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High Reliability in the Operating Room: Targeting System Vulnerabilities

By Joe Murphy, APR, NCPS public affairs officer

At the Birmingham VA Medical Center,[1] an interdisciplinary team representing key areas of the operating room (OR) was formed to address a number of concerns with patient care that affect both VA and private sector hospitals.

"It can be challenging to get everyone's attention in the OR when a patient is first brought in," said Teresa Abernathy, M.D., a facility anesthesiologist and co-chair of the project. "We wanted to help the surgical team focus on the patient. It's common for a surgical team and equipment representatives in the OR to be distracted by extraneous topics. For us, it's kind of like another 'day at the office.' Patients, on the other hand, don't come into the OR often and it can cause a great deal of anxiety."

The team found a number of avoidable distractions: for instance, excessive noise and conversations unrelated to the current case or patient. To improve the situation, they decided to focus on reducing such distraction during the time between a patient entering the OR through a patient's airway being secured.

"Focusing on the patient by eliminating unnecessary noise and conversations increases the patient's comfort," she said. "We encourage conversation, as long as the patient is included."

The team's first step was to define the specific areas of concern. Then they developed an approach to address these issues, encouraging all members of the OR team to participate and be empowered to remind others to do the same.

The team developed an acronym that represented the steps being promoted to enhance the OR experience for the patient. "We wanted to develop an easily remembered acronym that didn't create a defensive response when it was used to remind someone to focus on the patient," said Dr. Abernathy. "We believe that everyone wants to optimize a patient's environment; however, when it's something you do all the time, it's easy to forget that it is an unfamiliar situation for the patient."

The acronym the team chose is "I-SLEEP" and it encompasses their new approach:

- I – Introduction of the patient into the OR
- S – Stop unnecessary conversation and activity
- L – Listen, for the safety of the patient
- E – Engage with the patient and the process
- E – Everyone participate
- P – Please

Lindsay Crain, an OR scrub technician who also co-chairs the project, described the initial step of the process: "When a patient is brought into the OR, the person bringing him will say, 'This is Mr. Smith.' Everyone in the room then takes a moment to introduce him or herself, including the residents and other members of the team."

"So I might say, 'Hi Mr. Smith, I'm Lindsay and I'll be helping with your case today,'" she continued. "Even though I am scrubbed-in and arranging instruments, taking that moment with the patient provides reassurance and demonstrates that we are a team and are here for the patient."

The team wanted the acronym to be simple and to represent each of the areas that required a new approach. Along with the mentioned actions above, the "I" is intended to represent the personal responsibility each team member has in the process. The "SLEEP" represents the time frame of the focus, from entering the OR through a patient's airway being secured, which is when the patient "goes to sleep."

Ms. Crain explained: "We used an acronym related to what was going to happen to the patient. So when someone says 'we're going to sleep,' it doesn't seem out of place to the patient and it helps remind everyone what we need to do."

The team offered the new approach to the OR staff at a number of meetings. To optimize acceptance of the plan, they decided to have a team representative from each area explain it to their peers. For example, Ms. Crain and Jerolyn Cooper, R.N. a circulator, presented it to the scrub technicians and circulators; Dominador (Jun) Bitago, CRNA, to the anesthesia staff; Dr. Abernathy to the surgeons.

Ms. Crain suggested a short questionnaire to be given to staff members prior to team members explaining the program to each group. Staff members were asked to rate certain behaviors within the OR. This heightened awareness and achieved

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Safe Purchasing of Medical Devices

By Dawn Sillars, M.P.H., NCPS patient safety fellow

Products intended to prevent, diag nose or treat disease are considered to be medical devices by the U.S. Food and Drug Administration (FDA), with the exception of pharmaceuticals.[1] Medical devices can be as simple as a tongue de pressor or as complicated as an automat ed external defibrillator. Users of these devices range from experienced health care providers to children with complex medical conditions. A device may be used in a tightly controlled environment, such as an operating room, or a highly variable environment, such as the home of a teenager.

