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Title: Emergency Manuals: How Quality Improvement and Implementation Science can enable better perioperative management during crises

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Keywords: Emergency Manual, Cognitive Aid, Crisis Checklist, Patient Safety, Interprofessional Team, Implementation Science, Quality Improvement, Improvement Research

Synopsis/Abstract: How can teams manage critical events more effectively? There are commonly gaps in performance during perioperative crises, and emergency manuals are recently available tools that can improve team performance under stress, via multiple mechanisms. This article examines how the principles of implementation science (IS) and quality improvement (QI) were applied by multiple teams in the development, testing, and systematic implementations of emergency manuals in perioperative care. The core principles of implementation have relevance for future patient safety innovations perioperatively and beyond, while the concepts of emergency manuals and interprofessional teamwork are applicable for diverse fields throughout healthcare.

Keypoints:

- Concepts from quality improvement, implementation science, and improvement research are presented within the context of emergency manual implementation as a nascent successful patient safety innovation

- Stress can cause well-trained professionals, in diverse safety-critical industries, to omit key steps and diverge from optimal management

- Emergency manuals are tools that can help good teams to perform even better during rare critical events, with widespread dissemination and rising interest in their clinical use

- The Emergency Manuals Implementation Collaborative (EMIC) provides a central repository for implementation and training resources, links to cost-free downloadable tools from multiple groups, and more at www.emergencymanuals.org

Defining the problem

For many rare operating room (OR) crises, such as cardiac arrest, malignant hyperthermia, or local anesthetic systemic toxicity, there are stacks of published literature on optimal management. Yet, even expert clinicians often omit or delay key actions, with detrimental impacts on patient morbidity and mortality. [1] In multiple simulation-based studies, correct

performance of key actions during crises dramatically increased when emergency manuals, crisis checklists, or cognitive aids were used.[2–4]

This paper examines how the principles of implementation science (IS) and quality improvement (QI) have been applied in the development, testing, and systematic implementation of emergency manuals in perioperative care. We present evidence from simulation-based OR studies, reflect on related experiences in other safety-critical industries such as aviation, and describe a conceptual framework for implementation along with data from early clinical uses and implementations. We also explore the practical, organizational, and social processes that can influence implementation, and conclude with reflections on the future role of emergency manual implementation as a model for other quality improvement and implementation science efforts.

Terminology

- Emergency Manuals (EMs) are context-relevant sets of cognitive aids, such as crisis checklists, that are intended to provide professionals with key information for managing rare emergency events.
- Synonyms and related terms:
    - ‘Crisis Checklists’
    - ‘Emergency Checklists’
    - ‘Cognitive Aids’ – a much broader term, though often also used to describe tools for use during emergency events specifically

- Throughout this article we use the term ‘Emergency Manual (EM)’, except when referring generically to any of these as ‘tools’ or when describing a specific study with its own terminology. However, the synonyms above could be used interchangeably.

Enabling tools

Emergency Manuals are intended as both educational and clinical tools. They represent highly condensed repositories of practical knowledge that must be carefully designed and that require training to enable rapid use under conditions of significant pressure. EMs also seek to facilitate effective teamwork and decision making within the collective practice of healthcare professionals.

EMs are intended to be symbiotic adjuncts with, rather than replacements for, good preparation, teamwork, and judgment, and EM use should never precede necessary immediate actions such as chest compressions for a pulseless patient. Their intended use begins only once resources allow – either sufficient help is available for synchronous use from the beginning of a crisis, or initial clinical actions are already underway. Figure 1 shows emergency manuals being used during simulated critical events.

Emergency Manuals Implementation Collaborative: resources and reach

- For decades, Advanced Cardiac Life Support cards and Malignant Hyperthermia posters were the only readily available cognitive aids for OR clinical use during critical events.

- Now, the Emergency Manuals Implementation Collaborative (EMIC) provides a central location for links to multiple cost-free downloadable tools, as well as implementation and training resources for any such tool, and relevant published literature.[5] www.emergencymanuals.org/
- There has been broad dissemination of multiple tools, since EMIC began in 2012:
  - >80,000 downloads combined of multiple English-language tools
  - Translations of these tools into other languages have also spread rapidly e.g. >200,000 downloads of Chinese versions alone. [6]
  - Many downloaders state they shared the tool(s) with numerous colleagues at their local institutions, implying broader dissemination.
  - These tools seem to be filling a need, with active interest in the concept. Appendices A-C show examples from multiple available tools.
  - Yet, downloading is only one initial step towards systematic implementation and effective clinical use.

