39 Toward a Learning System for ERAS: Embedding Implementation and Learning Evaluation

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"The success of organizations depends on their ability to design themselves social learning systems."
– Etienne Wenger

Introduction

Contemporary colorectal surgery was often associated with long length of stay (8 days for open surgery and 5 days for laparoscopic surgery), high cost, and rates of surgical site infection approaching 20–30%. During the hospital stay for elective colorectal surgery, the incidence of perioperative nausea and vomiting (PONV) may be as high as 80% in patients with certain risk factors. After discharge from colorectal surgery, readmission rates have been noted in past to be as high as 35.4%.

The concept of a multimodal approach to recovery after surgery was initially proposed by Kehlet who explored the possible determinants of postoperative morbidity in the late 1990s [1]. He identified potential risk factors that need to be recognized and treated perioperatively to minimize the effects of surgical stress on the patient. Kehlet also championed the idea of working within an integrated multidisciplinary framework. Together these efforts have led to a series of interventions that are formulated into standardized protocols to span a patient's entire journey through the surgical process with distinct elements in the preoperative, intraoperative, and postoperative phases [2].

The outcomes of interest to patients and providers include freedom from nausea, freedom from pain at rest, early return of bowel function, improved wound healing, and early hospital discharge. The basic premise is that the impact of surgery on the metabolic and endocrine response systems are reduced, leading to earlier recovery. Successful implementation of ERAS leads to reduced length of hospital stay and earlier return to productivity. Systematic reviews of ERAS for various types of surgery have shown that the intervention has the potential to enhance patient outcomes but that consistent implementation is required [3, 4]. In this chapter, we describe how the concepts drawn from the field of implementation science can be used to improve the consistency and quality of ERAS implementation while engaging front line clinical staff [5, 6].

Management of Surgical Risk and Quality Improvement

It is widely understood today that the first step toward implementing ERAS to assure patient safety and quality of care is to address several factors that are external to the surgical process itself. Scaling up in new hospitals and countries requires attention to much more than the surgerical interventions and requires an appreciation for introducing standardized processes in complex systems and appreciation of the implementation contexts [7]. These steps involve (1) developing a standard set of activities that are needed to deliver ERAS within a health system (over and above the clinical steps themselves); (2) identifying the operational factors (e.g., political will, resources, schedules, supplies, equipment, etc.) that affect the implementation of ERAS within the system; (3) identifying the organizational factors (e.g., staff motivation, organizational culture, climate for innovation) that affect the implementation of ERAS; and (4) developing a tailored, locally appropriate and bottom-up strategies to address the organizational and operational factors based on local constraints and championship. In essence, effective hazard reduction and risk management requires a reframing of care from one that is task-oriented at the level of the

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practitioner to a systems-based, patient-centered one that looks to the actual relationships within the socio-technical surgical microsystems and the operational and organizational characteristics of the meso- (and possibly macro-) system in which care is conceived and delivered [8–10].

At the most basic, this involves a reconceptualization of the patient from the passive object of medical intervention to an active "consumer" or "user" of health services who *coproduces and "owns" their own health* [11]. The risks and hazards of health care are known frequently to be the result of ineffective systems design rather than poor performance by surgeons and other individual providers. Preventable errors occur in health care because of the interaction between "latent" organizational system failures and "active" errors by frontline actors, possibly in ignoring or responding inappropriately to system failures [12]. Multiple latent conditions, or "organizational pathogens," may be designed into the processes and structures of care, thereby increasing the likelihood/risk of failure/error at the patient-provider interface, sometimes because of unforeseen interactions between pathogens.

An Organizing Principle for ERAS Implementation: The Modified Donabedian Model

The Donabedian model is a well-known conceptual model developed in 1966 to examine factors affecting the quality of health care delivery [13]. The model describes the health system as comprising three major linked components: structure, process, and outcomes. *Structure* refers to the settings where care is delivered and encompasses the physical and organizational characteristics of the care delivery environment. *Process* incorporates not only the clinical activities performed by physicians and other care providers but also all the other aspects of delivery that affect the overall patient experience within the health system, such as short wait times, transparent and clear communications, dignity and respect for patient and family, or compassionate care. Finally, *outcome* encompasses not only the results of the surgical procedure but also the other quality domains identified by the US Institute of Medicine, such as patient centeredness, timeliness, reliability, equity, or efficiency [14].

We will use an expanded version of the Donabedian model as the organizing principle for this chapter [15]. The version, shown in Fig. 39.1, expands the process stage of the model to illustrate that the range of interventions needed to achieve outcomes extends beyond surgery and even beyond the interventions linked to the preparation for the surgical procedure into generic health system-strengthening interventions such as leadership development, technology infrastructure development, communications training, or, in low-resource settings, even foundational components of the setting such as staff hiring and retention, supply chain management, or equipment maintenance. The field of implementation science, which we present later in this chapter, focuses on how we learn as a system and defines the clinical and service interventions as "intervention-specific capacities" and the generic interventions as "general capacities" [16]. Both sets of capacities are needed for the successful, reliable, and sustained delivery of any clinical intervention, and these are particularly critical for multicomponent interventions such as ERAS that are a mix of medical, organizational, and behavioral interventions. The success of ERAS is based not only on how well the surgeon and anesthesiologist and other surgical team members perform but also on clear actionable information provided to patients on perioperative care, criteria for discharge, how to address post-discharge complications, and follow-up protocols [17].

