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23 July 2020
1115 – 1215 (ET)
Presenters

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“Medically Ready Force...Ready Medical Force”
William Gunnar, M.D., J.D.

- In 2018, William Gunnar, MD was selected as the Veterans Health Administration (VHA) Executive Director, National Center for Patient Safety in 2018.
- In this role, he provides oversight to the VHA National Safety Program, promotes high reliability organization principles and practice, authors VHA patient safety policy and guidance, administers the recall of medical products, manages multiple patient safety education programs, and facilitates capture, reporting, and investigation of patient safety events across the organization.
- He is a board certified cardiothoracic surgeon and holds a certificate in health law.
- From 2008 to 2018, Dr. Gunnar was VHA National Director of Surgery with oversight of 137 VHA Surgery Programs and the VA Surgical Quality Improvement Program.
Gary L. Sculli, Chief Program Analyst for the VJHA National Center for Patient Safety brings a unique and diverse perspective to patient safety.

He is a Registered Nurse with a master’s degree in Nursing Administration and has worked in multiple clinical specialties to include leadership and management.

He has served as an officer in the United States Air Force Nurse Corps.

Mr. Sculli is also a former airline pilot for a major US Airline and has developed and taught Crew Resource Management (CRM) programs in both aviation and healthcare.

Disclosures

- Dr. Gunnar and Mr. Sculli have no relevant financial or non-financial relationships to disclose relating to the content of this activity.
- The views expressed in this presentation are those of the presenter(s) and do not necessarily reflect the official policy or position of the Veterans Health Administration, nor the U.S. Government.
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Learning Objectives

At the conclusion of this activity, participants will be able to:

1. Identify at least two implementation strategies for High Reliability Organization (HRO).
2. Describe the available literature on HRO Implementation frameworks, metrics, and evidence of HRO implementation effects.
3. Outline the key components of the National Center for Patient Safety (NCPS) High Reliability Hospital (HRH) Model.
4. Analyze the outcomes associated with HRH Model implementation.
HRO Framework Evidence Review

- Extensive literature is available framing the principles of a High Reliability Organization (HRO).
- The components (structure, process) required for HRO implementation are not well characterized, making it difficult for health systems to put these principles into practice.
- In February 2019, the Veterans Health Administration (VHA) implemented a nation-wide HRO initiative beginning with 18 Lead Sites.
- A rapid evidence review of HRO implementation frameworks, metrics, and evidence of effects was requested by the VHA National Center for Patient Safety (NCPS) to support this initiative.

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Evidence Review Methods

- Published literature 2010 thru 2018;
- Articles included that describe:
  - Implementation Frameworks
  - Metrics for Measuring Progress
  - Evidence of the Effects of HRO Implementation
- Assessment:
  - Link between intervention and HRO principle
  - Intervention components and delivery
  - Implementation fidelity
  - Evaluation of the intervention
  - Adverse Events
  - Confounders
  - Use of a Concurrent Control Group

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Evidence Review Results

- 20 articles identified:
  - 8 described implementation frameworks
  - 8 described HRO metrics
  - 7 evaluated the effect of HRO implementation

- Implementation Frameworks
  - 5 implementation strategies of which The Joint Commission (TJC) High Reliability Health Care Maturity Model (HRHCM) and the Institute for Healthcare Improvement (IHI) Framework for Safe, Reliable and Effective Care most comprehensive

- HRO Metrics
- Effect of HRO Implementation

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Common HRO implementation strategies across 8 identified frameworks

<table>
<thead>
<tr>
<th>Key Strategy:</th>
<th>Developing leadership</th>
<th>Supporting a Culture of safety</th>
<th>Building and using Data systems</th>
<th>Providing Training and learning</th>
<th>Implementing quality improvement interventions</th>
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</thead>
<tbody>
<tr>
<td>ACHE Framework(^{14})</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Air Force Trusted Care(^{16})</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>ARCC Model(^{17})</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>High reliability team model(^{18})</td>
<td>✓</td>
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<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>IHI Framework(^{5})</td>
<td>✓</td>
<td>✓</td>
<td></td>
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<tr>
<td>JH’s Operating Management System(^{15})</td>
<td>✓</td>
<td></td>
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<tr>
<td>JH’s Safety and Quality Framework(^{13})</td>
<td>✓</td>
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<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>TJCs HRHCM(^{4})</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Number of frameworks addressing this strategy</td>
<td>6</td>
<td>6</td>
<td>7</td>
<td>6</td>
<td>6</td>
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</tbody>
</table>

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Five Common HRO Implementation Strategies

