

# **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

## Funding / Support

- National Institute of Child Health & Human Development of the National Institutes of Health (Award # R01HD099344 | PI: Mehul Raval, MD MS).

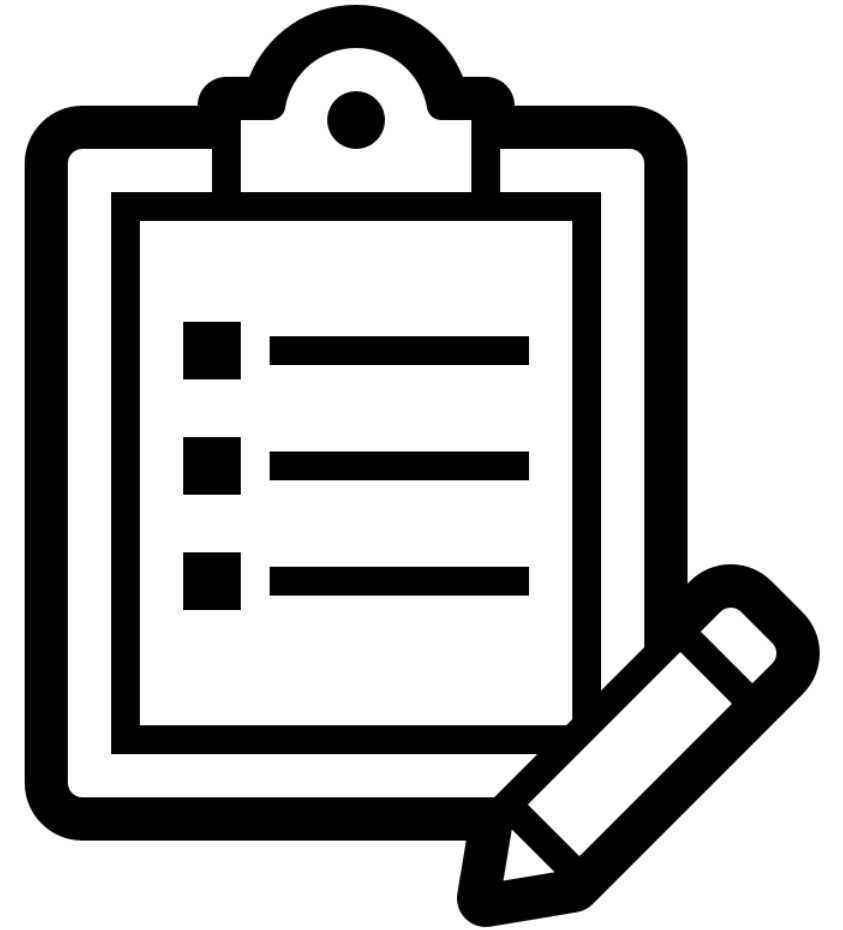
## Disclaimer

- 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



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- What we did
- What we see as lessons learned



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- 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?



# 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.**



\ Meet the Team \



**Mehul Raval, MD MS**  
Principal Investigator  
[VIEW PROFILE >](#)



**Salva Balbale, PhD**  
Assistant Professor  
[VIEW PROFILE >](#)



**Willemijn Schaefer, PhD**  
Research Assistant Professor  
[VIEW PROFILE >](#)



**Yao Tian, PhD MPH**  
Senior Biostatistician  
[VIEW PROFILE >](#)



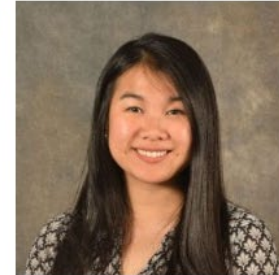
**Erin Wymore, MS**  
Project Administrator



**Deysi Paniagua-Perez, BA**  
Project Coordinator



**Kirsty Engelhardt, BA**  
Project Coordinator



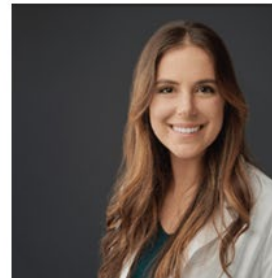
**Lynn Huang, MS**  
Data Analyst and Biostatistician



**Charesa Smith, MD**  
Pediatric Surgical Research Fellow



**Alison Lehane, MD**  
Pediatric Surgical Research Fellow



**Mallory Perez, MD**  
Pediatric Surgical Research Fellow

# 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

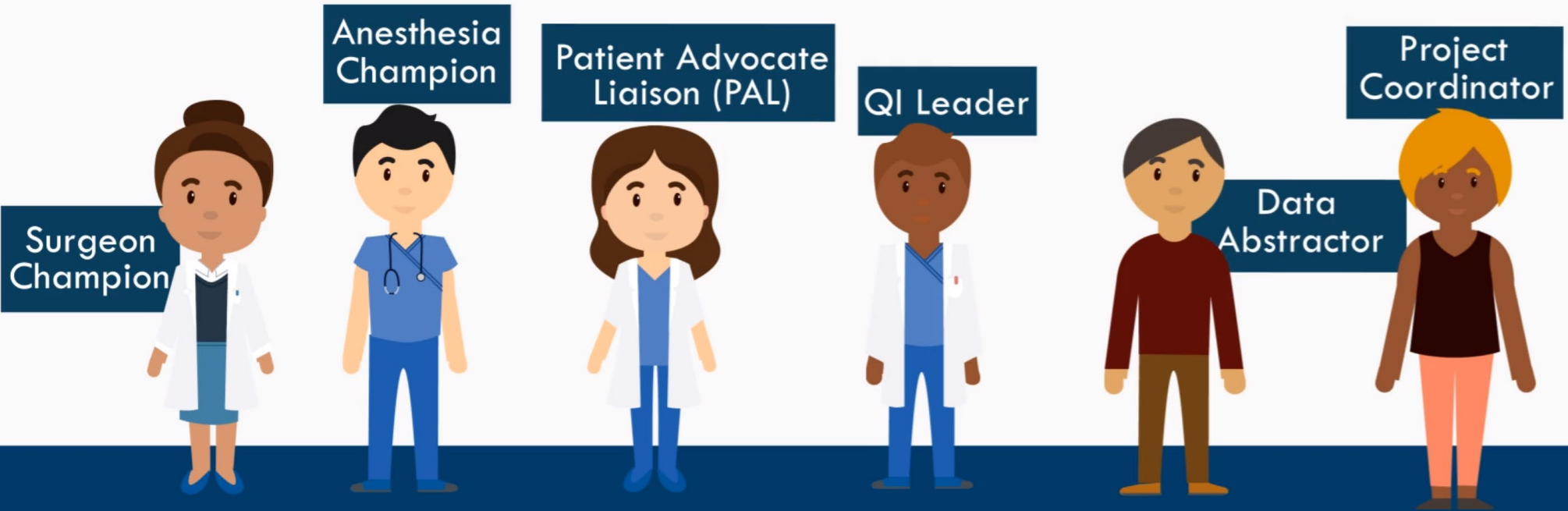


Enhanced  
Recovery = Getting  
better  
sooner

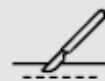
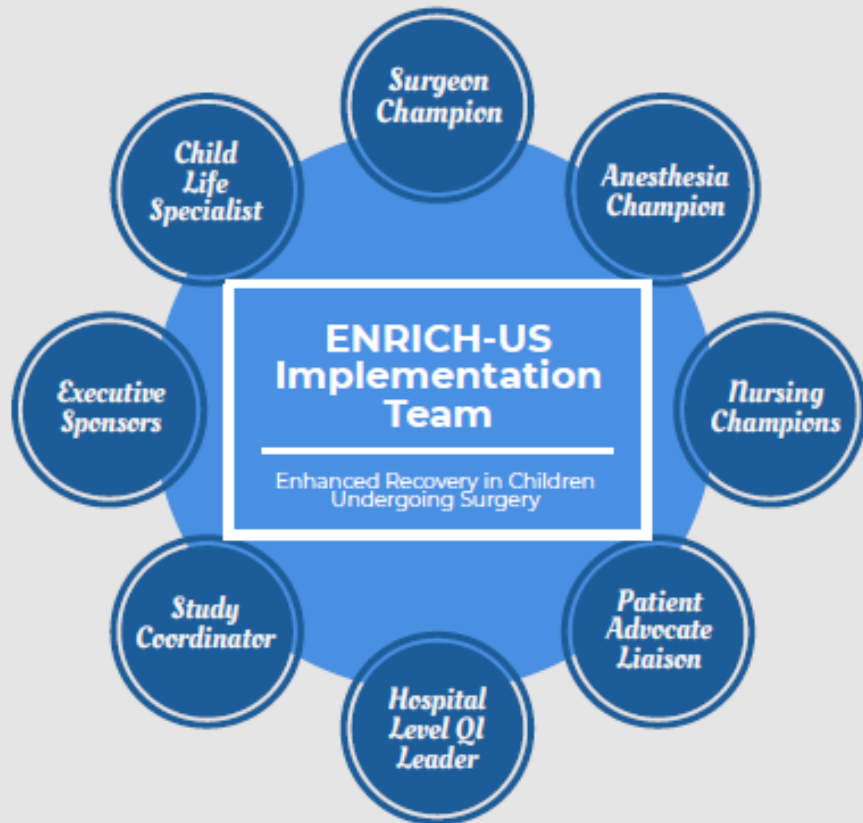
# More on ENRICH-US

- 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



# Team roles



## Surgeon Champion

- Implementation leader for surgery
- Secures leadership and colleague support
- Develops the ENRICH-US Protocol with Anesthesiology 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 Anesthesiology 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



