Evidence Brief: Implementation of High Reliability Organization Principles

Supplemental Materials

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Prepared for:

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APPENDIX A. SEARCH STRATEGIES

1. Search for current systematic reviews Date Searched: 1/31/19	
Sources:	**Strategy:**
AHRQ	Search: High-reliability
CADTH	Search: High-reliability
NICE (NHS Evidence)	Search: "High-reliability"
VA Products: VATAP, PBM, HSR&D publications, VA ART Database	A. http://www.hsrd.research.va.gov/research/default.cfm B. http://www.research.va.gov/research_topics/ C. http://art.puget-sound.med.va.gov/default.cfm D. https://www.hsrd.research.va.gov/publications/esp/ Search: High-reliability
Cochrane Database of Systematic Reviews	Database: EBM Reviews - Cochrane Database of Systematic Reviews <2005 to January 30, 2019> Search Strategy: -- 1 (High-reliability organization* or High-reliability practice* or High-reliability principle* or High-reliability healthcare or High-reliability health care).mp. (0) ****************************
BlueCross BlueShield Foundation Massachusetts	Search: High-reliability Relevant Results:
Campbell Collaboration	Search: High-reliability
CMS Policies	Search: High-reliability
Hayes	Search: High-reliability
Institute for Clinical Evaluative Sciences	Search: High-reliability
The National Academies of Science (formerly IOM)	Search: High-reliability
McMaster Health Systems Evidence	Search: High-reliability
Robert Wood Johnson	Search: High-reliability
UBC Centre for Health Services and Policy Research	Search: High-reliability
WHO Health Evidence Network	Search: High-reliability

2. Systematic reviews currently under development (forthcoming reviews & protocols) Date Searched: 1/31/19	
Sources:	**Strategy:**

PROSPERO (SR registry)	Search: High-reliability
DoPHER (SR Protocols)	Search: High-reliability

3. Current primary literature **Date Searched: 1/31/19**	
Sources:	**Strategy:**
MEDLINE	Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R) <1946 to January 28, 2019> Search Strategy: -- 1 (High-reliability organization* or High-reliability practice* or High-reliability principle* or High-reliability healthcare or High-reliability health care).mp. (211) ****************************
CINAHL	Database: CINAHL Plus with Full Text Search Strategy: -- 1 TX (High-reliability organization* or High-reliability practice* or High-reliability principle* or High-reliability healthcare or High-reliability health care) (370) 2 Limit Source Type: Academic Journals (217) ****************************
PsycINFO	Database: PsycINFO <1806 to January Week 3 2019> Search Strategy: -- 1 (High-reliability organization* or High-reliability practice* or High-reliability principle* or High-reliability healthcare or High-reliability health care).mp. (175) ****************************
CCRCT	Database: EBM Reviews - Cochrane Central Register of Controlled Trials <December 2018> Search Strategy: -- 1 (High-reliability organization* or High-reliability practice* or High-reliability principle* or High-reliability healthcare or High-reliability health care).mp. (1) ****************************
PubMed	Search: "High-reliability organization*"[All Fields] or "High-reliability practice*"[All Fields] or "High-reliability principle*"[All Fields] or "High-reliability healthcare"[All Fields] or "High-reliability health care"[All Fields]

APPENDIX B. LIST OF EXCLUDED STUDIES

Exclude reasons: 1=Ineligible population, 2=Ineligible intervention, 3=Ineligible comparator, 4=Ineligible outcome, 5=Ineligible timing, 6=Ineligible study design, 7=Ineligible publication type 8=Outdated or ineligible systematic review

#	Citation	Exclude reason
1	Brass SD, Olney G, Glimp R, Lemaire A, Kingston M. Using the Patient Safety Huddle as a Tool for High Reliability. Joint Commission journal on quality and patient safety. 2018;44(4):219-226.	E4
2	Carrico R. The Joint Commission aims for high-reliability health care, unveils framework to move hospitals toward zero harm. ED management : the monthly update on emergency department management. 2013;25(12):suppl 3-4, 139.	E7
3	Clements K. High-reliability and the I-PASS communication tool. Nursing management. 2017;48(3):12-13.	E4
4	Davenport PB, Carter KF, Echternach JM, Tuck CR. Integrating High-Reliability Principles to Transform Access and Throughput by Creating a Centralized Operations Center. Journal of Nursing Administration. 2018;48(2):93-99.	E2
5	Deloitte. Transforming into a high reliability organization in health care. 2017.	E2
6	Eriksson N. Followership for organizational resilience in health care. In: The resilience framework: Organizing for sustained viability. New York, NY: Springer Science + Business Media; US; 2018:163-179.	E10
7	Fieldston E, Tsarouhas N. CT hospital slashes door-to-balloon times to reduce patient harm. ED Management. 2014;26(7):80-83.	E7
8	Gabriel PE, Bergendahl HW, Burke SV, Solberg TD, Maity A, Hahn SM. Incident Learning in Pursuit of High Reliability: Implementing a Comprehensive, Low-Threshold Reporting Program in a Large, Multisite Radiation Oncology Department. Joint Commission Journal on Quality & Patient Safety. 2015;41(4):160-168.	E5
9	Griffith JR. Understanding High-Reliability Organizations: Are Baldrige Recipients Models? Journal of Healthcare Management. 2015;60(1):44-61.	E2
10	Hales DN, Chakravorty SS. Creating high reliability organizations using mindfulness. Journal of Business Research. 2016;69(8):2873-2881.	E5
11	Hendrich A, Haydar Z. Building a High-Reliability Organization: One System's Patient Safety Journey. Journal of healthcare management / American College of Healthcare Executives. 2017;62(1):13-17.	E2
12	Hershey K. Culture of safety. Nurs Clin North Am. 2015;50(1):139-152.	E7
13	Jones WS. Military Graduate Medical Education: Training the Military Health System into a High-Reliability Organization. Military medicine. 2015;180(11):1121-1123.	E7
14	Knox GE, Simpson KR. Perinatal high reliability. Am J Obstet Gynecol. 2011;204(5):373-377.	E7
15	Lyren A, Brilli RJ, Zieker K, Marino M, Muething S, Sharek PJ. Children's Hospitals' Solutions for Patient Safety Collaborative Impact on Hospital-Acquired Harm. Pediatrics. 2017;140(3).	E2
16	Magnano P, Platania S, Ramaci T, Santisi G, Di Nuovo S. Validation of the Italian version of the Mindfulness Organizing Scale (MOS) in organizational contexts. TPM-Testing, Psychometrics, Methodology in Applied Psychology. 2017;24(1):45-64.	E5

17	May EL. The power of zero: steps toward high reliability healthcare. South Carolina Safe Care Commitment. Healthcare executive. 2013;28(2):26.	E7
18	McCraw B, Crutcher T, Polancich S, Jones P. Preventing Central Line-Associated Bloodstream Infections in the Intensive Care Unit: Application of High-Reliability Principles. Journal for Healthcare Quality. 2018;40(6):392-397.	E2
19	McFarland DM, Doucette JN. Impact of High-Reliability Education on Adverse Event Reporting by Registered Nurses. Journal of nursing care quality. 2018;33(3):285-290.	E5
20	Middleton LP, Phipps R, Routbort M, et al. Fifteen-Year Journey to High Reliability in Pathology and Laboratory Medicine. American Journal of Medical Quality. 2018;33(5):530-539.	E2
21	Mossburg SE, Weaver SJ, Pillari M, Daugherty Biddison E. Manifestations of High-Reliability Principles on Hospital Units With Varying Safety Profiles: A Qualitative Analysis. Journal of nursing care quality. 2018;21:21.	E4
22	Oster CA, Deakins S. Practical Application of High-Reliability Principles in Healthcare to Optimize Quality and Safety Outcomes. Journal of Nursing Administration. 2018;48(1):50-55.	E7
23	Prasanna P, Nagy P. Learning from high-reliability organizations. J. 2011;8(10):725-726.	E7
24	Pronovost PJ, Armstrong CM, Demski R, et al. Creating a high-reliability health care system: improving performance on core processes of care at Johns Hopkins Medicine. Academic medicine : journal of the Association of American Medical Colleges. 2015;90(2):165-172.	E2
25	Provost SM, Lanham HJ, Leykum LK, McDaniel RR, Jr., Pugh J. Health care huddles: managing complexity to achieve high reliability. Health care management review. 2015;40(1):2-12.	E2
26	Quigley PA, White SV. Hospital-based fall program measurement and improvement in high reliability organizations. Online journal of issues in nursing. 2013;18(2):5.	E2
27	Roney L, Sumpio C, Beauvais AM, O'Shea ER. Describing clinical faculty experiences with patient safety and quality care in acute care settings: A mixed methods study. Nurse education today. 2017;49:45-50.	E2
28	Saunders CL, Brennan JA. Achieving High Reliability with People, Processes, and Technology. Frontiers of health services management. 2017;33(4):16-25.	E2
29	Shabot MM. New tools for high reliability healthcare. BMJ quality & safety. 2015;24(7):423-424.	E2
30	Sitterding M. Overview and Summary: Creating a Culture of Safety: The Next Steps. Online journal of issues in nursing. 2011;16(3):1-1.	E7
31	The Health Foundation. Evidence Scan: High reliability organisations. 2011.	E6
32	Thomas AD, Pandit C, Krevat SA. Race Differences in Reported Harmful Patient Safety Events in Healthcare System High Reliability Organizations. Journal of patient safety. 2018.	E4
33	Van Spall H, Kassam A, Tollefson TT. Near-misses are an opportunity to improve patient safety: adapting strategies of high reliability organizations to healthcare. Curr. 2015;23(4):292-296.	E7
34	Vogus TJ, Singer SJ. Creating Highly Reliable Accountable Care Organizations. Medical Care Research & Review. 2016;73(6):660-672.	E7
35	Wasden ML. High-Reliability Principles Must Be Tied to Value-Based Outcomes. Frontiers of health services management. 2017;33(4):26-32.	E7
36	Wentlandt K, Degendorfer N, Clarke C, et al. The Physician Quality Improvement	E7

	Initiative: Engaging Physicians in Quality Improvement, Patient Safety, Accountability and their Provision of High-Quality Patient Care. Healthcare quarterly (Toronto, Ont). 2016;18(4):36-41.	
37	Woodhouse KD, Volz E, Maity A, et al. Journey Toward High Reliability: A Comprehensive Safety Program to Improve Quality of Care and Safety Culture in a Large, Multisite Radiation Oncology Department. Journal of oncology practice/American Society of Clinical Oncology. 2016;12(5):e603-612.	E2

