



VA NCPS

Topics in Patient Safety®

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NCPS Approach to Achieving High Reliability

Robin R. Hemphill, M.D., M.P.H. and Gary Sculli, MSN, ATP

The remarkable improvements seen in the U.S. aviation system have attracted the attention of the health care industry, which seeks to adopt some of its strategies for improving care. One important strategy pursued by the VA National Center for Patient Safety (NCPS) since its founding is high reliability science, or the study of organizations in high-risk industries that operate in safety-sensitive settings while maintaining high levels of safety. Although High Reliability Organizations (HROs) have ample opportunity to fail, they have come to function in a manner that makes failures extremely rare. Members within such organizations structure their work toward the identification of failures. This results in the early identification of errors and error-producing processes. Weick and Sutcliffe (2007, 2015) have argued that HROs promote a manner of “organizational mindfulness” where all members watch for and report safety concerns before they pose risks to the larger organization.

The best performing HROs understand that disasters in complex sociotechnical systems are a result of multiple, small, and separate events that become intertwined and then amplified – ultimately allowing systems to “drift” into disaster. Regardless of the industry, those that have achieved the status of HRO share common features that are built upon intentional actions and ideas. Over time, these features de-

fine the “culture” (i.e. “the way things are done around here”) of these organizations – cultures that focus on safety. The challenge remains in how to translate the lessons articulated by Weick and Sutcliffe into a conceptual model that may yield for Veteran’s health care the successes enjoyed by other highly reliable industries.

For health care organizations, the term safety culture describes the contexts in which patient care is delivered as well as the shared values, attitudes and behaviors that determine how organizational members minimize patient harm during the delivery of care. A culture of safety has several elements: just culture, engaged leadership, high-functioning clinical teams, perpetual training cycles and an understanding of complexity that includes robust process improvement practices. These elements alone will not establish high reliability, but are an essential first step.

Just Culture

A just culture recognizes that even the most committed professionals will make mistakes and that unhealthy behaviors, such as short cuts and workarounds, are common in the face of pressures to maximize efficiency. However, there is no tolerance in a just culture for behaviors that repeatedly or purposefully violate steps put in place to maintain safety. Thus, both accountability and appropriate psychological safe-

ty are balanced. When a close call, or adverse event occurs, a just culture is focused on the “why” not the “who.”

Assuming that no one comes to work with purposeful intent to harm patients, it is important for organizations in the wake of adverse events to move beyond the blame and shame approach, which encourages workers to hide mistakes, and instead facilitate the thoughtful detection of imbedded system vulnerabilities that contribute to patient harm.

Engaged Leadership

Individuals in top leadership positions are the driving force behind how things function in a health system and are absolutely essential to creating a safe culture. It is critical for leadership to make safety part of the daily discussion and a center point of major meetings and strategy sessions. Top leaders must also craft a reporting relationship that ensures safety officers deliver unfiltered information to key decision makers in the organization.

High-Functioning Clinical Teams

Health care is provided by interdependent teams of medical professionals who should share a common goal toward delivery of Veteran care. To create such an environment, the members of the team must have a shared mental model that allows each person to maintain situational awareness regarding progress toward that shared goal.

Situational awareness is the continuous perception of team functioning in relation to a constantly changing environment, including the ability to make changes as appropriate to an evolving situation. It includes awareness of critical information, comprehending the true meaning of this information, communicating that information and planning for future possibilities.

High-functioning teams are well versed on leader strategies to foster participation so that all team members embrace the responsibility to speak up about perceived risks in the operational setting. Likewise, team members regularly implement standardized methodologies for practicing assertive inquiry and advocacy to preserve safety when necessary.

Perpetual Training Cycles

A hallmark of any high reliability industry is a steadfast commitment to perpetual training – both in the technical *and* non-technical elements of the job (such as competency in teamwork, communication and situational awareness). For example, the training signature in commercial aviation includes initial training followed by a series of recurrent training experiences at specified intervals that continue indefinitely for one’s professional life cycle. This training includes both team and individual practice followed by competence evaluation under observation using high-fidelity simulation. For health care to approach high reliability, it must – at a minimum – move away from single episode training toward a training signature where multidisciplinary teams train together on a perpetual basis.