Each of these components of the intervention needs to be alinged for effective ERAS outcomes such as reducing readmission rates, which means that in addition to the surgeon's skill, there is the need for effective communication, gaining the patients' trust, facilitating post-discharge compliance, assuring that the community is ready to receive the patient, and other processes that make up the targeted and generic service intervention components [18]. But while these components may be obvious in theory, the fact still remains that they are challenging to implement in practice [19]. Processes need to be designed, and interventions need to be implemented and

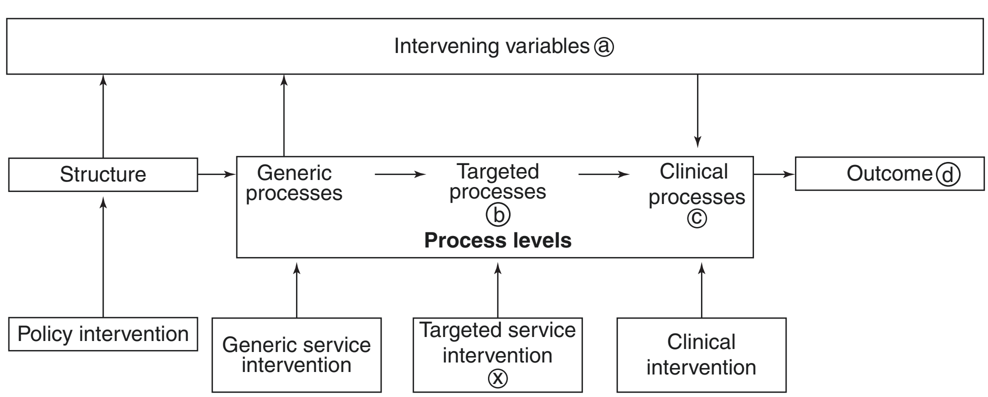


Fig. 39.1 Modified Donabedian causal chain. Interventions at structural (policy) and generic service level can achieve effects through intervening variables (such as motivation and staff-patient contact time) further down the chain. For example, an intervention at (x) produces effects (good or bad) downstream at (a), (b), (c), and (d)

adapted to fit the local context, which is highly shaped by the local culture and context, while still remaining true to the basic principles of ERAS [20]. We will use an implementation framework to operationalize the expanded Donabedian model.

The Design Focused Implementation Framework

Implementation scientists have developed more than a hundred frameworks to guide, assess, sustain, and improve the implementation process [21]. As yet, there is no standard methodology for framework selection, and implementation scientists use their expertise and judgment to select the best framework to suit the unique clinical or organizational needs. In this chapter, we select a framework that is best suited for implementing interventions de novo, where key delivery system processes do not exist and need to be designed from the ground up, such as when hospitals are planning to start implementing an ERAS program (Fig. 39.2) [22].

The framework consists of three components: design, implementation, and evaluation. The design component relies on the principles of experience-based co-design (EBCD) to develop delivery processes that best meet the needs of the patients and their families [23]. The implementation component identifies context-specific barriers and facilitators to implementation and develops strategies to overcome these barriers based on deep, local knowledge. The improvement component monitors both the process of implementation and the routine system performance post-implementation and uses this performance data to make necessary course changes to the system. The three components are linked together through a comprehensive mixed-methods process evaluation.

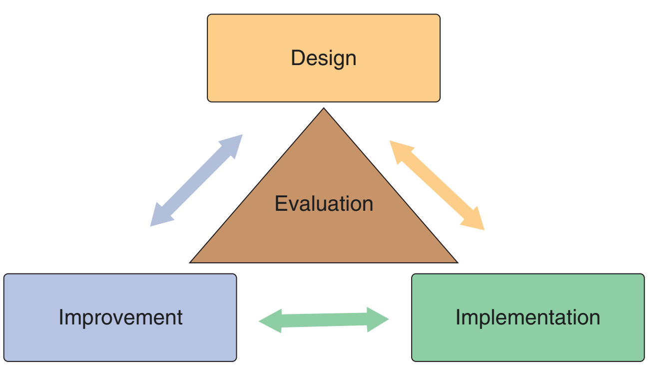


Fig. 39.2 Design Focused Implementation Framework (DFIF)

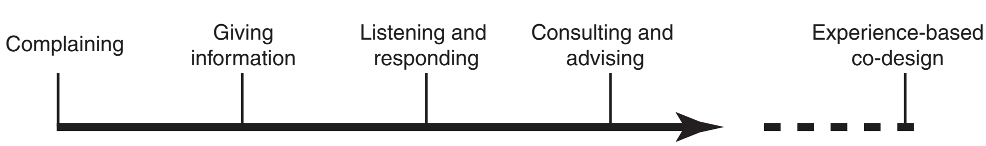
Designing the System: The Experience-Based Co-design Approach

Let us consider how this framework can be applied to create a comprehensive system for ERAS implementation. The first step is to create a set of standard clinical and organizational processes for the entire surgical experience. These processes could include pre-surgery consultation, orientation packages, communication prior to the surgery date, check- in processes on the day of surgery, patient mapping, discharge protocols, post-discharge communication, and follow-up in addition to the activities of the ERAS clinical intervention itself. The process mapping is designed with the needs of the patient, and their caregivers, in mind and is oriented to optimize the patients' experience during their interaction with the health system [24]. EBCD is a structured process that couples a detailed analysis of the facility workflow with video interviews of patients' to create "trigger films" for discussion. Patients and staff view the trigger films together to identify opportunities to improve the patients' experience and then charter small co-design, clinician led groups to address priority issues that arise [25]. The EBCD framework transforms and elevates the role of the patient to a true co-creator of the design process and services. Figure 39.3 shows the continuum of roles that a patient can play in interactions with the health system [23]. As we move from left to right in the figure, the power differential between the health system and the patient diminishes, a as the patient is actively involved in the co-production of the experience.