APPENDIX C. EVIDENCE TABLES

DATA ABSTRACTION: KEY QUESTION 1 STUDIES

Author Year	Name of Framework Purpose Setting	Main strategies of framework	Process for developing framework	Process for implementing framework	Who participates in implementing the framework?
Aboumatar[1] 2017	Name: Safety and Quality (SQ) Purpose: To build organizational capacity for SQ Setting: HCOs	Role-tailored capacity-building efforts; a supportive work environment; commitment to SQ; accountability systems; an operational management system to guide SQ efforts. · **Category 1**: Staff in direct care delivery. Overarching goal: Provide mindful safety-oriented daily practice--identify and participate in opportunities for improvement · **Category 2**: Local support and management staff. Overarching goal: Ensure delivery of SQ care within their work units/teams; Nurture a local culture of safety; Surface and address barriers to improvement and safe practice · **Category 3**: SQ experts. Overarching goal: Design and direct system improvement efforts; provide guidance and coaching to other healthcare workforce groups	Combination of literature review and consensus. Framework developed by Johns Hopkins Armstrong Institute for Patient Safety and Quality.	**Front line providers and staff:** · Authors developed a basic medical school education on SQ · Residents participated in online courses and workshops and experiential learning activities · SQ is central to the new employee orientation; an SQ presentation is held monthly. **Managers and local improvement personnel:** · Authors developed patient safety certificate program with online and in-person options; workshops on Lean Sigma, SQ, and other topics **Safety and quality leaders and experts:** · Professionals focused solely on SQ are encouraged to pursue formal degrees in healthcare services, translational research, or other relevant fields **Future processes:** · An evaluation plan to measure process and outcomes is underway. · Lessons learned include: the need for dedicated infrastructure to implement learning and development activities; the need for targeted communication efforts; the need for a database to track learning progress; the need for a longitudinal learning plan; the need for data analysis support among SQ leadership; and the need for frequent follow-ups with training progress.	Front-line providers and staff, managers and local improvement personnel, and Safety and Quality leaders and experts
ACHE 2017[2]	Name: Culture of	6 leadership domains:	Consensus	Suggested practices for implementing	CEOs and executive

Author Year	Name of Framework Purpose Setting	Main strategies of framework	Process for developing framework	Process for implementing framework	Who participates in implementing the framework?
	Safety Purpose: To assess and advance an organization's culture of safety Setting: HCOs	1. Establishing a compelling vision for safety 2. Build trust, respect, and inclusion 3. Select, develop, and engage your Board 4. Prioritize safety in the selection and development of leaders 5. Lead and reward a just culture 6. Establish organizational behavior expectations Strategies and practical tactics are divided into 2 levels: 1. **Foundational**: basic tactics and strategies essential for the implementation of each domain 2. **Sustaining**: strategies for spreading and embedding a culture of safety throughout the organization Framework also outlines expectations for CEOs in each domain		the core components of the model: 1. **Vision** - Foundational: Develop a vision of goals with leadership and select individuals; communicate the culture, etc. Sustaining: Clearly articulate the vision to staff, public, patients and families; benchmark culture progress; etc. 2. **Trust, Respect, Inclusion** - Foundational: Create expectations for this domain, practices it via open communication, just culture, workplace safety programs, etc.; Sustaining: Aim for total transparency, ensure for follow-up and feedback on identified safety issues, build metrics for this domain, etc. 3. **Board Engagement** - Foundational: More discussion on safety culture and metrics in board meetings; Sustaining: More in-person participation by Board members (*eg*, guided leadership rounds, bringing teams into Board meetings) 4. **Leadership Development** - Foundational: Communicate expectations for leadership roles; Sustaining: Incentivize safety metrics into leadership reviews, etcetera 5. **Just Culture** - Foundational: Educate and ensure commitment to just culture; use metrics to track; reward just culture; Sustaining: Implement programs (*eg*, peer support); hold workforce accountable; use media communication with the public 6. **Behavior Expectations** - Foundational: Implement safety surveys; address identified gaps; require, participate in, and give context for existing safety processes;	leadership

Author Year	Name of Framework Purpose Setting	Main strategies of framework	Process for developing framework	Process for implementing framework	Who participates in implementing the framework?
				Sustaining: Hold leadership accountable; educate the public; design and implement a crisis communications policy	
Chassin 2013[3]	Name: HRHCM Purpose: To assess hospitals' readiness for and progress toward high reliability Setting: Hospitals and health systems	3 domains and 14 components of HRHCM: 1. Leadership's commitment to zero patient harm (board, CEO/management, physicians, quality strategy, quality measures, information technology) 2. Safety culture (trust, accountability, identifying unsafe conditions, strengthening systems, assessment) 3. Robust Process Improvement (methods, training, spread) Each domain is assessed for one of these levels of maturity: 1. Beginning 2. Developing 3. Advancing 4. Approaching	Authors created the framework by combining the Joint Commission's knowledge of health care organizations with a literature review and input from subject experts. In a pilot test, an expert panel reviewed the framework and questionnaire and assessed the former for its face validity. In a 2nd pilot test, the leadership of 7 US hospitals tested the framework by using the questionnaire to assess their own hospitals. The results of this test were incorporated into the framework and questionnaire, to be finalized for field-testing.	Suggested practices for implementing the core components of the model: 1. Hospitals must assess their current state of maturity for each of the 14 components, then access proven tools/methods to advance their maturity. 2. **Leadership:** The board of trustees must establish the expectation for zero patient harm; physicians must champion quality improvement initiatives; quality must be measured and data shared widely; quality improvement should be incentivized; information technology should be used effectively. 3. **Safety:** employees should have enough trust in the system to report errors; the organization should eliminate behaviors that suppress reporting, fix reported errors and communicate the improvements; hold employees accountable to safety protocols; safety progress should be measured, analyzed, and reported. 4. **Robust Process Improvement** organizations should use validated tools, such as Lean Six Sigma and change management; employees should be trained, and their proficiency should be part of their performance appraisal.	Hospital leadership and employees
Day 2018[4]	Name: Operating Management System	5 domains: 1. **Governance, leadership, and accountability:** Leaders hold	Informed by advanced systems engineering and mission assurance	Examples of practices used to implement the core components of the model:	Hospital leadership

Author Year	Name of Framework Purpose Setting	Main strategies of framework	Process for developing framework	Process for implementing framework	Who participates in implementing the framework?
	Purpose: To organize processes and practices around HRO principles using a systems engineering approach. Setting: HCOs	themselves accountable for ensuring that others know the goals and their roles and have the skills to reach the goal 2. **Systems thinking, risk identification, and mitigation:** Performance results and identified risks may indicate the need for a detailed systems engineering assessment; Corrective and preventive actions are taken 3. **Capacity and infrastructure:** Using the fractal system approach to link all levels of organization and align staff around common goals 4. **Transparency, communication, and teamwork:** Leadership aims to be transparent; Staff are empowered to speak up on harm prevention; Workflows are designed and assessed to provide staff with upstream/downstream understanding of the impacts of their work 5. **Insight and innovation:** Data from various sources are synthesized to gain insights, which are then used to increase mindful variation and resiliency of the system.	methodology and research in high reliability organizing, the Johns Hopkins Medicine Armstrong Institute for Patient Safety and Quality created and continues to mature an integrated management system model for healthcare.	1. **Governance, leadership, and accountability**: A standard Management Discussion and Analysis (MD&A) reporting format is used with standardized content expectations and used by department directors to provide individual department reports; A Performance Subcommittee provides focused oversight 2. **Systems thinking, risk identification and mitigation**: Systems engineering methodology is used to improve teamwork; Data from safety culture/employee surveys and event reports are used to identify risks and develop solutions; A non-rate-based preventable harm initiative was established 3. **Capacity and infrastructure**: The role of vice chair for patient safety and quality was created for each department; Continuous learning opportunities about safety are provided; The Comprehensive Unit-based Safety Program (CUSP) creates teams to improve safety culture and provide caregivers with harm prevention tools 4. **Transparency, communication, and teamwork**: Patient and Family Advisory Councils are established with representatives; Lean Daily Management strategies include huddle boards; Implemented enhanced recovery after surgery (ERAS) protocols are used with CUSP to enhance engagement of front-line staff 5. **Insight and innovation**: Teams of	

Author Year	Name of Framework Purpose Setting	Main strategies of framework	Process for developing framework	Process for implementing framework	Who participates in implementing the framework?
				multidisciplinary, cross-entity stakeholders are convened regularly to work on safety and quality improvement; A cross-disciplinary analytics community synthesizes information from multiple sources to identify learning opportunities; A learning laboratory designs care systems	
Frankel 2017[5]	Name: Framework for Safe, Reliable, and Effective Care

Purpose: The framework aims to provide clarity and direction to health care organizations on the key strategic, clinical, and operational components for high reliability. Can be used as a roadmap for applying HRO principles or theoretically as a diagnostic tool.

