other clinical team members such as anesthesiologists and nurses; study coordinator)
Mixed-method sequential explanatory design

**Purpose**
- Gain understanding of center’s ongoing progress + extent of implementation
- Gain baseline understanding of key strengths / weaknesses of implementation progress

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- Gain baseline understanding of key strengths / weaknesses of implementation progress

**Purpose**
- Gain understanding of center’s implementation processes, challenges, facilitators, and opportunities for improvement from the perspective of center’s own implementation team
Our 5-step process

Step 1. Clarify intent + action plan

- Identify team members at the coordinating center who will be involved in feedback process
- As a team, align on purpose / protocol to generate and deliver rapid-cycle feedback
- Draft 1-page implementation report card template and what fields this should include
- Align on who the target audience is for report cards and what they should take away from report card

Step 2. Collect “good enough” data

- List key questions that should be addressed in data collection, report card fields in mind
- Identify low-cost data collection strategies and describe who will do what in a timely manner
- Collect data quickly and with detailed notetaking

Step 3. Engage in team-based evaluation / discussion

- Engage in reflective discussion with team around three questions:
  - What are we learning about this center’s efforts to implement the intervention? (What?)
  - For this center, what are the likely implications of our findings? (So what?)
  - What actions are required to improve implementation moving forward? (What now?)
- Results should allow center implementation teams to adjust implementation efforts

Step 4. Develop implementation report card as a team

- As data is collected, draft center-specific implementation report card that highlights major findings only
- Ensure report card is visually appealing
- Share completed implementation report card with other team members within the coordinating center for internal review before it is final

Step 5. Share report card directly with center

- Distribute final version of report card via email within 10 days after data have been collected
- Share report cards directly with center’s implementation team, including site PI
# Implementation Report Card

Enhancing Recovery in Children Undergoing Surgery

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**OVERALL SUMMARY**

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<td>• Bullet # 1</td>
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<td>• Bullet # 2</td>
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<td>• Bullet # 3</td>
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**NOTES**

- What does this report mean?
- This is a site-specific report showing how your site is doing with implementation of the ENRICH-US protocol. We are using a simple traffic light approach to visualize the current status of implementation at your site.
- Quarterly data sharing reports tell you about how you're doing with achieving patient-level clinical outcomes related to ERPs. This report card summarizes how you're doing in terms of implementation outcomes.
- This report is intended to help team members at your site reflect on how implementation is going well and identify how it can be improved.
Implementation Report Card
Enhancing Recovery in Children Undergoing Surgery

<table>
<thead>
<tr>
<th>SITE</th>
<th>Exemplar Hospital [Site Name Redacted]</th>
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<tr>
<td>CLUSTER</td>
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<td>SITE IMPLEMENTATION STATUS</td>
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SUMMARY
Despite a site PI change, the team and site PI have done an excellent job of implementing enhanced recovery protocol (ERP) elements. The site continues to hold monthly team meetings and has created several tools (e.g., badge buddies) that help communicate ERP and surgical site infection elements to residents/trainees.

Implementation Status Details

Excellent
- Engaged Surgeon Champion who has support of leadership and partnership with key stakeholders such as with anesthesia team members and nursing support.
  - Strong recognition of Surgical PNP and Study Coordinator who have been highly involved in operationalizing individual elements.
- Continued enrollment in the study with weekly assessment and monitoring for eligible patients.
- Continued monthly implementation team meetings.
- Creativity with communication (e.g., badge buddies)
- Dissemination of report card findings to surgeons, nurses, and other key stakeholders.

Needs Improvement
- Use of local/regional blocks in the multimodal pain management strategy.
- Creation of a long term sustainability plan that can use the electronic medical record system to provide metrics after the ENRICH-US study ends.
- Critical appraisal of discharge criteria and using each patient as a PDSA cycle to assess readiness for discharge.

Needs Significant Improvement
- None

NOTES
What does this report mean?
- This is a site-specific final report showing how far your site has come during implementation of the ENRICH-US protocol. We are using a simple traffic light approach to visualize the current status of implementation at your site.
- We have taken into consideration your Quarterly Data Reports to assess how you’re doing in terms of implementing the ENRICH-US elements.
- The report is intended to help the team members at your site reflect on where you are at the end of the 1-year implementation phase and identify the remaining areas that you should continue to work on.

How was our site graded?
- The ENRICH-US Implementation Team aggregated your site survey results and qualitative interview data and evaluated implementation outcomes and strategies used at your site. This information was used to determine the extent to which you have implemented ERPs according to the study protocol.
Lessons learned

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Current status + next steps

We aimed to assess feasibility of this approach, and we’re continuing to provide report cards to all 18 pediatric surgery centers enrolled.

Process uniquely highlighted overlapping goals between implementation science and healthcare quality improvement (QI), particularly in driving system-level change through evaluation and iterative improvements.

Future studies would look at how to improve the tool and understand its longer-term impact on implementation efforts.
Limitations

2 rounds of data collection for each center and a report card twice over 12-month implementation period

Conducting rapid-cycle process on a more frequent basis → could better promote iterative improvements to implementation and active engagement

Carrying out more rapid cycles would have encouraged engagement from other members of center implementation teams

Inviting a multidisciplinary group to participate consistently in the evaluation process may be beneficial and may increase enthusiasm around implementation locally

Sacrificing a purely inductive approach and focusing, instead, on quickly generating targeted insights
Take home points

Rapid-cycle feedback provided constructive / timely information to centers

This approach can complement traditional implementation evaluations

We still need to know whether this approach enhances uptake of ERPs
Discussion

Have you used similar approaches for rapid-cycle evaluation feedback in your research?

What has worked well? What could be better?
Thank you!

Salva.Balbale@northwestern.edu

@SalvaBalbale

www.enrich-us.org