Evidence Brief: Implementation of High Reliability Organization Principles

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PREFACE

The VA Evidence Synthesis Program (ESP) was established in 2007 to provide timely and accurate syntheses of targeted health care topics of importance to clinicians, managers, and policymakers as they work to improve the health and health care of Veterans. These reports help:

- Develop clinical policies informed by evidence;
- Implement effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures; and
- Set the direction for future research to address gaps in clinical knowledge.

The program is comprised of four ESP Centers across the US and a Coordinating Center located in Portland, Oregon. Center Directors are VA clinicians and recognized leaders in the field of evidence synthesis with close ties to the AHRQ Evidence-based Practice Center Program and Cochrane Collaboration. The Coordinating Center was created to manage program operations, ensure methodological consistency and quality of products, and interface with stakeholders. To ensure responsiveness to the needs of decision-makers, the program is governed by a Steering Committee comprised of health system leadership and researchers. The program solicits nominations for review topics several times a year via the program website.

Comments on this evidence report are welcome and can be sent to Nicole Floyd, Deputy Director, ESP Coordinating Center at Nicole.Floyd@va.gov.

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This report is based on research conducted by the Evidence Synthesis Program (ESP) Center located at the **Portland VA Health Care System, Portland, OR**, funded by the Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development. The findings and conclusions in this document are those of the author(s) who are responsible for its contents; the findings and conclusions do not necessarily represent the views of the Department of Veterans Affairs or the United States government. Therefore, no statement in this article should be construed as an official position of the Department of Veterans Affairs. No investigators have any affiliations or financial involvement (*eg*, employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties) that conflict with material presented in the report.

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EXECUTIVE SUMMARY

Objective: To systematically evaluate literature on frameworks for high reliability organization (HRO) implementation, metrics for evaluating a health system's progress towards becoming an HRO, and effects of HRO implementation on process and patient safety outcomes.

Key Findings

- We identified 5 common HRO implementation strategies across 8 frameworks. Based on those, the Joint Commission's High Reliability Health Care Maturity Model (HRHCM) and the Institute for Healthcare Improvement's Framework for Safe, Reliable, and Effective Care emerged as the most comprehensive, as they included all 5 strategies, contained sufficient detail to guide implementation, and were the most rigorously developed and widely applicable.
- The Joint Commission's HRHCM/Oro™ 2.0 is the most rigorously developed and validated tool available for evaluating health care organizations' progress on becoming an HRO; however, it has some conceptual gaps that may be addressed by incorporating metrics from other evaluation tools.
- Multicomponent HRO interventions delivered for at least 2 years are associated with improved process outcomes (*eg*, staff reporting of safety culture) and patient safety outcomes (*eg*, serious safety events). However, the overall strength of evidence is low, as each HRO intervention was only supported by a single fair-quality study.

Background

The ESP Coordinating Center (ESP CC) is responding to a request from the VA National Center for Patient Safety for a rapid evidence review on implementing High Reliability Organization (HRO) principles into practice. Findings from this review will be used to inform the implementation of the VA's High Reliability Organization Initiative.

Methods

To identify studies, we searched MEDLINE®, PsycInfo, CINAHL, Cochrane Central Register of Controlled Trials, and other sources from Jan. 2010- Jan. 2019. We used prespecified criteria for study selection, data abstraction, and rating internal validity and strength of the evidence. Full methods are available on PROSPERO register of systematic reviews (CRD42019125602)

High Reliability Organizations (HROs) are organizations that achieve safety, quality, and efficiency goals by employing 5 central principles: (1) sensitivity to operations (*ie*, heightened awareness of the state of relevant systems and processes); (2) reluctance to simplify (*ie*, the acceptance that work is complex, with the potential to fail in new and unexpected ways); (3) preoccupation with failure (*ie*, to view near misses as opportunities to improve, rather than proof of success); (4) deference to expertise (*ie*, to value insights from staff with the most pertinent safety knowledge over those with greater seniority); (5) and practicing resilience (*ie*, to prioritize emergency training for many unlikely, but possible, system failures). Nuclear power and aviation are classic examples of industries that have applied HRO principles to achieve minimal errors, despite highly hazardous and unpredictable conditions. As death due to medical errors are estimated to be the third leading cause of death in the country, a growing number of health care systems are taking interest in adopting HRO principles. In 2008, the Agency for Healthcare

Research and Quality (AHRQ) published a seminal white paper that described the application of the 5 key HRO principles in health care settings, including the specific challenges that threaten reliability in health care, such as higher workforce mobility and care of patients rather than machines. Adoption of these HRO principles in health care offers promise of increased excellence; however, major barriers to widespread implementation include difficulty in adopting organization-level safety culture principles into practice; competing priorities between HRO and other large-scale organizational transformation initiatives such as electronic health records; and difficulty in creating and implementing process improvement tools and methods to address complex, system-level problems.

In February 2019, the Department of Veterans Affairs (VA) rolled out a new initiative outlining the definitive steps toward becoming an HRO. As literature has emerged to guide health systems in implementing and evaluating their HRO journey, an understanding of the quality and applicability of existing HRO resources is important to developing best practices, identifying barriers and facilitators to implementation, measuring progress, identifying knowledge gaps, and spreading implementation initiatives to other systems. In this review, we evaluate literature on the frameworks for HRO implementation, metrics for evaluating a health system's progress towards becoming an HRO, and effects of HRO implementation on process and patient safety outcomes.

We identified 20 articles published on HRO frameworks, metrics, and evidence of effects. Eight articles addressed frameworks, and of these, the Joint Commission's High Reliability Health Care Maturity Model (HRHCM) and the Institute for Healthcare Improvement's (IHI) Framework for Safe, Reliable, and Effective Care emerged as the most comprehensive, rigorously developed, applicable, and sufficiently detailed to guide implementation. The most commonly reported implementation strategies across the 8 frameworks were: (1) developing leadership, (2) supporting a culture of safety, (3) building and using data systems to track progress, (4) providing training and learning opportunities for providers and staff, and (5) implementing interventions to address specific patient safety issues. Most of these frameworks were developed via a consensus process – typically with a group of health system leaders and experts in patient safety – and were intended to be implemented by a variety of health care providers and staff. Articles varied in the depth of information provided on how to implement these frameworks, with some providing specific guidance on implementation activities such as workshops and time frames for implementation and others providing overarching, conceptual guidance.

Eight articles and 1 online tool described metrics for measuring a health system's progress towards becoming an HRO. The Oro™ 2.0 tool emerged as the most rigorously designed and validated, as it was developed by a leading group in health care improvement, informed by industries leaders across HROs, and tested in a total of 52 US hospitals both within and outside of the VA. Otherwise, metrics varied in terms of the concept measured, ranging from surveys on culture of safety to extent of integration of HRO principles into practice. The process for developing these metrics also varied by tool. Many groups relied on a literature review or expert consensus, whereas others underwent rounds of revisions and piloted their tool in multiple hospital settings.

Seven articles evaluated the effects of HRO implementation, primarily in children's hospitals. The most notable finding is that organizations experienced significant reductions in serious

safety events (range, 55% to 100%) following the implementation of the 4 most comprehensive, multicomponent HRO initiatives. Moreover, time since initiation and safety improvements appear to have a dose-response relationship. Only one of these studies explicitly discussed using a framework identified in Key Question 1 (*ie*, the IHI framework). Common implementation activities included some form of basic error prevention training for staff and leadership training for leaders, enhanced root cause analysis processes using an electronic tracking system, provider peer safety coaches to coach their peers in the use of error prevention techniques, routine sharing of good catches and lessons learned, and increased communication through safety huddles. Successful facilitators to implementation include hiring an outside consultant (*eg*, Healthcare Performance Improvement), leadership commitment to implement HRO principles, and enacting policies to facilitate data-sharing. Barriers to implementation include competing priorities (*eg*, widescale implementation of an Electronic Medical Record systems) and high costs.

A major limitation of the literature is that none of these studies compared an HRO intervention to a concurrent control group. Therefore, it is difficult to determine whether these effects are due to HRO implementation or a concurrent intervention or secular trend. Studies also lacked information on whether intervention components were delivered with fidelity over time and whether the interventions were associated with unintended effects on provider workload or efficiency. Future HRO implementation research should utilize quasi-experimental designs, such as natural experiments that deliver HRO interventions at a group of sites with other sites serving as a wait list control, to evaluate the effects of specific intervention components and assess the mechanism of change driving outcomes.

EVIDENCE BRIEF

INTRODUCTION

PURPOSE

The ESP Coordinating Center (ESP CC) is responding to a request from the Department of Veterans Affairs (VA) National Center for Patient Safety for a rapid evidence review on implementing High Reliability Organization (HRO) principles into practice. The purpose of this review is to evaluate the literature on frameworks, metrics, and evidence of effects of HRO implementation. Findings from this review will be used to inform the implementation of the VA's HRO Initiative.