Setting: HCOs | Two domains that are synergistic and can/should be implemented simultaneously:
1. Culture (the product of individual and group values, attitudes, competencies, and behaviors that form a strong foundation for a learning system) which has subdomains of:
   a. Psychological safety
   b. Accountability
   c. Teamwork & communication
   d. Negotiation
2. Learning system (characterized by its ability to self-reflect and identify strengths and defects; identifies defects and acts on them; rewards proactivity rather than reactivity) which has subdomains of:
   a. Leadership
   b. Transparency
   c. Reliability
   d. Improvement & measurement
   e. Continuous learning | Consensus. Developed by IHI and Safe and Reliable Healthcare (SRH) to develop curriculum for the IHI Patient Safety Executive Development Program. Developed based on in-depth analyses of high-performing, proactive, and generative work settings. Initially developed for the acute care setting but has evolved to be applicable in any health care setting. | Suggested practices for implementing the core components of the model:
1. Organizations can check for, monitor, and encourage certain actions to cultivate stronger leadership.
2. Leaders must be role models; use coaching and feedback, hold one-one-one meetings with staff; and conduct huddles to achieve psychological safety. Organizations must convey the expectation of psychological safety.
3. Organizations need to implement an accountability algorithm, reflect this in all policies and practices, and share it with everyone.
4. Organizations must set the expectation that middle managers are responsible for setting the norm for teamwork and communication; teams need to practice these behaviors.
5. Organizations should consider building ongoing awareness of collaborative negotiation.
6. Transparency: Leaders must set expectations that managers will create learning boards.
7. Teams can use high-level flowcharts to visualize the current | Senior leaders, middle managers, frontline staff, patients and families |

Author Year	Name of Framework Purpose Setting	Main strategies of framework	Process for developing framework	Process for implementing framework	Who participates in implementing the framework?
				process/system. Next, target one subset of patients and improve reliability of care for them. 8. All staff must have knowledge of a systematic improvement approach; leaders and managers need deep understanding of it to implement it and provide coaching. Frontline staff and managers must know how to collect and display data for key measures. 9. Continuous learning: Organizations must share data as the basis for a robust learning system.	
Melnyk 2012[6]	Name: Advancing Research and Clinical practice through close Collaboration (ARCC Model) Purpose: Framework promotes HRO principles through building organizational capacity for evidence-based practice (EBP) Setting: HCOs	Implementation of ARCC model involves the following steps 1. Assess culture and readiness for EBP 2. Identify strengths and barriers to EBP implementation 3. Develop and use EBP mentors 4. Implement EBP	Consensus. Initial development based on strategic planning process to rapidly integrate research findings into clinical practice	6 workshops with 8 days of educational and skills building session over 1 year. Workshops consist of: 1. EBP skills building 2. Creating a vision to motivate a change to EBP 3. Transdisciplinary team building and effective communication 4. Mentorship to advance EBP 5. Strategies to build a EBP culture 6. QI processes 7. Data management and outcomes monitoring/evaluation and 8. Theories and principles of individual behavior and organizational change Teams also implement an EBP implementation project over 12 months focused on improving quality of care, safety, and/or patient outcomes.	EBP mentors are typically advance practice nurses, transdisciplinary professionals, or clinicians with bachelor's degrees. EBP mentors work with point-of-care clinicians.
Office of the Air Force Surgeon General 2015[7]	Name: Trusted Care Purpose: To transform the Air Force Medical	4 domains: 1. **Leadership Engagement**: Leaders at every level will display competence in safety science principles and be accountable. They will focus on patient safety by	Consensus and literature review. In 2015, AFMS contracted an external reviewer to conduct gap analysis and comparative analysis with other leading	Suggested practices to achieve goal: · Processes will be standardized and stabilized at the start. · Staff engage in behaviors that continuously improve standardized processes	All health care staff in the AFMS

Author Year	Name of Framework Purpose Setting	Main strategies of framework	Process for developing framework	Process for implementing framework	Who participates in implementing the framework?
	Service (AFMS) to a high reliability health care system Setting: AFMS	discussing its priority, focusing on processes, expecting and searching for failures, fostering a Just Culture, and recognizing staff that help improve care. 2. **Culture of Safety**: Essential aspects of culture of safety include: trust in leadership, leaders' trust in staff, willingness to admit error and identify unsafe conditions, respectful communication, and belief that safe care is everyone's duty 3. **Continuous Process Improvement**: This domain builds a robust process improvement framework to develop standard, reliable work processes. Essential parts of this domain include seeing the operational environment as a system of care that can be studied to effect positive change, eliminate gaps and reduce waste 4. **Patient Centeredness**: Focuses on work that adds value for patients and their families. Systems anticipate patients' expectations and excel in every aspect of their experience, engage patients as indispensable partners in ensuring safe care and zero harm.	health care systems. The gap analysis was informed by materials developed for Military Health Services Review, a literature review, interviews with AHMS leaders and experts, and consulting with an external company, HPI. HPI introduced leaders to safety science, then AFMS leaders began identifying HRO goals.	· Staff are enabled and mentored by servant leaders engaged in coaching behaviors · These leaders set intervening target conditions. Desired future state for the 4 essential domains include: 1. Leadership: safety commitment embedded in strategy, structure, and operations; unwavering focus on safety; emphasis on systems thinking; strong leadership development; visible presence at frontlines; accountability in creating just culture 2. Culture of Safety: safety training and accountability for all, rigorous reporting of near misses and harm; enhancement of just culture; thorough investigation of harm events; use of clinical standards and standard work. 3. Continuous Process Improvement: process improvement is normal daily management, focus on processes that generate patient value, sustained improvement and coaching patterns 4. Patient Centeredness: patients are active partners in their care, patient experience wins their trust, AFMS staff speak clearly to minimize misunderstanding and risk, commitment to transparency, demonstrate empathy and humility. There are also essential enablers to implementation of CONOPS which include:	

Author Year	Name of Framework Purpose Setting	Main strategies of framework	Process for developing framework	Process for implementing framework	Who participates in implementing the framework?
				· Establi2sh the AFMS as a learning organization · TeamSTEPPS: evidence-based teamwork system designed to improve communication and teamwork skills among healthcare professionals · Medical modeling and simulation · Integration of Trusted Care into AFMS strategy	
Riley 2010[8]	Name: High-reliability Team/ High-reliability Patient Care Unit Purpose: To form high-reliability teams, which are essential for the success of HRO Setting: HCOs	3 domains: 1. *In Situ* **Simulation**: Experiential learning; Application; Test for gaps 2. **TeamSTEPPS**: Define the team; Use the tools; Coach to sustain 3. **Just Culture**: Principles of risk; Accountability; Focus on behavior	NR	Suggested practices for implementing the core components of the model: 1. *In Situ* Simulation: Teams practice behaviors (briefing, huddle, debriefing). Participants lead the discussion on process errors and improvements. Team members learn in what clinical context to use non-technical skills. 2. TeamSTEPPS: Teamwork curriculum developed by Department of Defense and AHRQ with 4 skills: Leadership, Situation Monitoring, Mutual Support, Communications. Curriculum affirms the importance of interdisciplinary teams being trained together, instead of separately. 3. Just Culture: A framework that bases the response to poor outcomes on the behavioral choices of the team member(s) involved and not on the severity of the outcome	Nursing professionals

Abbreviations: ARCC – Advancing Research and Clinical practice through close Collaboration; AFMS – Air Force Medical Service; EBP – evidence-based practice; HCO – health care organization; IHI – Institute for Healthcare Improvement; SRH – Safe and Reliable Healthcare; SQ – Safety and Quality

DATA ABSTRACTION: KEY QUESTION 2 STUDIES

Author Year Name of metric	Concepts measured by the metric Process for developing the metric	Main characteristics of metric (*ie*, domains, scale)	To what extent have the metrics been validated or used to inform health system decision-making?
ACHE 2017[2] Culture of Safety Organizational Self-Assessment Tool	Self-assessment of culture of safety Consensus	Questions address execution of each domain of the Culture of Safety model. Recommended that a diverse team completes the assessment, including C-suite executives, clinical leadership, patient safety leadership, and patient and family representatives. 1. **Establishing a compelling vision for safety:** Members of organization can articulate vision for safety, and patient safety dashboard that includes safety culture metrics is regularly reviewed. 2. **Value trust, respect, and inclusion:** Organization uses and evaluates formal respect programs, implements workforce safety programs, shares information and metrics around harm events and has action plans for improvement. 3. **Select, develop, and engage your Board:** Board completes education and self-assessments on culture of safety, performance assessments and incentives include safety measures, the amount of time spent discussing safety is on par with time spent discussing financial issues. 4. **Prioritize safety in the selection and development of leaders:** Leaders receive patient safety science/safety culture training; there are defined roles, safety competencies and development programs for leaders; there are opportunities for learning across departments or from other organizations and industries. 5. **Lead and reward a just culture:** Just culture policy is present, organization regularly reviews metrics for just culture, there is one set of standards for the entire workforce, there is measurement of just culture as part of employee surveys and as part of performance reviews 6. **Establish organizational behavior expectations:** Organization uses a formal training program and defined processes for teamwork and communication, implements	Not reported

Author Year Name of metric	Concepts measured by the metric Process for developing the metric	Main characteristics of metric (*ie*, domains, scale)	To what extent have the metrics been validated or used to inform health system decision-making?
		professional accountability standards, and has a program for recognition and celebration when individuals/teams excel at key safety and culture metrics; organization conducts and reviews a patient safety survey every 12-18 months	
		Each domain has 3 statements. Participants score from 1 (never true for my organization) to 5 (always true for my organization), with 0 for (unsure of the response). For each domain, score between 0-4 prompts a review of the foundational tactics, score 5-9 prompts a review of both foundational and sustaining tactics, score 10-15 prompts a review of sustaining tactics.	
Chassin 2013[3] Oro 2.0 High Reliability Assessment Tool	Readiness and progress of hospitals on the implementation of HRO using the HRHCM framework The authors separately created a self-assessment questionnaire for hospital leaders designed to assign each of the 14 components to one of the 4 stages of maturity. This was an early version of the Oro.	3 domains and 14 components of HRHCM: 1. **Leadership**'s commitment to zero patient harm (board, CEO/management, physicians, quality strategy, quality measures, information technology) 2. **Safety culture** (trust, accountability, identifying unsafe conditions, strengthening systems, assessment) 3. **Robust Process Improvement** (methods, training, spread) 4 stages of maturity: 1. Beginning 2. Developing 3. Advancing 4. Approaching	The metric was pilot tested in 7 US hospitals. The leadership of each hospital completed the questionnaire for their own hospital. The results were used to improve the framework and questionnaire for field-testing.
Ikkersheim 2011[9] (none)	Qualitative framework for understanding reliability in health care organizations Authors conducted a literature review and identified core elements of high reliability organizations mentioned in papers.	4 domains of reliability: 1. **Process optimization and standardization**: Articulating/mapping goals of a process; using checklists, decision aids, reminders; bundling processes to ensure proper execution; adding failure identification and mitigation. 2. **Outcome measurement and monitoring**: Registering adverse events; informing professionals of their performance; benchmarking with other hospitals through information technology. 3. **Responsibilities and accountability of medical**	Not yet evaluated or validated. Authors suggest that most hospitals globally are "mostly in reliability phase 0 or 1"

