Available online at www.sciencedirect.com

ScienceDirect

Procedia Manufacturing 3 (2015) 258 – 263

Procedia MANUFACTURING

6th International Conference on Applied Human Factors and Ergonomics (AHFE 2015) and the Affiliated Conferences, AHFE 2015

Safer systems, safer care: Bringing the tools and strategies to clinical service areas through applied patient safety programs

Tandi M. Bagian[a], Katrina Jacobs[a], Robin Hemphill[a], Nancy J. Lightner[b]

[a]*VHA National Center for Patient Safety, Ann Arbor, MI, USA*
[b]*VA Center for Applied Systems Engineering, Indianapolis, IN, USA*

Abstract

Along with creating and supporting a trained network of Patient Safety Managers across the U.S. Veterans Health Administration, the National Center for Patient Safety brings an increased, shared awareness of patient safety goals and strategies to disciplines of healthcare, beginning with the biomedical engineers at VHA facilities. This presentation outlines a 'roadmap' for the journey to high reliability healthcare and shares the training approach and results to date. This roadmap is modelled after that used at NASA and contains four development phases beginning with an awareness of human limitations and ending with proactive analysis to anticipate causes of safety episodes. The goal of the roadmap is to systematically ensure the care given to patients is done as safely as possible by incorporating best practices from mature industries.

*Keywords:*Patient safety; Roadmap; VeteransHealth Administration; Best practices

1. Introduction

The U.S. Department of Veteran's Affairs (VA) has over 15 years of experience building and sustaining a culture where patient safety is foundational to all care given in the largest integrated health care system in the nation, the Veterans Health Administration (VHA). VHA has over 1,700 sites of care, including more than 150 medical centers.The VA's National Center for Patient Safety (NCPS) is a headquarters division of VHAfocused on the reduction and prevention of inadvertent harm to patients as a result of their care as well as nurturing a culture of safety. To aid in accomplishing this goal, NCPS provides training to Patient Safety Managers (PSMs) staffed at VHA medical centers; ensuring that facility-based employees are able to capture details aboutpotential or actual adverse events, determine the root causes, and take effective actions. PSMs are critical employees tasked to lead

doi:10.1016/j.promfg.2015.07.142

analyses of events in which patients were harmed or could have been harmed. When engagement with facilities is needed to remove hazards, NCPS can direct national action through Patient Safety Alerts,so all VA facilities implement steps to remove or contain a vulnerability that could cause patient harm. With this patient safety network, organizational learning occurs. Every care team at every VA facility benefits from what any one individual discovers using the patient safety tools provided by NCPS. It is a VA core value that care provided should never harm a patient; hence, the tag line of 'Safer Systems, Safer Care' reflects this core value and represents a system of PSMs utilizing patient safety tools so that the entire workforce learns from every adverse event or close-call.

When an adverse event or close-call occurswithin a facility, the reporter shares the information with the PSM who enters the report into a confidential quality improvement national database. Details are important to document, and the database of over one million entries, which allows for VA to recognize trends in how various systems can fail those trying to deliver critical care to our Veterans. Actions are then recommended to reduce the likelihood and/or severity of future such events. Ideally the recommendations for improvements that come from a root cause analysis process, will leadto recommendations for improved design as manufacturers learn of new vulnerabilities with the use of their medical technology in the field. Success of this patient safety system relies on a number of sustained organizational elements. Hospital leadership needs to appreciate that learning *why* something happens is more important than identifying *who*to blame for an inadvertent outcome. The organization must be committed to prevention, rather than punishment, in order to improve patient safety. Employees need to believe that it is safe to discuss situations that did not result in the intended outcome, and that punishment will not result from making honest errors. And the PSM needs to see that the hospital director supports the structured analysis of events and close-calls, and will allow multi-disciplinary teams the time to gather and determine the root causes of an adverse event or close-call. Most importantly, every individual hospital needs to believe that it is worth the investment of time to thoroughly understand the root cause(s) of an event and share it through NCPS so that others have the opportunity to benefit from what was learned.Based on lessons learned from recurrent failures, NCPS develops improvements for implementation across the entire VHA enterprise.Successful implementation of improvements requires a commitment to the Veteran and to the organization that supports his or her care. One obstacle occasionally encountered is local leadership's interest in fixing a local problem and moving on instead of addressing a larger, systematic problem.