BACKGROUND

In their 2000 report "To Err is Human," the Institute of Medicine's (IOM) Committee on Quality of Health Care in America cited deaths due to medical errors as more common than those due to motor vehicle accidents, breast cancer, or AIDS.[1] Despite continued widespread, discrete process improvement initiatives such as handwashing protocols, patient identification to reduce 'wrong person' procedures, protocols for clear communications between care teams and visual indicators for high risks such as fall injury or allergies, a 2016 *British Medical Journal* report estimated that medical errors continue to be the third leading cause of death in the US.[2] Additionally, the IOM Committee identified care fragmentation as a root cause of medical errors.[1] In response, they called for a comprehensive, system-level approach to improve patient safety, that shifts the focus away from a culture of blame to one of error analysis and process improvement. Therefore, health care organizations have begun to explore system-level approaches to cultivating a culture of safety, with a focus on collaboration, communication, and coordination.

HRO is one such organizational approach to achieving safety, quality, and efficiency goals.[3,4] At the core of HRO is a culture of "'collective mindfulness', in which all workers look for, and report, small problems or unsafe conditions before they pose a substantial risk to the organization

and when they are easy to fix."[3,5] Use of HRO is designed to change the *thinking* about patient safety through the following 5 principles: (1) sensitivity to operations (*ie*, heightened awareness of the state of relevant systems and processes); (2) reluctance to simplify (*ie*, the acceptance that work is complex, with the potential to fail in new and unexpected ways); (3) preoccupation with failure (*ie*, to view near misses as opportunities to improve rather than proof of success); (4) deference to expertise (*ie*, to value insights from staff with the most pertinent safety knowledge over those with greater seniority); (5) resilience (*ie*, to prioritize emergency training for many unlikely but possible system failures).[4] See Figure 1 below.

Figure 1. Five HRO principles

HRO was originally pioneered in extremely hazardous industries, such as nuclear power and commercial aviation, where even the smallest of errors can lead to tragic results. These industries have achieved and sustained extraordinary safety levels, thereby generating much interest in how to adapt HRO principles to health care and replicate this success. In their 2007 book "Managing the Unexpected," Weick and Sutcliffe define the 5 principles of HROs and describe how these principles can be applied to improve reliability across diverse industries.[5] In their 2008 seminal Agency for Healthcare Research and Quality (AHRQ) white paper, Hines et al apply these 5 principles to health care settings and describe the specific challenges threatening health care reliability, such as higher workforce mobility and care of patients rather than machines.[4] Implementation of HRO initiatives into health care settings is an inherently complex and costly process that involves organizing people, processes, and resource activities across often large organizations. For example, the Nationwide Children's Hospital's HRO journey involved increasing their quality improvement (QI) personnel from 8 in 2007 to 33 in 2012, with a budget increase from $690K to $3.3M.[6] External consultants, such as Healthcare Performance Improvement, LLC, can provide support to organizations undertaking an HRO journey. HRO interventions commonly include activities like basic error prevention education; leadership training in reinforcement approaches; enhanced root cause analysis processes using an electronic tracking system; promotion of a 'just culture' – a culture in which providers and staff are fairly penalized for mistakes – that supports routine reporting errors; sharing good catches and lessons learned; and training in error prevention technique by provider peer safety coaches.

Examples of health systems' successful adoption of HRO principles are already emerging. Providence St. Joseph Health – a national, not-for-profit Catholic health system comprised of more than 50 hospitals, 800 clinics and 5 million patients across 7 states – has had success implementing their HRO program, Caring Reliably. Two years after implementation of the program, which included partnering with an outside consulting firm to coach them through a

leader toolkit, which focused on culture, and a toolkit for everyone, which reduced errors, Providence St. Joseph Health experienced a 5% improvement in the safety climate domain of the Safety Attitudes Questionnaire and a 52% decrease in serious safety events (G. Battey, oral communication, February 2019).[7] The VA has also experienced HRO implementation successes. The Harry S. Truman Memorial Veterans Hospital began a 3-year HRO project in March 2015 by partnering with the VA National Center for Patient Safety to deliver Clinical Team Training to every inpatient and outpatient clinical service. This included formal interactive classroom training, application of the principles in a project that was unique for each clinical area, and refresher classroom and simulation training after one year. In May 2016, Truman VA augmented their HRO program using a 23-module HRO Toolkit provided by VISN 15, as part of its HRO initiative rolled out across all 7 of its medical centers. According to Truman VA Associate Director Robert Ritter (R. Ritter, oral communication, February 2019), their HRO program has already resulted in remarkable improvements in staff attitudes and perceptions and significant increased participation in morning multidisciplinary huddles. However, despite the promise of increased excellence as described in the 2013 Joint Commission's HRO report,[3] major barriers to widespread implementation readiness of HRO at the VA and elsewhere include the complexity of organization-wide incorporation of safety culture principles and practices and prioritizing the adoption of process improvement tools and methods, among other competing priorities.

To reaffirm their commitment to high reliability and zero harm (working to "reduce errors and to ensure that any errors that may occur do not reach our patients and cause harm"), in February 2019, the VA rolled out a new initiative outlining the definitive steps for becoming an HRO.[8] The first step is for HRO activities to begin at 18 lead facilities selected based on greater readiness as demonstrated by higher levels of safety performance, leadership commitment, and staff engagement. Initial HRO activities include the establishment of work groups, performance readiness assessments, and conducting training events and programs. Following analysis of lessons learned from these lead sites, the VA plans a national roll-out to achieve the goal of an VA-wide HRO transformation. To ensure success of HRO-related activities and consistent outcomes across the enterprise, VA is using resources from the Joint Commission Center for Transforming Healthcare resource library, including the Oro 2.0 High Reliability Assessment tool. Additionally, VA is working on developing a standard set of HRO tools, including training, implementation models, and measures.

Emerging literature can guide health systems in implementing and evaluating their HRO journey.[9,10] However, an understanding of available frameworks, metrics, and initiatives and their use are currently limited by their complexity and wide variability of their key characteristics, their target participants (*eg*, leadership, medical staff), their foundation, their structure, which of the 5 HRO principles they address, and health system setting type. Understanding the quality and applicability of existing HRO resources is important to developing best practices, identifying barriers and facilitators to implementation, spreading implementation initiatives to other systems, measuring progress, and identifying knowledge gaps.

SCOPE

This rapid evidence review will address the following key questions and eligibility criteria:

KEY QUESTIONS

Key Question 1: What are the frameworks for guiding HRO implementation?

Key Question 1A: What are the main implementation strategies of these frameworks?

Key Question 1B: What were the processes for developing these frameworks (*eg*, consensus, literature review, *etc*)?

Key Question 1C: What are the intended settings of these frameworks?

Key Question 1D: Who participates in implementing these frameworks?

Key Question 1E: What are the processes for implementing these frameworks?

Key Question 2: What are the metrics for measuring a health system's progress towards becoming an HRO?

Key Question 2A: What are the main characteristics (*ie*, domains, scales) of these metrics?

Key Question 2B: What were the processes for developing these metrics (*eg*, consensus, literature review, *etc*)?

Key Question 2C: To what extent have these metrics been validated or used to inform health system decision-making?

Key Question 3: What is the evidence on HRO implementation effects?

Key Question 3A: On patient safety/organizational change goals (*eg*, number of sites that met goal of 50% reduction in serious safety events)?

Key Question 3B: On patient safety/organizational change measures (*eg*, mean change in number of serious safety events)?