## 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

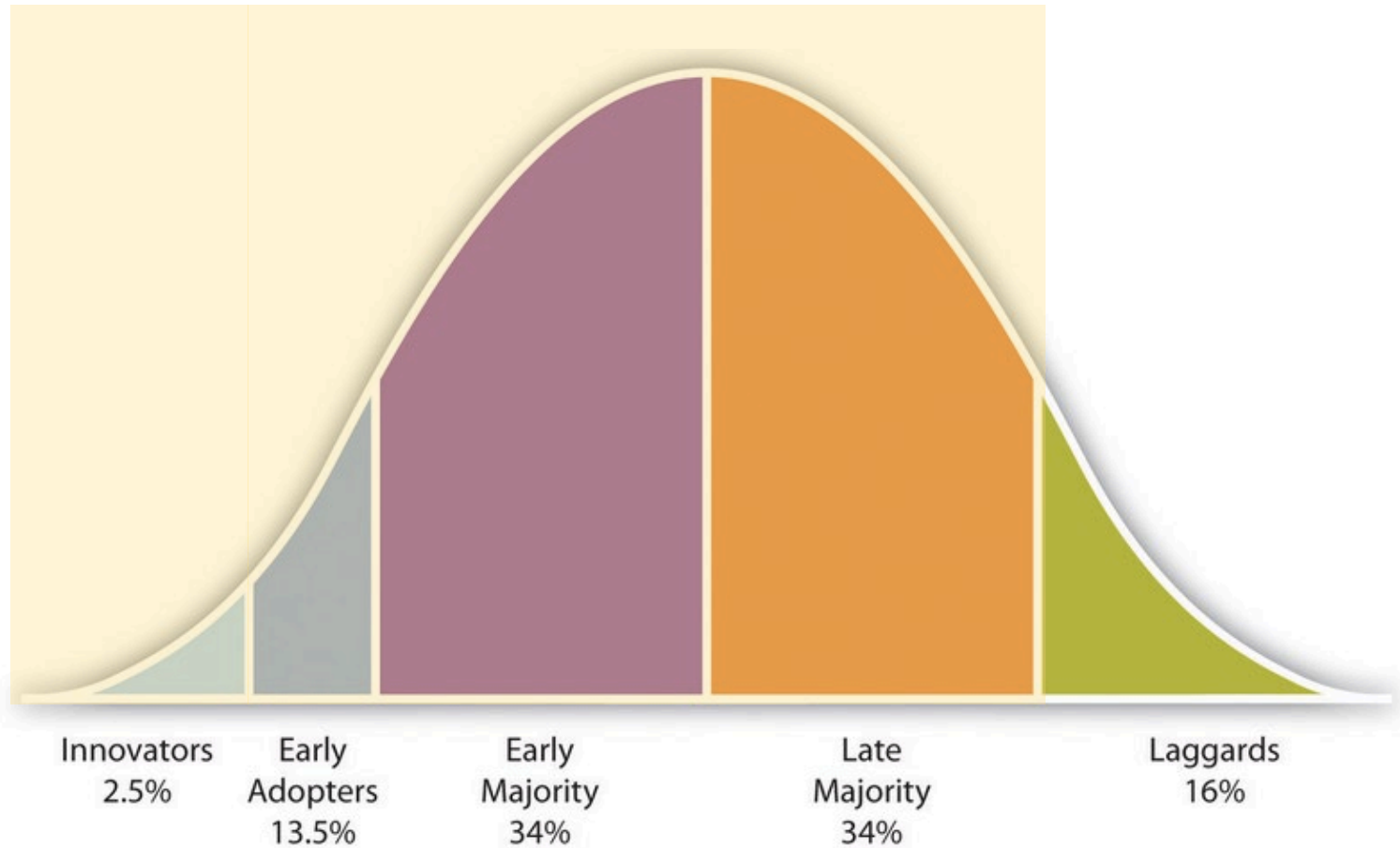
- Plan and conduct rapid cycle improvements
- Helps the implementation team navigate system level changes (e.g., order sets, patient education materials).
- Works with the Study Coordinator to organize Local Implementation Team meetings



## 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

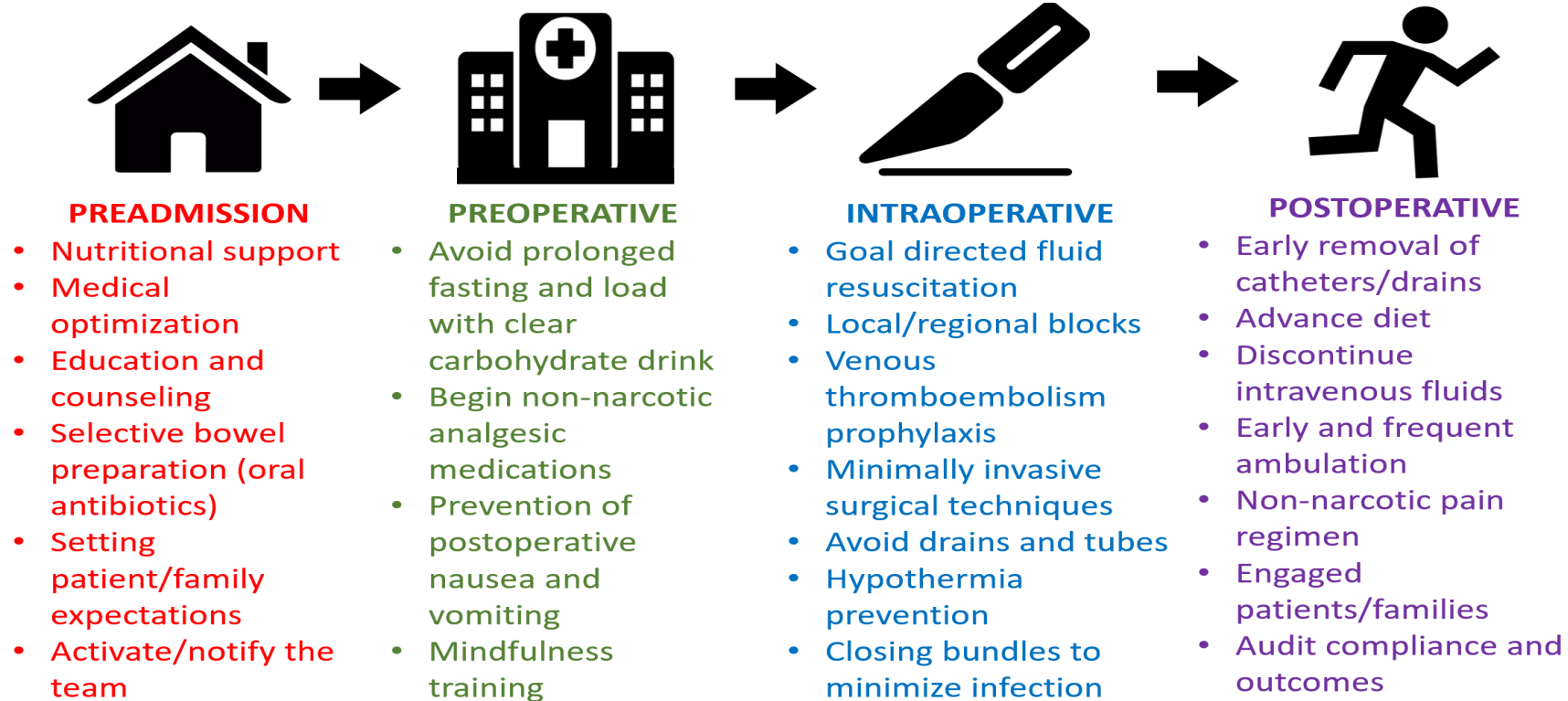


**Strong evidence that interventions take 20 years to get from bench to bedside**

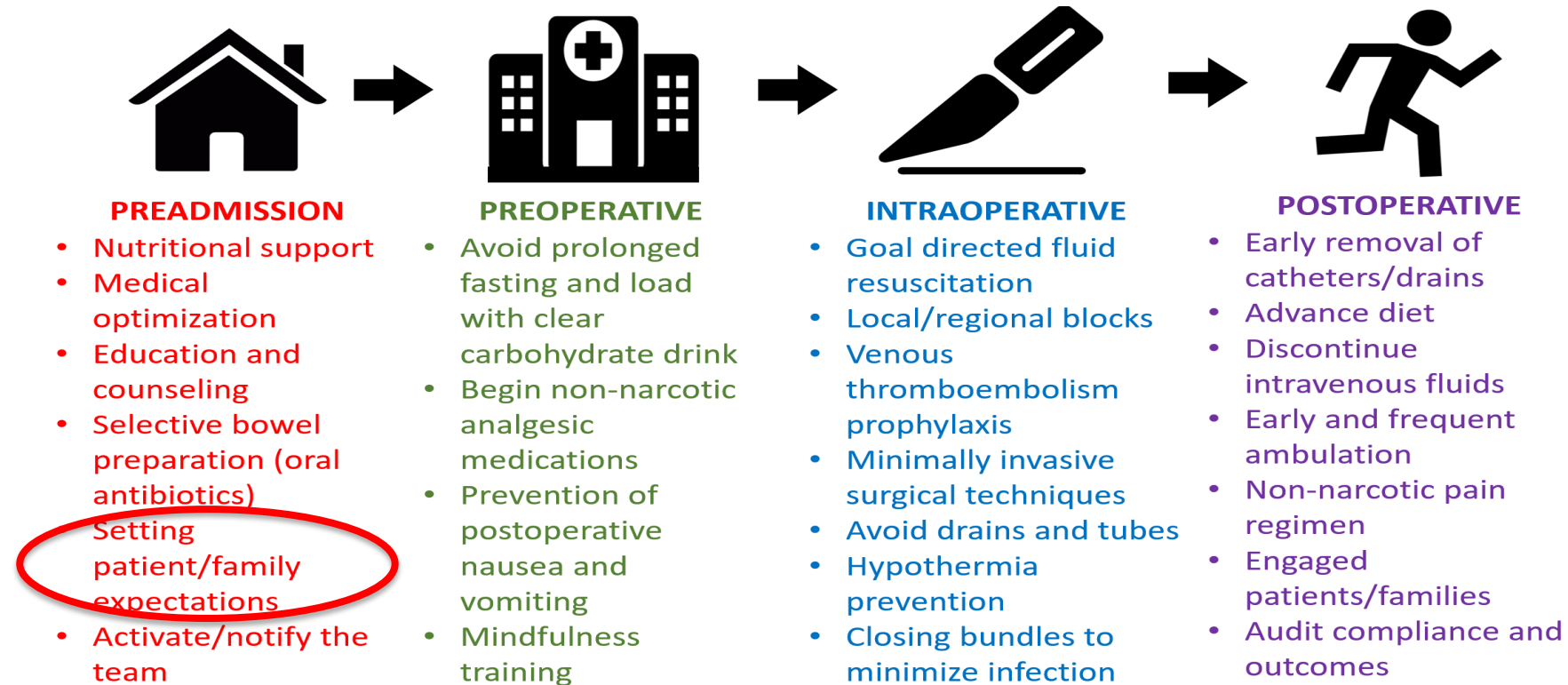
**Many effective surgical interventions from clinical trials and health services research ultimately fail to be translated into clinical practice**