Implementing the Design: The Role of Implementation Research

The outcome of the design process is the set of processes, protocols, organizations, physical structure, materials, etc. that wrap around the clinical intervention to facilitate and support its success. But a good design alone is inadequate unless it is implemented well [5]. The emerging field of implementation science is dedicated to the study of local and organizational factors that affect the success of implementation and to develop and test context-appropriate implementation strategies that can enhance the acceptability and adoption of an innovation within an organization [6]. The design of the ERAS system can be more effectively implemented using the frameworks and tools of implementation science. One of the most commonly used frameworks is the Consolidated Framework

Fig. 39.3 The continuum of co-design roles of the patient. (Reprinted with permission from Bate and Robert [23])



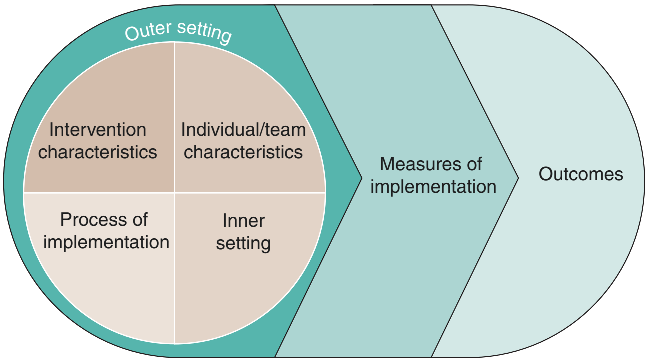


Fig. 39.4 Consolidated Framework for Implementation Research (CFIR). (Figure modified from Rojas Smith et al. [27])

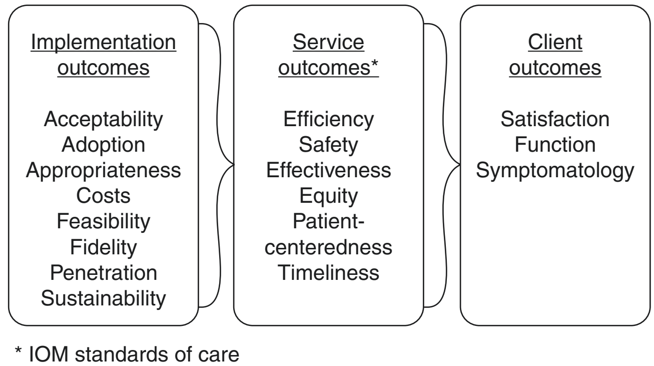


Fig. 39.5 Implementation, service, and client outcomes. (Reprinted with permission from Proctor et al. [29])

for Implementation Research or CFIR [26]. The basic structure of CFIR, shown in Fig. 39.4, defines five factors or domains that affect the quality of implementation [27, 28]. They are (1) outer setting, or the environment within which the implementation takes place (e.g., hospital or national policies or variations across surgical disciplines that may influence what is or is not possible to implement); (2) inner setting, or the characteristics of the organization such as the appetite for innovation or the organizational culture (e.g., rigid hierarchical organizations may not provide individuals the freedom to innovate); (3) intervention characteristics (e.g., the processes designed may be too complex or burdensome to implement even if they are supported by patients); (4) individual characteristics (e.g., the staff may not be motivated to implement the intervention or may lack general or intervention-specific capability); and (5) the implementation process (e.g., the communications about implementation may be disorganized, or there may be no systematic implementation plan).

Frameworks such as CFIR can be invaluable in elevating and analyzing the factors that affect the uptake, implementation success, and sustainability of an ERAS system in a particular department or hospital. It is important to recognize that the factors illustrated in Fig. 39.4 likely vary from site to site and from surgical specialty to surgical specialty. The CFIR provides a framework with measurement tools and instruments for a varied set of constructs in each domain. Using these instruments to identify the local barriers to implementation can help systems identify the key constraints that must be addressed to enhance the likelihood of successful implementation.

How do we measure the success of implementation? Implementation research defines a set of constructs called "implementation outcomes" that are separate and distinct from health outcomes. Figure 39.5 illustrates these outcomes [29]. As the figure suggests, implementation outcomes act as mediators or moderators to health or patient outcomes. Some desirable patient outcomes related to an effective ERAS program may be patient satisfaction, post-surgical complications, early discharge, or reduced patient readmissions [30]. As described previously, these outcomes depend both on the surgical process itself but even more so on a myriad of systems factors. Implementation outcomes provide a systematic approach for determining the variables that need to be considered and monitored in advance of the implementation and in a particular organizational context. For example, in a health system in which there is a rigid hierarchical organizational structure, ERAS—which requires trust, honest feedback and planning, teamwork, and communication—may not be acceptable to the surgical staff. In health-care systems where a single surgeon may circulate across multiple facilities, ERAS may not be feasible.