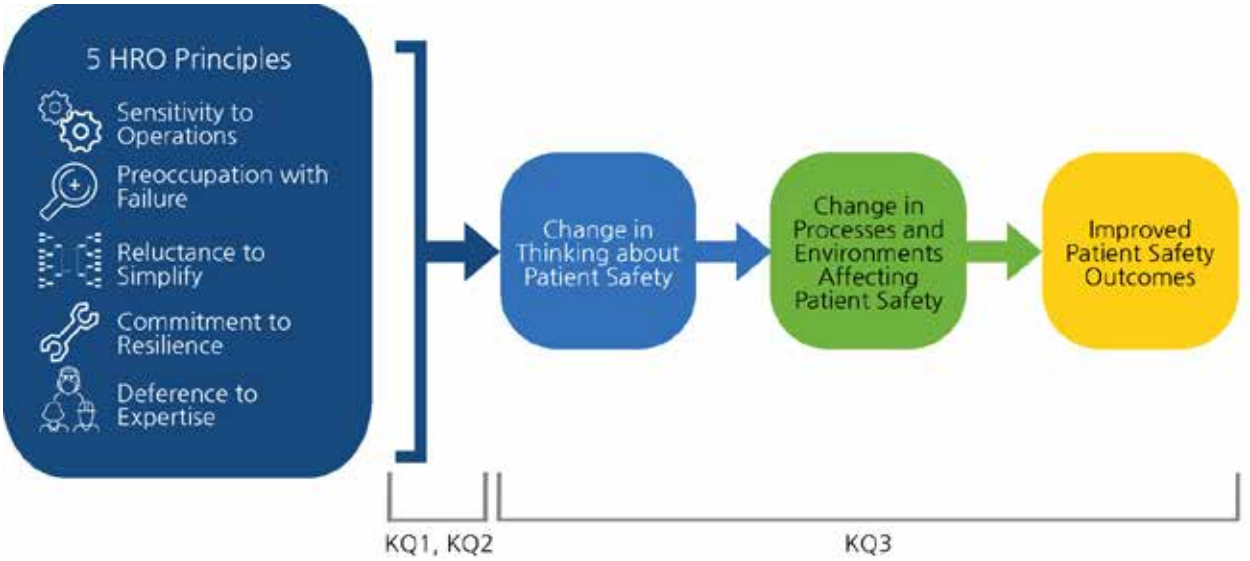
Key Question 3C: On process measures (*eg*, mean change in inter-departmental communication, provider or patient satisfaction)?

ELIGIBILITY CRITERIA

The ESP included articles published from January 2010 to January 2019 that describe implementation frameworks, metrics for measuring progress towards becoming an HRO, and its effects. The timeframe of 2010 and onward was selected because it is 2 years after the publication of AHRQ's 2008 white paper, when one could reasonably expect publication of new research on implementing HRO principles in health care settings. To be included, articles needed to be explicitly grounded in HRO theory and specifically seek to advance organizational or cultural change. We operationalized this by only including articles that evaluated HRO principles at the organization level or higher (*ie*, we excluded articles of HRO implementation in individual departments). Outcomes for KQ3 include any that are linked to the pathway between the 5 principles of HROs (*ie*, sensitivity to operations, reluctance to simplify, preoccupation with

failure, deference to experience, and resilience) and the ultimate goal of health care organizations: exceptionally safe, consistently high-quality care, as outlined in the AHRQ white paper.[4] See Figure 2 below for the logic model linking the 5 HRO principles to the end goal of improved patient safety outcomes, based on the model described in Hines 2008.[4]

Figure 2. HRO logic model



We prioritized articles using a best-evidence approach to accommodate the timeline (*ie*, we considered meeting safety goals [KQ3A] to be a higher priority than intermediate outcomes [KQ3B and KQ3C]). We also prioritized evidence from systematic reviews and multisite comparative studies that adequately controlled for potential patient-, provider-, and system-level confounding factors. We only accepted inferior study designs (*eg*, single-site, inadequate control for confounding, noncomparative) to fill gaps in higher-level evidence.

METHODS

To identify articles relevant to the key questions, our research librarian searched MEDLINE, CINAHL, PsycINFO, and Cochrane Central Register of Controlled Trials (CCRT) using terms for *high reliability* and *health care* from January 2010 to January 2019 (see Supplemental Materials Appendix A for complete search strategies). Additional citations were identified by hand-searching reference lists and consultation with content experts. We limited the search to published and indexed articles involving human subjects available in the English language. Study selection was based on the eligibility criteria described above. Titles, abstracts, and full-text articles were reviewed by one investigator and checked by another. All investigators have expertise in conducting systematic reviews of health services research. Any disagreements were resolved by consensus.

No standard tool is currently available to assess the quality of complex interventions. We therefore culled concepts from reporting checklists for complex interventions, QI initiatives, and implementation interventions – including the Standards for Quality Improvement Reporting Excellence (Squire 2.0),[11] Standards for Reporting Implementation Studies (StaRI),[12] and Template for Intervention Description and Replication TIDieR[13] – to develop a 7-item quality assessment checklist. Through this checklist, we evaluated whether the study adequately reported on (1) the conceptual link between the intervention and HRO principles, (2) intervention components and delivery, (3) implementation fidelity, (4) evaluation of the intervention, (5) adverse events, (6) confounders, and (7) the use of a concurrent control group. We considered items 1-4 to be basic criteria in determining whether the study was reported well enough to be reproduced. We considered items 5-7 to be advanced criteria that would increase our confidence that bias was minimized in the study results (see Supplemental Materials Appendix C for detailed information on the quality assessment checklist). All quality assessments were completed by one reviewer and then checked by another. We did not quantify inter-rater reliability through a kappa statistic; however, qualitatively, our agreement was generally high. Disagreements were generally limited to interpretation of individual risk of bias domains and not overall risk of bias ratings for a study. We resolved all disagreements by consensus.

We abstracted data from all studies and results for each included outcome. All data abstraction and internal validity ratings were first completed by one reviewer and then checked by another. We resolved all disagreements by consensus. We informally graded the strength of the evidence based on the AHRQ Methods Guide for Comparative Effectiveness Reviews by considering study limitations (includes study design and aggregate quality), consistency, directness, and precision of the evidence.[14] Ratings typically range from high to insufficient, reflecting our confidence that the evidence reflects the true effect.

Where studies were appropriately homogenous, we synthesized outcome data quantitatively using StatsDirect statistical software (StatsDirect Ltd. 2013, Altrincham, UK) to conduct random-effects meta-analysis to estimate pooled effects. We assessed heterogeneity using the Q statistic and the I^2 statistic. Where meta-analysis was not suitable due to limited data or heterogeneity, we synthesized the evidence qualitatively.

Throughout the report, we use the following terminology to describe different levels of HRO theory and implementation (Table 1).

Table 1. HRO terminology used throughout report

Term	Definition
Principles	Key principles of HRO theory, first described by Weick and Sutcliffe (2007)[5]
Implementation strategies	Concrete, high-level strategies for implementing HRO principles
Implementation activities	Lower-level, granular tasks that health systems can do to advance high-level implementation strategies
Complementary practices for strengthening implementation	Complementary practices that cross-cut different implementation strategies to strengthen overall HRO delivery

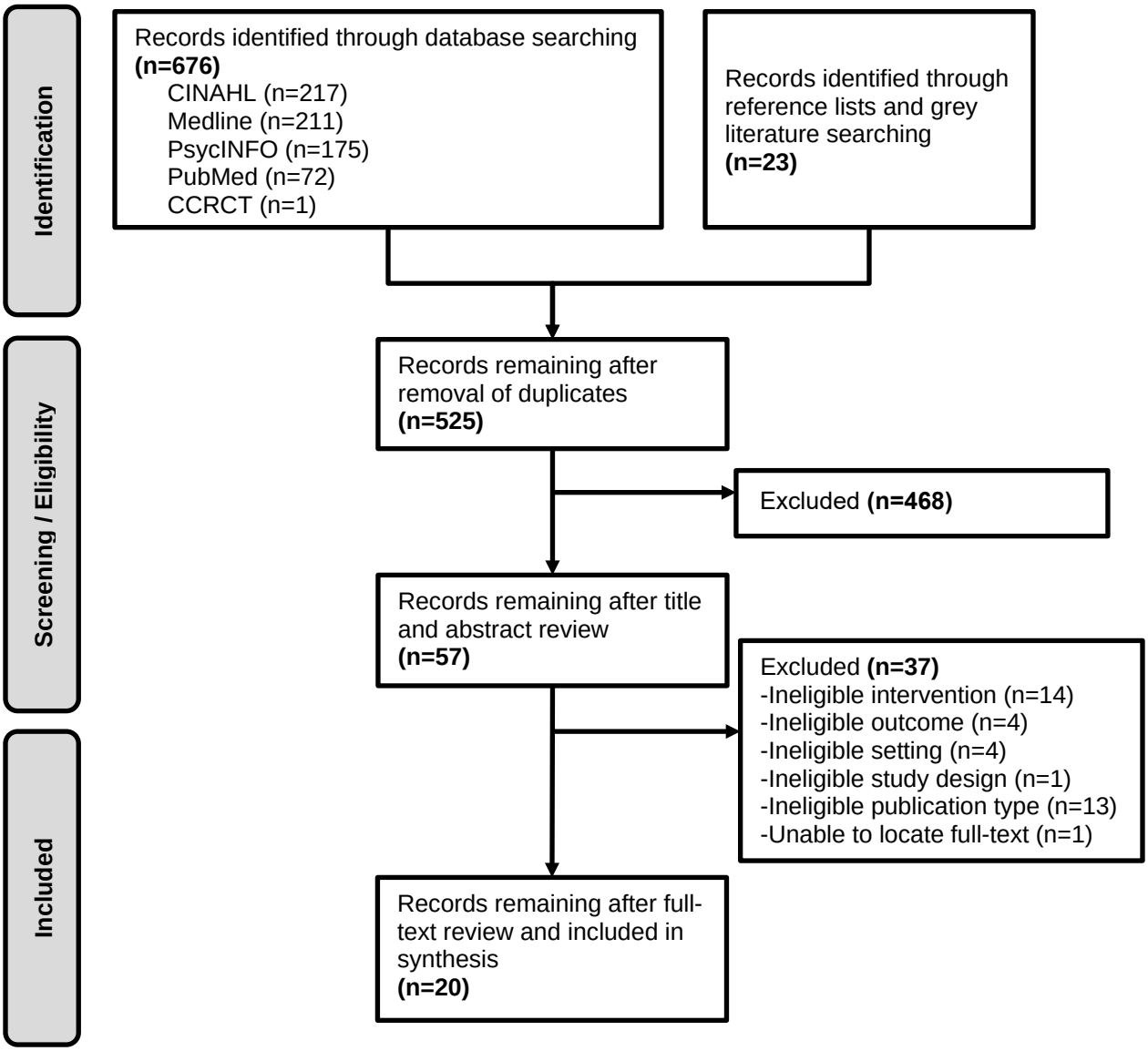
The complete description of our full methods is available on the PROSPERO international prospective register of systematic reviews (http://www.crd.york.ac.uk/PROSPERO/; registration number CRD42019125602). A draft version of this report was reviewed by peer reviewers as well as clinical leadership. Their comments and our responses are presented in the Supplemental Materials (see Appendix D).