# Enhanced Recovery Protocol

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

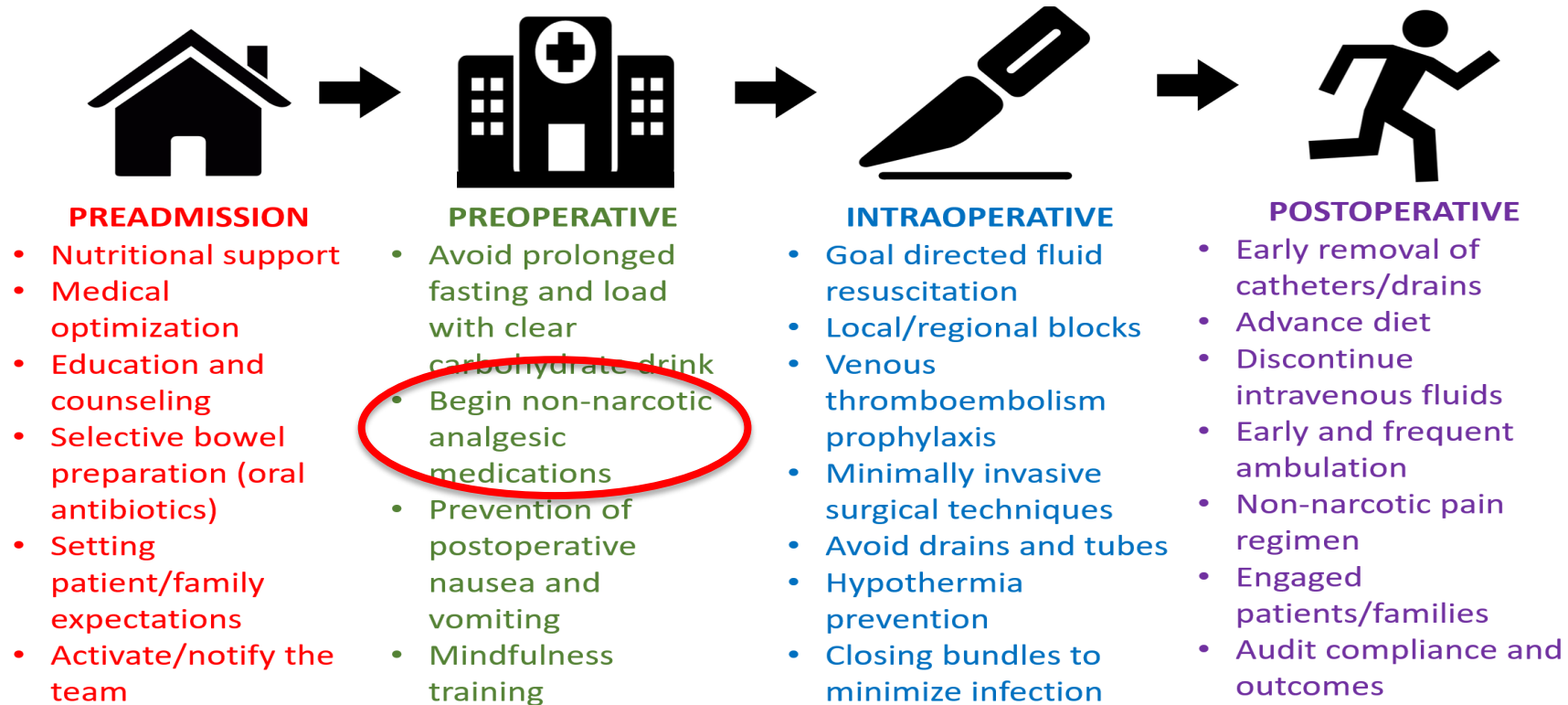


# What's an example of an ERP?





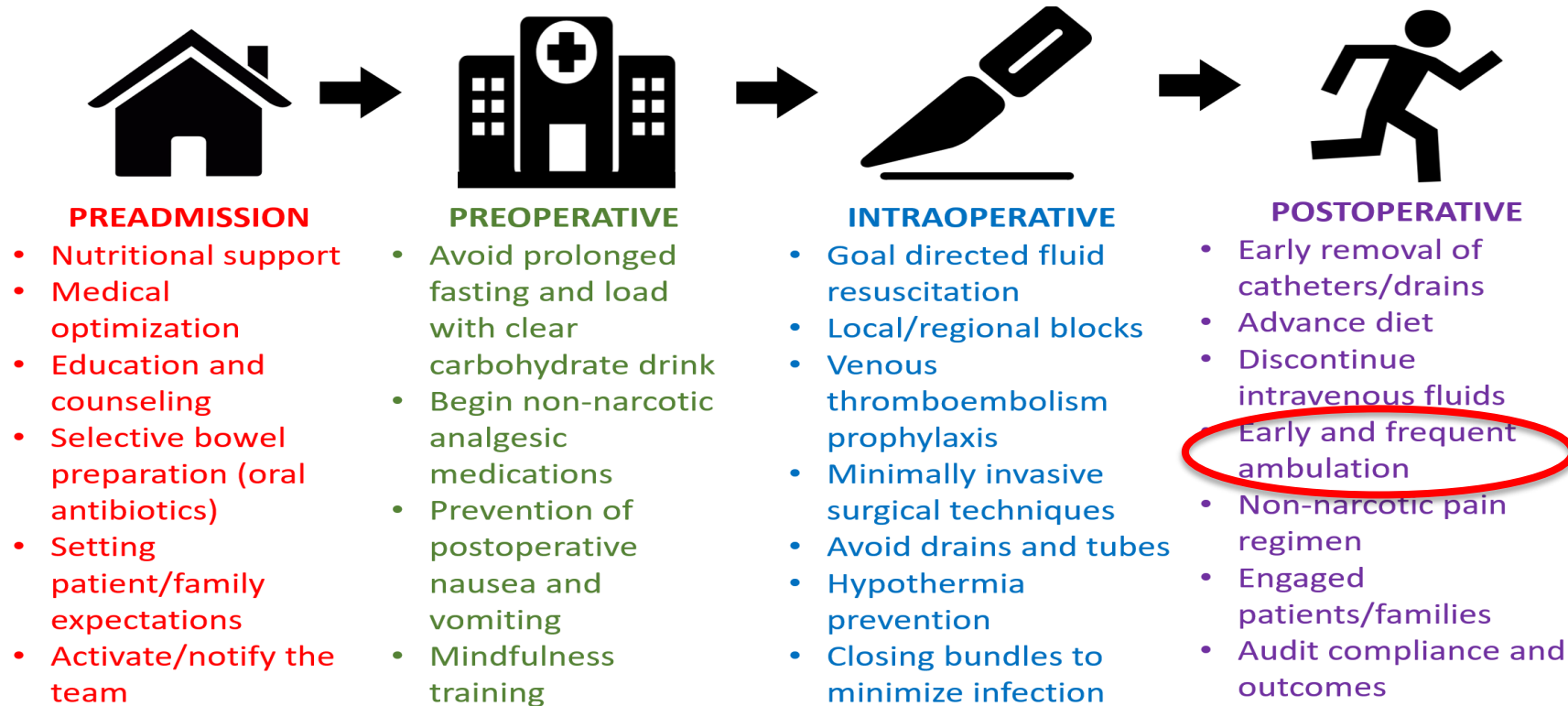
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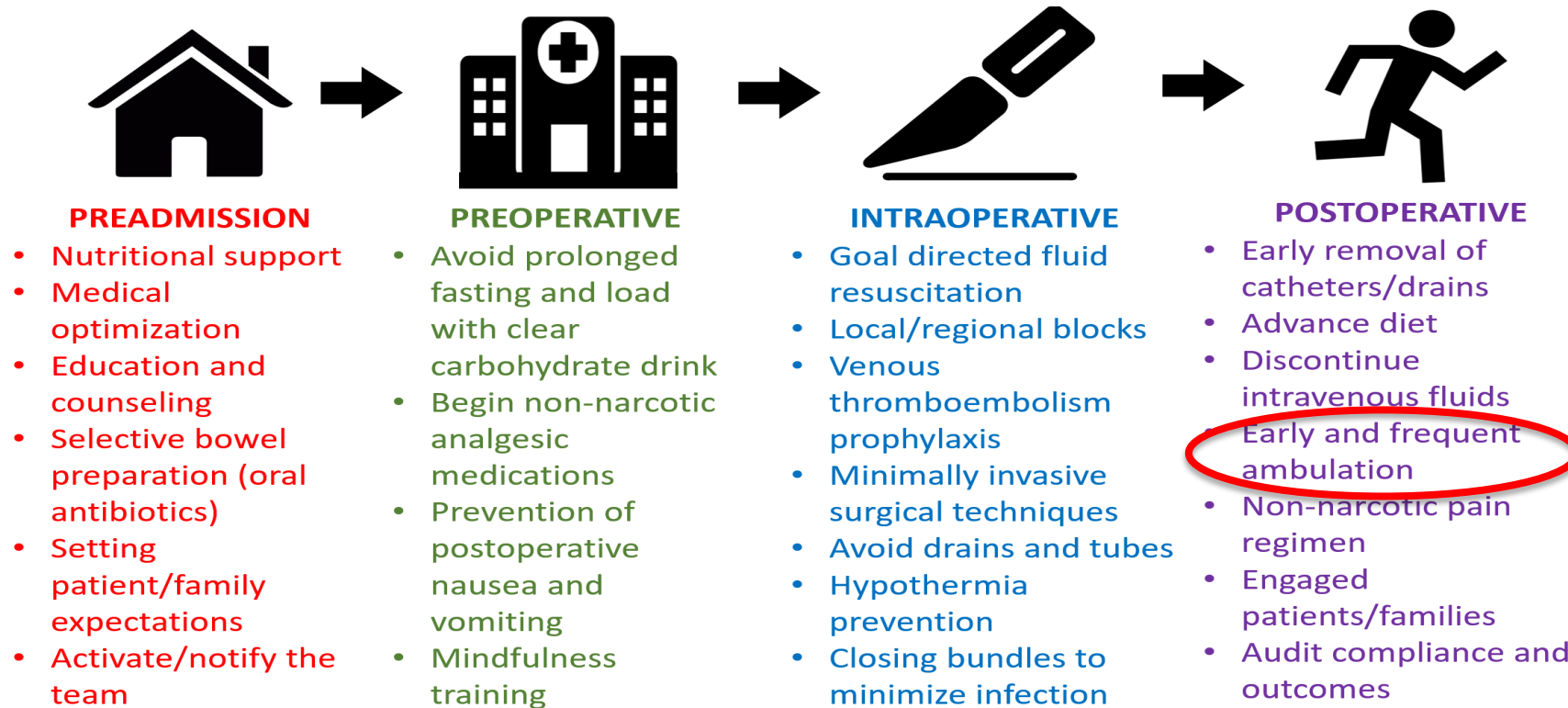
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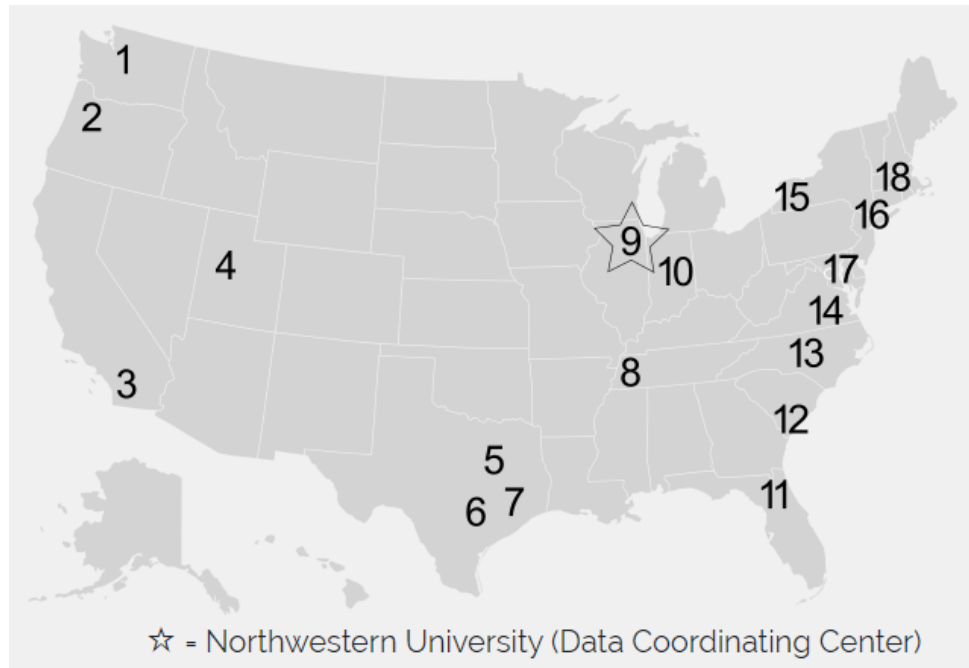
# What's an example of an ERP?