Learning from other industries

Safety-critical industries, such as aviation and nuclear power, actively use emergency manuals and similar tools in their operational activities. Professionals in these industries undertake regular training in the management of emergency scenarios and the use of EMs, and rely on EMs in actual emergency events. Relying on memory alone is a risky strategy in time-pressured, high-stakes emergency situations.

Even well-trained and highly experienced professionals are often not able to retrieve and deploy detailed knowledge under stress, and this is particularly the case for rarely used information[7,8]. This is equally the case in healthcare. Common errors during management of simulated OR critical events include both diagnostic and therapeutic cognitive errors,[9] and also cognitively recalling but never completing an action. One of the reasons for the latter is a failure of prospective memory– forgetting to do something you intended to do. Prospective memory is particularly vulnerable to interruptions, which are frequent during crises.[10] The use of EMs -- combined with good training, teamwork, and judgment - is beginning to address these issues.[11–13] Still, rigorous larger studies using mixed quantitative and qualitative methods are needed to further understand and guide appropriate EM clinical implementation and use.

Emergency Manuals: a history and a framework

The development and use of emergency manuals builds upon a century of related efforts to improve patient safety. The first known mention of EMs was almost a century ago. In 1924, Dr. Wayne Babcock (the surgeon famous for Babcock forceps) wrote "If a response is not instantly obtained by simple measures" (i.e. immediate actions); "a fixed emergency routine" (i.e. an EM or similar tool); "posted on the walls of every operating room" (i.e. accessible where needed); "and drilled into every member of the staff should be enforced" (i.e. prior training along with a culture of expected use).[14] An in-depth history of simulation, teamwork training, cognitive aids, and checklists is beyond the scope of this article, but further background is provided in multiple References.[10,15–20]

For many years, Advanced Cardiac Life Support cards and Malignant Hyperthermia posters were the only readily available cognitive aids for OR critical events. Early work by Gaba's/Howard's and Runciman's groups developed succinct content for cognitive aids spanning a wider range of critical events.[10,15,21] In the past few years, development work by multiple groups in parallel has provided cost-free access to several OR emergency manuals, which are designed for use during crises and each linked to via the EMIC website.[22] For examples, see Appendices A-C. At the same time, Gawande's popular book *The Checklist Manifesto*,[18] along with multiple healthcare implementations and studies of routine checklists,[23,24] spread the concept that human memory is fallible and increased the receptivity of clinicians to the potential benefits of emergency manuals.

When Babcock made his proposal more than ninety years ago, the healthcare community was seemingly not yet ready to accept and embrace the utility of EMs. In contrast, the message is now spreading quickly. There is also an increasing recognition that all cognitive aid use exists within the broader context of teamwork and dynamic decision-making skills (See Figure 2, on Crisis Resource Management key points). Gaba has provided a detailed description of how emergency manuals developed within anesthesiology from a rich broader history of cognitive aids and checklists, highlighting contributions of multiple groups globally.[25]

A conceptual framework for clinical implementation of EMs has been developed and can be applied to any field of healthcare. It defines four key elements that enable effective implementation.[26] (See Figure 3). In practice, these elements overlap and interact non-linearly:

1) **Create** (often by locally customizing an existing tool): Refine EM content and design for the specific practical tool to be implemented;
2) **Familiarize**: Train clinicians for EM use, including why, when and how to apply in practice;
3) **Use** clinically: Put into practice, ensuring accessibility in all needed locations and supporting all appropriate team-based interactions, such as triggering EM use and enabling a 'reader' role;
4) **Integrate:** Embed EM use into local culture and professional practice, shaping clinician expectations, attitudes and behavior as described in the fields of implementation science and improvement research. [27]

As with other improvement efforts in healthcare, early experiences show that addressing these vital elements is greatly enabled by leadership engagement, local champions, and inter-professional implementation teams.[28,29] Simulation studies and early clinical implementation have made it clear that having a tool available to implement is a necessary start, but is vastly insufficient for enabling effective use.

Simulation-based studies of emergency manuals

One of the most important ways of enabling effective clinical use of emergency manuals involves engaging clinicians immersively to demonstrate both the rationale of why to use

emergency manuals and the practical details of how. There is now a decade of studies examining whether the use of EMs helps clinicians, or teams, perform better during simulated OR crises. The preponderance of the data points to "yes", though there are clearly important nuances involved in *how* to best use these tools. A relevant subset of these simulation studies are described here.