We suggest that studies measuring implementation outcomes and using frameworks such as CFIR to understand the factors that affect the successful implementation of ERAS will go a long way towards a deeper and more nuanced understanding of how to best engage clinicians in meaningful dialogue around change. These studies will build the knowledge of the targeted and generic service interventions that are the optimal precursors for successful ERAS implementation and sustained patient outcomes [31].

Adaptations and Improvement: The Model for Improvement and Implementation

Implementation outcomes and patient determinants are context-specific, and while studies measuring outcomes and CFIR constructs may enhance the body of knowledge about factors that need to be taken into account to implement ERAS successfully, the solutions to address these factors necessarily need to be local [32]. Interventions need to be adapted to address and overcome local barriers related to leadership, need for provider autonomy, variable trust levels, and other organizational contexts [33]. The process of adaptation does not happen magically; it requires the systematic and disciplined testing of a sequence of explicit adaptations to arrive at a version of the intervention that makes sense to the local clinicians, is not thretening and is feasible and flexible [34]. Adaptations can be made in both the clinical and the implementation aspects of the intervention, but local leaders need to keep in mind the inherent tension between the fidelity to the clinical intervention itself (i.e., making sure the key mechanisms through which the intervention works are not modified) and, the need for local fit to clinicians' workflow. This ground up apporach will support local championship and engagement.

For a multicomponent intervention such as ERAS, clinical leaders should carefully consider each component of the ERAS protocol. They need to determine its adaptability, and what elements need to be adapted and customized, based on previous local knowledge in this specific communty about desired implementation steps to engage clinicians, and be open about how best to acknowledge and address the potential barriers. Some ERAS components such as the use of antibiotic prophylactics or avoidance of premedication prior to surgery may be considered core and not adaptable, but other components such as early mobilization and early oral nutrition post-surgery can and should be tailored to local and cultural and reimbursement practices. For example, the menus for postoperative oral nutrition could be designed to match the ethnic and cultural preferences of the patients. This approach helps to attenuate barriers to practice changes [35].

Adaptations for successful implementation can be guided by the Model for Improvement and Implementation (MFII), shown in Fig. 39.6 [36]. The left side of the figure is the well-known MFI and is used to guide the quality of improvement initiatives. This part of the model helps to determine which adaptations need to be made to the clinical intervention itself. By asking what changes need to be made to the intervention to improve the fit to the local context and department/hospital culture, the implementers can develop a site-specific version of ERAS that remains true to its core elements but is locally acceptable and feasible. But even an adapted intervention may not be successfully implemented if the organization is not ready or if staff members do not trust each other and are not motivated to change their workflow. The right side of the figure asks questions related to implementation barriers and seeks to develop and customize implementation strategies (e.g., leadership engagement, staff training and communications, team-building exercises, etc.) to address these barriers [35].

The Plan-Do-Study-Act (PDSA) cycle, which guides the iterative tests of change, binds these components together [37]. We suggest that clinical systems intending to imple-

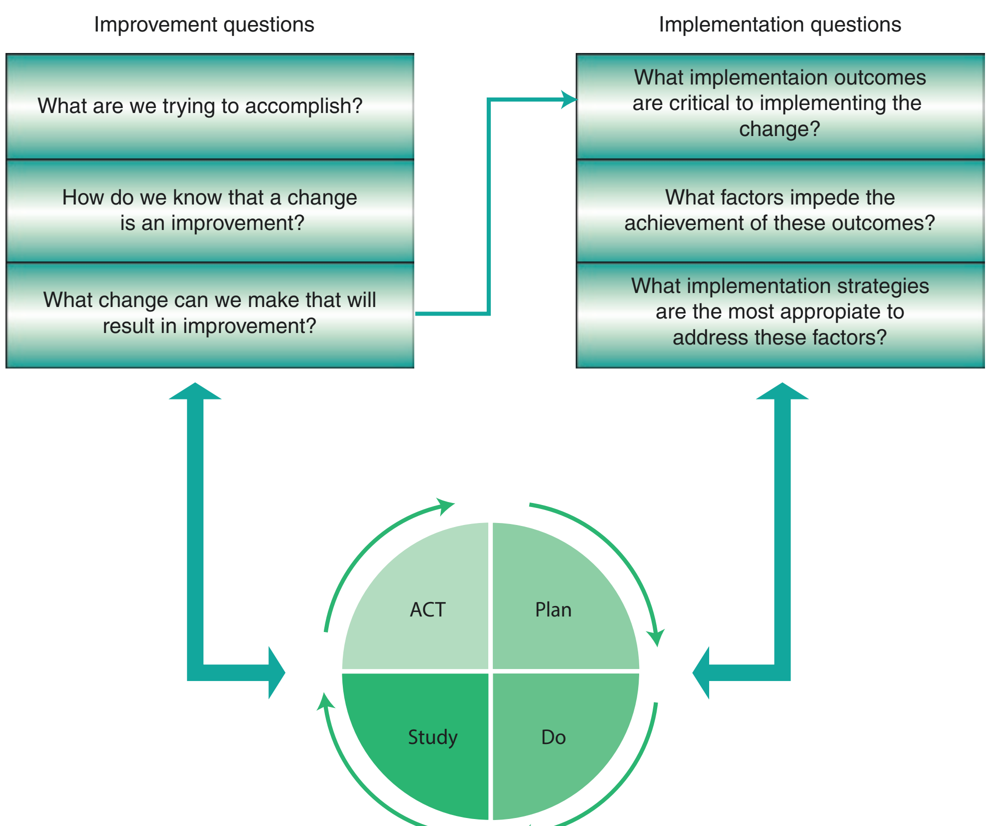


Fig. 39.6 Model for Improvement and Implementation (MFII). (Modified from Hirschorn and Ramaswamy [36])