# **Individual ERPs are relatively simple, but ...**

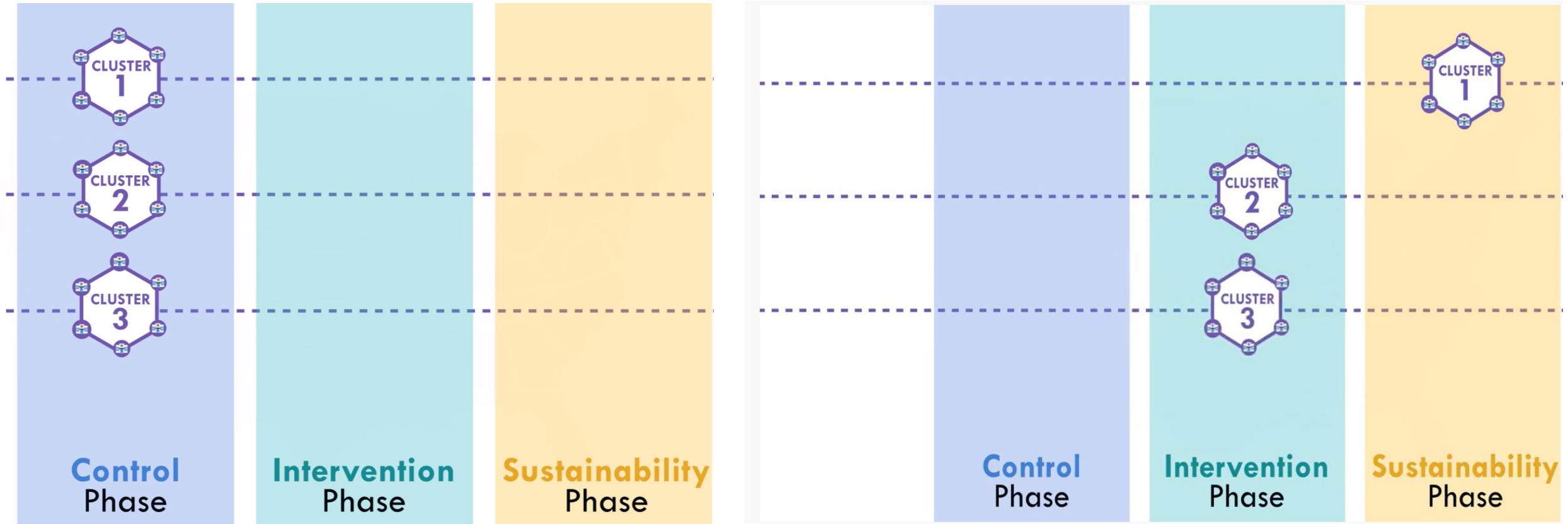
**...Together, their combination (i.e. bundle) requires contextually adapted, coordinated efforts across multiple clinical care teams at each stage of surgery**

# 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. Feinstein 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





STUDY PROTOCOL

Open Access

# 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<sup>1,2\*</sup>, Erin Wymore<sup>1</sup>, Martha-Conley E. Ingram<sup>1,2</sup>, Yao Tian<sup>1</sup>, Julie K. Johnson<sup>1</sup> and Jane L. Holl<sup>3</sup>

ELSEVIER

journal homepage: [www.JournalofSurgicalResearch.com](http://www.JournalofSurgicalResearch.com)

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



Salva N. Balbale, PhD,<sup>a,b,\*</sup> Willemijn L.A. Schäfer, PhD,<sup>c</sup> Teaniese Davis, PhD, MPH,<sup>d</sup> Sarah C. Blake, PhD, MA,<sup>e</sup> Sharron Close, PhD, MS,<sup>f</sup> Joseph E. Perry, BS,<sup>e</sup> Raul Perez Zarate, BS,<sup>e</sup> Martha-Conley Ingram, MD, MPH,<sup>b,c,g</sup> Jennifer Strople, MD,<sup>h</sup> Julie K. Johnson, PhD, MSPH,<sup>b,c</sup> Jane L. Holl, MD, MPH,<sup>i</sup> and Mehul V. Raval, MD, MS<sup>b,c,g</sup>



Contents lists available at ScienceDirect

Journal of Pediatric Surgery

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## A baseline assessment of enhanced recovery protocol implementation at pediatric surgery practices performing inflammatory bowel disease operations☆☆☆★



Jonathan Vacek<sup>a,\*</sup>, Teaniese Davis<sup>b</sup>, Benjamin T. Many<sup>a</sup>, Sharron Close<sup>c</sup>, Sarah Blake<sup>d</sup>, Yue-Yung Hu<sup>a,e,f</sup>, Jane L. Holl<sup>e</sup>, Julie Johnson<sup>e,f</sup>, Jennifer Strople<sup>g</sup>, Mehul V. Raval<sup>a,e,f</sup>

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Davis et al.