In a 2006 observational study of anesthesia residents managing simulated malignant hyperthermia (MH) cases, Harrison et al. found a positive correlation between the frequency of MH cognitive aid use and appropriate treatment of MH.[2] Burden et al. found that the majority of anesthesia and obstetrics residents did not use easily accessible cognitive aids, and proceeded to omit key actions during management of MH and obstetric cardiac arrest simulated scenarios. However, when a medical student 'reader' was explicitly charged with reading to the team from the cognitive aid, key actions were then performed and the help appreciated, suggesting the question of how teams can be trained to trigger appropriate use and reader roles themselves.[30] Bould et al. found no difference in management of neonatal resuscitation with and without a cognitive aid poster, but importantly subjects were not familiar with the poster before the scenario and most in the 'intention to treat' intervention group did not use it frequently, i.e. if it is not used it cannot help.[31] Neal et al. found that anesthesia residents performed significantly better in managing a surprise scenario of local anesthetic systemic toxicity (LAST) when randomized to have access to a previously introduced, therefore familiar, LAST checklist versus not having access to the checklist. Moreover, within

the intervention group, the residents who used the LAST checklist more frequently performed even better.[3]

Arriaga et al. studied interprofessional OR teams managing eight different OR crises. Each team was randomly assigned to half of the events with, and half without, crisis checklists (CCs), serving as their own controls. The teams were familiarized with the CC concept and format, though not the specific events. When CCs were available versus not, 6% versus 23% of key management steps were missed, signifying a large improvement in event management.[4]

Marshall broadly reviewed cognitive aid literature from a variety of settings and also discussed the potential impact of design factors for cognitive aids in healthcare.[32] Subsequently, Marshall's group conducted multiple simulation studies to understand the impacts of cognitive aid designs and use on team functioning and non-technical teamwork skills.[33,34] Watkins *et al.* studied paper and electronic versions of EMs in simulated settings, where residents were briefly familiarized with both EM formats, but had not typically used EMs previously. They found that about a third of participants did not use the assigned tool when confronted with an applicable critical event, that paper tended to be preferred over electronic, and that both formats had only limited impacts on performance. This suggests that factors beyond the simple use of a cognitive aid are important -- such as more extensive training on when and how to use such tools, and tool design.[35,36] Goldhaber-Fiebert and Howard put the healthcare simulation literature into context with findings from other safety-critical industries and decades of

iterative simulation-based development and testing, proposing the four-element implementation framework described above.[26]

Early clinical implementations and trainings: data and further resources

Neily et al. surveyed Veteran Health Administration (VHA) anesthesia professionals six months after national VHA implementation of a 14-event clinical cognitive aid for OR critical events, which was initiated at the Palo Alto VHA and drew on prior work from the book *Crisis Management in Anesthesiology*.[10,37] Of the respondents, 87% knew it existed, half had used it as a reference, and 7% had used it during a crisis. All crisis users felt it was helpful and had used it previously as a reference, which likely improved their familiarity with and awareness of the tool. Training varied across VHA sites, and crisis users were more likely to have received formal training.[37] While 7% may not sound like much, the relevant denominator of applicable critical events in six months since implementation is not known and likely is itself small with only a subset of respondents even encountering an applicable opportunity.

Following recent widespread cost-free dissemination of Ariadne Lab's crisis checklists (ACC),[38] Stanford emergency manual for perioperative critical events (SEM) [39] and Society for Pediatric Anesthesia's (SPACC) critical events checklists,[40] there have been case reports[11,12], case series of uses[13], and many personal accounts of effective clinical uses of EMs during clinical critical events. For example pages from the above tools, see Appendices A-C. The common emerging themes from clinical uses to date include:

- Importance of EM accessibility and familiarity

- Value of interprofessional immersive trainings (can be low-tech simulations)
- The need for someone on the team to suggest or trigger use
- Helpfulness of a reader role, separate from event leader, when resources allow
- The potential for EMs to improve team communication
- The potential for EMs to improve patient management actions

Many biases exist when single case uses are described individually. However, the multiple early reports do suggest that these tools are being used clinically and that at least some clinicians have found them to be helpful for patient care, underscoring the need for more formal mixed-methods research on clinical implementation and use of EMs.