RESULTS

LITERATURE FLOW

The literature flow diagram (Figure 3) summarizes the results of search and study selection (see Supplemental Materials Appendix B for full list of excluded studies). Our search identified 525 unique, potentially relevant articles. Of these, we included 20 articles that addressed one or more of our key questions. Eight articles addressed Key Question 1,[3,15-21] 8 articles addressed Key Question 2,[3,16,22-27] and 7 articles addressed Key Question 3.[6,17,28-32]

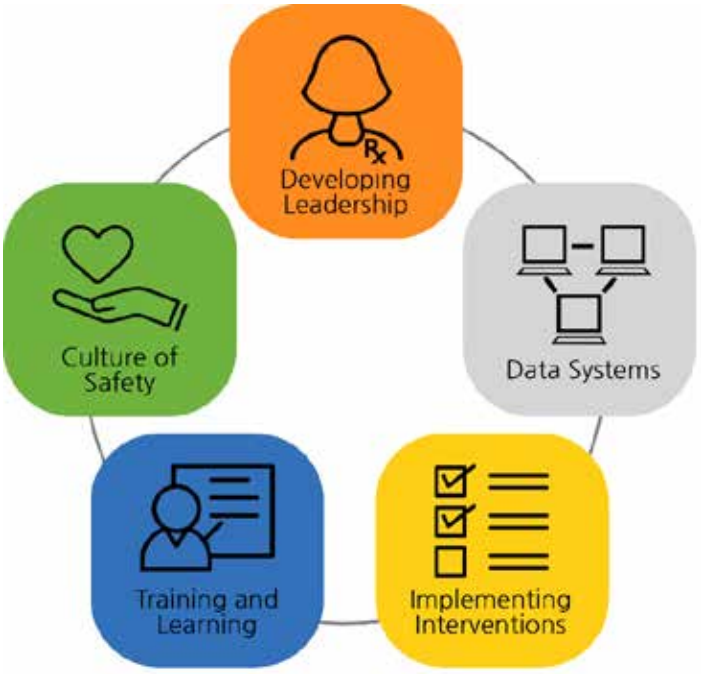
Figure 3. Literature flowchart



KEY QUESTION 1: What are the frameworks for guiding HRO implementation?

We identified 8 frameworks that guide implementation of HRO principles into a health care system: the Joint Commission's High Reliability Health Care Maturity Model (HRHCM)[3]; the Institute for Healthcare Improvement's (IHI) Framework for Safe, Reliable and Effective Care[18]; the American College of Healthcare Executives' (ACHE) Culture of Safety framework[16]; 2 frameworks developed at Johns Hopkins' (JH) Armstrong Institute for Patient Safety and Quality including an Operating Management System[17] and a Safety and Quality framework[15]; the Office of the Air Force Surgeon General's Trusted Care framework[19]; Advancing Research and Clinical Practice through close Collaboration (ARCC) Model[20]; and a framework focused on developing high reliability teams.[21] The Joint Commission's HRHCM and IHI Framework for Safe, Reliable and Effective Care emerged as the most comprehensive, as they both covered all 5 strategies commonly reported across frameworks (Figure 4); were the most rigorously developed; were broadly applicable; and were sufficiently detailed to inform implementation.

Figure 4. 5 Common HRO implementation strategies



Appendix C of the supplementary materials contains full details on these frameworks' implementation strategies, development process, and intended settings, as well as staff and processes required for implementation. Highlighted findings appear below.

KQ1A: What are the main implementation strategies of these frameworks?

Table 2 summarizes the 5 commonly reported key HRO implementation strategies from these 8 frameworks.

Table 2. Common HRO implementation strategies across 8 identified frameworks

Key Strategy:	Developing leadership	Culture of safety	Data systems	Training and learning	Implementing interventions
ACHE Framework[16]	ü	ü	ü		
Air Force Trusted Care[19]	ü	ü	ü	ü	ü
ARCC Model[20]		ü	ü	ü	ü
High reliability team model[21]		ü		ü	ü
IHI Framework[18]	ü	ü	ü	ü	ü
JH's Operating Management System[17]	ü		ü		
JH's Safety and Quality Framework[15]	ü		ü	ü	ü
Joint Commission's HRHCM[3]	ü	ü	ü	ü	ü
Number of frameworks addressing this strategy	**6**	**6**	**7**	**6**	**6**

The first key strategy is *developing leadership*. The Joint Commission discussed the need for leadership (*eg*, board members, CEO/management, and lead physicians) to commit to the goal of zero patient harm.[3] IHI described the need for leaders to facilitate and mentor teamwork, improvement, respect, and psychological safety.[18] ACHE incorporated elements from both of these frameworks, including selecting, developing, and engaging a board; prioritizing safety in the selection and development of leaders; and establishing a compelling vision for safety. The JH Operating Management System framework and the Air Force emphasized the importance of leadership accountability.[17,19] The JH Safety and Quality framework encouraged QI leaders to pursue formal degrees to support their work.[15] The ARCC and high reliability team models did not explicitly discuss leadership as a key strategy, although the ARCC model did discuss the importance of developing and using mentors to guide evidence-based decision-making.[20]

The second key strategy is *supporting a culture of safety*. The Joint Commission described building trust, accountability, identifying unsafe conditions, strengthening systems, and assessment as key activities within this strategy.[3] The IHI listed culture, including psychological safety, accountability, teamwork and communication, and negotiation, as one of their major 2 domains.[18] The ACHE named their framework "culture of safety" and emphasized the need to both lead and reward a just culture and establish organizational behavior expectations.[16] The Air Force described the importance of trust between leaders and staff, respectful communication, and willingness to admit errors within their culture of safety domain.[19] The ARCC model incorporated an assessment of culture as a key aspect of implementation,[20] and the high reliability team model emphasized that responses to

poor outcomes should be based on behavioral choices and not severity of outcome.[21] Neither JH frameworks explicitly discussed culture of safety.

The third key strategy is *building and using data systems to measure progress*. The Joint Commission discussed the need to track and display quality measures and to involve IT support in the development of solutions to quality problems.[3] IHI described the need for open sharing of data and other information concerning safe, respectful, and reliable care and to continually improve work processes and measure progress over time.[18] The JH Operating Management System discussed the need to share and synthesize data to gain insights to make new discoveries and improve processes,[17] and their Safety and Quality framework included a plan to evaluate processes.[15] The Air Force described standardizing processes to gather and share information about patient care episodes, knowledge data, and processes to improve care delivery.[19] The ARCC model described data management and outcomes monitoring as one of their implementation workshops.[20] The high reliability team model did not include a strategy related to measurement of progress.

The fourth key strategy is *providing training and learning opportunities for providers and staff*. The Joint Commission discussed the importance of training all staff on robust process improvement (*eg*, a blended performance improvement model aimed at improving patient safety in health care settings by integrating Lean Six Sigma and formal change management principles) as appropriate to their jobs.[3,33] IHI and the Air Force discussed developing learning systems, although the learning has more to do with implementing QI initiatives and learning from results, rather than learning how to implement HRO principles.[18,19] The JH Safety and Quality framework listed examples of training that each type of staff member should receive.[15] The ARCC model described a workshop dedicated to evidence-based practice skills-building,[20] and the high reliability team model discussed implementation of TeamSTEPPS, a teamwork curriculum for health care staff.[21] ACHE and the JH Operating Management System did not specifically discuss training or learning opportunities.