Understanding Complexity

Health care systems are complex: They consist of a multitude of interdependent and diverse components that adapt to changes in the environment. Because the components of the health care system will interact and adapt as change is introduced, it is imperative that a culture values the reporting of errors, concerns, risks or near misses in order for it to prevent or mitigate potential harms. The only way to identify emerging vulnerabilities is to develop an organizational culture that is willing to bring up,

discuss, and address its problems. This is why a just culture is such a critical part of any complex system. To have any hope of catching vulnerabilities before they cause harm, we must have vigilant staff continuously scanning for minor vulnerabilities that may conspire to result in major accidents. Those staff must be armed both with the tools to deeply understand the evolution of harm through the care delivery system, as well as the ability to analyze and improve their own work environment. Critical to accomplishing this objective is a leadership that is receptive to staff feedback regarding errors, concerns and near misses.

Improving Processes

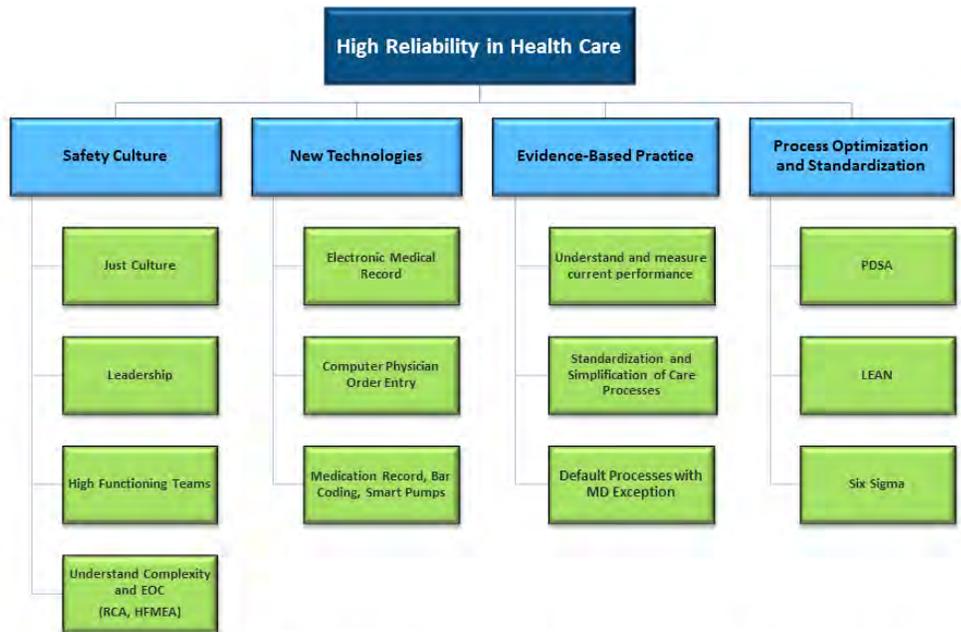
Successful integration of quality improvement strategies within health care settings require organizations to meet a number of well-defined challenges, including the complexity of human disease and the dynamic nature of safety. Chief among these hurdles is the inability of a narrow “tools and methods approach” to institutionalize quality improvement. For example, most organizations never make it past thinking of Lean as a series of “tools” that can improve the system. Unfortunately, the best tools will fail to yield lasting improvements if the existing culture upon which the tools are dispersed is lacking the rudiments of a safe and transparent culture. Process improvement efforts must also be communicated in concert with continuous efforts to create, nurture, and sustain a foundationally safe culture. In this way, VA utilizes Lean as a standardized methodology for how process improvement is approached.

To develop a health care organization where staff freely and respectfully challenge supervisors when safety is in question, a trust must be cultivated that communicates to staff

that they will not be penalized for doing so. A major goal of the health care industry today is to morph from a culture that sees errors as ‘weakness, laziness, or lack of commitment’ subject to punishment, to one where errors are seen as an inevitable consequence of the limits of human performance. In the latter, errors are freely voiced as part of a just culture: They are discussed as teachable moments for learning more about prevention and management. Team members are therefore encouraged to not only follow standard procedures, but also contribute to problem-solving via prompt intervention when preventable errors and harms are anticipated.