Clinical implementation research for EMs is nascent. In a Stanford mixed-methods survey study of early clinical uses, 19 (45%) of respondent residents had used an EM during a clinical perioperative critical event in the 15 months since implementation.[13] The vast majority of users felt the EM helped their teams deliver better care to their patient, and none felt it hurt or distracted from care. There was a wide variety of event types for which EMs were used. Residents also reported that OR safety culture supporting appropriate cognitive aid use improved since implementation and that the most impactful exposures were mannequin-based simulations of critical events coupled with self-review.

A study of OR staff trainings for EMs and teamwork skills, showed increased awareness of, familiarity with and intention to use EMs in the future, using in-situ low-tech simulation during brief but widespread division-based trainings.[41] The full training curriculum, instructor guide,

and handouts are available for local use or adaptation.[42] Multiple groups have published or shared video-based materials for why, how, and when to effectively use EMs.[43–45]

As more institutions are pursuing EM implementation locally, they are finding important factors to support success include the following [29]

- leadership engagement
- local champions
- interprofessional implementation teams
- broader culture of safety and quality improvement efforts
- local customization at least for key phone numbers and conformity with local policies

Making manuals work: implementation and improvement

Implementing emergency manuals is a complex process that confronts difficult practical challenges. Many of the greatest challenges and vital components concern the complex, socially adaptive work that is required to integrate EMs into frontline practice by changing collective knowledge, attitudes, and behaviors. Historically, efforts to develop and implement various cognitive aids in healthcare have followed a common pattern. They have started with an intense focus on the design and immediate use of the tool itself, and then gradually broadened and deepened to consider the social and cultural challenges that arise when attempting to reshape professional practice and reorganize coordinated action in complex healthcare institutions.[46]

Because EMs often aim to facilitate effective teamwork, decision making, and management actions, close attention must be paid to the design and customization of the tools; the

knowledge and skills of individual clinicians; the collective attitudes, norms, and beliefs; and the organisational processes and systems that all shape professional behavior in real world settings. A range of research in this area has clear implications for implementing EMs and other safety innovations, spanning four interrelated areas: establishing a problem to motivate changes in professional practice; local ownership; organizational systems; and customization. (See Table 1).

Establishing a Problem

First, changing professional practice depends on professionals accepting that practice should and can be changed. The 'work before the work' requires defining and agreeing that there is a problem—and an opportunity to improve.[47] For EMs, this often involves establishing that human fallibility is universal, that fallibility can have particularly detrimental effects in emergencies, and that there are supportive tools such as EMs that can address these problems. Demonstrating this through the use of locally relevant data, supplemented by immersive experiences or engaging stories can be a powerful way of preparing professionals for the need to change practice.[48] Establishing that there is a problem that can be addressed, the rationale for why change is needed, coupled with a sense of urgency, is the first step in building the social receptivity to change.

Local Ownership

Second, a sense of ownership of a new intervention is vital to successful uptake.[49,50] This can be fostered by local individuals 'championing' a particular intervention, such as a new EM. However, champions need to be well-respected and seen as legitimate within the professional

group they are seeking to influence, often requiring multiple interprofessional champions. Such champions need to demonstrate the value of the intervention in their own behavior, and that of other respected role models, as well as challenge inappropriate behaviour.[51] Local data and clinical stories of uses, e.g. within case conferences or morbidity and mortality presentations, can be powerful ways of illustrating local success. It is also important that, in championing an intervention like newly introduced EMs, debate and challenge is encouraged about what works and why, and what does not work and can be improved. This can encourage openness and broad ownership, and engage rather than alienating critics, all essential for the widespread implementation of EMs, that ultimately need to be owned, understood and shared by the vast majority in a professional practice. Building this sense of collective ownership—as well as peer-support and peer-accountability—can provide a strong driver to the social adoption of new practices and tools.[48,52]

Organizational Systems

Third, EMs need to be aligned with and supported by local organizational systems and resources, and embedded in collective practice. Like any tool for supporting and organizing coordinated action, EMs are dependent on the skills and training of those who are responding to an emergency, as well as the resources and equipment available and broader organizational mechanisms that support frontline professionals. The introduction of EMs can act as a catalyst to improve and restructure broader organizational systems prompting helpful changes to the way other processes are organized.[53] In some cases, implementing an EM may represent a process of standardization, which can reveal gaps in and intersect with other processes, such as

the reliable provision of relevant equipment or coordination among multiple professions in preventing or responding to crises. Equally, EMs are most effective when they are part of usual and expected, collective practice for crisis management. This requires effective familiarization and training, which in turn requires organizational resources and systems to support that training.[54] Interprofessional simulations or drills can help increase familiarity with the tool and the tasks required—they can also, critically, increase trust and improve interprofessional communication, common weak points in preventing or managing emergencies, with potentially far reaching benefits.[51]