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Implementation Science  
Communications

RESEARCH

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



Teaniese L. Davis<sup>1\*</sup>, Willemijn L. A. Schäfer<sup>2,3</sup>, Sarah C. Blake<sup>4</sup>, Sharron Close<sup>5</sup>, Salva N. Balbale<sup>2</sup>, Joseph E. Perry<sup>4</sup>, Raul Perez Zarate<sup>6</sup>, Martha Ingram<sup>2,3,7</sup>, Jennifer Strople<sup>8,9</sup>, Julie K. Johnson<sup>2,3</sup>, Jane L. Holl<sup>10</sup> and Mehul V. Raval<sup>2,3,7</sup>



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- How to speed up evaluation of bundled interventions implemented across facilities
- How to deliver evaluation feedback to facilities to iteratively improve implementation



## Implementation Report Card

Enhancing Recovery in Children Undergoing Surgery

- Needs Significant Improvement
- Needs Improvement
- Excellent

SITE	
CLUSTER	
DATE	
SITE IMPLEMENTATION STATUS	*change color of this cell to correspond to final grade*
OVERALL SUMMARY	

**Implementation Status Details**

<b>Excellent</b>
<ul style="list-style-type: none"> <li>Bullet # 1</li> <li>Bullet # 2</li> <li>Bullet # 3</li> </ul>
<b>Needs Improvement</b>
<ul style="list-style-type: none"> <li>Bullet # 1</li> <li>Bullet # 2</li> <li>Bullet # 3</li> </ul>
<b>Needs Significant Improvement</b>
<ul style="list-style-type: none"> <li>Bullet # 1</li> <li>Bullet # 2</li> <li>Bullet # 3</li> </ul>

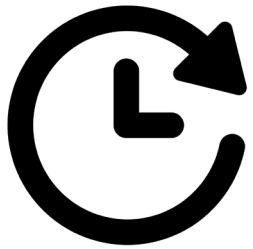
**NOTES**

*What does this report mean?*

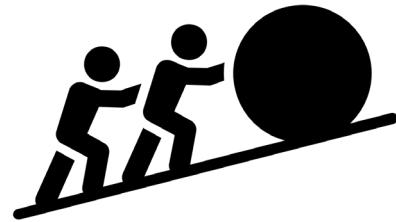
- This is a site-specific report showing how your site is doing with implementation of the ENRICH-US protocol. We are using a simple traffic light approach to visualize the current status of implementation at your site.
- Quarterly data sharing reports tell you about how you're doing with achieving patient-level clinical outcomes related to ERPs. This report card summarizes how you're doing in terms of implementation outcomes.
- 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. *How was our site graded?*
- 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 ERPs according to the study protocol.

QUESTIONS? Email [enrich-us@northwestern.edu](mailto:enrich-us@northwestern.edu) or visit the [ENRICH-US study website](#)

# Key attributes of this work



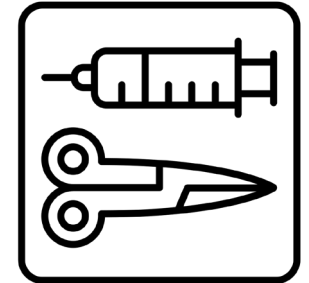
**Timely,  
constructive  
feedback**



**Collaborate  
within our team  
+ with pediatric  
surgery centers**



**Create and  
deliver feedback  
using report  
cards**



**Improve surgical care  
delivery + outcomes**

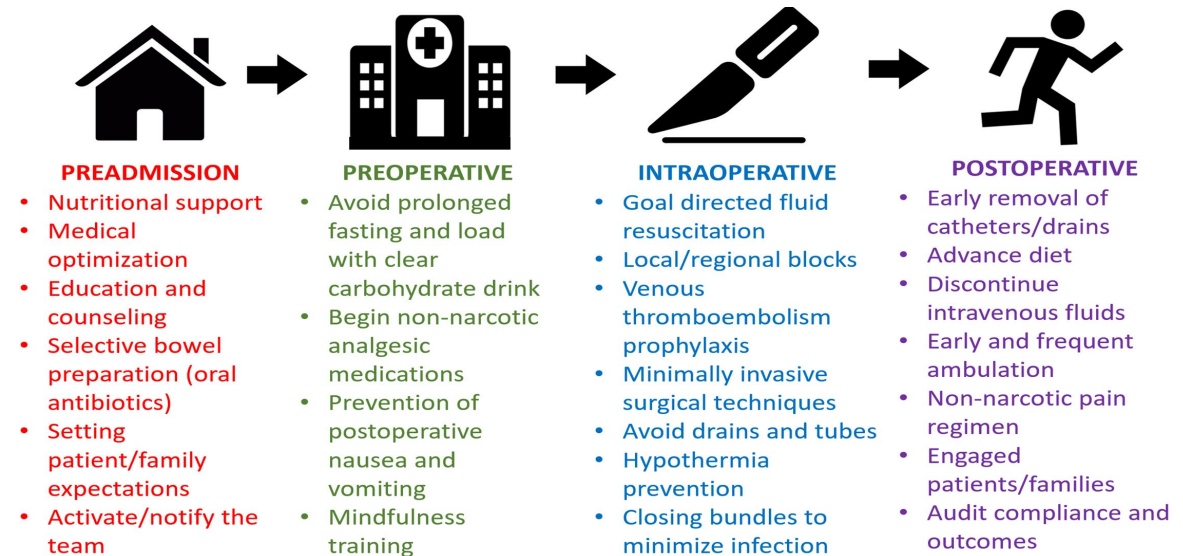
# **We started with a problem**

# 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

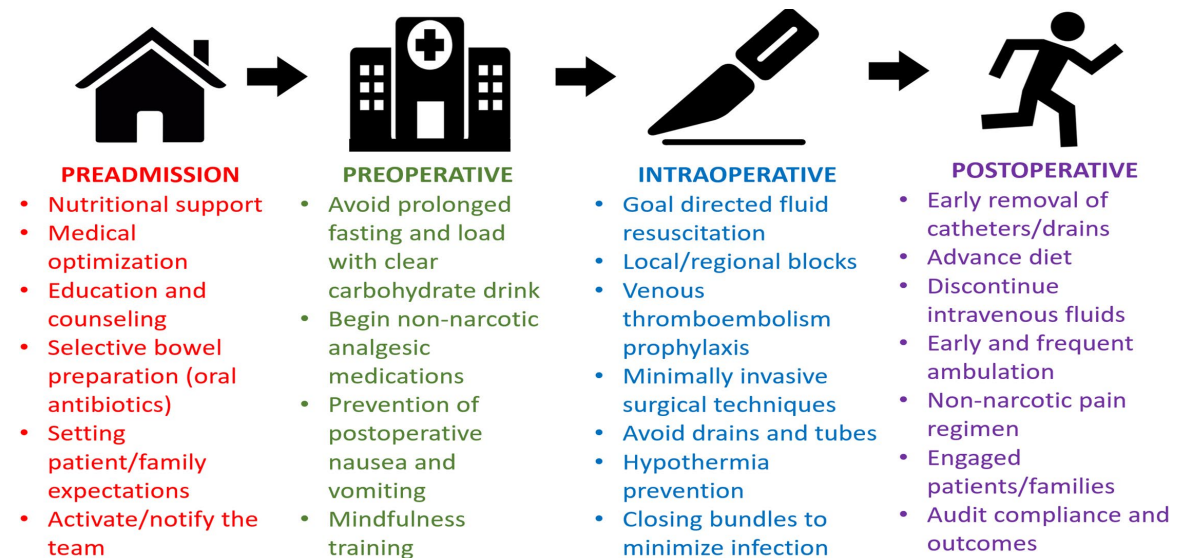
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- We can learn many **valuable insights when we evaluate how that implementation process goes for each center**
- Insights that pediatric surgery centers + ENRICH-US coordinating center can benefit from
- Except that evaluating implementation can take a really long time!
- We thought centers may also benefit from **more timely information on what's going well and what can be better**