ment ERAS use iterative PDSA cycles to adapt their intervention over time and allow for adequate time to refine the local iterative change model. We then encourage these health systems to use implementation methods to identify the implementation barriers and use the PDSA cycles to develop and test implementation strategies to address these barriers. Clearly, as Fig. 39.6 suggests, these are not independent activities.

Implementation challenges may require additional adaptations to the ERAS interventions, and these adaptations may result in the need for new implementation approaches. Figure 39.7 illustrates that an effective innovation (such as ERAS) is only one aspect of achieving successful and safe patient outcomes [38]. Effective evaluation of ERAS implementation and other components such a supportive hospital policies, patient centeredness, dedication to teamwork, focus on learning, etc. are all needed [15]. The MFII provides a structure to experiment and learn about how to strengthen all aspects of an ERAS system. Eight well-known quality tools are available to help organizations better understand and improve their ERAS processes [39, 40]. These tools include:

- Checklists
- Cause-and-effect diagrams
- Process flowcharts
- Pareto charts
- Scatter diagrams
- Probability plots
- Histograms
- Control charts

These tools help to visualize the system of care by mapping out the service lines at various levels of detail, helping to collect data to hone in on performance gaps, reviewing temporal and nontemporal performance patterns in the data that might cause deviation from consistent performance, quering as to what are the root causes for these deviations, and initiating PDSA cycles to address them. Training on these tools should be required for all members of the ERAS team before attempting to implement ERAS [41].

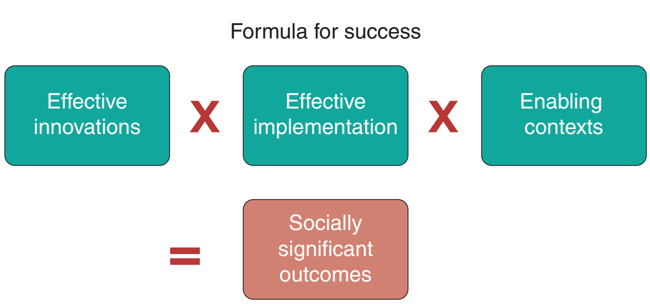


Fig. 39.7 Formula for successful implementation and update of clinical interventions [38]

Continuous Learning from Evaluation

It should be clear by now that successful implementation of an ERAS program requires not just the clinical studies to show that the intervention works in controlled study settings but also must be supported by a continuous organizational learning platform to understand how and what actually works in practice [42]. Evaluation methods for assessing the effectiveness of ERAS therefore need to determine not only whether patient outcomes have been achieved but also under what mechanism(s) they were achieved, for whom, and in what context. This requires the creation of an internal learning system that can document the results of the PDSA cycles described earlier, harvest learning, and share it with leaders in other facilities and systems so that knowledge about implementation becomes as pervasive as the knowledge about the intervention itself [16].

Learning is the acquired, relatively permanent or persistent change of behavior or behavior potential resulting from instruction, training, and practice (intentional learning) or experience (incidental learning). In 1984, Kolb described an experiential learning model, which argued that learning occurs through a cycle of reflective observations of concrete individual or team experiences in order to gain an understanding of what can be learned from each specific experience. This adaptive learning approach supports new ideas, which are applied to future experiences, renewing the cycle and supporting the professional joy and practice of the clinicians [43].

Figure 39.8 shows how a learning evaluation approach could work [44]. Each department or health system implementing ERAS uses the MFII to conduct PDSA cycles to create locally viable programs. The results of the PDSAs are discussed openly and regularly within each organizational microsystem in learning meetings, such as morbidity and mortality and staff meetings, and further adaptations and improvements are made, resulting in the next cycles of testing. At the same time, learning is shared across departments and hospitals in the system to build a robust system-wide knowledge base. This is hard, takes time to build trust and a requisite willingness to honestly evaluate each team and the entire microsytems' effectiveness, and does not happen automatically [45]. Infrastructure for common data collection, mechanisms for feedback and data sharing, and a joint and regularly articulated commitment to learning are all critical prerequisites for successful learning evaluation [46].