The fifth key strategy is *implementing quality improvement interventions to address specific patient safety issues*. This strategy is discussed in broad strokes as robust process improvement by the Joint Commission and Air Force,[3,19] and as improvement and measurement by the IHI.[18] In the ARCC model, participants complete a 12-month evidence-based practice implementation project focused on improving quality of care, safety, and patient outcomes.[20] The JH Safety and Quality framework discussed the role of safety and quality experts in designing and directing system improvement efforts and provided examples of potential initiatives.[15] The high reliability team framework described simulation training where teams can practice briefing, huddles, and debriefing strategies.[21] Neither the ACHE nor the JH Operating Management System explicitly discussed QI initiatives.

In addition, we identified several *complementary practices for strengthening implementation*. We identified these by looking across the 8 frameworks to see what complementary practices were commonly recommended. These complementary practices are meant to be applied *across* implementation strategies to strengthen the overall delivery of HRO.

- *Incorporation of justice, equity and patient-centeredness:* The ACHE describes building trust, respect and inclusion as a key domain of building a safety of culture.[16] The

framework encourages leaders to value diversity and inclusion when selecting leaders and staff and to work towards evaluating and eliminating disparities in patient care. The Air Force selected patient-centeredness as a key domain of its framework.[19] This practice could be integrated into HRO delivery through activities such as hiring a diverse workforce or prioritizing QI initiatives that address safety issues that disproportionately affect patients from racial/ethnic minority groups.

- *Involvement of a variety of stakeholders involved in health care delivery, including patients and families:* The JH Operating Management System described establishing patient and family advisory councils as an implementation activity that could be undertaken to advance one of their key implementation strategies.[17] Other possible activities include assessing patient perspectives of culture of safety or inviting patients to serve on HRO leadership committees.

- *Assembling transdisciplinary teams*: Several frameworks – including the JH Operating Management System,[17] ARCC model,[20] and high reliability team framework[21] – discuss forming transdisciplinary teams as an important activity towards advancing HRO. This practice could be integrated into HRO delivery through activities like inviting providers from different specialties to attend daily safety huddles; or having nurses, physicians, and staff all attend the same HRO training sessions together.

- *Utilizing change management strategies such as Lean Six Sigma to promote change:* Most frameworks recommended health systems use complementary change management strategies – such as Lean Six Sigma,[15-17] IHI's Model for Improvement,[18] or a combination of strategies such as the Joint Commission's robust process improvement[3,19] – to implement HRO principles into practice. This complementary practice could be integrated into several aspects of HRO delivery, such as training staff on Lean Six Sigma, or applying Lean thinking to root cause analysis to identify what is contributing to patient safety events and identifying and implementing solutions.

KQ1B: What were the processes for developing these frameworks (*eg*, consensus, literature review, *etc*)?

The Joint Commission's HRHCM stood out as being the most rigorously developed framework, as the process involved a literature review, consensus among subject experts, pilot testing among an expert panel, and pilot testing with leadership at 7 US hospitals. However, the latter pilot testing effort was primarily focused on evaluating the tool to measure a health system's progress on the framework (KQ2). The Air Force[19] and JH Safety and Quality framework[15] were developed through both a literature review and consultation with health care leaders and content experts. The IHI[18] framework was developed specifically for the IHI Patient Safety Executive Development Program curriculum and was informed by an analysis of high-performing, proactive, and generative work settings. The ACHE framework was developed through partnership between the ACHE, the IHI, and the National Patient Safety Foundation (NPSF) Lucian Leape Institute (LLI). It involved consensus-building with industry leaders and experts who have had success in transforming their organizations into system-wide cultures of safety.[16] The ARCC model was initially developed through a strategic planning process on how to rapidly integrate research findings into clinical processes.[20] The 2 remaining articles did not discuss the

process of how frameworks were developed (JH Operating Management System,[17] high reliability teams[21]).

KQ1C: What are the intended settings of these frameworks?

All frameworks were intended to be delivered in any health care delivery setting, except for the Air Force's framework, which was designed specifically for the Air Force Medical Service.[19] IHI's framework was initially developed for use in acute care settings, although it has since evolved to be applicable to other settings.[18]

KQ1D: Who participates in implementing these frameworks?

Most frameworks were intended to be implemented by a variety of health care leaders, providers, and staff, including frontline providers, local and middle managers, and high-level managers and executives, as well as safety and quality leaders, across a variety of service areas.[3,15,18-20] IHI's framework also included components to be implemented by patients and families.[18] Exceptions are the ACHE[16] and the JH Operating Management System[17] frameworks, which were specifically designed for health care leadership,[16] and the high reliability team framework which was designed for nursing professionals.[21]

KQ1E: What are the processes for implementing these frameworks?

Articles varied in the depth of information provided on how to operationalize the implementation of these frameworks, with the ARCC, Joint Commission, and IHI models emerging as the most comprehensive.

- The ARCC model provided details on providing learning and training opportunities (*ie*, 6 educational workshops, 8 days of educational and skills-building sessions over 1 year), as well as on implementing an intervention to address a specific patient safety issue (*ie*, 12-month project focused on improving quality of care, safety, and/or patient outcomes).[20]

- The Joint Commission[3] and IHI[18] provided high-level recommendations for operationalizing HRO implementation, including building and using tools to measure progress (*ie*, assess the current state of HRO maturity; develop tools to advance maturity), as well as specific examples of activities that could advance these strategies.

Other frameworks provided some guidance on how to operationalize implementation, although they were less comprehensive.

- ACHE described 2 levels of implementation practices: foundational practices which focus on laying the groundwork for HRO implementation and sustaining practices which focus on spreading and embedding HRO concepts, specifically a culture of safety.[16]

- The JH Operating Management System suggests approaches to implementing the core concepts of the model, including developing and using data systems (*ie*, providing leaders with a standardized reporting format to assist in reporting on department progress), using systems engineering methodology, and convening stakeholder groups.[17]

- The JH Safety and Quality initiative provided recommendations based on the role of a specific health care provider or staff member. For example, they have specific suggestions on training and learning opportunities (*ie*, provide front line providers and staff with basic medical school education on safety and quality; provide managers with patient safety certificate programs and workshops on Lean Six Sigma and other change management processes).[15]

- The Air Force's suggestions for operationalization include standardizing and stabilizing processes, engaging staff in behaviors to continuously improve these processes, mentoring staff, and leadership goal-setting, as well as a description of the desired future state of HRO integration into practice.[19]

- The high reliability team framework described specific approaches that touch on several implementation strategies including learning and training opportunities (*ie*, simulation training and provision of a structured HRO curriculum) and supporting a culture of safety (*ie*, development of a just culture system for penalizing staff when patient harm occurs).[21]

KEY QUESTION 2: What are the metrics for measuring a health system's progress towards becoming an HRO?

We identified 8 articles[3,16,22-27] on 6 tools for measuring the progress toward becoming an HRO (Table 3). The Joint Commission's HRHCM/Oro™ 2.0 emerged as the most rigorously developed, validated, and applicable tool for VA settings. However, other tools such as the ACHE's Culture of Safety Organizational Self-Assessment Tool[16] may be useful in developing specific items missing from the Oro™ 2.0 framework, such as teamwork culture and system-focused tools for learning and improvement.[27] Four additional tools have unclear applicability to the VA, as they were developed in countries outside the US,[22-25] did not report measurement items,[23,24] or require qualitative expertise to analyze results.[22] Full details on these studies appear in Supplementary Materials, Appendix C, and selected findings appear below.

Oro™ 2.0

The tool that most comprehensively addressed all 5 HRO implementation strategies identified in KQ1 was the HRHCM/Oro™ 2.0.[3,34] As discussed in KQ1, the HRHCM is the Joint Commission's framework for implementing HRO principles. This framework includes 4 levels (beginning, developing, advancing, approaching) for each of the 14 components (56 total) to guide health care leaders in assessing their systems' level of maturity on becoming an HRO. The Oro™ 2.0 is a web-based application that uses branching logic to guide health care leaders through the HRHCM assessment and produces a visual report that synthesizes data from multiple respondents within a single hospital.[34] Of note, the Oro™ 2.0 was designed to be used at the individual hospital, rather than at a system level, and is only available to Joint Commission-accredited organizations. The tool outputs data into reports that could theoretically be shared between hospitals but it is not an automatic feature.