- Developing Leadership
- Supporting a Culture of Safety
- Building and Using Data Systems to Measure Progress
- Providing Training and Learning Opportunities for Providers and Staff
- Implementing Quality Improvement Interventions to Address Specific Patient Safety Issues

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## Metrics for measuring progress on becoming an HRO

<table>
<thead>
<tr>
<th>Name of tool</th>
<th>Concept measured</th>
<th>Format of tool</th>
<th>HRO Implementation Strategies Measured</th>
<th>Target</th>
<th>Extent of validation</th>
<th>Outcome of validity testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oro 2.0 High Reliability Assessment Tool/HRHCM framework(^{1,23,24,31})</td>
<td>Readiness and progress on becoming an HRO, in terms of beginning, developing, advancing, or approaching stages</td>
<td>Survey</td>
<td>✓ ✓ ✓ ✓ ✓ ✓</td>
<td>Leadership, Data Systems, Training and learning, Patient Safety, Interventions, Leadership, Providers and staff, Patients and families</td>
<td>Advanced</td>
<td>High internal reliability, good content validity</td>
</tr>
<tr>
<td>ACHE Culture of Safety Organizational Self-Assessment Tool(^{14})</td>
<td>Readiness on becoming an HRO in terms of whether practices currently being implemented are foundational or sustaining</td>
<td>Survey</td>
<td>✓ ✓ ✓ ✓ ✓ ✓</td>
<td>Leadership, Data Systems, Training and learning, Patient Safety, Interventions, Leadership, Providers and staff, Patients and families</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Cultural Assessment Survey (CAS)(^{20})</td>
<td>Initial level and progress towards developing a culture of patient safety</td>
<td>Survey</td>
<td>✓</td>
<td>Leadership, Data Systems, Training and learning, Patient Safety, Interventions</td>
<td>Basic</td>
<td>High internal reliability, good content validity</td>
</tr>
<tr>
<td>University of Tehran HRO readiness assessment(^{21})</td>
<td>Readiness for HRO implementation</td>
<td>Survey</td>
<td>Unclear</td>
<td>Leadership, Data Systems, Training and learning, Patient Safety, Interventions</td>
<td>Basic</td>
<td>Good content validity</td>
</tr>
<tr>
<td>University of Tehran HRO knowledge and integration assessment(^{22})</td>
<td>Knowledge of HRO concepts and extent of integration of HRO principles in practice</td>
<td>Survey and checklist</td>
<td>✓ ✓ ✓ ✓ ✓ ✓</td>
<td>Leadership, Data Systems, Training and learning, Patient Safety, Interventions</td>
<td>Basic</td>
<td>High internal reliability, good content validity</td>
</tr>
</tbody>
</table>

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Evidence Review Summary

- TJC HRHCM and the IHI Framework for Safe, Reliable, and Effective Care the most comprehensive, applicable, and sufficiently descriptive for implementation;
- TJC HRHCM/Oro 2.0 identified to be the most comprehensive and rigorously developed;
- Multicomponent HRO interventions incorporating common HRO implementation strategies delivered for at least 2 years are associated with improved process outcomes (e.g., staff perceptions of patient safety) and patient safety outcomes (e.g., reduced Serious Safety Events);
- The overall strength of evidence is low as each HRO intervention was only evaluated in a single fair-quality study;
- Barriers to HRO implementation include competing priorities and costs;
Evidence Review Summary

- Significant gaps in knowledge on HRO Implementation:
  - Cause and effect between HRO implementation and process improvement and safety outcomes (no control groups)
  - Comparison between implementation frameworks
  - Identify the contextual factors (ex barriers and facilitators) affecting successful HRO Implementation
High Reliability Hospital (HRH) Model

- Created to concentrate multiple efforts in one Veterans Administration Medical Center (VAMC)
  - 3 year study period (2016 – 2019)

- Truman VAMC – Columbia, MO
  - Tenured Patient Safety Officer
  - Dedicated HRO Lead
  - Strong Facility Leadership
  - Network Support

- Memorandum of Understanding

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NCPS High Reliability Hospital Model

Patient Safety On-Site Assessment
Standardization Initiative
Just Culture Seminar for Hospital Leadership
Quarterly Clinical Team Training (CTT)
RCA Training & Team Participation - Front Line Staff
Yearly Simulation Boot Camp
Safety Culture Assessment

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Monthly
Coaching - Unit Based Improvement Project Implementation
Leadership Walk Rounds
Safety Forums

Weekly
Teleconference huddle calls with NCPS staff and Truman Patient Safety / HRO Lead

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Patient Safety On-site Assessment