The FDA has recently increased their focus on premarket usability testing of medical devices, seeking to prevent adverse events. Usability testing seeks to understand how users will interact with the product, followed by modifications to the design based on those observations. The FDA has released draft guidance for applying human factors and usability engineering to optimize medical device design.[2] Through the development of formalized usability testing requirements, the FDA expects to realize the following benefits:[3]

- Safer connections between device components and accessories
- Easier-to-read controls and displays
- Better user understanding of device status and operation
- More effective alarm signals
- Easier device maintenance and repair
- Reduced need for user training and retraining
- Reduced risk-of-use error, adverse events and product recalls

Beyond the regulatory measures put into place by the FDA, purchasers of medical devices can have an effect on the safety of medical devices by incorporat ing usability assessments as a part of their organization's procurement process.

Reviewing the affordances of a medical device is one valuable type of usability assessment. An affordance is the design aspect of an object which sug gests how the object should be used.[4] The following section describes four catego ries of affordances: cognitive, physical, sensory and functional.[5]

Cognitive Affordances

Cognitive affordances facilitate thinking and/or knowing about something.

Example: Labels identifying the function of a button will assist users in knowing what buttons to select in order to accomplish a task.

Physical Affordances

Physical affordances aid in the physical manipulation required during a task.

Example: The diameter of a handle on a medical device can affect the ability of users to grasp the device, as well as the duration of time until performance is degraded due to muscular fatigue.

Sensory Affordances

Sensory affordances use visual, auditory and somatic senses to assist users in task completion.

Example: The ability to act upon the receipt of critical test results for a patient may be expedited by critical test results displaying in relatively larger text compared to non-critical test results.

Functional Affordances

Functional affordances relate to the degree in which a design feature is useful in accomplishing a task.

Example: The functional affordance of a chair for the purpose of sitting is very high. The functional affordance of a chair for the purpose of obtaining an object out of reach is lower in relation to sitting, due to the increased risk of falling prior to successfully reaching the object.

The following section is adapted from Zhang and his colleagues,[6] who combined the usability work by Nielsen[7] and Shneiderman[8] into the Nielsen-Shneiderman Heuristics. When employed as a tool for usability assessment during the procurement process, devices selected are less likely to have design features which can put patients at risk for harm.

For ease of use, the section below is available online as an Excel® document in the TIPS section of the NCPS website.[9]

Nielsen-Shneiderman Heuristics

Visibility of the current state of the system

Users should be informed regarding what is going on with the system.

a. Can the user readily determine the current state of the system? (Is it on? Is it off? Is it in hibernation mode?)

b. Is the user able to determine what options are available in each current state? (How does this turn on? Turn off?)

c. Can users easily determine how to navigate any available menus?

d. If a change will occur as a result of an action performed by the user, is it easily apparent what happened?

Match the prior experience of the users

The actions required by users should match actions intuitively performed by users. Buttons are pressed, knobs are turned, handles are pulled, and switches are flipped.

Simple user interface

Avoid extraneous information which can distract the user, and slow down information processing. Consider the environment and context in which the device will be used. If a device is often used in emergency situations, requiring the user to process unnecessary information could result in a delay of patient care.

Minimize reliance on the user's memory

Users should not be required to memorize information more than necessary in order to carry out tasks.

a. Does the item rely on recognition or recall of information? Example: A menu displaying options vs. a blank command prompt.

b. Keep reference information visually available. Example: Prior values used for settings are displayed for reference.

c. If default values are used, what could be the unintended consequences?

d. Does the interface guide the user with concrete examples? (e.g., DD/MM/YY).

Messages are informative/actionable

Messages should provide adequate, timely information to allow for action and error recovery.

a. Phrased in clear language, avoid obscure codes. Example of obscure code: "Error code 147."

b. Is the information displayed in a precise manner, rather than general or vague? Example of precision information: "Cartridge replacement is required within 48 hours. To avoid interruptions in operation please replace cartridge now," instead of "Cartridge replacement is required."

Deliberate and judicious use of customization and shortcuts

Give users the flexibility of creating customization and shortcuts to accelerate their performance, while maintaining safe use of the product. Does the system allow expert users to customize the user interface, or offer shortcuts for frequently used functions?

Error prevention and mitigation

Is the system designed to prevent errors and/or mitigate errors if they occur?

Clear closure of actions

Every task has a beginning and an end. Users should be clearly notified when a task has been completed.