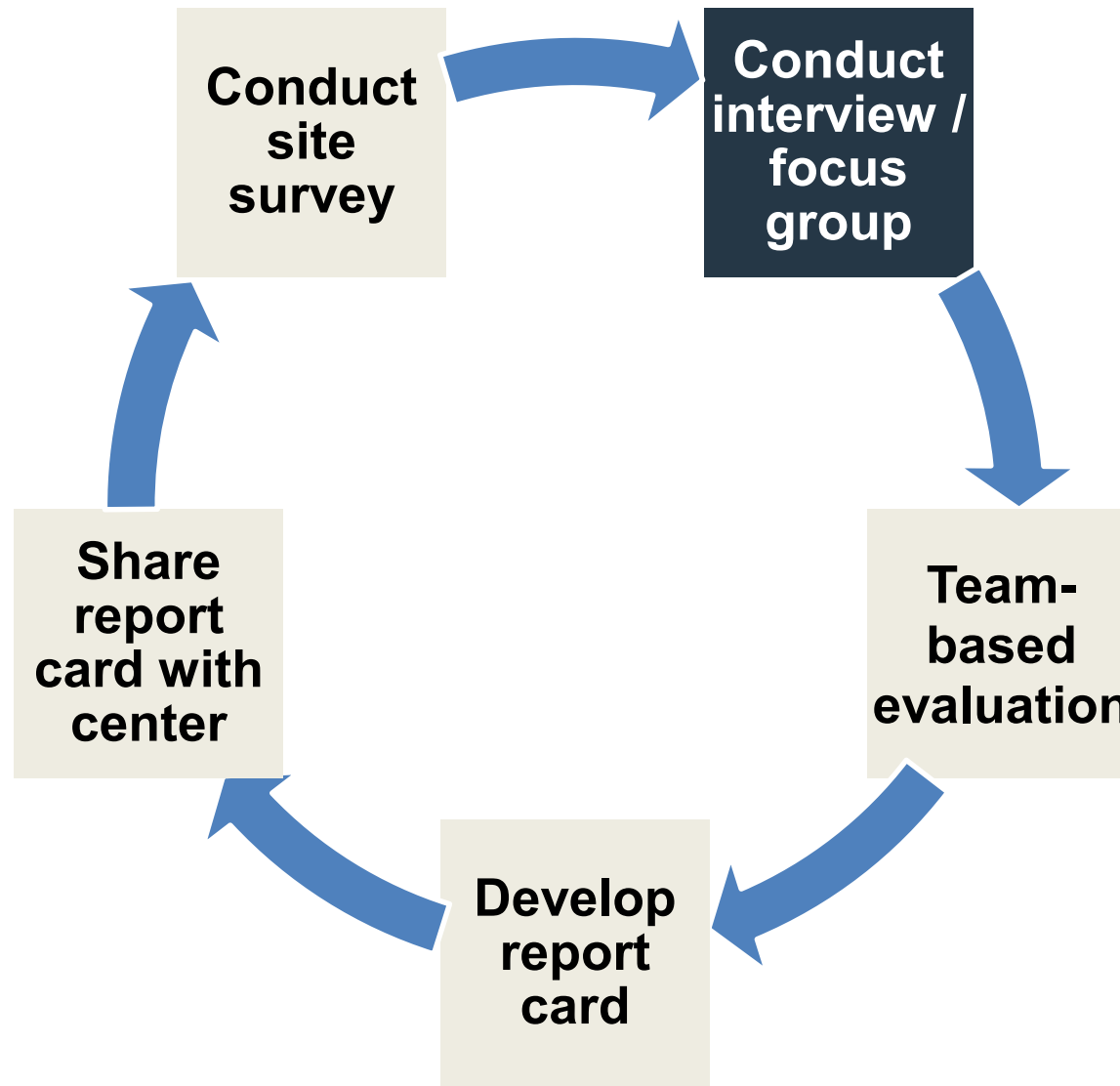


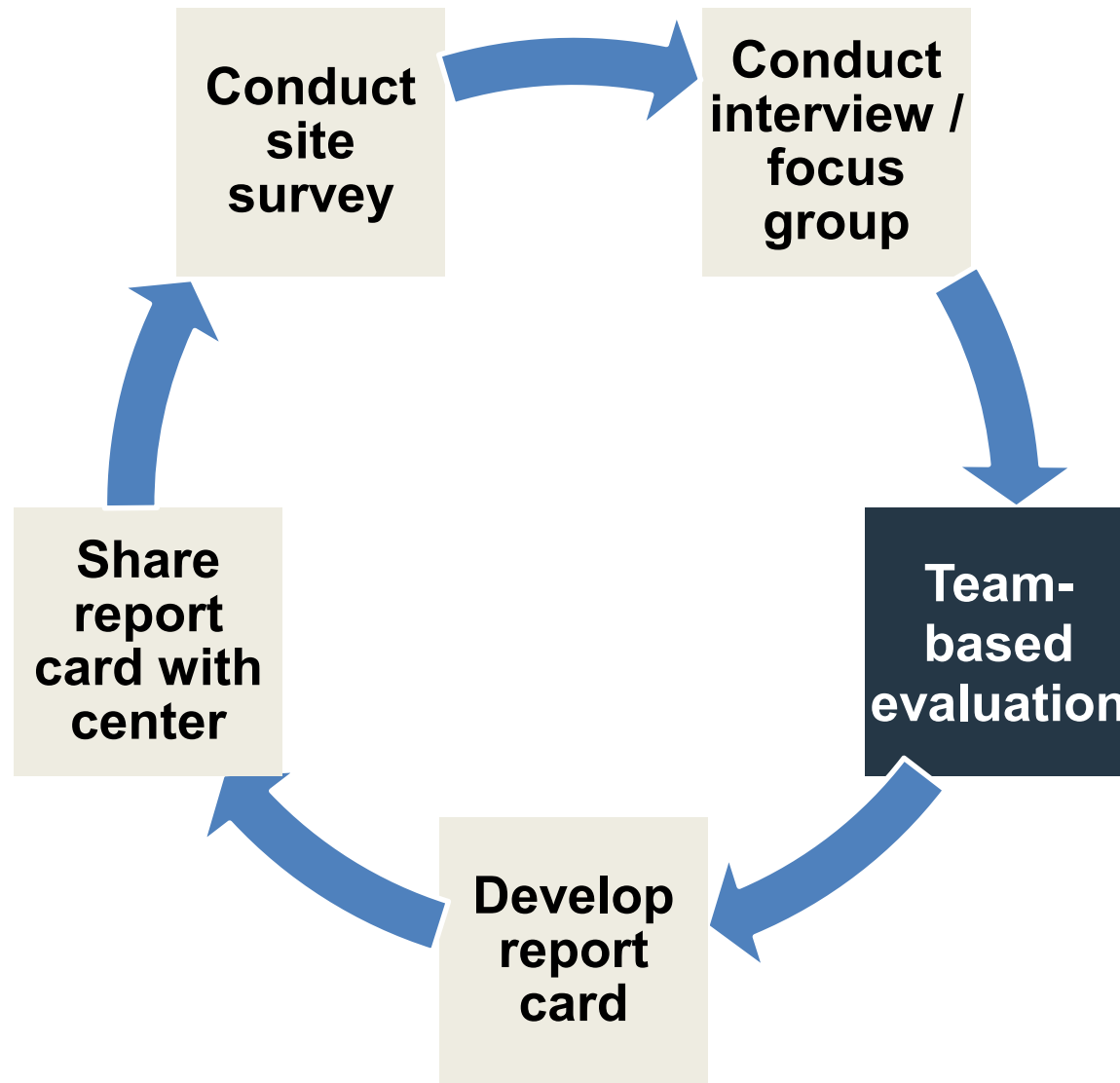


**How can we support pediatric surgery centers with quick, practical feedback to promote iterative improvements as we get enhanced recovery protocols into practice?**