To develop the metrics used in by the HRHCM/Oro™ 2.0, a team at the Joint Commission spent over 2 years engaging with high reliability experts from academia and industry, leading safety scholars outside of health care, and the published literature.[3] Iterative testing with hospital

leaders – first among 5 individuals in executive leadership positions, then among leadership teams from 7 US hospitals – was conducted to finalize the framework and included metrics. The resultant tool has since been validated in peer-reviewed research studies, including 1 study that tested the content validity of the tool at 6 VA sites.[27] Another study tested the internal reliability and discriminative ability in detecting different levels of HRO maturity in 46 hospitals from the Children's Hospitals' Solutions for Patient Safety network.[26]

The VA study was a secondary analysis of qualitative data from 138 VA employees with patient safety expertise at various levels of leadership (*eg*, patient safety managers, executive leadership and service chiefs, infection control nurses) from 6 VA sites. The original study validated the AHRQ-developed patient safety indicator tool; the secondary analysis looked at how well responses mapped onto the Joint Commission's HRHCM model. Researchers found that 12 of the 14 HRHCM components were represented, indicating good content validity. Two additional HRO components were identified through interviews that were not represented in the HRHCM model: teamwork culture and systems-focused tools for learning and improvement. While less applicable to the VA, the study that tested the HRHCM in 46 children's hospitals found that the HRHCM had good internal reliability (Cronbach's alpha = 0.72 to 0.87, depending on the domain), good discriminative ability (*ie*, health system average scores on beginning, developing, advancing, and approaching levels of maturity resembled a bell curve), and was responsive to change (*ie*, safety culture decreased after major organizational changes), indicating it may perform well at detecting progress on becoming an HRO.

Table 3. Metrics for measuring progress on becoming an HRO

Name of tool	Concept measured	Format of tool	HRO Implementation Strategies Measured					Organizational Level			Extent of validation	
			Leadership	Culture of Safety	Data Systems	Training and learning	Patient Safety Interventions	Leadership	Providers and staff	Patients and families	Process of validity testing	Outcome of validity testing
Oro™ 2.0 High Reliability Assessment Tool/HRHCM framework[3,26,27,34]	Readiness and progress on becoming an HRO, in terms of beginning, developing, advancing, or approaching stages	Survey	ü	ü	ü	ü	ü	ü			Advanced	High internal reliability, good content validity
ACHE Culture of Safety Organizational Self-Assessment Tool[16]	Readiness on becoming an HRO in terms of whether practices currently being implemented are foundational or sustaining	Survey	ü	ü	ü			ü	ü	ü	None	None
Cultural Assessment Survey (CAS)[23]	Initial level and progress towards developing a culture of patient safety	Survey		ü				ü	ü		Basic	High internal reliability, good content validity
University of Tehran HRO readiness assessment[24]	Readiness for HRO implementation	Survey	Unclear					ü			Basic	Good content validity
University of Tehran HRO knowledge and integration assessment[25]	Knowledge of HRO concepts and extent of integration of HRO principles in practice	Survey and checklist		ü		ü		ü	ü		Basic	High internal reliability, good content validity
Delft University of Technology qualitative framework on hospital reliability[22]	Level of reliability in a hospital, defined in stages of health care as craft, watchful professional, collective professionalism, and high reliability	Qualitative framework		ü	ü			ü	ü		None	None

ACHE Culture of Safety Organizational Self-Assessment Tool

While less comprehensive, rigorously developed, or evaluated than the HRHCM/Oro™ 2.0, the ACHE's Culture of Safety Organizational Self-Assessment Tool is an additional metric for evaluating progress on becoming an HRO. It incorporates additional perspectives (*ie*, patients, families) and specific items (*eg*, teamwork culture) that may be informative to the VA.

The ACHE tool addresses 3 (leadership, culture of safety, and data systems) of the 5 key HRO implementation strategies. It consists of 18 items concerning an organization's capabilities and processes scored on a 5-point Likert scale. Lower (worse) scores prompt a review of foundational tactics towards becoming an HRO, moderate scores prompt a review of both foundational and sustaining tactics, and higher (better) scores prompt a review of sustaining tactics.[16]

The ACHE tool was developed through partnership with the IHI/NPSF LLI and others as described in KQ1.[16] The tool has not undergone any formal validation processes. While limited in terms of the number of strategies covered and extent of validity testing, the ACHE tool offers 2 additional features not covered by the HRHCM/Oro™ 2.0. First, it specifically seeks perspectives beyond leadership, including providers and staff, as well as patients and families. However, of note, patients and families may have difficulty completing many of the ACHE tool items, such as the extent to which board members spend discussing patient safety issues in meetings and the extent to which leadership performance assessments and incentives are aligned with patient safety metrics. Second, the ACHE tool includes items related to teamwork and systems, such as the item: "My organization uses and regularly reviews a formal training program and defined processes for teamwork and communication."

Other tools

We identified 4 additional tools that covered 2 or fewer of the 5 HRO implementation strategies. They have more limited applicability to the VA due to their narrower focus, lack of reporting on the specific tool items, and/or development outside the US.

The Cultural Assessment Survey (CAS) is a metric used to measure culture of patient safety and was designed specifically for use in obstetric units in Canada.[23] The CAS had a rigorous development process, including a literature review to develop a list of over 100 values and practices that support a culture of safety, a short list of prioritized values and practices developed after sending the 300 surveys to employees at 8 hospitals, a pilot test of the short list at 10 hospitals, and testing of its internal reliability and content validity. However, the article did not include a copy of the tool or the items included in the tool. The narrow focus on obstetric units also limits the applicability of the tool to the VA's broad HRO implementation.

The University of Tehran developed 2 metrics: The first is a 55-item survey assessing a health care system's readiness for HRO implementation. It was developed through a literature review and pilot-testing among 98 senior or middle managers from 15 hospitals.[24] The second is a 24-item survey and checklist that assesses knowledge of HRO concepts and integration of HRO principles into practice. It was developed through interviews with managers and staff at 80 medical and nonmedical departments.[25] These metrics are notable as being the only ones specifically designed around the 5 HRO principles described by Hines et alia 2008.[4] However,

both metrics were limited in terms of the extent to which they covered HRO *implementation* strategies – with one assessing 2 out of 5 strategies[25] and the other with unclear coverage, as it did not report any specific examples of its metric items.[24] Both of these were evaluated in terms of their content validity and performed well. However, the applicability of these tools to the VA is unclear, as they were developed for a specific health care system in Tehran, Iran.

One additional metric developed by the Delft University of Technology in the Netherlands offers a qualitative framework for assessing level of reliability.[22] This framework resembled the HRHCM/ORO 2.0 in that it has 4 stages of maturity: craft, watchful professional, collective professionalism, and high reliability. It was developed through literature review to identify the common domains that are essential to high reliability hospitals and did not undergo any validity testing. This metric also has unclear applicability to the VA, due to significant differences between the US and Dutch health care systems. Delivering the framework in its current state at the VA would also be challenging, as it has open-ended items to promote thinking about the overall strengths and limitations of a health care system, rather than specific questions to which a provider or health care leader could concretely respond (*eg*, under organizational culture, a less reliable hospital would have qualities of "learning by doing" while a more reliable hospital would have "a preoccupation with possible failure.")

KEY QUESTION 3: What is the evidence on HRO implementation effects?

We identified articles from 7 health care organizations, primarily children's hospitals, on the effects of HRO initiative implementation on safety culture, HRO process, and patient safety measures.[6,17,28-32] Full details on these articles are available in Supplementary Materials Appendix C, and selected findings appear below.

The most notable finding is that organizations experienced significant reductions in serious safety events (SSEs) (range, 55% to 100%) following the implementation of the 4 most comprehensive, multicomponent HRO initiatives.[6,29-31] Moreover, time since initiation and safety improvements appear to have a dose-response relationship, and the improvements were maintained for upwards of 9 years (Table 4).[6,29-31] Of note, only one of these studies explicitly discussed using one of the frameworks discussed in KQ1 (*ie*, the IHI framework).[6] Two years after implementation, SSE reductions were 55% and 83%, respectively, in hospitals with a 12-month average of 0.9 (Ohio Children's Hospital Association)[30] and 1.15 (Nationwide Children's Hospital)[6] SSEs per 10,000 adjusted patient days. At 4 years, Cincinnati Children's Hospital Medical Center reported a 67% reduction in SSE rates and a baseline 12-month average of 0.9 events per 10,000 adjusted patient days.[31] After 9 years, Genesis Health System reported achieving its goal of zero SSE (100% reduction).[29] In these studies, SSE was typically defined as "the most serious harm events that occur in hospitals and are defined by serious patient harm events that directly results from a deviation in best practice or standard of care."[30] Improvements in safety culture were also reported, including improvement in safety attitudes[6] and an increase in safety success story reporting,[29] but changes across various other safety culture dimensions had mixed results.[31] At Cincinnati Children's Hospital Medical Center,[31] responses to the AHRQ Hospital Survey on Patient Safety Culture indicated improvements in organizational learning and continuous improvement, feedback and communication about error, and staffing. However, they

reported no change in supervisor/manager expectations and actions promoting safety, teamwork within hospital units, nonpunitive responses to error, and a decline in communication openness.