The programs of NCPS in partnership with many other entities and people across VHA are working to make care safer, with an eye toward consistent improvement.

The diagram below is a conceptual framework for achieving high reliability – while achieving a culture of safety is critical, many additional efforts are needed.



Frankel, A.S., Leonard, M.W., & Denham, C.R. (2006). Fair and just culture, team behavior, and leadership engagement: The tools to achieve high reliability. *Health Serv Res, 41* (4 Part 2), 1690-1709.

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PATIENT SAFETY CENTERS OF INQUIRY UPDATE:

Pittsburgh’s Center for Medical Product End-User Testing

Jamie L. Estock, MA, director, Center for Medical Product End-User Testing

The VA National Center for Patient Safety (NCPS) manages several Patient Safety Centers of Inquiry (PSCI). These centers develop, disseminate and implement clinically relevant innovations that improve patient safety throughout the Veterans Health Administration (VHA).

One such PSCI is the Center for Medical Product End-User Testing (CMPET) located at the VA Pittsburgh Healthcare System (VAPHS). CMPET assesses the risk for medical product use-related hazards with the goal of reducing or preventing adverse events across VHA. CMPET focuses on the use of human factors principles to improve patient safety, an NCPS high-priority area of study. CMPET conducts human factors evaluations involving the intended users



CMPET team members participate in a training scenario to better understand ESU use errors.

of medical products performing representative tasks under variable and sometimes stressful conditions. CMPET's three-year plan involves the completion of projects to support the NCPS Purchasing for Safety initiative.

The NCPS Purchasing for Safety initiative prioritized electrosurgical units (ESUs) as the medical product for CMPET to evaluate in fiscal year 2016. ESUs are used for surgical cutting and controlling bleeding by causing coagulation (hemostasis) at the surgical site. The FDA received over 23,000 reports of adverse events associated with ESUs over a seven-year period, with one of the most serious use-related hazards being charring of healthy tissue. Three commonly reported use errors that could result in charring of healthy tissue are: (1) setting the incorrect power, (2) connecting the incorrect instruments, and (3) selecting the incorrect mode. CMPET staff conducted three separate studies to investigate each use error individually. In each study, CMPET staff compared two ESU models. The objective was to identify the specific ESU design features that can help prevent or mitigate these use errors.

Thirty-five registered nurses and one medical technician who use ESUs as part of their primary duties participated in all three studies. The evaluation took place in an unused isolation room in the post-anesthesia care unit at VAPHS. To simulate a real-world operating room (OR) environment, the isolation room was equipped with technology used during a typical surgery. Two standardized actors from the University of Pittsburgh portrayed OR staff who interacted with the participant during the scenario. The standardized actors followed a script to guide the participant through the scenario. Three study co-investigators portrayed OR staff who were present in the room but did not interact with the participant.

The study co-investigators observed whether the participant completed the requested task correctly and how long it took them to complete the task. After using each ESU model, the principal investigator interviewed the participant to obtain feedback about the interface design features that supported or hindered accurate and efficient task completion.

Once analyses are complete, CMPET staff will upload the results tables onto the CMPET SharePoint site at <https://vawww.visn4.portal.va.gov/pittsburgh/home/Research/MPE/default.aspx>, where VHA stakeholders can access results from this and previous CMPET medical product evaluations. Stakeholders can use the results to ensure that VHA facilities are purchasing ESUs that are less likely to elicit use errors. This can reduce the burden of risk experienced by Veterans undergoing surgical procedures in which ESUs are utilized.



The New Generation Risk Tool for VA HFMEA

The New Generation Risk Tool for VA HFMEA

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VA NCPS*

Failure Mode and Effect Analysis (FMEA) is a method that engineers across industries use to systematically detect and prevent process and product problems before they occur. VA has adapted the FMEA methodology to health care processes in order to reduce the frequency of unanticipated adverse events and ensure safer care for Veterans.¹ VA Healthcare Failure Mode and Effect Anal-

ysis (HFMEA) also helps VA facilities comply with The Joint Commission standards, which require accredited hospitals to select a high-risk health care process and perform at least one risk assessment every 18 months.²

Currently, teams at VA hospitals carry out the HFMEA methodology manually using white boards, easel paper and large printed worksheets to organize ideas. Later, they transcribe the information into electronic documents and propose actions to leadership.