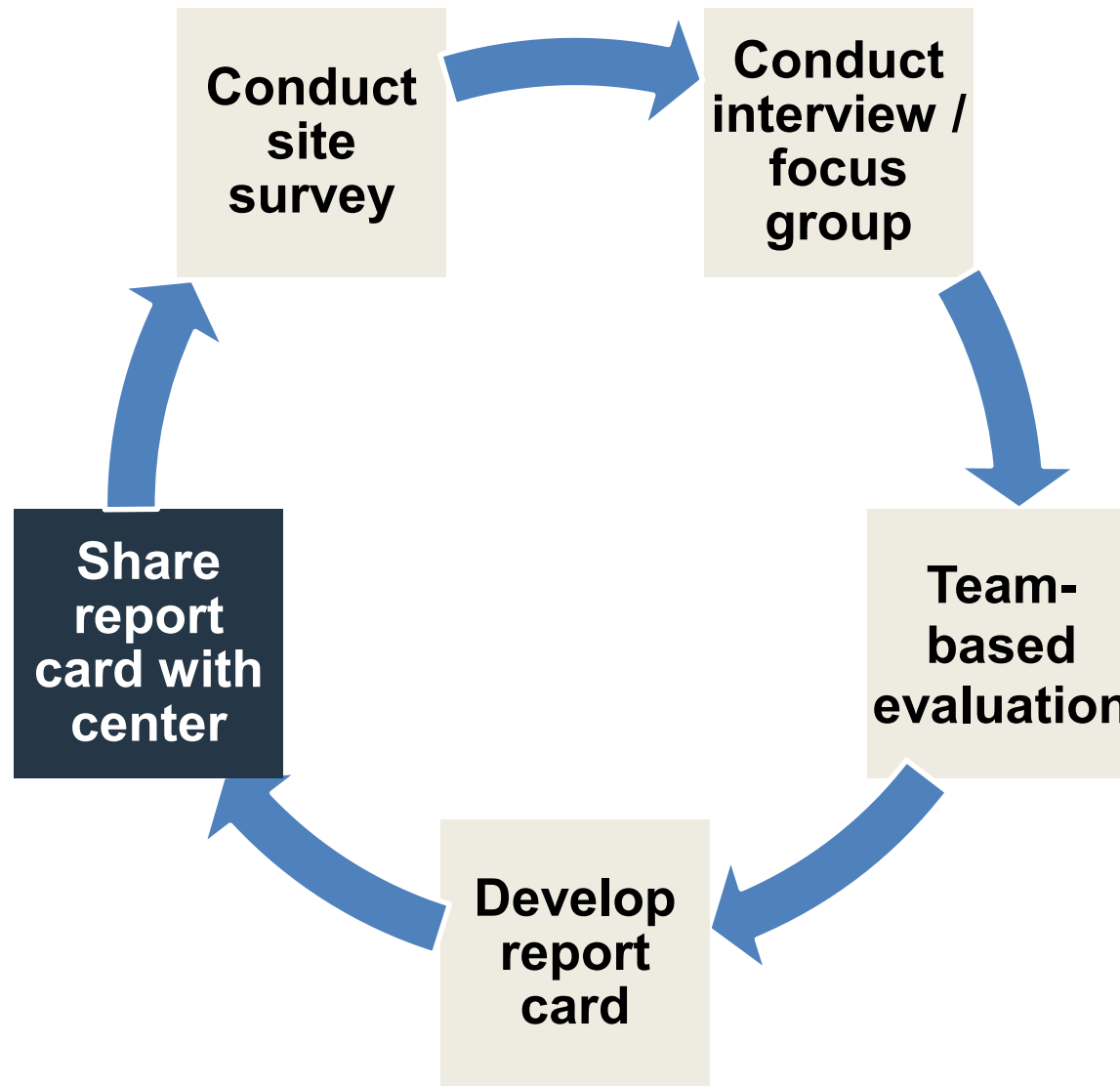













METHODOLOGY

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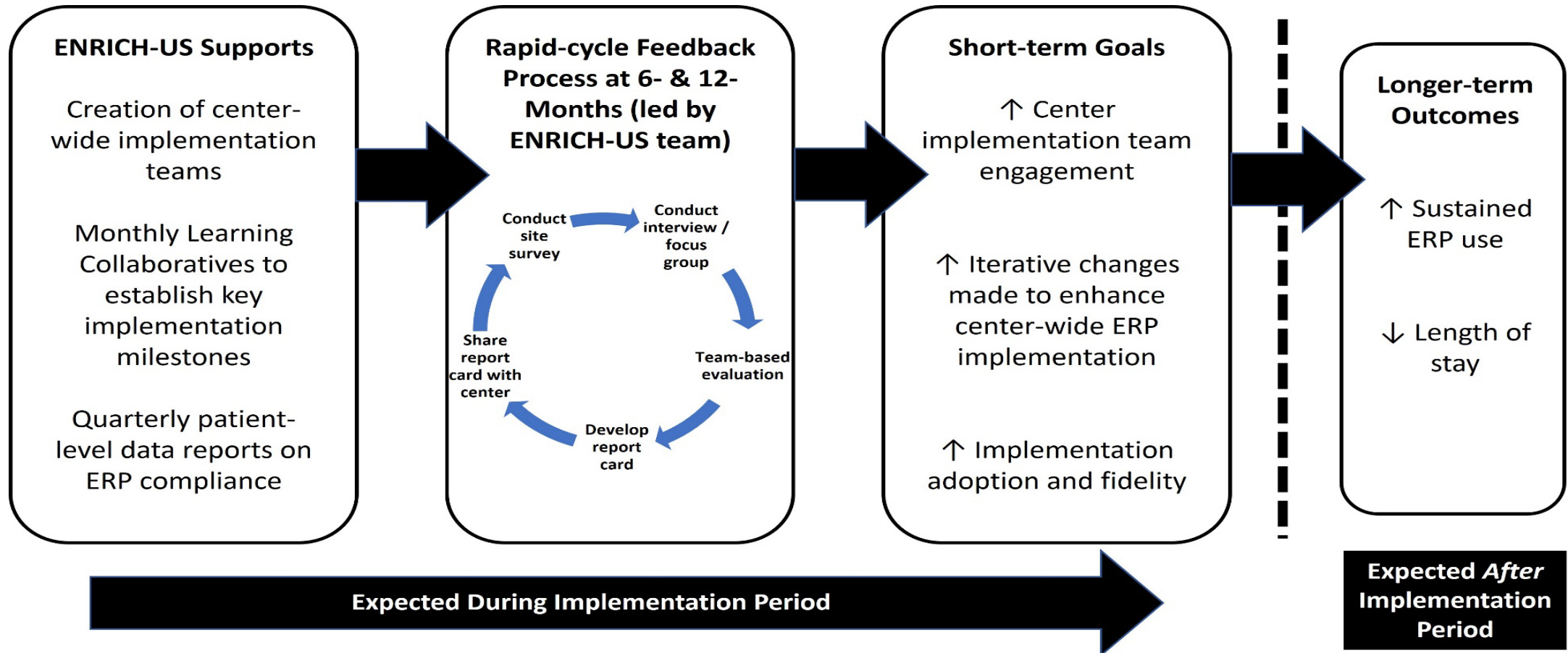
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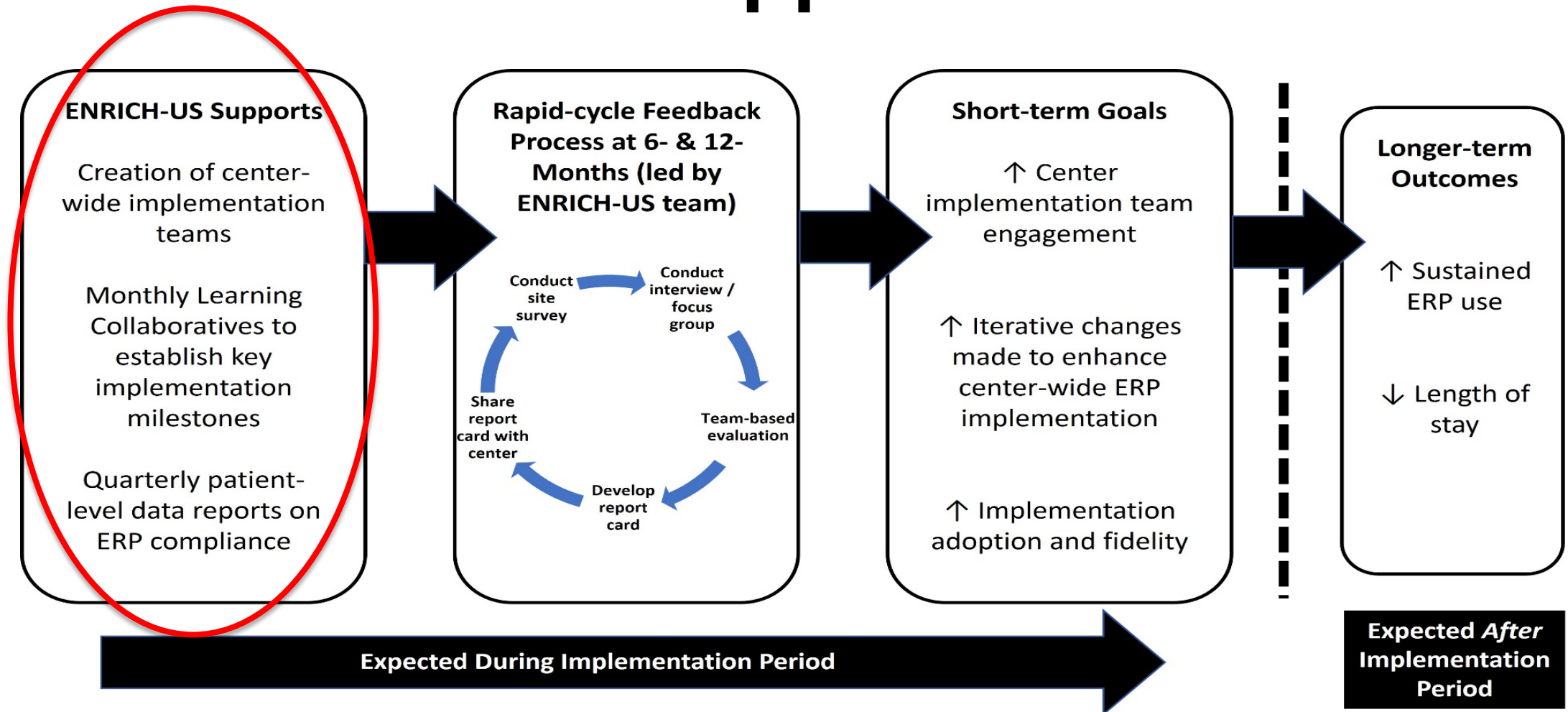
# Our approach