A commonality across the 4 hospitals that reported SSE reductions is that they implemented their HRO initiative with the help of the same external consultant, Healthcare Performance Improvement (HPI), LLC.[6,29-31] Although the components varied somewhat across these 4 hospitals, they generally aligned with the 5 strategies discussed in KQ1: (1) developing leadership (*eg*, leadership training); (2) supporting a culture of safety (*eg*, increased communication through safety huddles; routine sharing of good catches and lessons learned); (3) providing training and learning opportunities for providers and staff (*eg*, error prevention training for staff; provider peer safety coaches coached their peers in use of the error prevention techniques); (4) building and using data systems to track progress (*eg*, enhanced root cause analysis processes using an electronic tracking system); and (5) implementing interventions to address specific patient safety issues (*eg*, embedding "time outs" and "debriefs" into standard surgical processes, using standardized checklists). Despite these similarities, initiatives conceptualized their goals of zero patient harm in different ways: one initiative's board encouraged management to "aspire to eliminate preventable harm" by reducing the preventable harm index to zero[6]; one aimed to reduce SSEs to zero[29]; and 2 others aimed to reduce SSEs by 75%-80%.[30,31] In addition, the structure of the Ohio Children's Hospital Association was unique in that it is a state-wide collaboration of 8 tertiary pediatric referral centers that specifically refuse to compete on matters related to patient safety.[30] To promote transparent sharing of critical safety data among the collaborative to facilitate lessons learned without fear of undue liability, Ohio House Bill 153 was passed in 2010 to provide a legal framework expressly providing peer review protection for the 8 participating hospitals.

In addition to the 4 HPI-assisted initiatives, we also identified a similarly comprehensive initiative independently implemented by JH Hospital and Health System: the Operating Management System.[17] Although the study did not report on SSEs, the authors reported improved compliance in Joint Commission process measures and a 79% reduction in potential preventable harms.

Finally, we found that process improvements are possible even with less intensive HRO initiatives that are more focused in scope.[28,32] When the Riley Hospital for Children at Indiana University Health implemented a Daily Safety Brief, they found improvement in communication, awareness, and working relationships, but not in comfortability in sharing errors.[32] The Children's National Medical Center experienced an increase in Apparent Cause Analysis (ACA) reliability scores following implementation of 13 interventions across education, process, and culture categories. They also reported an *increase* in efficiency (4 fewer days to turn around ACA) and increased satisfaction with the process.[28]

While the results of these studies are promising, the overall strength of this evidence is low. Each initiative was only evaluated in a single study (consistency unknown), and each study was fair quality (common methodological weaknesses included lack of reporting on implementation fidelity and no concurrent control groups), with generally indirect outcomes and populations (few reported whether they met their goal of zero harm; none were conducted in Veterans). The main strengths of these studies were that they generally provided sufficient detail on how the intervention is conceptually linked to HRO, their main intervention components, and

how they evaluated effects. Their main limitation was that a cause-effect relationship could not be established between these HRO initiatives and outcomes, because no study used a concurrent control group that would have ruled out the possibility that the effect was due to concurrent interventions (*eg*, implementation of an Electronic Medical Record [EMR]) or improved specialty-specific disease management).[6]

Table 4. Key findings from studies assessing effects of HRO implementation

First Author, Year Location	Goal	Main Components	Process measures (state of mindfulness; culture; engagement)	Safety measures (met goal, mean change)
Brilli 2013[6] Nationwide Children's Hospital	Eliminating all preventable harm by 2013	Training of staff and leadership; root cause analysis process augmented; adoption of PHI; provider peer safety coaches	Safety Attitudes Questionnaire: Increased from 72 in 2009 to 76 in 2011 *(P*<.05)	Between 2010 and 2012: SSE: ↓ 1.15 to 0.19 events per 10,000 adjusted hospital days (83.3%) PHI: ↓ 35.5%
Crandall 2017[28] Children's National Medical Center	Increase Apparent Cause Analysis Reliability from 86.4% reliable to 95% reliable by December 2016 and sustain for 6 months	13 interventions across Education, Process, and Culture categories	Reliability score increased from 86.4% to 96.1%	NR
Cropper 2018[29] Genesis Health System	Zero SSEs	7 components: Safety rounding, safety oversight teams, safety huddles, safety coaches, good catches/safety heroes, safety education, the red rule	Steady increase in Safety Success Story reporting (reflected increased engagement)	SSE rate per 100,000 adjusted patient days plus long-term care day: 8.1 in 2009 to 0 in 2017
Lyren 2016[30] Ohio Children's Hospital Association – group of 8 tertiary care referral hospitals	To become the safest state in the country for children to receive health care, eliminating serious harm by the end of 2015	Developed 5 state-level task forces that meet monthly to set and review goals and identify barriers and solutions: Error Prevention; Leadership Methods; Cause Analysis; Lessons Learned; Safety Governance	NR	SSE rate monthly average per 10,000 adjusted patient days: 0.9 at baseline (Jul 2008-Jan 2010); ê 55% by October 2012
Saysana 2017[32] Riley Hospital for Children at Indiana University Health	NR	Riley Daily Operations Brief	Comfortability sharing errors and issues, belief that the Daily Operations Brief was beneficial to daily operations and feeling prepared to represent the department did not significantly improve. Communication between departments, awareness of daily events, and working relationships	NR

First Author, Year Location	Goal	Main Components	Process measures (state of mindfulness; culture; engagement)	Safety measures (met goal, mean change)
			between departments significantly improved pre- to post-implementation.	
Day 2018[17] Johns Hopkins Hospital and Health System	≥ 96% compliance for each core Joint Commission Accountability Measures (process measures)	Operating Management System with 5 core elements: (1) Governance, leadership, and accountability; (2) Systems thinking, risk identification, and mitigation; (3) capacity and infrastructure; (4) transparency, communication and teamwork; (5) insight and innovation	Compliance Joint Commission Accountability Measures: é from 42.9% in 2011 to 85.7% in 2012 and 2013	Potential preventable harms: ê from 3800 in 2012 to 800 in 2017 (79% reduction)
Muething 2012[31] Cincinnati Children's Hospital Medical Center	Reducing SSEs by 80% within 4 years	Interventions focused on: (1) Error prevention; (2) restructuring patient safety governance; (3) new root cause analysis process and common cause database; (3) highly visible lessons learned program; (3) specific tactical interventions for high-risk areas	Response rates to the AHRQ Health System Patient Safety Culture survey gradually improved over time. Between 2005 and 2007, overall ratings of patient safety decreased, but some domains within patient safety, especially at the hospital level, improved (hospital management support for patient safety; teamwork across hospital units; and hospital handoffs and transitions).	SSEs per 10,000 adjusted patient-days decreased from a mean of 0.9 at baseline in 2005 to 0.3 in 2009 (-67%; *P*<.0001).

Abbreviations: AHRQ = Agency for Healthcare Research and Quality; PHI = Preventable Harm Index; SSE = serious safety event

SUMMARY AND DISCUSSION

To our knowledge, this is the first evidence review to systematically evaluate primary research on the effects of HRO implementation in health care settings. Furthermore, although much has been written about the concepts of HRO and individual health care systems' experience with HRO implementation, few have looked *across* different systems to describe similarities and differences in frameworks and metrics, and what lessons might be learned based on the successes and challenges encountered using different approaches. Gaining a better sense of how HRO has been successfully delivered is critical to informing the work of the VA and other health systems as each embarks on its HRO journey.

Although a variety of frameworks for implementation of HRO principles are available, the Joint Commission's HRHCM and the IHI's Framework for Safe, Reliable, and Effective Care stand out as being the most comprehensive, applicable, and sufficiently descriptive to be used by the VA. Both of these frameworks cover 5 common HRO implementation strategies seen across frameworks, including (1) developing leadership, (2) supporting a culture of safety, (3) building and using data systems to track progress, (4) providing training and learning opportunities for providers and staff, and (5) implementing interventions to address specific patient safety issues. Complementary practices to strengthen implementation seen across these frameworks include the need to incorporate an awareness of justice, equity, and patient-centeredness into all elements of HRO implementation; the importance of involving a variety of stakeholders involved in health care delivery, including patients and families; and the value of integrating change management strategies into HRO delivery. The selection of one of these frameworks – or development of a new framework – should be informed by the staff being targeted for HRO implementation (*eg*, all providers and staff, only leadership, only nursing professionals); the approach desired (*eg*, developing a high-level operations management system vs training staff and providers on HRO principles and practices); and the capacity of the system in implementing certain components of the HRO framework (*eg*, a system that does not have strong leaders in evidence-based medicine may not want to implement the ARCC model).