Author Year Name of metric	Concepts measured by the metric Process for developing the metric	Main characteristics of metric (*ie*, domains, scale)	To what extent have the metrics been validated or used to inform health system decision-making?
		professionals: Medical staff work together in teams to improve communication and situational awareness; clinical leadership is responsible to colleagues and central management for team results; patient care tasks are designated to best-suited person, not by hierarchy 4. **Organizational culture**: Leaders instill zero-tolerance culture; resilience and a focus on the "why" of what went wrong; lessons learned are shared to other departments; "preoccupation with failure" and "collective mindfulness" 4-point scale used to measure reliability on these 4 domains: Phase 0 (craft), Phase 1 (watchful professional), Phase 2 (collective professionalism), and Phase 3 (highly reliable).	
Kenneth 2010[10] Cultural Assessment Survey (CAS)	Safety culture, in 4 phases: 1. Literature review and key informant interviews on patient safety, best practices of health care environments, and principles of HROs 2. Surveys, interviews and focus groups of health care providers (N=393) 3. Pilot testing of CAS in 10 hospital sites 4. Reliability analysis of CAS at 4 hospital sites	Survey measured 6 domains: 1. Patient safety as everyone's priority 2. Teamwork 3. Valuing individuals 4. Open communication 5. Learning 6. Empowering individuals A 5-item response scale was used to respond to each survey item.	Validity and reliability were assessed in this article. Overall internal consistency reliability (Cronbach's alpha) was 0.95. Responses to individual items tended to be normally distributed. Means increased from Time 1 (before Managing Obstetrical Risk Efficiently [MORE] Program) to Time 2 (after MORE Program) indicating the tool was detecting a change in culture.
Mousavi 2016[11] (none)	Readiness of hospitals for the establishment of HRO	55-item questionnaire, with 6 domains: 1. Observing safety considerations in hospitals (8 items) 2. Preoccupation with tolerance of failure correction (9 items) 3. Reluctance to simplify interpretations (17 items) 4. Sensitivity of managers to hospital performance (8 items) 5. Commitment of managers to resilience and flexibility (10 items) 6. Deference of managers to expertise (8 items)	Validity was calculated through the Content Validity method (index of 0.83) using 10 experts in the area of hospitals' accreditation, and its reliability was calculated through test-retest method with a correlation coefficient of 0.90.
Mousavi 2018[12]	The knowledge of hospital staff on	Questionnaire on knowledge of HRO models had 24	For the questionnaire: Validity confirmed by

Author Year Name of metric	Concepts measured by the metric Process for developing the metric	Main characteristics of metric (*ie*, domains, scale)	To what extent have the metrics been validated or used to inform health system decision-making?
(none)	HRO and the extent of HRO implementation in one hospital in Iran, 2015-2016 Questionnaire was researcher-made and tested among 80 administrators and staff members. Checklist was developed based on 5 elements of HROs and administered to medical and non-medical departments.	items, of which 22 are listed in the paper, including: (1) Dimensions of model HROs, (2) How to develop the culture of HROs model, (3) Activities of the coworkers in addition to specialized tasks, (4) Control processes of medical and non-medical error control and prevention, (5) Talent, knowledge, and awareness in detection and prediction of the incidents, (6) Patient safety regulations and guidelines in the hospital and their value, (7) Foresight in the model of HROs, (8) Holding sessions with managers and staffs to present ways for error prevention, (9) Factors leading to irritation and discouragement of the managers and staffs, (10) How to prevent personal errors and mistakes, (11) Important factors in error prevention by implementation of HROs model, (12) Important factors in identification of HROs, (13) Informed relationship among staffs, (14) Avoiding simplification of analyses, (15) Reluctance to simplify interpretations, (16) Final objective of establishment of HROs model, (17) Outcome of respectful interactions of staff s, 1(8) How to analyze incidents and problems in the hospital, (19) How to receive feedback on self-activities the hospital, (20) How to access required resources to confront unexpected events, (21) How to gain experience from mistakes and errors of other staffs, (22) How to transfer critical information and make efforts to improve effective performance of organization Checklist of extent of HRO implementation had 6 domains: 1. Assessment of attention to patient safety 2. Hospital concern about correcting medical errors 3. Reluctance to simplify interpretations by the staffs and managers 4. Sensitivity to operation 5. Commitment to resilience in the organization 6. Deference to expertise Both the questionnaire and checklist used a 3-point scale ("not at all," "to some extent," and "very much")	expert panel. Reliability assessed by Alpha-Cronbach method (0.85). For the checklist: Validity confirmed by expert panel. Results from the study highlighted gaps in HRO knowledge among staff and places to improve implementation in the assessed hospital.

Author Year Name of metric	Concepts measured by the metric Process for developing the metric	Main characteristics of metric (*ie*, domains, scale)	To what extent have the metrics been validated or used to inform health system decision-making?
Randall 2018[13] (none)	Integration of high reliability practices in children's hospitals based on Joint Commission's High Reliability Health Care Maturity Model (HRHCM) HRHCM model was transformed into a cross-sectional, online survey. It was then pilot-tested by a collaborative of children's hospitals (n=46 institutions) that provided feedback, which was then integrated into the final survey process.	Performance assessed by 3 domains: 1. Leadership (Governing Board Engagement; CEO/Management Engagement; Physician Engagement; Quality Strategy; Quality Measures: Information Technology) 2. Safety Culture (Level of Trust; Accountability; Identification of Unsafe Conditions; Strengthening Systems; Assessment of Safety Culture) 3. Robust Process Improvement (RPI Methods; RPI Training: Spread of RPI Methods) 4-point scale to quantify the extent that high reliability is implemented: 1 - beginning; 2 - developing; 3 - advancing; 4 - approaching	Internal consistency (Cronbach's alpha) of the overall high reliability scale = .87; leadership domain = .72; safety culture domain = .79; RPI = .82. The mean score for overall high reliability was 42.3 out of 52 (SD: 5.8); leadership was 18.7 out of 24 (SD: 3.0); safety culture was 14.9 out of 20 (SD: 2.3); and RPI was 8.8 out of 12 (SD: 1.8). The majority of organizations scored in the "approaching high reliability" stage. When sites reported major organizational changes, a statistically significant (P=.039) decrease was seen in the safety culture domain but not overall high reliability or RPI (P=.067) or leadership (P=.289).
Sullivan 2016[14] Measurement of High Reliability Health Care Maturity (HRHCM) model	Qualitative assessment of 6 VA's HRO maturity based on Joint Commission's High Reliability Health Care Maturity (HRHCM) model Derived from the literature	Semi-structured interviews covering a comprehensive set of specific domains of organizational structures and processes that influence patient safety. These interviews determined a health care organization's maturity level on the HRHCM model (see Chassin 2013).	This metric was used at 6 VA hospitals, with an average of 24 interviews per hospital. Authors used component descriptions from the HRHCM model to evaluate content validity. During interviews, there were no examples of: adoption of codes of behavior or leaders' championing of efforts to remove threatening behavior (safety culture domain), board leadership (leadership domain), or assessment (safety culture domain). There were also a few components of HRO maturity in the literature that didn't appear in the HRHCM model: teamwork culture, and system-focused tools for learning and improvement. There was differentiation between hospitals on 3 of the applicable 9 components, but for 6 of the components there was no differentiation.

Abbreviations: HRO = High Reliability Organization; HRHCM = High Reliability Health Care Maturity Model; NR = Not reported; SD = standard deviation; VA = Veterans Affairs

DATA ABSTRACTION: KEY QUESTION 3 STUDIES (PART 1)

Author Year	Study design Sample size Duration of follow-up	Setting/context Timing Population	Implementation complexity
Brilli 2013[15]	Before-after study 1 hospital that has 25,000 hospital admissions/year 5 years	Nationwide Children's Hospital (large free-standing urban children's hospital). 2008-2013 Hospital staff	Contracted with HPI to implement HRO transformation
Crandall 2017[16]	Before-after study 1 hospital 2 years	Children's National Hospital Aug. 2015 - Mar. 2017 Hospital staff and leadership	Focused interviews and stakeholder surveys guided identification of the key drivers of education, process, and culture and established interventions
Cropper 2018[17]	Longitudinal analysis 1 health care system 9 years	Genesis Health System 2008-2017. Baseline data were collected between 2008-2011. Follow-up occurred through 2017. Hospital staff, leadership, and board members	Health system-level project to implement a safety program with 7 elements and to use established methods (HRO principles, A3 lean principles, Baldridge criteria) to improve system processes and behaviors
Lyren 2016[18]	Before-after study 8 tertiary pediatric referral centers 2 years	8 tertiary pediatric referral centers which comprise the Ohio Children's Hospital Association (OCHA) Jan. 2010- Oct. 2012. Baseline data established between Jul. 2008-Jan. 2010. Hospital staff, leadership, and board members	Developed consensus for 5 pediatric quality measures adopted by the state of Ohio. Created a legal framework to allow the transparent sharing of data between collaborating hospitals, which was possible through the passage of state-level legislation. Consulted with HPI
Saysana 2017[19]	Before-after study 1 pediatric hospital 5 weeks	Riley Hospital for Children at Indiana University Health (291-bed tertiary care pediatric hospital within a large Midwest health care system) Pre-implementation survey occurred in Jun 2012. Post implementation survey occurred 5 weeks later.	Hospital CEO required department leads to participate in a daily safety brief, reporting daily events and unexpected outcomes within their scope of responsibility. Representatives from quality and safety met with department leads to explain the purpose of the meeting and gave them a template of information to report.