As a result of the attention on VA spending formeetings, strict limits were imposed on travel. These limits reduced opportunities for face-to-face training of PSMs and travel to support facilities with their understanding of events. Additionally, a leadership decision was made to allow each medical centerDirector to determine where in the organization the PSM reported, as opposed to the original structure of having Patient Safety report to the Director at every VA medical center. The seeming reduction in underlying support of the patient safety role served as a catalyst to consider programmatic design changes to sustain the robust culture of patient safety pioneered by the VA. This paper will describe this 'organizational engineering' and shares the benefits seen to date with Applied Patient Safety programs.

2. A systematic approach to patient safety training

An important part of creating the Applied Patient Safety training was to create a 'roadmap' to guide the strategic direction of the program.This helps every employee across the organization see where we are, and where we are going as an Agency, in a simplified manner. The first 'stop' is to see each task as part of a system, and realize how as humans our performance is affected by various factors and vulnerabilities in our environment, in the task, and in ourselves on any given day - human factors. We depend on our VA workforce to capture the factors that influence our performance by documenting clearly how events happened, and defining the root causes. As a large organization our next stop on the journey is utilizing experience and data to better understand the real-world performance envelope; awareness is created by evaluating what has gone wrong and considering actions to avoid additional adverse outcomes. The third stop on the roadmap is to rigorously look at what can change – with the task, with the environment, or with the user – to proactively consider changes instead of addressing them ad hoc. As the last stop on the journey, we have a discussion with our partners in industry who are extremely interested in the safe use of their products. Together we look at which failure modes we've each analyzed, and anticipate other system failures for more robust patient care. This 'Purchasing for Safety' initiative consists of VA and the U.S.

Food and Drug Administration's (FDA) Medical Product Safety Network (MedSun) partner hospitals recognizing the leadership of industry partners who provide their analysis, including limit-testing data. MedSun consists of approximately 250 user-facilities (e.g., hospitals) who voluntarily report concerns about medical devices. The FDA shares de-identified reports and lessons learned with the clinical community and the public so they make take necessary preventive actions. See http://www.fda.gov/MedicalDevices/Safety/MedSunMedicalProductSafetyNetwork/ucm2005297.htm for details.

Finally, for the Applied Patient Safety training, along with 'where are we going' the trainees were given a clear sense of 'what does that stage look like'. We plan to take the high achievers that are hired and create high performers; employees who want to learn what has gone wrong and who actively consider what could go wrong with everything they do. We plan to take existing employees that are high performers and help them become team members who follow the Road Map to share what they see and what they are concerned about so the entire team considers these same factors and can generate a shared plan of action (in essence we seek to create a team situational awareness than can supplant and supersede the situational awareness of the individual). Those team members will participate in a high reliability organization as they see their relationship between teams, and between medical centers, and as an organization that can practice planning for challenges such as supply shortages, hiring freezes, new diseases, etc. VHA as a high reliability organization would help drive an overall high reliability heath care industry, perhaps with standards for human interfaces, suggested/prescribed proficiency regimens, and 'go/no-go' criteria for use of technology or process.

Fig. 1.VA Patient Safety Strategic Road Map.