- 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

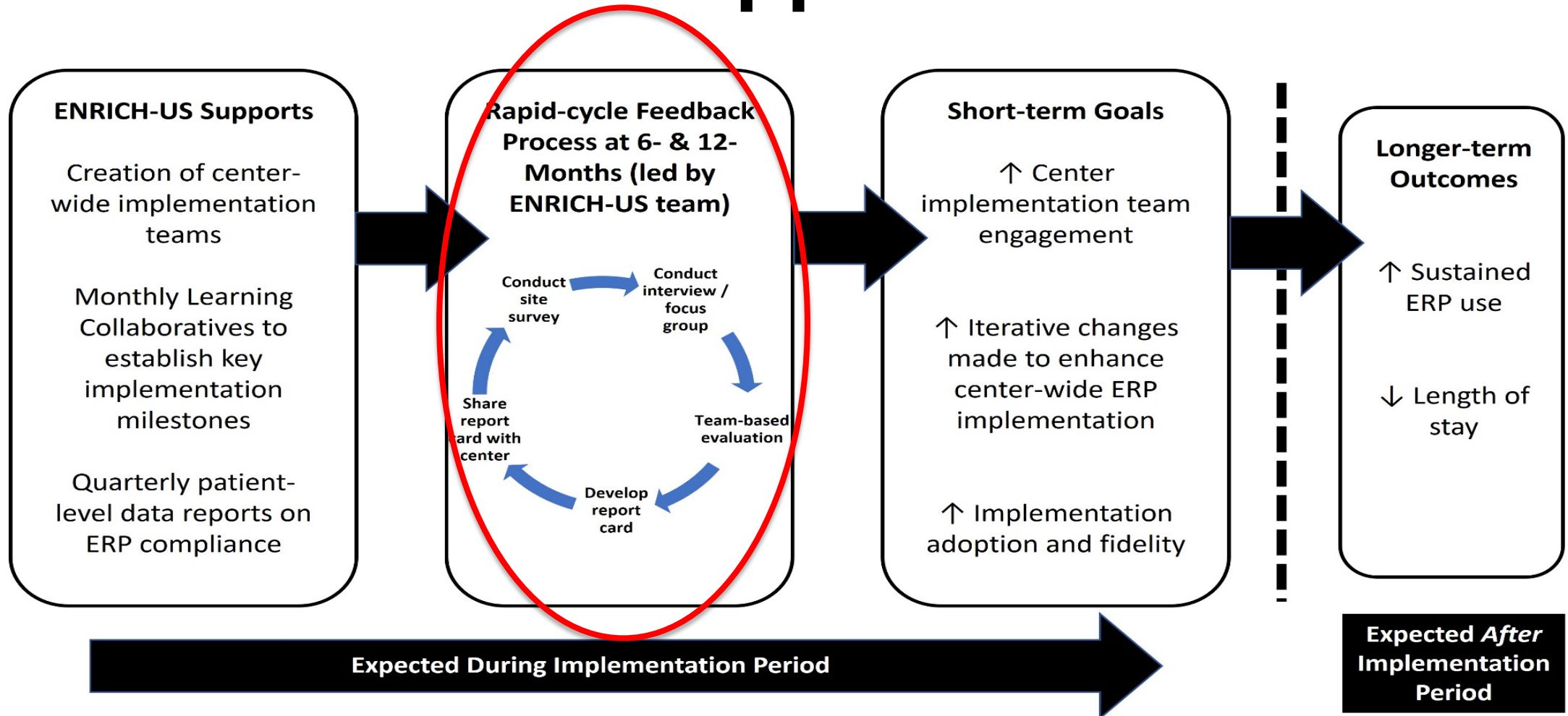
# Our approach



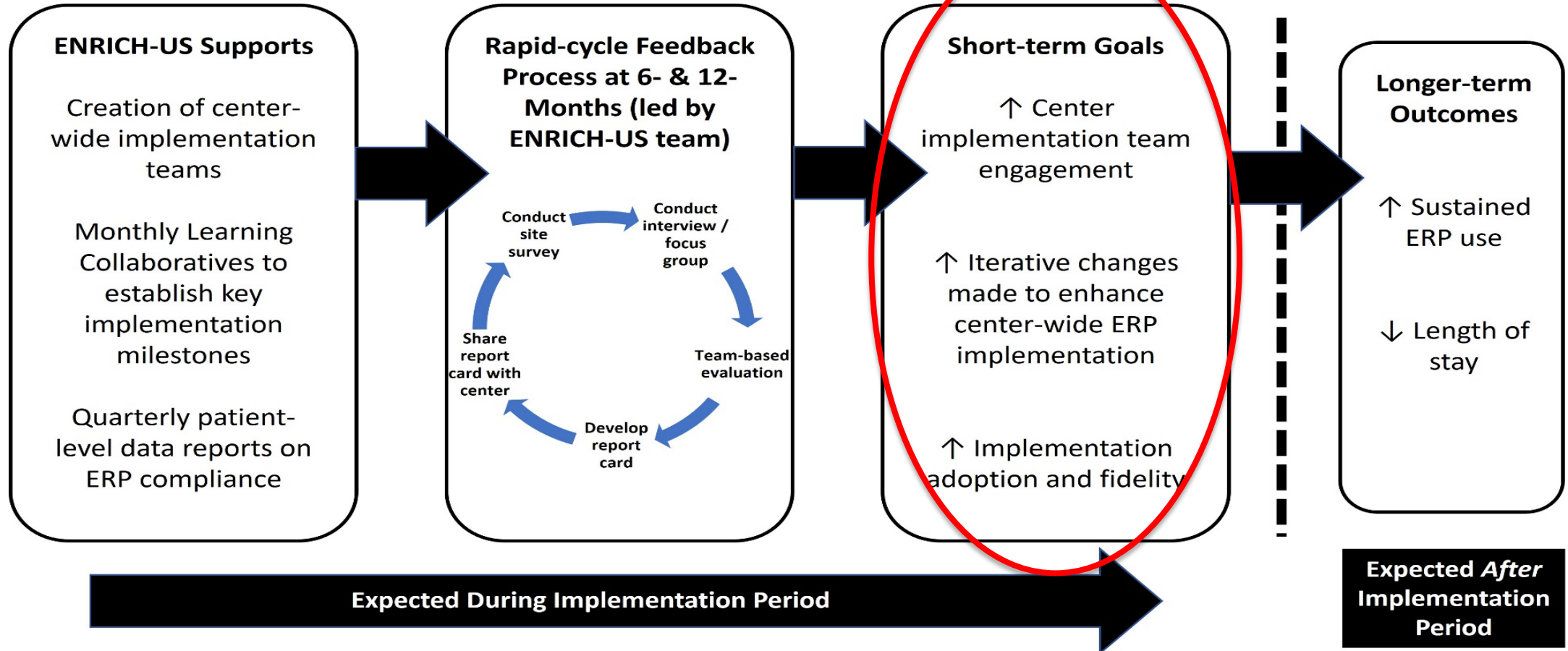
# Our approach



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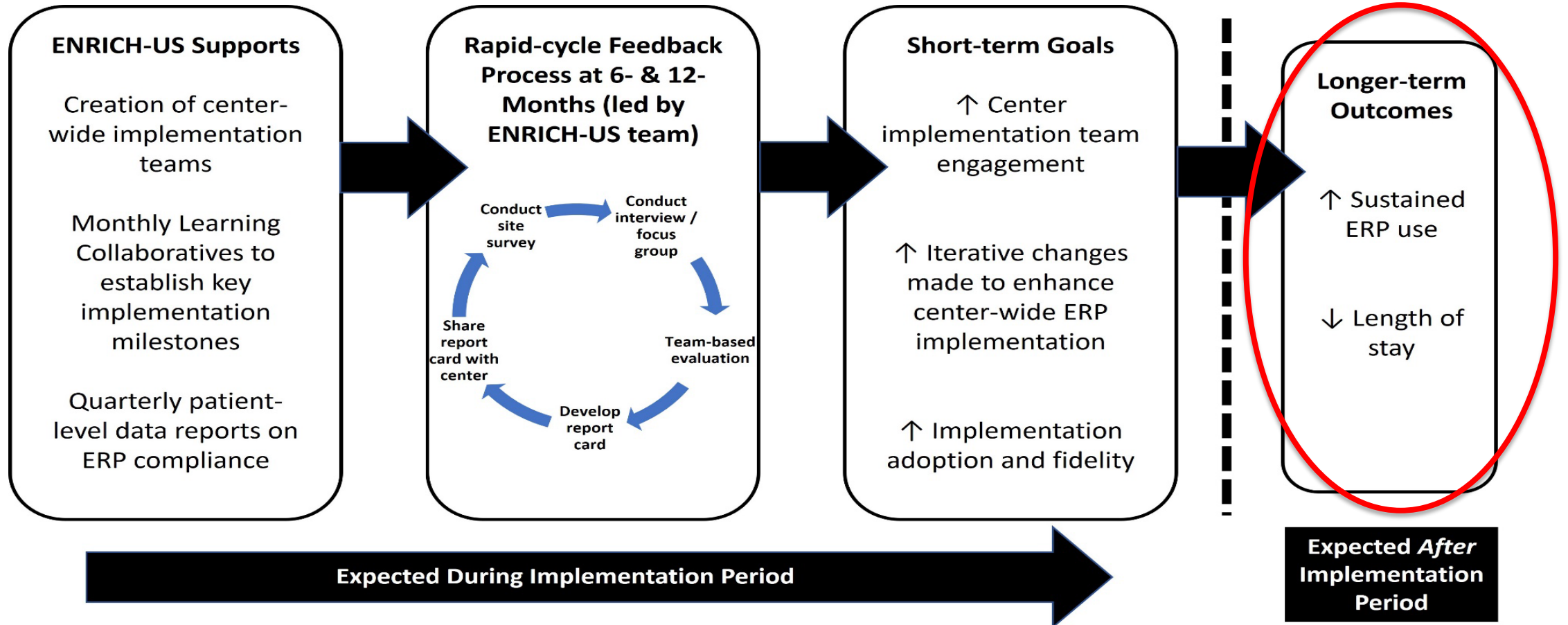


# Our approach

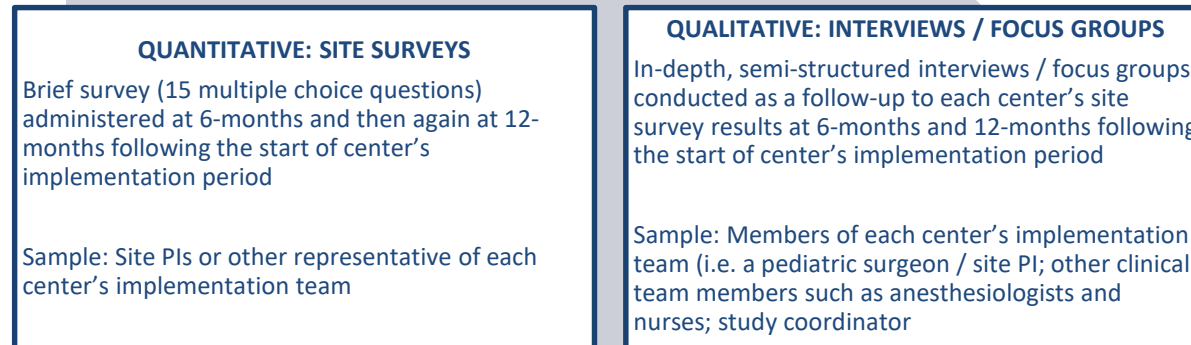




# Our approach



# Mixed-method sequential explanatory design



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## 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)

## 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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## 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



SITE	
CLUSTER	
DATE	
SITE IMPLEMENTATION STATUS	*change color of this cell to correspond to final grade*
OVERALL SUMMARY	

Implementation Status Details
<b>Excellent</b> <ul style="list-style-type: none"> <li>Bullet # 1</li> <li>Bullet # 2</li> <li>Bullet # 3</li> </ul>
<b>Needs Improvement</b> <ul style="list-style-type: none"> <li>Bullet # 1</li> <li>Bullet # 2</li> <li>Bullet # 3</li> </ul>
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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.
- 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.



Needs Significant Improvement

Needs Improvement

Excellent

<b>SITE</b>	Exemplar Hospital <i>[Site Name Redacted]</i>
<b>CLUSTER</b>	<i>[Redacted]</i>
<b>Date</b>	<i>[Redacted]</i>
<b>SITE IMPLEMENTATION STATUS</b>	Excellent
<b>SUMMARY</b>	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

Potential Benefits	Enabled <u>quick understanding of variation</u> in implementation and corresponding needs across centers
	Helped <u>provide actionable feedback</u> efficiently to centers about their implementation
	Helped to <u>facilitate partnerships with centers</u> through our mixed method data collection and feedback process
Potential Challenges	<u>Revealed that even rapid approaches require substantial resources</u> particularly around time and personnel support
	<u>Demonstrated that consensus among team members is still essential</u> in terms of aligning on the rapid approach and content of center-specific feedback
Practical Considerations	Identified critical need to <u>balance timeliness of rapid feedback with its comprehensiveness</u>
	<u>Actively engaged members of each center's implementation team</u> (e.g. physicians, nurses, QI professionals, patients, and caregivers)
	<u>Adopted an iterative and reflexive approach</u> to promote improvements in implementation over time

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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!



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