Of the metrics available to evaluate a health system's progress towards becoming an HRO, the Joint Commission's HRHCM/Oro 2.0™ is the most comprehensive, rigorously developed, and applicable to the VA HRO initiative, given that its content validity has been evaluated at 6 VA hospitals.[27] This tool was not designed to facilitate sharing data across hospitals; however, the tool outputs data into reports that could be shared. Of note, findings from the VA validation study[27] indicate that certain concepts (teamwork culture and system-focused tools) are missing from the HRHCM framework and should be added. An example from the ACHE tool that might address these concepts include: "My organization uses and regularly reviews a formal training program and defined processes for teamwork and communication."[16] The VA HRO Initiative may consider adding these or similar concepts to the current tool being used to assess VA sites' progress on becoming HROs. Additionally, other tools published prior to 2010 may be appropriate for capturing process outcomes on the pathway between the 5 HRO concepts and the end-goal of improved safety outcomes, such as the Safety Attitudes Questionnaire[35] and the Safety Organizing Scale.[36]

Multicomponent HRO interventions that incorporate some of the 5 common HRO implementation strategies identified in KQ1 and that are delivered for at least 2 years are associated with improved process outcomes (*eg*, staff reporting of safety culture) and patient

safety outcomes (*eg*, SSEs). However, the overall strength of evidence is low, as each HRO intervention was only evaluated in a single fair-quality study. Successful facilitators to implementation may include hiring an outside consultant (*eg*, HPI) to assist in the implementation, enacting of policies to facilitate data sharing (*eg*, passage of a state house bill to enable a collaborative of children's hospitals to share critical safety data[30]), and leadership committing to implementing HRO principles. Barriers to implementation may include competing priorities, such as widescale implementation of an EMR system[30], and costs (*eg*, one system increased quality improvement staff from 8 to 33, with a budget increase of over $2 million[6]).

LIMITATIONS

Primary study limitations

HRO interventions and other complex interventions are inherently difficult to study, because many interventions are implemented by many different people across multiple time points. Each hospital may also choose to implement different components of HRO interventions, depending on their individual needs and context. As a result, isolating the specific components of an HRO intervention that cause a specific effect on process and patient safety outcomes is difficult.[37] Furthermore, without a control group, we cannot conclude that the HRO intervention, rather than another concurrent intervention or secular trend, caused the change. One study commented that other simultaneously implemented interventions, including EMR implementation and improved specialty-specific disease management, may have contributed to improved outcomes.[6] EMR implementation is likely to be a confounder across multiple studies and could improve patient safety by making it easier to find and use patient health information, to collaborate with colleagues in other departments, and by building checklists and other automated processes into patient appointments. Other plausible confounders include utilization of other change management strategies, such as Lean Six Sigma, before or during the HRO implementation. Therefore, while promising, evidence of improved outcomes after HRO implementation should be interpreted cautiously.

Many studies commented that HRO was delivered among high-performing hospitals. Whether or not lower-performing hospitals would have the same outcomes is unclear. In addition, few studies commented on the fidelity of implementation or compliance, such as whether providers attended the required number of trainings or continually maintained safety event reporting systems. Therefore, we cannot determine whether health care staff continued to be invested in HRO implementation over time. Studies that reported some compliance measures reported that staff responses to culture surveys increased over time and the number (but not percent) of providers that completed trainings. Only 1 study described the potential unintended consequences of HRO implementation (*ie*, ACA turnaround time decreased).[28] Study authors hypothesized that reasons for this increased efficiency included the availability of a standardized toolkit, clear rubrics to follow, and the availability of additional resources facilitated completion of the process. The effect of HRO implementation on provider and staff workload and efficiency is an important research question that should be the subject of future research.

Rapid review limitations

First, searching from 2010 forward means that we did not include earlier publications on HRO framework design and implementation. However, our search strategy and consultation with topic experts likely resulted in identification of the most recent and relevant articles that incorporated

AHRQ's conceptualization of the 5 HRO principles in healthcare settings. Second, our use of a single investigator to review articles, with second reviewer checking, may also have resulted in missing eligible studies. However, we used objective criteria to minimize the potential for differences between investigators. Finally, our quality assessment checklist on complex interventions was not designed to conduct a comprehensive assessment of all areas of bias, but rather to ascertain whether the study authors reported enough information that the intervention and evaluation could be reproduced and to highlight common issues in reporting and methodology seen across studies. Therefore, while it may not have captured all areas of bias seen in these studies, the use of another more formal tool would likely not have changed our conclusions.

GAPS AND FUTURE RESEARCH

The biggest gaps in knowledge on HRO implementation are (1) whether the improvements in process and safety outcomes are truly caused by HRO interventions or due to concurrent interventions or secular trends; (2) if HRO does indeed lead to improved outcomes, which components of HRO interventions are causing the effects; (3) whether certain implementation frameworks lead to better outcomes; and (4) what are the contextual factors (such as barriers and facilitators) affecting successful HRO implementation. Randomized controlled trial study designs are not a practical option for evaluating HRO interventions due to both the complexity of intervention as well as the delivery; therefore, other study designs such as quasi-experimental or natural experiments should be utilized instead. The VA HRO initiative is in a unique position to conduct these types of experiments. Implementing HRO principles at a select number of VA sites while other sites serve as a "wait-list" control would create a natural experiment to see if HRO implementation leads to improved outcomes. If this approach is taken, consideration should be given to how much wait-list control sites have begun implementing HRO concepts on their own or whether they're implementing similar initiatives such as Lean Six Sigma. In addition, the widescale implementation of HRO across different sites likely means that each site will deliver slightly different interventions based on their individual contexts. Careful recording of the intervention components, when they were delivered, where they were delivered (*eg*, medical or surgical service areas), and whether they continued to be delivered may help to elucidate the effects of some of these individual intervention components on outcomes. This can inform where to invest future resources, and to tailor HRO delivery to specific contexts.

In addition, we were unable to determine what the mechanism of change was between HRO implementation and improvement in outcomes. While HRO delivery is theorized to lead to *change in thinking about patient safety*, resulting in improved processes and outcomes, this was not empirically examined in any of our included studies. Instead, some studies suggested that the impact of HRO on other process measures, such as safety culture, is mixed.[31] This indicates that the mechanism of action driving changes in outcomes is more complex. Future studies should evaluate what is the mechanism of change, such as improved mindfulness or safety culture, to help answer both the how and why HRO implementation may lead to improved patient safety outcomes. Future studies may also want to consider the extent to which HRO implementation overlaps – or doesn't – with system redesign strategies, as these are complementary approaches to improving quality of care.

CONCLUSIONS

A variety of frameworks and evaluation tools are available for HRO implementation and evaluation, with the Joint Commission's High Reliability Health Care Maturity (HRHCM)/ORO 2.0 among the most rigorously developed and validated. Multicomponent HRO interventions that include several of the 5 common implementation strategies and that are delivered for at least 2 years are associated with improved process outcomes, such as staff perceptions of safety culture, and important patient safety outcomes, such as reduced SSEs. Future research studies should incorporate concurrent control groups through quasi-experimental designs to rule out the possibility that the effects are due to other interventions or secular trends. Future research should also focus on identifying whether certain frameworks, metrics, or components of interventions lead to greater improvements.

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In designing the study questions and methodology at the outset of this report, the ESP consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicting opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

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Operational Partners

Operational partners are system-level stakeholders who have requested the report to inform decision-making. They recommend Technical Expert Panel participants; assure VA relevance; help develop and approve final project scope and timeframe for completion; provide feedback on draft report; and provide consultation on strategies for dissemination of the report to field and relevant groups.

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Quality Enhancement Research Initiative

Technical Expert Panel

To ensure robust, scientifically relevant work, the TEP guides topic refinement; provides input on key questions and eligibility criteria, advising on substantive issues or possibly overlooked areas of research; assures VA relevance; and provides feedback on work in progress. TEP members are listed below:

Laura Damschroder, MPH, MS
Center for Clinical Management Research
Ann Arbor, MI

Key Informants

The ESP sought input from 2 Key Informants with diverse experiences and perspectives in implementing HRO interventions into large, integrated health care systems.

Glenda J. L. Battey, PhD
Providence St Joseph Health
Renton, WA

Robert G. Ritter, FACHE
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Peer Reviewers

The Coordinating Center sought input from external peer reviewers to review the draft report and provide feedback on the objectives, scope, methods used, perception of bias, and omitted evidence. Peer reviewers must disclose any relevant financial or non-financial conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The Coordinating Center and the ESP Center work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

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