3. Phased training

3.1. Phase I – Three day 'Boot Camp' for TCF Biomedical Engineers

In 2013, NCPS broadened the scope of patient safety training and approached other groups of VA employees who serve or may impact on the care of the patient in the hospital setting. NCPS first reached out to the Biomedical Engineers (BMEs), connecting with their national Program Director within the VHA Office of Healthcare Technology Management (HTM), and creating a three day 'Boot Camp' training on patient safety for all BMEs in VA's Technical Career Field (TCF) Program. TCF BMEs are engineering trainees specifically hired as possible future Chief Biomedical Engineers at VA medical centers. The training was built upon core concepts of 'Patient Safety 101" that are used to train all PSMs (thus ensuring a common set of core competencies): how human factors impact task performance, how using a common structure for event reporting allows greater ability to eliminate or control vulnerabilities seen in-use, and how proactively examining systems to determine and impact the most vulnerable parts of the task increases the organization's chances for success. The training scenariosincorporated situations encountered by a BME, such as what to do when there is an adverse event or close-call; or when personalities contribute to less than effective communication. During their two-year TCF Program these BMEs are now *required* to take the NCPS training in Patient Safety. Five groups have received this training in the last two years. The result is a cadre of BMEs ready to help PSMs utilize Root Cause Analysis (RCA) as a tool to understand why an event occurred; ready to participate in Healthcare Failure Mode and Effect Analysis (HFMEA) to improve the most vulnerable parts of our systems; and to create strong actions to minimize the chances that adverse events will occur again. As an aside, the inclusion of this partner in patient safety resulted in a re-energized work force at the individual hospital, to the point of replication and testing to confirm the root causes their RCA team identified. Engineers by education and training are typically very familiar with the need to perform RCA, so creating a relationship between the PSM and the BME strengthened the interest in a thorough incident analysis.

3.2. Phase II – Three day 'Jump School' for VHA Biomedical Engineers

The next phase in this partnership was to provide training for existing VHA BMEs, to accompany the exposure the incoming workforce was receiving. NCPS created a three-day 'Jump School', which was the initial conception of an Applied Patient Safety Training. This experience was to help the BME recognize how, as a large health care system, we have the ability for organization learning. It was also intended to assist employees in considering how they might best communicate relevant information throughout VA. Thinking organizationally, rather than as an individual medical center, these engineers experienced how reaching out and sharing their perspectives and experiences could benefit the entire VA healthcare system. Through hands-on exercises tackling real issues in health care, they discovered their own power, and dedicated themselves to working together to create a better system of care by integrating their ideas into a national 'best practice' for all VA facilities. The first piece of work these groups saw as critical was to make sure they had a standardized plan for reacting to a medical device incident within their facility. Rather than individually hoping they thought of everything in the moment that would help protect evidence and clues to why an event occurred they wanted to work together and capture everyone's best ideas as a national guidance for each of them, should an adverse event occur at their facility.

4. Results

This commitment to work as a team across the entire VA organization has taken root. A Patient Safety Workgroup has been established that is co-led by NCPS, HTM, and the VHA Center for Engineering and Occupational Safety and Health (CEOSH). The VHA Alerts and Recalls Website hosted by NCPS has expanded such that aclosed-loop communicationsystem is now available to the BMEs for medical device safety notices and field corrections from manufacturers, andat a glance they can determine at a national-level how many VA facilities have completed the necessary corrective actions on medical devices, such as a critical software update, replacement of faulty hardware, or have updated manuals with changes to the Instructions For Use. The Patient Safety

Workgroup is standardizing the processes, which results in a tremendous increase in VA's ability to confirm system readiness.

Two important things have occurred that were beyond anticipated benefits. The first is that individual engineers at a given facility, who were told by a medical device manufacturer that a 'glitch' in critical patient monitoring software was unusual and was likely nothing to worry about, were able to utilized the closed-loop communication system to 'reach out' to their fellow engineers and determine that other VA facilities had also reported this same event to the manufacturer. When this occurred previously, each facility was unaware of this happening anywhere other than to them. The Applied Patient Safety training included a 'Healthcare Engineering Reach Out', or HERO exercise, which involved working together to accomplish a task – and which drove home the importance of working as a team to determine the best path forward.