We suggest that the conduct of coordinated studies on ERAS programs that build on Peter Senge, Edwards Deming, and Don Berwick's work can drive clinical and continuous practice improvement, for example, by incorporating registries and/or pre-specifying quasi-experimental designs and creating conditions that support incremental learning across clinical microsystems using learning loops [47–49]. We propose that the aggregation of iterative learning loops within and across the various ERAS elements guided by national

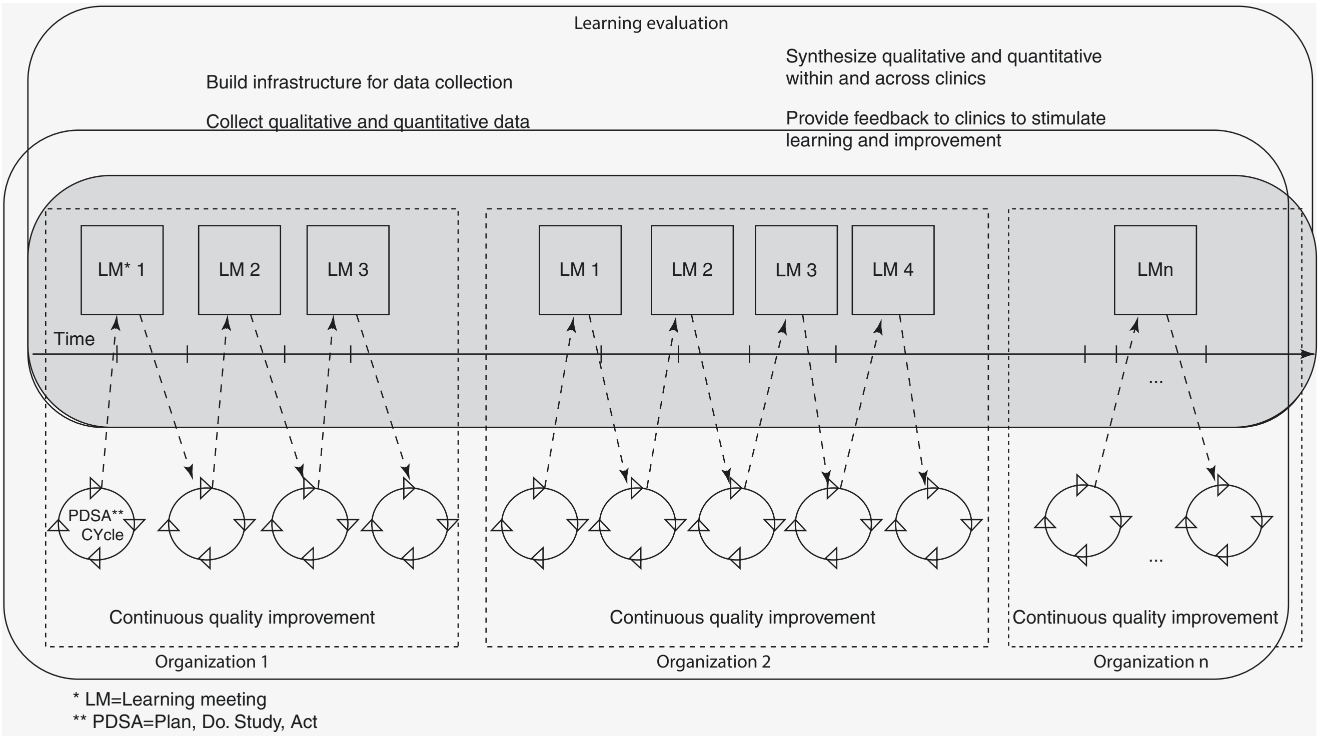


Fig. 39.8 A systems learning evaluation approach. (Reprinted with permission from Balasubramanian et al. [44])

and the international ERAS Societies can provide the conditions to rapidly accumulate knowledge, thus allowing the field to incorporate new understandings into new and improved structures and processes of care, consistent with the practices of double- loop learning [50].

Implementing ERAS: Some Foundational Considerations for Scale-Up and Sustainability

We have emphasized the need for ERAS implementation to be a system-wide approach, extending beyond the relatively narrow purview of the surgery itself and encompassing activities that affect the entire system up and downstream within which patient care is provided. For this to occur, and for the methods and tools of the design-focused implementation framework to be used effectively, some foundational elements of the system must be explicitly in place and be strengthened. We describe these principles now.

Principle 1: Building Trust for Organizational Resilience

The foundation of any successful cross-disciplinary collaboration is the building of a culture of trust. Trust must be based on more than merely being employees of the same organization because much of the state-of-the-science ERAS care requires groups of clinicians to work in teams, and patients must trust the overall team as well as its individual members [51]. Cultivating the trust of providers and patients in the teams delivering care would be simpler if those teams were well established, but many teams do not function well. The authors are aware from their experience how at times specialties regard each other in a negative manner, gaming of data, lying to each other and at times involving attending physicians who comment to residents that physicians in another specialty or based in the community were not "real doctors" [52].

Trust building is a slow, staged process and highly dependent on people's willingness to adapt a new professional intervention (sense-making) [53, 54], report honestly about their performance without fear (psychological safety) [55], accept input that may be critical of their work, and give their time in the pursuit of collective goals [56]. Frankel et al. [45] propose trust-ing building measures including:

1. Recognize that physician-physician relationships are consequential; they should be given the same level of attention and intention as patient-physician and interprofessional relationships.
2. Value differences in perspective; harness them as a resource. Disrespectful behavior in or around ERAS meetings that inhibits the participation of others, or the refusal to engage with others, eliminates the possibility of creating local adaption of ERAS protocols through dialogue, truth telling, and ultimately harming everyone, especially patients.

3. Notice the quality of the surgical team relationships when embarking on an ERAS program; be accountable and hold others accountable for creating patterns of respect, honoring profesional dissension and collaboration.