Author Year	Study design Sample size Duration of follow-up	Setting/context Timing Population	Implementation complexity
		Hospital department leaders	
Day 2018[4]	Before-after study	Johns Hopkins Medicine	An integrated systems management tool was developed and implemented.
	1 health care system	2012-2017	
	5 years	Hospital leadership	
Muething 2012[20]	Before-after study	Cincinnati Children's Hospital Medical Center (a large, urban pediatric hospital with >32,000 inpatient admissions)	Healthcare Performance Improvement was contracted to conduct interviews with hospital leaders, physicians, and staff. SSE team also participated in AHRQ's HRO learning network.
	1 hospital		
	5 years	2006-2011	
		Hospital staff and leadership	

Abbreviations: HPI – Healthcare Performance Improvement; SSE = serious safety event; AHRQ – Agency for Healthcare Research and Quality; HRO – high reliability organization

DATA ABSTRACTION: KEY QUESTION 3 STUDIES (PART 2)

Author Year	Intervention & comparator	Impact on patient safety goals?	Impact on patient safety/organizational change measures?	On process measures?
Brilli 2013[15]	Intervention consisted of 3 major elements: **Culture change:** 1. Past SSEs were analyzed and reviewed for common causes and error prevention tools were selected 2. Intervention labeled "Zero Hero" patient safety program and marketing materials created 3. Training course in error prevention was completed by clinical and non-clinical staff members 4. Leadership training conducted to reinforce HRO concepts 5. Procedures put into place to address individual and system failures 6. "Safety coach" program implemented to enable front-line providers to train peers in error prevention **QI program enhancement:** 1. IHI Model for Improvement used to guide trainings (external QI courses and internal "project-based experiential learning") 2. More QI staff hired as project managers and data analysts 3. Use of event reporting system, trigger tools, pharmacy interventions, and analysis of complaints and grievances **Measurement and operations** 1. Multidisciplinary teams focused on addressing 8 harm domains 2. Adverse drug events severity level 4-9 3. Preventable non-ICU cardiac arrests 4. Significant postsurgical complications 5. Serious falls 6. PU detection 7. Miscellaneous significant harms 8. SSEs through a variety of strategies (including developing bundles to prevent events, measuring compliance with bundles, huddle debriefing, *etc*)	NR	1. Number of SSEs per quarter decreased by 85.1%, from 6.7 to 1, resulting in a reduction of 63 SSEs over 11 quarters ($P<.001$) 2. Preventable harm index increased between 2009 and 2010 then decreased between 2010 and 2011. Peak in 2010 was 530 annual events and low in 2012 was 342 annual events (35.5% change, $P<.001$) 3. PUs increased to peak in 2011, then decreased from mean of .55 PUs per 1,000 patient-days to .31 in 2012 ($P<.009$). PU prevention bundle compliance also increased from 55% in Jan. 2011 to 80% in Dec. 2012. 4. Mean number of ADEs per 1000 dispensed doses increased initially then decreased from 0.17 to 0.09 ($P<.001$). ADE bundle compliance exceeded 90% since Oct. 2010. 5. Annual HAIs decreased from 76 in 2009 to 50 in 2012 (P=NS) 6. The observed mortality rate was 0.75% for the period 2009-2012 (post-Zero Hero), compared with 1.0% for 2001-2008 (pre-Zero Hero) ($P<.001$). Expected mortality rate did not differ in these time frames.	The percent positive safety climate score increased from 72 (pre-Zero Harm) to 76 (post-Zero Harm).
Crandall	Created and implemented a high reliability toolkit to	NR	NR	ACAs completed after

Author Year	Intervention & comparator	Impact on patient safety goals?	Impact on patient safety/organizational change measures?	On process measures?
2017[16]	help health care staff develop action plans and connect action items with reliability principles. This toolkit was modified throughout the intervention, including centralizing resources, creating electronic ACA, and revising the ACA materials themselves. Health care leaders also received just culture education. Key drivers and interventions were: **Education (knowledge)** 1. Provide cause analysis training 2. Integrate a high-reliability toolkit **Process** 1. Measure ACA leader satisfaction 2. Establish follow-up process 3. Change format/wording 4. Create electronic ACA 5. Create contact list 6. Establish ACA criteria 7. Centralize resources **Culture** 1. Spread learnings 2. Incorporate just culture 3. Establish accountability 4. Department identification of ACAs			June 1, 2016 were a minimum of 95% reliable, with some months as high as 97% reliable. Average ACA reliability score improved from 86.4% to 96.1% Average ACA turnaround time decreased from 13.2 days to 8.6 days
Cropper 2018[17]	Intervention had 7 components: 1. **Safety rounding:** senior leaders identified what can be improved upon and tools needed 2. **Safety oversight teams:** senior leaders and staff members reviewed information from rounding, literature and safety huddles, examined patterns of SSEs, and monitored action plans 3. **Safety huddles:** 5-10 min meetings at the beginning of shifts to discuss potential safety issues 4. **Safety coaches:** mentors that monitored near misses and errors and rewarded for recognizing and preventing safety events 5. **Good catches/safety heroes:** Reported as safety success stories (SSS) and shared with wider system.	The goal of a zero SSE rate was achieved in the 9th year.	SSEs consistently declined 9 years after baseline was established, from 9.6 SSEs per 100,000 adjusted patient days in 2011 to 0.0 SSEs/100,000 in 2017. The monthly SSE rate per 10,000 adjusted patient days went from just below 0.3 in Jul. 2013 to 0 in Aug. 2017.	The program created "keen situational awareness among the staff" which was measured through increased safety success stories (2931 total in 2014 to 6404 total in 2017). Note: table indicates the target was 440 SSS/month, but this was not described as a goal in the text.

Author Year	Intervention & comparator	Impact on patient safety goals?	Impact on patient safety/organizational change measures?	On process measures?
	6. **Safety education:** Curriculum to educate staff, leaders, and hospital board members was put into place, with a time frame of 2 years. 7. **Red rule:** not described Safety critical policies were selected, and staff were trained on how to approach each. Training and systems were also put into place to for staff to report unusual occurrences, safety success stories, safety catches, and near-miss events on the Midas database system. Unusual events were investigated by risk specialists, the safety officer, and the chief medical officer. A multidepartment committee evaluated these events, and a root cause analysis was performed.			
Lyren 2016[18]	Two components to implement the Collaborative Organizational Framework: 1. Changing culture through HRO principles 2. Developing microsystem-driven process improvement in specific areas of harm (*eg*, engaging content experts, quality improvement specialists, data managers, *etc*) Developed state-level task forces that meet monthly to set and review goals and identify barriers and solutions: · **Error Prevention Task Force** trained >30,000 hospital employees in basic error prevention (*eg,* standardized handoff, communication techniques, team member checking) · **Leadership Methods Task Force** trained hospital leaders in methods to reinforce error prevention behaviors and to hold employees accountable · **Cause Analysis Task Force** organized an event review process, including for root causes and near-misses · **Lessons Learned Task Force** worked with the communication, risk management, and legal departments of all the hospitals to share safety events and good catches · **Safety Governance Task Force** focuses on CEOs and Board of Trustees at all hospitals to support their work and to develop safety dashboards shared	Aim 1: Reduce serious harm index by 50% by end of 2013 and 95% by end of 2015. System reduced serious harm events by 40% "to date." Aim 2: Reduce incidence of SSEs by 50% by end of 2012 and 75% by end of 2015. System reduced harms by 55% "to date."	NR	NR

Author Year	Intervention & comparator	Impact on patient safety goals?	Impact on patient safety/organizational change measures?	On process measures?
	at board meetings			
Saysana 2017[19]	Riley Daily Operations Brief (DOB) is a 15-minute, face-to-face (with a call-in option) safety brief with department leaders occurring Mon.-Fri. mornings. Each leader was to report what happened in the previous 24 hours, what was predicted for the next 24 hours, any issues needing resolutions, and unexpected outcomes. HIPAA-compliant abbreviated minutes from the DOB were shared by email with the organization.	NR	NR	Communication between departments, awareness of daily events, and working relationships between departments significantly improved pre- to post-implementation. Comfortability sharing errors and issues, belief that the DOB was beneficial to daily operations, and feeling prepared to represent the department did not significantly improve.
Day 2018[4]	A variety of actions (standardizing reporting; creating subcommittees and oversight positions; measuring and utilizing data to address problems - more examples described in KQ2) were taken to address each of the 5 HRO components. Provision of role-tailored continuous learning opportunities (trainings) for 3 categories of health care workforce (1. clinical and non-clinical workers who interact with patients; 2. managers and local improvement personnel; 3. those with dedicated careers to patient safety).	The Joint Commission Top Performer on Key Quality Measures program has an established set of accountability measures and set a target of 95% compliance for organizations seeking to be a top performer. In 2011 (pre-implementation), this healthcare system only had 42.9% of core measures met the >96% compliance goal. In 2012-2013, post-implementation, 85.7% of core measures met compliance.	79% reduction in potentially preventable complications between 2012 (N>3800) and 2017 (N=800)	Number of health care employees that completed continuous learning courses: Category I courses had >40,000 completions; Category 2 courses had >13,000 completions; Category 3 completions not reported.
Muething 2012[20]	Initial work: SSE reduction team was formed to help meet safety goals. The team reviewed safety literature, the 35 most-recent SSEs at CCHMC, and CCHMC's survey results from AHRQ's Hospital Survey on Patient	Goal of 80% reduction in SSEs was not reached, but safety improvements were	SSEs per 10,000 adjusted patient-days decreased from a mean of 0.9 at baseline to 0.3 (P<.0001). The days between SSEs increased from a mean	>8100 employees received error prevention training. >300 employees

Author Year	Intervention & comparator	Impact on patient safety goals?	Impact on patient safety/organizational change measures?	On process measures?
	Safety Culture (HSPSC).

Intervention components fell into 3 categories: Error prevention, restructuring patient safety governance, a cause analysis program, a lessons learned program, and tactical interventions for high risk areas-

Error prevention:
1. Safety behavior expectations were developed after a literature review and consultant expertise.
2. An error prevention training program was designed for all direct patient caregivers, staff in a microsystem or clinical unit, and leaders who may affect patient safety. Trained staff members led classes for other staff.
3. Volunteer safety coaches encouraged safety behaviors, open communication, improvement opportunities, and accountability among staff. Each coach completed >4 observations (of staff behavior) per month and provided feedback, which was submitted to an online database to plan figure interventions.
4. Teams practiced safety behaviors through simulations. Significant capital was invested to upgrade the simulation center.
5. Hospital leadership were held accountable for safety through reward programs, yearly reviews, and performance-based privileging.
6. Processes were developed allowing family members to report safety concerns and to "stop the line" until concerns were addressed.
7. A pediatric early warning score (to detect clinical deterioration), real-time situational awareness, and a medical emergency response team were successfully developed and implemented.

Restructuring patient safety governance
8. A patient safety oversight group (5 members) was formed to ensure accountability, strategically allocate resources, maintain transparency with the public, and ensure patient safety was included in board meetings. | found to be statistically and clinically significant (62 fewer SSEs in the past 5 years). | of 19.4 at baseline to 55.2 ($P<.0001$). | volunteered to be safety coaches. >600 leaders underwent safety training sessions.