In early 2016, the VA National Center for Patient Safety (NCPS) began brainstorming the next generation of the VA HFMEA in collaboration with the Veterans Engineering Resource Center (VERC) Data Engineering Resources team in Indianapolis and developed a prototype called the Proactive Assessment for Safer Systems (PASS).

What is PASS?

PASS is an electronic tool created to help VA hospitals perform and document HFMEAs. The goal of PASS is to empower clinical and patient safety staff across VA to carry out proactive risk assessments more simply and effectively.

The features of the PASS web-based application will be structured around the HFMEA methodology and designed to ensure ease of use for beginners and experts alike. PASS will streamline HFMEA facilitation by providing a platform for teams to electronically input the five HFMEA steps:

- 1) Selecting the process
- 2) Assembling the team
- 3) Identifying process steps
- 4) Identifying failure modes
- 5) Identifying actions.

This will eliminate the need for paper worksheets, but more importantly, it will allow for an enterprise view throughout VA to help facilities standardize processes

nationally. The PASS tool will promote organizational learning by maintaining a searchable database. Users will be able to search for completed HFMEAs by topic area, allowing for the innovations and outcome measures generated at one site to benefit teams at all VA medical centers. HFMEA teams will be able to review items such as process steps and sub-steps, failure modes, actions and outcome measures that other teams across the country have previously entered into the PASS system. This ability adds a new and exciting layer to HFMEA that will enhance the quality and consistency of analyses and increase the effectiveness of planned actions and outcome measures.

The application will be accessible anywhere within the VA network, requiring no software installation. Embedded tips, a user manual and reference materials will be available to guide users through the methodology. Each team's designated HFMEA coordinator will have access-granting rights so that they can invite team members to view and edit ongoing analyses.

Developing and Testing PASS

In order to best translate existing practices into the electronic tool, the development team will work with teams of clinical and patient safety staff in the field to introduce, explore and evaluate the new features of PASS. The development team plans to facilitate pilot sessions during facility level HFMEAs to gain valuable insight from end users.

A phased development and implementation plan will create opportunities for discussion, analysis and mid-course improvement. The first version of PASS will feature full HFMEA functionality. Users will be able to construct static process diagrams, conduct basic searches of archived HFMEAs, and print completed

process diagrams and HFMEA worksheets. The second version of PASS will equip users with more advanced features including a "drag-and-drop" flow diagram, a personalized "dashboard" to view and resume HFMEAs, and the ability to print isolated HFMEA components. Finally, in a third release, PASS will enable VA service chiefs to develop standard health care process templates that are either specific to one service line or span multiple service lines. This will create an opportunity for service chiefs to lead large scale, multidisciplinary, multi-facility HFMEAs leveraging the insight of staff from numerous sites and service areas. Aggregate HFMEA findings will strengthen VA's capacity to proactively identify vulnerabilities and take corrective actions.

The Future of VA Proactive Risk Assessments

Reliance on reactive, piecemeal improvements to small elements of a complex system ultimately cannot help identify or remediate the things

that could go wrong. Alternatively – when we study how processes intertwine, thoughtfully determine which vulnerabilities we can control, and challenge ourselves to acknowledge our weaknesses – we empower each other to overcome those weaknesses and proactively address broken systems before they cause harm. PASS, with its broad accessibility, user and team-friendly interface, and database of solutions, will provide a pathway for teams in the field to accelerate VA's proactive approach to building safer systems.

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Patient Safety 101 and 201

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For More Information or to Register:

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VA National Center for Patient Safety

Great Catch: Magnetic Attraction

Crissy Knox, MSN, RN, patient safety manager, and Kim Reibling, MSN, RN, quality improvement specialist, Robley Rex VAMC

Patient and individual safety is a critical component of all Magnetic Resonance Imaging (MRI) programs. The core, or center, of the MRI machine is a very high-strength magnet capable of pulling metallic objects into the machine at high speeds. Both implanted and environmental metallic items are attracted to the magnet; when in proximity to the machine, these items are abruptly pulled into the machine and can cause serious patient injury or death. Screening individuals for potentially hazardous items is vital to patient safety.