Allow users the opportunity to undo actions

Human error should be anticipated, and the user given the opportunity to recover from slips, lapses and mistakes. Does the system offer the user the opportunity to confirm actions that are highly significant? Example: "Please confirm here to delete this order."

Language

The language should be always presented in a form understandable by the intended users.

Consistency

Users should not have to wonder whether different words, situations, or actions mean the same thing.

a. If colors are used, do they have consistent meanings?

b. Does the formatting add function to the interface, or result in distracting the user from the workflow?

Help and documentation

If the user requires assistance, how would they obtain it?

a. Match the help available with the current state of the system.

b. Avoid expecting the user to rely on user manuals at the point of care. Embedded help is preferred.

Learn More

All links below retrieved April 30, 2015.

Take an online human factors awareness course through the Federal Aviation Agency: *https://www.hf.faa.gov/HFPortalnew/Training.aspx?AspxAutoDetectCookieSupport=1#gsc.tab=0*

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High Reliability in the Operating Room: Targeting System Vulnerabilities

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consensus that a problem existed. Dr. Abernathy and Ms. Crain agreed this ap proach helped achieve "buy-in" when the project was presented, immediately after the questionnaire.

High Reliability

The team credits their success to a number of actions that are in line with practices of high-reliability organizations, such as aviation. Such high-reliability organizations operate in high-risk areas, but have low-adverse event rates.

As noted in a recent study, some techniques used in high-reliability organizations to maintain high levels of safety cannot be directly applied in today's hospitals; rather, a series of incremental changes are recommended to advance toward the goal of high reliability. The changes include:

- Leadership's commitment to achieving zero patient harm
- Developing a culture of safety throughout the organization
- Widespread deployment of process improvement tools [2]

Birmingham's actions also mirror those promoted by VA to enhance patient safety, based on a systems approach to problem solving that focuses on preven tion, not punishment.

Over a decade ago, VA took the lead in developing programs and initiatives − rooted in successful approaches developed by high-reliability organizations − that have been shown to enhance patient safety. For instance, the team:

- Garnered support and "buy-in" from senior leadership
- Chose an enthusiastic, cooperative team who believed in the benefits of the project
- Adopted a "no blame" approach
- Created an easily remembered acronym and easily identifiable visual reminder
- Empowered all members of the operating team to be involved

"We needed buy-in from our leadership, as well as everyone in the OR who was going to participate," said Dr. Abernathy. "We presented the plan to our leadership and they immediately gave it their support. As an example, after I presented it to the surgeons, the chief of surgery said he felt the plan was very important because it was based on the core principle of providing respect to patients. When the leadership in each area vocalizes support, it makes a significant difference in how those within that department perceive the information."

As a number of VA studies and reports over recent years indicate, patient safety efforts can be significantly enhanced through such things as the use of checklists, cognitive aides, involving patients in their care, and initiatives that focus on improving teamwork and communication.[3-7]

Making a Difference

Comments from the operating room staff and random audits at Birmingham have confirmed improvement in numerous areas, such as:

- Patient-centered care
- Team dynamics
- Participation by all members of the team during critical points
- HIPAA compliance

"The results from the follow up questionnaire, approximately six months after implementation of I-SLEEP, indicated significant improvement had been achieved," Dr. Abernathy said. "Fifty percent of the staff felt we had improved conditions in the OR by 50-75 percent, and 23 percent of the staff felt conditions had improved 75-100 percent. That means three quarters of our staff feel substantial progress was made through the initiative."

"We are excited," she continued, "because we feel the initiative has made a much calmer environment for the patient. We focus on them, personally, when they first come into the OR. We've worked to eliminate extraneous conversations, which means fewer distractions and a safer environment."

Because of the inclusive nature of the initiative's roll-out, employee working relations have improved in the OR. "Our effort was based on a non-confrontational approach, which helps to prevent a defensive response from team members when someone brings something up," said Ms. Crain. "No one feels reprimanded. We believe we are working together to enhance patient safety by better focusing on the patient. It's easy to understand why so many staff members believe our project was the right thing to do."

Team Members

- Co-Chair: Teresa Abernathy, M.D.
- Co-Chair: Lindsay Crain, OR scrub technician
- Dominador (Jun) Bitago, CRNA.
- Jerolyn Cooper, R.N., circulator

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