The second, also unintended result was that the concept of providing a drill, what was named the 'BME Challenge', was embraced by leadership as a way for the organization to better define and appreciate the variability which exists in our health care system. Because every VA medical center is a little bit different due to the history and culture, along with the patient population being served, the lines of accountability lie with the hospital leadership and it has traditionally been up to each facility to be the best they could be. With the initiation of Applied Patient Safety, many individuals in the biomedical engineering workforce truly embraced the opportunity to work toward the best solutions for the entire organization – be those devices, policies, or processes. Creating a BME Challenge where every facility will react to a scenario we create (based on a true event documented in the NCPS database) will allow organizational learning of how variable our systems are. In order to make every system safer we need to better appreciate the diversity that we have within and across system elements; we also will see how our solutions are more robust when they are informed by multiple perspectives.

Applied Patient Safety for HTM now builds upon initial patient safety training for incoming employees, and creates national conversations on best approaches to solve real issues any individual employee might need to face at their facility. There is a national/headquarters focus so the status of our health care system is immediately available, and leadership support to 'reach out' and practice as a workforce, so we are better able to understand and support the diversity of our individual sites.

Other VA service areas are interested in utilizing some of the tools of patient safety. Pharmacy Benefits Management is also going to utilize the NCPS closed-loop communication system to confirm that important messages regarding drug safety are received and actions taken at all impacted facilities. The National Surgery Office, the VA Chief of Anesthesia, and the VA Chief of Radiology all utilize de-identified 'cases' from the NCPS database for quarterly calls with the field. This confirms leadership commitment to discussing and anticipating adverse events, and preparing each employee to see themselves as part of a system of care where perfection is a goal, but not a likely outcome.

Finally, as the role of the PSMis at the discretion of each medical center Director, NCPS created an Applied Patient Safety template for use in any safety-related discussion. This template boils the lectures and tools of patient safety down to a very simple approach, which we've labelled Care-Share- Dare. The following contains an outline for this VA initiative, useful to all purchase teams, facility planning teams, and other activities where there is a stated interest in including Patient Safety

1. CARE to learn all you can, practice, 'read the manual'; check websites
   a) Humans arenot 100% perfect, let's see how human factors have impacted task performance
   b) Humans are part of a *system*, try to see the system along with your part of the system
   c) Keep up your skills and knowledge – things change!
2. SHARE your experiences with others – what worked well, what hasn't
   d) Shared mental model of what we're doing
   e) Strategy for confirming, helping, anticipating, communications and handoffs
   f) Capture and use what others have learned, see if you can add to the understanding of what could happen in different situations
3. DARE to imagine what could change
   g) Heuristics – how could this go wrong? What could change the situation?

Fig. 2. VA National Center for Patient Safety logo.

h) Simulation and proficiency – practice before you perform in different conditions; explore design tolerance
i) Limits of use – when are you 'no-go'? Ask the vendor/owner!

Figure 2 contains the logo developed by NCPS as a reminder of the initiative.

5. Conclusions

In conclusion, establishing a point of contact at each VA medical center and helping those employees sustain a 'fluency' in patient safety provides a foundation for the importance of systematically addressing patient safety. In addition, directed training creates partners at the facility who are also passionate about advancing active investigation, avoiding known harm, and understanding the limits of human performance to design fault tolerant systems. This is done by 'translating' examples and exercises to the different service areas and stimulating a conversation across the VHA service area, instead of the traditional limitation of discussion to a RCA team at a single facility. Beginning with a cadre of engineers who are comfortable with the tools of RCA and HFMEA, VA as an organization is expanding their ability to improve health care by better framing issues where the envisioned performance is not achieved due to variable conditions associated with the real-world. As these national conversations expand to vendors and policy-makers, the VA reality includes sustained improvement in safer patient care based on real in-use experience.