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). |

Author Year	Intervention & comparator	Impact on patient safety goals?	Impact on patient safety/organizational change measures?	On process measures?
	Cause analysis program 9. HPI developed a new root cause analysis process. Lessons learned program 10. Staff were given access to information, creating a highly visible, transparent feedback mechanism. Tactical interventions for high-risk areas 11. High-risk areas (*eg,* operating rooms) incorporated behaviors like "time outs" and "debriefs"			

Abbreviations: ACA – apparent cause analysis; DOB – daily operations brief; ICU – intensive care unit; IHI – Institute for Healthcare Improvement; HAI – Hospital-acquired infection; HRO – high reliability organization; NR – not reported; PU – pressure ulcer; QI – quality improvement; SSE – serious safety event

QUALITY ASSESSMENT OF INCLUDED PRIMARY STUDIES

	Basic Criteria				Advanced Criteria			
Author, Year	Was there sufficient detail on how the intervention is conceptually linked to HRO (yes/no)?	Was there sufficient detail on the intervention that it could be reproduced, including what interventions were delivered, timing of delivery, processes of delivery, and staff involved (yes/no)?	Was there sufficient detail on how successful the implementation was, such as fidelity to implementation or compliance (yes/no)?	Was there sufficient detail on the evaluation of the intervention that it could be reproduced, including measurement definitions and timing of measurement (yes/no)?	Did study authors purposefully look for or report on adverse events or unintended consequences (yes/no)?	Was there description on contextual factors or co-occurring interventions that might have influenced results (*eg*, other QA initiatives, increased funding, *etc*) (yes/no)?	Was a concurrent control group (*eg*, another site that did not deliver an HRO intervention) included (yes/no)?	Overall rating
Brilli 2013[15]	Yes	Yes; gave detailed description of intervention elements	Yes; compliance measured	Yes; measurements and time points were defined, although it was sometimes unclear what time point was being reported	No, although they had a comprehensive set of outcomes that could have theoretically captured some of these harms.	No, although more funding was put into QI department to support the program	No	Fair quality
Crandall 2017[16]	Yes; detail provided in supplemental materials	Yes; detail provided in supplemental materials	No	Yes; detailed description of reliability measures and timing is clear.	Yes, they reported on turnaround time which they feared would be worse after implementation.	No	No	Fair quality
Cropper 2018[17]	Yes; outlined the 5 components of HRO they applied and used A3 criteria and Baldrige criteria	Yes; gave detailed description of most of the 7 elements of the intervention (except for red rule) and who completed them	Yes; the authors considered reporting of SSEs to be a measure of adherence to HRO principles	Yes; gave detailed description of measures and charted progress over time	No, although they had a comprehensive set of outcomes that could have theoretically captured some of these harms.	No, but they explicitly commented that that they cannot prove the intervention caused the outcomes	No	Fair quality
Day 2018[4]	Yes; described an HRO implementation framework	Yes; gave examples of how HRO framework was implemented at their site	No, although they comment on the number (but not percentage) of people that	Yes; gave defined measurements and time points	No	No	No	Fair quality

Author, Year	Basic Criteria				Advanced Criteria			Overall rating
	Was there sufficient detail on how the intervention is conceptually linked to HRO (yes/no)?	Was there sufficient detail on the intervention that it could be reproduced, including what interventions were delivered, timing of delivery, processes of delivery, and staff involved (yes/no)?	Was there sufficient detail on how successful the implementation was, such as fidelity to implementation or compliance (yes/no)?	Was there sufficient detail on the evaluation of the intervention that it could be reproduced, including measurement definitions and timing of measurement (yes/no)?	Did study authors purposefully look for or report on adverse events or unintended consequences (yes/no)?	Was there description on contextual factors or co-occurring interventions that might have influenced results (*eg*, other QA initiatives, increased funding, *etc*) (yes/no)?	Was a concurrent control group (*eg*, another site that did not deliver an HRO intervention) included (yes/no)?	
			completed HRO training courses					
Lyren 2016[18]	Yes; HRO was used as a conceptual framework and paired with microsystem process improvement	Yes; gave descriptions of each task force and what they did	No	Yes; gave clearly defined measurements and time points	No	No	No	Fair quality
Muething 2012[20]	Yes; described 5 HRO components and the specific areas they implemented HRO principles in the discussion	Yes	Yes; survey response rates increased over time (although numbers were not reported), and they reported the number (but not percentage) of people that completed trainings.	Yes; gave defined measurements and time points	No	No; the authors commented that patient volume increased during implementation, but that would have likely led to worse, rather than better, outcomes by putting a strain on staff capacity.	No	Fair quality
Saysana 2017[19]	Yes; the intervention was described as one step towards becoming HRO	Yes	No; average attendance at the daily safety briefing could have been reported but was not.	Yes; provided survey questions, time points, and a few other process outcomes	No; they reported unexpected outcomes experience by different departments of the hospital, but not on unexpected	No	No	Fair quality

	Basic Criteria					Advanced Criteria		
Author, Year	**Was there sufficient detail on how the intervention is conceptually linked to HRO (yes/no)?**	**Was there sufficient detail on the intervention that it could be reproduced, including what interventions were delivered, timing of delivery, processes of delivery, and staff involved (yes/no)?**	**Was there sufficient detail on how successful the implementation was, such as fidelity to implementation or compliance (yes/no)?**	**Was there sufficient detail on the evaluation of the intervention that it could be reproduced, including measurement definitions and timing of measurement (yes/no)?**	**Did study authors purposefully look for or report on adverse events or unintended consequences (yes/no)?**	**Was there description on contextual factors or co-occurring interventions that might have influenced results (*eg*, other QA initiatives, increased funding, *etc*) (yes/no)?**	**Was a concurrent control group (*eg*, another site that did not deliver an HRO intervention) included (yes/no)?**	**Overall rating**
					outcomes of the intervention.			

Abbreviations: HRO – high reliability organization; QI – quality improvement; SSE – serious safety event

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APPENDIX D. PEER REVIEW COMMENTS

Comment #	Reviewer #	Comment	Author Response
Are the objectives, scope, and methods for this review clearly described?			
1	1	Yes	*None.*
2	2	Yes	*None.*
3	3	Yes	*None.*
4	4	Yes	*None.*
5	5	Yes	*None.*
6	6	Yes	*None.*
7	7	Yes	*None.*
Is there any indication of bias in our synthesis of the evidence?			
8	1	No	*None.*
9	2	No	*None.*
10	3	No	*None.*
11	4	No	*None.*
12	5	No	*None.*
13	6	No	*None.*
14	7	No	*None.*
Are there any published or unpublished studies that we may have overlooked?			
15	1	No	*None.*
16	2	No	*None.*
17	3	No	*None.*
18	4	No	*None.*
19	5	Yes - Zero Harm: how to achieve patient and workforce safety in health care, 2019, Clapper, Merlino & Stockmeier (editors). Press Ganey associates inc.	*We added a reference to this book in the "Background" section.*
20	6	No	*None*
21	7	No - I think that ESP was very thorough in their literature search and found all the relevant articles for this review. There is a book titled Managing the Unexpected: Sustained performance in a complex world, by Karl Weick	*Added a description of the Safety Organizing Scale (as it is referred to by Weick & Sutcliffe in 2007) to the discussion.*

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		& Kathleen Sutcliffe, 3rd Edition, Wiley & Sons, New York, NY., that has a Mindful Organizing Scale (p. 43) that is noteworthy. This scale was originally published in 2007, so it fell outside of the scope of this review. It is one of the few such scales and may be worth mentioning in the review.	
Additional suggestions or comments can be provided below. If applicable, please indicate the page and line numbers from the draft report.			
22	1	This is an excellent and well-written report of a difficult topic (because of it's "fuzzy" definitions) in a quick timeframe. I would say it's quite responsive to our partners' request for state of published knowledge on HRO. It will provide an excellent starting point to inform VA's push toward more mature HROs throughout the system. My comments below are suggested in the spirit of further strengthening the report.	*Thank you.*
23	1	1. The authors seem to rely on the AHRQ report on HRO as the "core" or "standard" definition for HRO. This is implied by the timeframe for review starting with 2008 (2 years after AHRQ's 2008 report). If this is the case, then this should be stated at the beginning and reinforced throughout. 1a. E.g., L40, p1: needs a citation…AHRQ?	*Added a sentence describing the Hines 2008 paper as a seminal white paper describing the adaption of HRO principles into healthcare settings.* *We do not include citations in the executive summary.*
24	1	2. The authors need to more clearly differentiate the domains of HRO (as listed in the AHRQ report) versus the components (or strategies) for *implementation*. This language needs to be set forth early in the report. The KQs all relate to information about *implementation* (of the AHRQ-defined HRO framework with the 5 domains)…and measurement	*Changed terminology used in KQ1 from "implementation domains" to "implementation strategies." The 5 components of the AHRQ HRO model are described as "principles."*
25	1	2a. Starting L10, P2 and L8/P10 and Table 1 and elsewhere: Terminology around "Implementation frameworks" needs clarification. For example, referring to five "domains" across the implementation frameworks and five domains of AHRQ's HRO. My suggestion is this: refer to implementation frameworks that are comprised of high-level strategies for implementing HRO. (you could cite Nilsen 2015, who would characterize these frameworks as "prescriptive" …which are frameworks that help guide implementations). The five strategies listed all have active verbs except the first one which should be reworded	*We used the Nilsen 2015 article to guide us in developing a table that defines the terminology we use throughout the report. This table appears in the "Methods" section and defines the terms: HRO principles, implementation strategies, implementation cross-cutting themes, and implementation activities.* *In the findings section, we changed the terminology to indicate that "implementation frameworks" comprised of "implementation strategies" or just "strategies." We also changed "leadership development" to "developing*