- NCPS personnel visit facility once per year over the 3 year period
- The site visit conducted according to the NCPS site visit checklist
  - Patient Safety Assessment Tool (PSAT)
    - Patient Safety Infrastructure
    - Root cause analysis (RCA) Review
    - Published Patient Safety Alerts
    - Specific Clinical Areas i.e. MHEOCC
  - Patient Safety Culture Survey Review
  - Walk-around / Staff interviews
- Formal debrief and follow-up report
Standardization Initiative

- HRIs have dedication to Standardization
  - Language
  - Equipment
  - Standard Operating Procedures (SOP)

- Standardization team
  - Detect variation
  - Select one item to work on organization wide each year
Just Culture Program

- Just Culture Program delivered in 2016 and 2018
  - Delivered only to Leadership (top-mid-frontline)
  - Select group of Leaders deliver to staff
  - Wide spread use of a “Decision Support Tool”

- Highlights
  - Emphasized the role of “Drift”
  - Line between drift and unacceptable risk
  - “Decision Support”
  - Leader accountability for system failures

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Clinical Team Training

CRM based training quarterly – heaviest lift

Initial and recurrent training at 12 months – all units

Curriculum and Tools

- Systems, Error Management, HRO theory
- Leadership
- Followership
- Situational Awareness Threat Countermeasures
- Simulation

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Clinical Team Training cont.

- 54 units trained over 3 years— at least one UBSP per unit

- Monthly coaching calls (or on-site meetings) with NCPS staff and each unit change team

- CTT Training
  - Completed by NCPS
  - Then joint NCPS faculty and facility Master Trainers
  - Then all Truman
Assertive Communication

Effective Followership Algorithm

Use Chain of Command

Engage Team

Four-Step Assertive Tool
- Get Attention
- State Concern “I’m Uncomfortable with…”
- Offer Solution
- Pose Question

TAKE ACTION!
Anywhere, at Any Point

3 Ws
- What I See
- What I’m Concerned About
- What I Want

Feedback
SHOULD BE:
- Specific
- Direct
- Concise

AVOID:
“Hint and Hope” Communication

Sculli et al. ASHRM Journal 2015

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RCA Training and Team Participation
(Front Line Staff)

- Robust RCA process integral to:
  - Patient safety program
  - Response to failure

- Occurred each year of the 3 year model period

- Goal
  - Develop a cadre of front line staff fully able to see and participate in lifecycle of safety event investigation
Safety Forums

- Monthly meetings open to all staff
- Run by Executive Leadership and Safety Officer
- Reinforces commitment to Patient Safety Program (no accountability focus)
  - Systems and the RCA process
  - Reporting
- Reinforces concepts, values, and actions associated with Fair and Just Culture (accountability focus)
- Began July 2016, >1500 employees during 3yr period
Safety Forums

The Executive Leader must be a present and active participant throughout the Safety Forum.

<table>
<thead>
<tr>
<th>Time (Approx.)</th>
<th>Activity</th>
<th>Speaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00 – 8:05</td>
<td>Greeting</td>
<td>Executive Leader</td>
</tr>
<tr>
<td>8:05 – 8:15</td>
<td>Event Case #1</td>
<td>Safety Officer</td>
</tr>
<tr>
<td>8:15 – 8:25</td>
<td>Event Case #2</td>
<td>Safety Officer</td>
</tr>
<tr>
<td>8:25 – 8:35</td>
<td>Encourage Reporting</td>
<td>Safety Officer</td>
</tr>
<tr>
<td></td>
<td>• JPSR - Safety Reports</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Stop the Line</td>
<td></td>
</tr>
<tr>
<td>8:35 – 8:40</td>
<td>Reward Reporting</td>
<td>Executive Leader</td>
</tr>
<tr>
<td>8:40 – 8:50</td>
<td>Review / Reinforce Just Culture</td>
<td>Executive Leader</td>
</tr>
<tr>
<td>8:50 – 9:00</td>
<td>Q&amp;A</td>
<td>Executive Leader</td>
</tr>
</tbody>
</table>

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Additional Elements

- Leadership Walk Rounds
  - Occurred Monthly

- Simulation Boot Camp
  - Occurred Yearly
  - Open to Clinical and Simulation Educators

- Weekly huddles with NCPS and Columbia HRO Lead
Safety Culture Assessment

■ VAMC Wide
  - NCPS Patient Safety Culture Survey
  - AES Patient Safety Module

■ Unit Level
  - Teamwork and Safety Climate Questionnaire (TSCQ)
  - All units completing CTT
    - Baseline
    - 6 Months
    - 12 Months