Physicians, like other people, can so focus on the technical aspects of their work that at times they do not notice the relational aspects. Confidence building requires years of collaborative effort. With increasing interpersonal familiarity comes interprofessional understanding and ultimately strong levels of commitment and engagement. Recent work in Alberta, Canada, suggests that thoughtful application of the Theoretical Domains Framework (TDF) through building trust, changing surgical care, and application of the Quality Enhancement Research Initiative (QUERI) to support system-wide implementation of an ERAS program for patients undergoing colorectal surgery has allowed successful implementation across multiple sites [31, 57].

Principle 2: Design Multi-stakeholder Collaboration and Authentic Learning Partnerships

The clinical microsystem provides a conceptual and practical performance and measurement framework for thinking about the organization and delivery integration of an ERAS program. Formed around a common patient service line or clinical need, and often embedded within larger organizations, a clinical microsystem is a small, inter-reliant group of people working together regularly to care for specific patient groups [10]. A clinical microsystem is characterized by a common aim, shared work processes, and a shared information environment. Optimally functioning ERAS clinical microsystems deliver the best quality health-care services by deeply engaging all team members (both clinical and administrative) so they understand each process and outcome failures and near-misses and to also understand that what is most important to the people who make up the ERAS microsystem is key to continuous improvement [58]. The main driver and facilitator of learning within this environment are its uncompromising internal climate of learning, radical transparency and a culture of improvement. Awareness of the presence and support of the microsystem by its members, and support for its activity by the organization's leaders within which it is embedded, is therefore essential for the optimal functioning of the ERAS microsystem. Recent work shows that by building trust and local clinician engagement, ERAS colorectal guideline implementation can succeed across a health-care system resulting in patient outcome improvements, similar to those obtained in smaller stand-alone implementations [57]. The compliance in following the ERAS protocol in the study was 60%, with lower compliance in adopting postoperative care elements, thereby illustrating the greatest opportunity for practice changes across the health-care team.

Principle 3: Select and Train the ERAS Team

Effective ERAS implementation depends on the willingness of front line clinicians from diverse backgrounds to cooperate in varied clinical settings (i.e., clinic, operating theater, intensive care unit, surgical wards) toward a shared goal, communicate and work together effectively, and improve [59]. To achieve high reliability and consistent performance, each team member must be able to (1) anticipate the needs of the others [60]; (2) adjust to each other's actions and to the changing environment; (3) monitor each other's activities and distribute workload dynamically; and (4) have a shared understanding of accepted processes and how events and actions should proceed.

Effective ERAS implementation requires an understanding of how individuals and crews behave during ordinary and crisis situations. Implementers must discuss in a deliberate and entrusting manner how best to optimize patient flow, communicate, and negotiate available resources and develop skills in dynamic decision-making, interpersonal behavior, and teamwork that lead to safe outcomes [61].

The Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS) training program provides a standardized, evidence-based curriculum for ERAS team training [62]. TeamSTEPPS aims to teach four fundamental competencies that constitute teamwork (leadership, situation monitoring, mutual support, and communication) with the aid of patient scenarios, case studies, multimedia, and simulation [63, 64]. The TeamSTEPPS program applied to a variety of surgical settings has been shown to enhance teamwork within the operating room, improve operating room efficiency and reduce patient safety concerns in the process [65, 66]. Table 39.1 lists questions to consider when evaluating the performance of or ERAS teams.

Table 39.1 Questions to consider when evaluating the performance of an ERAS team

1. Is the team the right size and composition?
2. Are there adequate levels of complementary skills?
3. Is there a shared goal for the team?
4. Does everyone understand the team goals?
5. Has a set of ERAS spefic performance goals been agreed on?
6. Do the team members hold one another accountable for the group's actions and results?
7. Are there shared protocols and performance ground rules?
8. Is there mutual respect and trust between team members?
9. Do team members communicate effectively and regularly meet to review and debrief team perfomrance?
10. Do team members know and appreciate each other's roles and responsibilities?
11. When one team member is absent or not able to perform the assigned tasks, are other team members able to pitch in or help appropriately?

Principle 4: Establish Learning Collaboratives

Horizontal learning through a learning collaborative can be powerful took to improve ERAS learning, is an innovative and comprehensive approach to multidisciplinary "action research" that brings researchers, clinicians, and policy makers together to create a "community of practice" [67]. Evidence has shown that this "community of practice" builds trust, shares knowledge, and generates empirical evidence for use and spread of innovation of quality improvement initiatives. The approach represents a fundamental paradigm shift in that it actively seeks to bridge disciplinary silos and address knowledge gaps within and across the ERAS care delivery system. It can support the creation of an integrated research and implementation continuum stretching from the prehospital care phase to long-term wellness that can transform the care delivery services and spread innovation and uptake [68].

Principle 5: Integrate Practices from Human Factors Engineering into ERAS Microsystem Functioning

Design the physical environments for ERAS success that are based on sound human factors principles and constraints. Design for human cognitive failings and the impact of performance-shaping factors—fatigue, poor lighting, noisy settings, and so forth. Human factors usability evaluations and interventions should take place early in the design and system development processes. They should include tools such as work domain analysis, function allocation, probabilistic risk assessment, and usability testing, among others [69, 70].