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		slightly to: "Developing leadership"	*leadership."*
26	1	2b. L47, P2: use the term "strategies" instead of "components" Nilsen P. Making sense of implementation theories, models and frameworks. Implementation science. 2015 Dec;10(1):53.	*Changed "components" to "strategies."*
27	1	3. P1/L51 – (and again later in the report) the authors cite lack of leadership commitment to "zero patient harm." Is this how the goal is worded/conceptualized in the literature? There is much discussion about how singular focus on zero harm may cause unintended negative consequences. Some refer to this goal as "zero avoidable harm" – or link it to key cultural goals (e.g., just or safety culture). Can something be said about this, or is the literature (the 20 articles) silent on this important point?	*Revised to say "leadership commitment to implement HRO principles" and framed as a facilitator rather than a barrier, as it is more often framed this way in the literature.* *There is much variation in the literature on how 'zero harm' is characterized. For clarification, we added the VA's definition of "zero harm"- reducing errors and ensuring that errors that do occur do not reach patients and cause harm- to the fifth paragraph in the introduction.* *Yes, we agree that we should add something about this variation of 'zero harm characterization and to illustrate this variation, we also added a sentence about how the 4 most comprehensive HRO initiatives defined their goals of zero harm to the "Findings" section.*
28	1	3a. What about leaders' lack of "managerial patience" – i.e., are leaders lacking commitment to zero harm as an end goal altogether, or do focus at first and then lose interest? I ask this in context of the finding related to dose-response relationship with time. This linkage could be made more clear even in EXEC SUMMARY bullets by acknowledging the 2-year outcomes based on the articles, but that 2-year horizon may be limited by the lack literature; though there may have been good initial effects in focused areas, this timeframe may be too short for lasting, meaningful effects. Is 2 years realistic…are there indications that longer timeframe is needed to achieve more lasting effects – especially related to changes in culture?	*Of the studies >2 years long, there continued to be improvements over time in patient safety outcomes (i.e., SSE rates continued to decrease) or improvements were maintained (i.e., SSE rates plateaued at a rate lower than baseline). We have added a sentence in "Findings" to indicate improvements were maintained.* *There is no clear pattern in whether HRO interventions resulted in improvements in process outcomes (i.e., safety culture), which includes results >2 years after initiation of the intervention.*
29	1	4. L42, p2 (and elsewhere). Authors refer to strategies	*Edited throughout to indicate our identified studies were*

		working in "primarily children's hospitals." It's not that these findings only work in children's hospitals…rather that these findings come from studies only done in children's hospitals (a potential limitation). It's notable that a couple of different systems/networks of children's hospitals (Nationwide and CHSPS Network) have led the way with HRO – they are early adopters.	*primarily conducted in children's hospitals- not that we only found improvements in children's hospitals.*
30	1	5. L9/P3: authors should acknowledge the impracticality of RCTs to test HRO because of its complexity and complex implementation. Highlight the need for pragmatic, quasi-experimental study designs with full transparent reporting as a way to more feasibly build the knowledge base needed.	*Edited this section as well as "Future research needs" to speak to the impracticality of RCTs and how quasi-experimental designs with detailed reporting of intervention elements should be utilized instead.*
31	1	6. L37/P4: Build the history of HRO more clearly. It started within the nuclear and aviation industries and then AHRQ is the seminal report introducing/defining HRO for healthcare, yes? Did AHRQ describe the same 5 domains as used in nuclear and aviation industries?	*Added a sentence on the 2007 Weick and Sutcliffe book that defined the 5 principles of HROs. The Hines 2008 paper built on this by applying the principles to health care settings.*
32	1	7. L5/P5. Lists of "components" (should be strategies) seem to be differently described in different places. Be consistent	*Changed this sentence to indicate these are common HRO intervention activities. Activities are the actual tasks that a health care organization would take to implement the more overarching implementation strategies.*
33	1	8. Paragraph starting L13/p5: suggest flipping the order of the Providence St Joseph case with the VA to better segue into the next paragraph about VA.	*Put the Providence St. Joseph Health example before the VA example.*
34	1	9. L10/P13: I'm not sure how KQ1E differs from the overall goal to ID frameworks to guide implementation of HRO. This paragraph muddles concepts: intervention, process, implementing. I think this can be clarified by providing more detailed descriptions for how to operationalize the 5 high-level strategies in the implementation frameworks. For example, educational workshops might be a way to "Provide training and learning…"	*Revised this paragraph to make it clear we are talking about how to operationalize HRO implementation and linked the 5 implementation strategies to the specific implementation activities described by each model.*
35	1	10. We have found that it's impossible to use JC's Oro system for measurement because participants are told not to share with anyone outside their organization, and the questions seem to shift. Is there any reference to this in the literature? Sullivan's article seems to have the best	*This isn't explicitly discussed in the literature, but the ORO 2.0 website discusses how it's designed to be used in at the individual hospital level rather than the health system level. We added a sentence and reference to this. In this section, we also discuss how*

		open definitions/operationalization of their domains.	*the tool uses branching logic, which explains why the questions shift.*
36	1	10a. Their "RPI" domain relies on a trademarked (proprietary?) program, I think.	*Noted.*
37	1	10b. These are all limitations to using this system for measurement…though the development and intent of it, is the best developed.	*Noted.*
38	1	11. Love Table 2!	*Thank you.*
39	1	12. L60/P16: It would be clearer to refer to AHRQ HRO rather than Hines 2008 – this is first mention of Hines other than in the reference list	*In response to an earlier comment, we added a description of Hines 2008 to the introduction, so this sentence now refers back to that description.*
40	1	EXECUTIVE SUMMARY 1. Comments about the bullets • Add a bullet that identifies AHRQ source as the "seminal" (or core or foundational) definition of HRO which has 5 (fuzzily defined) domains	*Added a sentence describing the 2008 AHRQ paper to the first paragraph of the ES.*
41	1	• Clarify that the current 1st bullet (L8+/p1) refers to *implementation* frameworks.	*In response to an earlier comment, we edited this to indicate there were 5 implementation strategies across frameworks.*
42	1	• Also, 5 are listed here, but later in the report, 8 were identified…	*Edited to indicate we identified 5 common HRO implementation strategies across 8 frameworks.*
43	1	• Oro 2.0 may be well-defined/develop but may have an issue of not being openly/publicly available (see comment above)	*Edited the "Findings" section to indicate this tool is only available to Joint Commission-accredited organizations.*
44	2	Great report!	*Thank you.*
45	3	none	*None.*
46	4	I thought this Evidence Brief was well written and describes my intuitive understanding of the current state of HRO frameworks, metrics, and effects. I thought the authors did a nice job of simplifying what can sometimes be very complicated concepts. I've provided several questions and clarifying comments below.	*None.*
47	4	Page ii: Table 3 title capitalization looks off	*Fixed this.*
48	4	EXECUTIVE SUMMARY page 1	*Added the healthcare-related definition of each HRO principle in parentheses and added a description of the*

		lines 40-52: might mention how HROs differ for health care (similar to background section)	*unique challenges that threaten reliability in health care to this section.*
49	4	page 2 line 3-5: may move "spreading implementation initiatives" to the last thing mentioned in the sentence.	*Moved "spreading implementation initiatives" to the end of the sentence.*
50	4	lines 17-20: although there were 5 common domains, it would be interesting to mention some of the other domains not reported as commonly.	*Added a list of additional complementary practices that emerged from the literature.*
51	4	line 21: might say a little more about what consensus process means here	*Added language to indicate this consensus process typically involved a group of health system leaders and experts in patient safety.*
52	4	line 32: how many does multiple hospitals refer to?	*Clarified the tool/framework was tested in 52 hospitals.*
53	4	line 33-34: might give an example of "the variation in concepts measured" also I think the phrase "types of measures" is missing from that sentence. I might also define what levels of practice refers to	*Revised to indicate the range of concepts measured and removed "levels of" before practice.*
54	4	lines 55-58: It's striking that there are so few barriers to implementation in the literature given all we know about implementation and organizing for quality. This seems like a major limitation.	*The identification of barriers and facilitators to HRO implementation was not a key aim of our review. Therefore, we did not do a thorough search or analysis of these outcomes, but instead provide a few examples that were discussed in our included articles. More details on these barriers we found are available in the "discussion" section.*
55	4	INTRODUCTION page 4 line 55-56: add "in health care organization" or hospitals after the phrase " Implementation of HRO initiatives... is an	*Added "into healthcare settings."*
56	4	page 5 lines 3-10: I do not see provide training in systems redesign (e.g. LEAN six sigma, Kaizen events, hFEMA, etc) or robust process improvement tools listed	*Our findings did not indicate that systems redesign training was a key component of HRO implementation success. However, we agree it is important to discuss these change management strategies in this report, so we added a description of which frameworks recommend which strategies to the "Findings" section.*
57	4	lines29-33: Could the caring reliably program assess if it was the toolkit or the consulting which made the differences or was it bundled?	*It was a bundled initiative.*
58	4	line 36-40: Were the barriers reported in a particular type	*These are more general barriers.*

		of service (e.g. focus on medical or surgical) or more general?	
59	4	page 7 line 13-15: might outline the 5 HRO principles again here.	*Defined the 5 HRO principles again here.*
60	4	page 8 line 9-10: what was the rational for hand-searching references lists and consulting with content experts?	*These are both steps typically conducted in systematic reviews.*
61	4	line 15-15: describe the types of expertise the investigator/staff had Experiences health services research, HROs, evidence briefs, etc.	*Added that all investigators have expertise in conducting systematic reviews of health services research.*
62	4	line 34-35: What was the level of disagreements which needed to be resolved by consensus?	*Agreement was generally high. We added a qualitative description of level of agreement to the report.*
63	4	page 10 lines 37-60: seeing the table made me think about what were the other domains highlighted in the articles but not shown here.	*Added a list of additional complementary practices that emerged from the literature under KQ1 in response to an earlier comment.*
64	4	page 11 lines 50-53: might define what robust process improvement means. It can be a confusing term.	*Added definition of robust process improvement.*
65	4	page 12 line 58-59: say more about what variety of health care leaders, providers and staff means... what service areas do they cover ? what type of managers? are safety and quality leaders executive level leaders or middle level managers?	*Added more detail here to indicate the range of leaders, providers, and staff targeted by these frameworks. Also added detail to indicate these frameworks target a variety of service areas.*
66	4	page 13 lines 24-46: There is a lot of information in this paragraph and it's easier to get lost in the details. It might be easier to comprehend it if it was provided in a bulleted format to allow easier comparison across frameworks.	*Added bullet points to this paragraph.*
67	4	page 14 line 42-42: "VA sites were interviewed about integration of HRO into their health care systems" is not an accurate depiction of this study. I believe the study assessed patient safety practices aligned with HRO principles. It was a secondary analysis of data collected for a study focused on patient safety indicators.	*Revised this section to better describe the original study and the secondary data analysis.* *Also included the fact that the ORO 2.0 was designed to be used in a single hospital in response to an earlier comment.*