When a provider orders an MRI at the Robley Rex VAMC in Louisville,

a patient safety screening tool is completed multiple times in multiple areas: at the time the MRI is ordered, upon arrival to the MRI suite, and in a face-to-face conversation between the MRI technician and the Veteran.

Recently, while preparing for an MRI procedure, our MRI technician learned a Veteran had magnets implanted in his fingertips. This type of magnetic implantation is a procedure performed in tattoo parlors that allows individuals to feel certain electrical currents.

The Veteran was adamant that it would be safe to undergo the MRI. The MRI technician was not so confident about completing the

procedure. As a precaution, the technician reached out to the radiologist, who validated that the MRI was not safe. In order to provide the best care for the patient, the MRI technician sought an expert opinion from an MRI safety expert who agreed that the MRI was indeed not safe. The MRI technician did a great job of reviewing the information with the patient and learning about the magnets. This was a great catch – something that could have easily been missed and, consequently, brought harm to the patient. For his commitment to Excellence and Veteran safety, the MRI technician was awarded an ICARE certificate.

NCPS Staffer Receives Prestigious Oliver Hansen Outreach Award

Human Factors Ergonomics Society (HFES) and VA National Center for Patient Safety (NCPS)

On September 20, 2016, the Human Factors and Ergonomics Society (HFES) presented The Oliver Keith Hansen Outreach Award to Linda C. Williams, VA National Center for Patient Safety (NCPS) – This is the same award that “Miracle on the Hudson” Pilot Captain Chesley (Sully) Sullenberger received in 2010.

“Linda Williams has dedicated nearly two decades of service to improving care for Veterans through the education of nurses, physicians, and allied healthcare staff in the principles of human factors engineering,” said Dr. Robin Hemphill, VA Acting Assistant Deputy Under Secretary for Health for Quality, Safety and Value.

Williams has collaboratively initiated the development of the Advanced Patient Safety Fellowship, a national interdisciplinary patient safety program within the VA that fosters an environment in which human factors engineers, health care



NCPS Staffer Linda Williams receives The Oliver Keith Hansen Outreach Award

clinicians, and other professionals collaborate to share expertise and design safer systems.

As a leader in this and other national training initiatives for more

than a decade, Linda has exposed thousands of clinicians to human factors techniques that support the safer design of healthcare systems. Within the VA, she has created an environment that fosters the development of long-term relationships between HF/E practitioners and clinicians. Her efforts have resulted in both individual and organizational transformation in metacognition and approach to design.

“Participants of her many workshops, boot camps, and courses are better prepared to deal with uncertainties and complexity of healthcare. Linda’s legacy are the many patient safety leaders she has developed including dozens of graduates of the VA National Center for Patient Safety Advanced Fellowship in Patient Safety and the Chief Resident in Quality and Safety,” said Dr. Douglas Paull, VA NCPS Director of Patient Safety Curriculum and Medical Simulation.

Chief Resident in Quality and Safety

Eric Yanke, M.D., staff hospitalist, William S. Middleton VA, Madison, Wis. and Derek D. Atkinson, public affairs officer, VA NCPS

The VA National Center for Patient Safety (NCPS), in partnership with the VA Office of Academic Affiliations, has developed the Chief Resident in Quality and Patient Safety (CRQS) program. The CRQS program is a one-year program for recently graduated residents. During their chief year, residents focus on learning and teaching about quality and patient safety, and engaging in improvement activities at their home facility.

The CRQS program now includes 83 chief resident positions at 57 VA medical centers. Each chief resident will participate in the national curriculum led by NCPS, which includes a week-long, face-to-face meeting and monthly sessions using distance technology. In addition, CRQS participants pursue projects at their home facility.

NCPS public affairs officer, Derek Atkinson, recently discussed the CRQS program with former chief resident Dr. Eric Yanke from the Madison VAMC:

How did you hear about the CRQS program and what interested you in it?

Our Associate Chief of Staff for Education at the time mentioned it to me and invited me to Washington, D.C. for the national meeting of CRQS program directors. I went with him and our Chief of Staff and got a great look at the program “behind the scenes,” so to speak. This was during my 2nd year of internal medicine residency, so it was an easy decision to apply for a CRQS position during my 3rd (final) year of residency. The University of Wisconsin Internal Medicine Program has a strong patient safety curriculum, particularly at the VA. I really enjoyed that experience during my residency, and taking a year to devote to quality improvement and patient safety sounded very interesting.