Conclusions and Research Recommendations

The ERAS® Society has helped to show that enhanced recovery after surgery programs represents a paradigm shift in how surgical care is delivered and how changes in practice can be disseminated and implemented. These results rely on a new approach to meaninful teamwork, continuous audit, and support of data-driven change and improvement [19].

The real challenge remains how to translate these findings into new settings. Introducing and implementing ERAS practice is a complex challenge requiring what Deming calls the "profound knowledge" of improvement [71]. This involves four key components: (1) a deep knowledge of the system through which ERAS is delivered; (2) understanding system variation and the aspects of variation that can be tolerated or even required (as in adaptations) and those that need to be eliminated; (3) willingness to experiment to continually improve and be bold in advancing testable theories of improvement; and (4) engaging front line staff in the improvement process with transparency, truth telling, and trust building.

While emerging data is showing that thoughtful implementation of ERAS improves the opportunity for rapid, uncomplicated recovery after surgery with both short- and long-term benefits for patients, decreases patient readmission rates, and leads to significant cost savings, the benefits can never be realized at scale without a rapid diffusion of ERAS into mainstream using timely and robust methods for systems improvement and clinician engagement.

The nature of introducing complex systems such as ERAS is that small changes to inputs may produce large changes in results across the system. Therefore thoughtful implementation with an eye on key system leverage points reinforced by engaged learning communities may result in rapid acceleration of ERAS uptake once a "tipping point" is reached. By the same token, negative feedback loops may result in rapid deterioration of uptake from which systems may find it difficult to recover. The ERAS implementation tools require thoughtful application: They are not a hammer that can be universally employed in all circumstances. They are not an end in themselves. Instead they provide a starting place for systematic reflection, staff engagement, deepening trust and staff support, and enabling a deep and meaningful culture of continuous improvement. The process of implementing ERAS is iterative and cyclical. It should promote engagement among clinicians, staff, administration, and patients. It is systematic and based upon measurement and consultation with all stakeholders involved in the process.

Even if initial outcomes are achieved, the practice could determine how to produce an even better outcome or achieve it more efficiently and with less cost. Continuous quality improvement (CQI) is necessary and requires significant change in how surgical care is delivered. It explicitly seeks to be not only better but the best that a team can deliver under these circumstances. The staff ownership of the ERAS improvement process and adaptability of the intervention to address future quality outcomes are considered key strengths.

Research ERAS Road Map

This chapter has demonstrated that the tools and frameworks of ERAS design, implementation and improvement for implementing complex interventions in complex settings, as well as trust, truth telling among colleagues, and collaboration within the team are essential in developing sustainable and effective ERAS programs that not only affect patient outcomes but can also result in a transformed way of doing work. However, as mentioned previously, these tools do not offer a prefabricated solution to replicate innovative practices in complex settings. They can't be magically applied to ERAS without additional research to determine how they need to be adapted to the particular contexts of different settings and surgical procedures [72].

We highlight below a number of unresolved research questions that need to be addressed about optimal ERAS uptake, scale, sustainability, and effectiveness. We organize these research questions into those that should be addressed in nearer term research and those that can be considered after the initial research phase is well under way.

Nearer-Term Research Questions

1. What does a generic ERAS process look like, and what are its variations? Based on the key principles of ERAS, can we develop a process and service map that can serve as a guideline for local implementation?
2. What are the critical moments of contact with patients in the ERAS process ("moments of truth")? What are the patient expectations at each of these moments, and what should be the measurable quality requirements (e.g., timeliness, consistency, compassion, etc.) that indicate that these expectations are being met?
3. What are the key barriers and organizational challenges for implementation of ERAS? How do we develop standard instruments that can easily applied to measure these barriers across surgery types and settings?
4. What kinds of implementation strategies are most effective? How do they vary by different organizational, insurance coverage, and cultural differences in order to address these barriers? How do we test these implementation strategies rapidly without the need for complex, expensive, and time-consuming research designs?
5. What kinds of methods are most appropriate for determining what aspects of the ERAS process can be adapted? What aspects need to be delivered with fidelity and which can succeed with low fidelity?
6. What are the mechanisms for harvesting, documenting, and sharing best practices related to ERAS implementation that can enable rapid learning across large healthcaresystems and stakeholders?

Longer-Term Research Questions

1. Since ERAS is a complex intervention consisting of multiple components, how do we determine the relative contribution of each component in achieving ERAS outcomes? How do we understand the interactions between these components and their relative contributions?
2. What are the mechanisms by which the various components of the ERAS process (e.g., clinical processes, operational processes, relationships among team members) contribute to lasting patient outcomes? How can an understanding of these mechanisms lead to better design of future ERAS programs?
3. What generic service interventions (e.g., system-strengthening interventions such as leadership development, communication processes, transparency organizational dashboards, equitable decision-making, etc.) need to be in place for successful ERAS programs to take root and be owned by clinicians? What are the best methods for developing, incentivizing, and implementing these interventions within the context of ERAS?
4. To what extent can programs such as ERAS facilitate change in the organizational culture of surgery departments that can result in long-term transformation to the way effective surgical, anesthetic and nursing care is provided? What are the mechanisms by which this transformation can take place?
5. What are the key elements of ERAS that can be adapted for low resource countries settings? What can be done to rapidly accelerate this uptake, scale-up, and sustainability given wide differences in cultures and work-related values [73]?

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