		An important shortcoming of the ORO 2.0 tool is that it is not meant to compare results across multiple hospitals. As it has developed, I'm not sure if Joint Commission's opinion has moved on this. I'm not certain if any of the tools presented have tried to compare cross-hospital progress.	
68	4	page 17 line 38: term SSE hasn't been used in awhile, may want to define here again.	*Added definition here.*
69	4	SUMMARY AND DISCUSSION A few discussion points come to mind as I read this section. 1) it is critical to think about context	*Added a statement on how health care systems may implement different HRO interventions depending on their individual needs and contexts to our "Limitations" section in response to another comment.*
70	4	2) How do these tools allow for cross-hospital comparisons? Is this the goal of VA's HRO initiative?	*Correct, the VA is looking for tools that allow for cross-hospital comparisons. We added a statement to the "Findings" and "Discussion" sections to describe that the although the ORO 2.0 (the most comprehensive HRO evaluation tool) was not designed specifically for cross-hospital comparisons, the data is output in a way that it could be shared and analyzed between VHA hospitals.*
71	4	3) the need for training on HRO principles may not be enough to move an organization. I did not see training on system redesign tools and methodologies listed	*Agreed that HRO training may not be enough to move an organization. We added a statement to "Gaps and future research" suggesting that future research may want to explore the extent to which HRO training does- or doesn't- address/overlap with system redesign.*
72	4	4) It's unclear how HRO frameworks deal with differences in HRO practices across different service (e.g. medical, surgical). Should they? Have frameworks focused on this?	*We only included studies that assessed HRO implementation at a system level (ie, included both medical and surgical units as appropriate), so all our frameworks addressed multiple services and none conducted subgroup analyses by service type. We added a statement to the "Gaps and future research" suggesting that future research studies note where intervention components were delivered (eg, medical or surgical service areas) to help tailor HRO delivery to different contexts.*
73	4	5) Have HRO frameworks been developed and aligned with organizational transformation models or other frameworks for improving quality? There may be other measures or concepts to assess which have not been presented in this evidence-brief.	*Yes, 6 out of 8 frameworks recommended using other change management strategies in HRO implementation. We added a description of which frameworks recommend utilization of which change management strategies to the "Findings" section in response to an*

			earlier comment.
74	4	LIMITATIONS page 23 lines 12-14: I might mention HRO intervention are inherently difficult to study because they can have many different components (potentially with different foci across different hospitals)	*Added that each hospital may also choose to implement different components of these interventions, depending on their individual needs and context.*
75	4	GAPS AND FUTURE RESEARCH page 24 line 7-8: "3) whether certain implementation frameworks or facilitators lead to better outcomes" could be separated out to 3) whether implementation or other frameworks for improving quality frameworks are applied and lead to better outcomes and 4) what the factors affecting HRO implementation are.	*Revised to split up #3 into 2 parts.*
76	4	line 10-11: the wait-list control point is a good one BUT many facilities already have in place high reliability practices at baseline which will need to be assessed. Many sites could also have already participated in initiatives so they are more prepared for the journey (Improvement capacity/adoption of Lean Six Sigma, old Clinical Teams training, etc). How do we account for these on-going or older initiatives?	*Added language to indicate consideration should be given to how much wait-list control sites have begun implementing HRO on their own, or are delivering similar interventions such as Lean Six Sigma*
77	4	line 27-28: say more about mechanism for change.... is this organizational transformation? something else?	*Added that the mechanism of change might involve improving mindfulness or safety culture, as this aligns with our conceptual model based on Hines 2008. We see organizational transformation as the end-goal, represented through improved patient safety outcomes.*
78	4	CONCLUSION I might mention something about measurement here as it is a key aim of the brief.	*Changed "tools" to "metrics" in the last sentence of the conclusion.*
79	5	P1 L47: I would be cautious in stating that medical error is the 3rd leading cause of death in the affirmative and/or saying continues to be as the Makary & Daniel article was a commentary based off of extrapolated data from current literature attempting to articulate how big a problem it is. Since medical errors are not listed as the cause of death this number is difficult to find and the assessment of death from harm is not as black and white in all cases. I would	*Changed to indicate that death due to medical errors are estimated to be the third leading cause of death in the country.*

		recommend stating something along the lines of if we were to document medical error as cause of death, Makary and Daniel have ascertained that it would be the 3rd leading cause of death in the country.	
80	5	P2 L10: remove total, reads as if there are only a total of 20 articles published which is not the case.	*Removed "total."*
81	5	P5 L33: In review of the additional reviews of measurement, I don't recall if I mentioned that we also improved on the Safety Climate Domain of the Safety Attitudes Questionnaire (SAQ) from 2016 to 2017 (during the time of everyone up and running on training) by 5 percentage points with a sample size greater than 68,000 respondents so it was found to be quite significant. In addition, when drilling down to our regions, all showed improvements from 3 to 10 percentage points. Your option to add if you so choose.	*Added that Providence St. Joseph Health had a 5% improvement in the safety climate domain of the Safety Attitudes Questionnaire.*
82	5	P5 L37: "lack of leadership commitment to zero patient harm" I would revise to indicate that it is lack of what it takes to get to zero harm. Most leaders would agree yes we need to get to zero patient harm and even indicate that they are doing work to do so. What doesn't happen from my experience is they believe in it but do not provide the resources (people, money, skills) that it takes to get there. This sentence also needs a colon and some comas to separate the ideas of the list.	*Revised this section to remove "leadership commitment to zero patient harm" in response to an earlier comment and included additional detail on what are the barriers to incorporating safety culture principles and practices and adopting process improvement tools and methods.*
83	5	P16 L35 Many who assess HRO use some form of Safety Climate survey as part of the assessment such as Safety Attitudes Questionnaire (SAQ) which was created by Sexton and team at Univ Texas and reflects similarities to the Flight Management Attitudes Questionnaire used in aviation to assess some of its HRO components. Something to consider adding as a measurement perhaps.	*Since this tool was published before 2010, we added a discussion of this tool to the "discussion" section*
84	6	Thank you for providing me the opportunity to review this report. Excellent rapid review on a complex topic. See some suggested revisions below: For the Key Findings box contained within the Executive Summary, it would have been helpful to have an initial	*Added the "objective" of the report to the key findings box. Because we want to keep this section brief, and the 5 common implementation strategies appear shortly afterward in the executive summary, we did not add these to the key findings box.*

		bullet that succinctly listed the goals of the report, such as the aims described in the last sentence of the second paragraph of the Executive Summary. It would have also been helpful to have the 5 domains listed in the first bullet of the Key Findings box.	
85	6	In the Background section of the Introduction, in the fourth paragraph, the Joint Commission's 2013 HRO report is noted, but should also be cited/referenced.	*Added citation.*
86	6	In the Background section of the Introduction, in the sixth paragraph, the second sentence states that an understanding of available frameworks and their use is limited, but what about our understanding of available measures, and the impact of initiatives on those measures? Given the aims of this report, should note these areas as well.	*Added "metrics and initiatives" to this sentence as the description of variability actually applies to all 3 key questions.*
87	6	Under Eligibility Criteria, why not extend the search from 2008 to present, instead of 2010? Seems like if AHRQ is publishing a white paper in 2008, others may have also begun publishing on this topic at this time.	*2010 was chosen as a start date in consultation with the operational partner. We expected it would take at least 2 years for research integrating the 5 HRO principles discussed by Hines 2008 to be published.*
88	6	In the Oro 2.0 section, third paragraph, last sentence, did safety culture decrease as described, or is this a mistake, and did it increase?	*Safety culture did indeed decrease. Study authors don't note what these organizational changes were, but it appears they negatively affected safety culture.*
89	6	In Table 3, please include abbreviation for PHI in the Table legend; in the third row of the Table, "zero SSE rate achieved in 2017" seems redundant with the statement directly above; in the fourth row of the Table, in the last column, please include Month and Year for the baseline	*Added definition of PHI to table key.* *Deleted "zero SSE rate achieved in 2017" from Cropper 2018 study.* *Added dates used for baseline data in Lyren 2016 study.*
90	6	In the first paragraph in the Summary and Discussion, in the second sentence, please change the order to "frameworks and metrics", rather than "metrics and frameworks", to better match the aims.	*Reordered "frameworks and metrics."*
91	6	In the Limitations section, in the first paragraph, second sentence, please consider citing: J Clin Epidemiol. 2014;67(11):1181-91. PMID: 25438663	*Added this citation.*
92	6	In the Conclusions, please change the order of the first sentence to read: "frameworks and evaluation tools". The second sentence should probably read "reduction in SSEs" rather than simply "SSEs".	*Reordered "frameworks and metrics."* *Revised to say, "reduced SSEs."*

93	7	Overall, I think this evidence brief is excellent. It is thorough, thoughtful, and very well done! The ESP team identified their Key Questions, which were tied to the request from the Office of the National Center for Patient Safety. The method was clearly laid out and executed. The Key Questions were answered, gaps identified, and plans for future research addressed.	*Thank you.*
94	7	I found "Table 1. Common HRO implementation domains across 8 identified frameworks," very useful. This table quickly identified all 8 HRO frameworks and their included components. Only 3 of the 8 contained all 5 HRO components.	*None.*
95	7	Table 2. – Metrics for measuring progress on becoming an HRO – was also extremely enlightening. This side-by-side comparison of the 6 methods identified by the ESP group will be helpful for VHA Leadership to understand the differences between these methods, and then select the best one.	*None.*
96	7	Table 3 highlighted the challenge of comparing studies of disparate quality, methods, measures, and results reporting. This is a shortcoming in the HRO literature and was clearly communicated in this table.	*None.*
97	7	I agree with the ESP assessment of the gaps in the research. It is theorized that the implementation of HRO principles leads to improved safety outcomes and a culture of safety. This has not been validated by the research, nor has the mechanism by which these changes and improvements occur. The secular trends mentioned on page 24, which cannot be ruled out as contributing to improvements in patient safety outcomes, could be expanded on. What are these secular trends, and how are they impacting patients safety outcomes?	*Added a sentence on the role that EMR could play in improving patient safety outcomes. Also added a sentence that implementation of Lean Six Sigma before or during interventions could plausibly affect outcomes as well.*
98	7	I also agree with the statement about the VA being in a unique position to conduct a natural experiment with the current HRO Initiative. This is an excellent insight on the part of the ESP team. I am not criticizing, only providing additional information. The HRO Initiative is limited to 18 lead sites, but many other sites are clamoring to be part of it. I am not clear on the criteria VISN Directors used to select the lead sites, but it is likely that other sites within	*Added that consideration should be given to the extent to which "wait-list control" sites are implementing HRO on their own or using other types of change management strategies in response to an earlier comment.*

their VISNs, and across the VHA, are not experimentally naïve. I am aware of 2 other sites within VISN 15 that are on HRO journeys already, and were not selected as the lead site for that VISN. I imagine that is may be true for other VISNs as well. There is no "perfect" way to conduct this type of research, and all research has limitations of some kind. I personally would love the opportunity to be involved in that kind of research.

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