Describe your experience in the program?

I was the first CRQS at our site, so I had a lot of flexibility with the year. Our local leadership was very supportive in both my academic and more practical quality improvement projects. My academic work used a human factors engineering model (SEIPS model) to analyze how well we adhered to C. difficile infection prevention practices, specifically, the VA’s nationally mandated C. difficile infection prevention bundle. I hosted focus groups with residents, attendings, nurses, and environmental services, which yielded some fascinating insight into the workflow of various groups.

My more practical project was redesigning our inpatient insulin infusion protocol to streamline the ordering process and better adhere to national guidelines. The main goal was to reduce hypoglycemia while on the insulin infusion, which we definitely achieved based on our post-intervention analysis. It was a lot of work getting our changes through all the various committees, but it was completely worth it.

Did it change your perception on the role/importance of patient safety?

Absolutely. My biggest shift in perception was recognizing the crucial role that our built systems of care play in both patient safety and medical errors. This encompasses our electronic health record, physical envi-



Former chief resident Dr. Eric Yanke is now a hospitalist at the Madison VAMC.

ronment, and institutional culture (in addition to many more). Previously, there was a small part of me that felt if providers worked harder, spent more time, or were “more careful,” most medical errors could be avoided. Now, I recognize our systems of care play just as important a role as individual providers’ skill and knowledge.

How did the program prepare you for your current position?

As an attending hospitalist, I am always working with residents and medical students on the medicine wards. My CRQS year provided significant insight into how the VA system works and specifically how the VA approaches quality and safety. When residents and students point out problems or systems issues, I can usually find the right person to help them begin addressing the issue. I also have been fortunate enough to continue my academic work during my non-clinical time. We still have lots of focus group data to analyze and publish from my CRQS year!

NCPS Patient Safety Boot Camp for Biomedical Engineers

Katrina Jacobs, M.S., biomedical engineer, VA NCPS

During the week of August 8th, the VA National Center for Patient Safety (NCPS) hosted its seventh Patient Safety Training Course for Biomedical Engineers (BMEs) in VA's eminent Technical Career Field (TCF) Program. This course has become known as NCPS' Patient Safety Boot Camp for TCF BMEs.

The TCF Program is one of the largest training workforce development programs in the Veterans Health Administration (VHA). Bio-medical Engineering is one of fifteen career fields represented in the TCF Program, which VHA anticipates staffing needs and where VA-specific knowledge as well as experience is desirable for success in the field. Individuals selected for two-year TCF positions are trained, coached, mentored and supervised by an approved preceptor. BME TCF trainees must complete field specific curriculum to include NCPS' Patient Safety Boot Camp.

The goal of this training course is for participants to walk away with the engineering tools necessary to en-



A group of TCF biomedical engineers pose for a picture during the NCPS Patient Safety Boot Camp.

hance patient safety across VHA. The training was built upon core concepts of NCPS' Patient Safety 101 that are used to train all VHA patient safety managers, thus ensuring a common set of core competencies. Areas of focus include: just culture, root cause analysis, healthcare failure mode and effect analysis, high reliability, risk management, requirements definition, recalls, and reporting.

Participants learn how human factors impact task performance, how using a common structure for event reporting allows greater ability to eliminate or control vulnerabilities and how proactively examining systems increases the organization's chances for success.

Biomedical Engineering is the key in implementing engineering approaches into medical practice. BMEs have the unique ability to recognize what can change – with the task, with the environment, and with the user – to proactively consider changes instead of addressing them ad hoc. Through a systems approach to problem solving, utilizing human factors engineering principles and applying concepts from high reliability organizations to target and eliminate system vulnerabilities, BMEs can improve safety and performance within their health care facilities.

NCPS' Patient Safety Boot Camp for TCF BMEs brings an increased, shared awareness of patient safety goals and strategies across other disciplines of health care. By growing the commitment to creating a safer system, VA furthers its commitment to providing safer care to all patients.

Putting a Face to a Name: Your Patient Safety Team



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