Customization and Improvement

Fourth, adaptation and the continual improvement of EMs and similar tools is important so that they are customized appropriately to the local setting. This customization process can also broaden engagement and a local sense of ownership of the tool, making it more likely that it will be incorporated into usual practice. Engaging in customization requires developing clarity regarding which elements of a tool and its implementation are core and essential, and which peripheral elements benefit from local customization.[55] For EMs, customization often involves adding or adapting one or more of local: emergency phone numbers, specific response to massive hemorrhage, formulary medication names and dosing, and available equipment or resources.

There are also risks that local customizations might inadvertently reduce the effectiveness of a tool, for example by altering essential elements of its design, introducing typographic errors, or

adding so much content that it is less readable. As such, it is important that local customization is properly managed and reviewed. Rigorous processes have been established in other sectors such as aviation, where master checklists are produced by equipment manufacturers and approved by national regulators, then each operator has dedicated employees with expertise in checklist development for locally adding or tailoring certain elements according to their own systems and processes.[56] High reliability organisations, such as nuclear power stations and airlines, regularly review their emergency checklists, updating or improving them when necessary through processes of ongoing testing, advancements in the field, incident reporting and input from front-line professionals.[57,58] This ensures that frontline staff retain a sense of ownership, as well as harnessing real-world uses and simulation trainings as opportunities to also test the tool against the demands of reality.[52,59]

Emergency Manual Futures: Discussion and Implications

Perioperative medicine has reached a tipping point in enabling effective use of emergency manuals to help teams deliver better patient care during critical events. The evidence base from other safety-critical, high-reliability industries and from simulation-based healthcare studies has shown both a need to more reliably manage crises, and that EMs can fill this need when used effectively. Several cost-free tools are now widely available for OR clinical settings, along with detailed implementation and training resources.

The data described here combine to suggest a useful role for EMs in helping clinical healthcare teams deliver optimal care to patients during critical events. Many important implementation

challenges and research questions are worthy of further exploration. Among the next priorities regarding OR emergency manuals are to:

- Describe dissemination, adoption, implementation, and clinical uses
- Assess barriers and facilitators for EM implementation and use
- Further share effective implementation, training, and use strategies
- Actively seek out and mitigate any potential harms

The implementation of perioperative EMs also provides a potentially powerful broader model of how quality improvement efforts can interact synergistically with implementation science. Many of the transferrable lessons involve the important roles of: leadership support, local champions, training and simulation, inter-professional involvement, and combining both scientific data and immersive experiences to influence practice. Almost all safety interventions in healthcare represent complex practical, social, and adaptive problems, involving the intersections of individual clinicians' knowledge, skills, and attitudes; broader teamwork and communication; systems processes; and local cultures. It is therefore unsurprising that improvement efforts also require complex and adaptive approaches to be successful. The lessons from the implementation of emergency manuals described here, integrating contextually-sensitive and socially-adaptive approaches early in the process, are likely applicable to effectively implementing many other safety interventions in anesthesiology and perioperative care.

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Table 1. Social and organizational processes underpinning implementation of safety innovations, such as emergency manuals

Social and organizational process	**Approach to implementation**

Establishing a problem	Building agreement and acceptance that there is a gap between current and desired outcomes, which EMs can help address. This process is often effective in motivating a change in professional practice via a blend of data presentations, immersive experiences, and stories from respected thought leaders.
Local ownership	Fostering a sense of local ownership and buy-in through creating an interprofessional team who lead the implementation and respected champions who model engagement with EMs.
Organizational systems	Reorganizing local systems to ensure resources are provided, equipment is in place, incentives are aligned, and training is routinized to enable EM use.
Customization and improvement	Supporting appropriate customization and adaptation of EM to fit with local requirements, and careful consideration of interactions with existing local processes of care delivery. Pearl: Preserve the core essence of the innovation, while adapting the periphery of the innovation to better fit the local setting.