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<table>
<thead>
<tr>
<th>Question</th>
<th>Time Period</th>
<th>Baseline</th>
<th>6 month</th>
<th>12 month</th>
<th>Favorables</th>
</tr>
</thead>
<tbody>
<tr>
<td>12: Briefings are common in this clinical area</td>
<td></td>
<td>0.60</td>
<td>0.74</td>
<td>0.65</td>
<td></td>
</tr>
<tr>
<td>4: The physicians and nurses here work together as a well-coordinated team</td>
<td></td>
<td>0.66</td>
<td>0.74</td>
<td>0.65</td>
<td></td>
</tr>
<tr>
<td>13: I am satisfied with the quality of collaboration that I experience with staff physicians in this clinical area.</td>
<td></td>
<td>0.24</td>
<td>0.28</td>
<td>0.45</td>
<td></td>
</tr>
<tr>
<td>2: In this clinical area, it is difficult to speak up if I perceive a problem with patient care. (showing rates for those who disagree)</td>
<td></td>
<td>0.60</td>
<td>0.74</td>
<td>0.60</td>
<td></td>
</tr>
<tr>
<td>16: I would feel safe being treated here as a patient.</td>
<td></td>
<td>0.68</td>
<td>0.74</td>
<td>0.64</td>
<td></td>
</tr>
<tr>
<td>3: Decision-making in this clinical area utilizes input from relevant personnel</td>
<td></td>
<td>0.57</td>
<td>0.66</td>
<td>0.60</td>
<td></td>
</tr>
<tr>
<td>10: Important issues are well communicated at shift changes.</td>
<td></td>
<td>0.65</td>
<td>0.60</td>
<td>0.60</td>
<td></td>
</tr>
</tbody>
</table>

Figure 1 - 95% Probable Intervals: Favorable Response Rate of Each Question

- 580A4 Average for this training group
- All CTT minus this training group

Statistical Change from Baseline: s = significant, ns = not significant.
Findings - Safety Culture

- 2019 Truman PSCS scores were significantly greater than All VHA scores for all PSCS questions.
- Comparing 2016 and 2019 Truman scores, the percent of Agree/Strongly Agree scores significantly improved for all questions except two.
- Number of PSCS questions with a score >4.0 increased from 5 (33%) to 10 (66%)
- Number of Agree/Strongly Agree responses >80% increased from 5 (33%) to 7 (47%).
Findings – Reporting

- Reporting of total patient safety events/10k uniques increased significantly from 344.9 to 424.9 (23.1%) from the pre to post-intervention (P <0.001)

- Truman reporting of total patient safety events was significantly greater than All VHA through the entire study (P <0.001) during which All VHA patient safety event reporting also increased significantly
Findings Reporting

- The proportion of Truman total patient safety reports identified as potential serious safety events decreased from 30% (103.9/344.9) to 10% (41.8/424.9) between the pre and post intervention periods.

- The Truman serious safety event rate (SSER) did not significantly change whereas the All VHA SSER increased significantly from 0.6 to 1.0 (P <0.001) between the pre and post intervention periods.
Findings – Reporting

- The increase in Truman patient safety reports was associated with a significant rise in low harm event reporting rates from 241.0 to 382.1 (58.5%, P≤0.001).

- What does this say about safety culture and reporting at Truman?
Findings – Outcomes

■ Standardized Mortality Ratio

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Findings – Outcomes

**Complications Ratio**

![Complications Ratio Over Study Period](image)

- Pre-Intervention Slope p-value 0.002
- Year 1 Intervention Slope p-value 0.011
- Year 2 Intervention Slope p-value <0.001
- Year 3 Intervention Slope p-value <0.001
- Post Intervention Slope p-value 0.102

*The p-value for the difference in slopes is < 0.020*

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Sustainment

Truman has sustained model elements:

- CTT
  - Competency day monthly
  - New Employee Orientation
  - Large cadre of Master Trainers
- Safety Forums
- Leader Walk Rounds
- RCA Training
- Just Culture
- Resources moved to Network
Limitations

- Single site implementation only

- Compared to ALL VHA - no matched control

- Post Implementation too short to draw conclusions about model effectiveness and durability

- Further study is needed
Key Takeaways

- While some frameworks exist, there overall strength of evidence on HRO implementation and its effect on safety and quality is low.
- The VA National Center for Patient Safety (NCPS) implemented a comprehensive HRO Model at one VAMC, called the High Reliability Hospital (HRH) Project, over a 3 year period starting in 2016.
- The model demonstrated positive outcomes on patient safety culture, reporting, and clinical outcomes.
- More study is needed to determine efficacy of the HRH Model
References


References


References


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   b. Complete the Evaluation
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