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Biomedical Engineers: Teaming up for Patient Safety

By Joe Murphy, NCPS public affairs officer

Biomedical engineers apply the fundamentals of mathematics, physics, chemistry, biology and engineering to the medical field.

"If you were to define our work in two words, it would be problem solver,' " said Bryanne Patail, a member of the NCPS biomedical engineering staff.

"Our primary function here is to investigate medical device incidents that occur at our VA facilities," said Lori King, another member of the NCPS biomedical staff. "And the information we receive from patient safety managers is particularly important to us."

Shortly after King first started at NCPS, a potentially serious reprocessing issue was reported by a patient safety manager (PSM). Though equipment used for prostate biopsies was being cleaned and disinfected after each procedure, VA inspectors found that some of the equipment was not being scrubbed by a brush after each use, resulting in the remote possibility of infection. The VA offered follow-up testing at a number of locations to determine if any veterans had been exposed to infectious diseases.

"This investigation resulted in the largest patient notification in VA's history and it really got the ball rolling," King continued. "One incident reported by one PSM prompted VA to look closely at its reprocessing of reusable medical equipment."

Biomedical engineers are also key members of the patient safety team. "We encourage all of the biomedical engineers at VA facilities to be active with the PSMs," said another member of the NCPS biomedical engineering team, Tom Bauld, who also represents NCPS on VA's Biomedical Engineering Advisory Board.

When he meets with facility biomedical engineers, inside and outside of the VA, Bauld also urges them to get their staff members involved: "Tell them they are an active part of the patient safety process at their site," he continued. "This should be part of their training, their orientation, and their job description. And at the VA, their key liaison is the PSM."

He also routinely approaches PSMs, asking "What is your relationship with the biomedical engineers?" Fortunately, a clear majority has said, "We have a close working relationship."

Patail would like to see more biomedical engineers become a part of root cause analysis (RCA) teams, and not just those related to medical devices. "It's because these people are trained to be trouble-shooters and problem-solvers," he said. "And device-related RCAs are fairly small compared to the total number, about two percent."

King urged that they become members of Healthcare Failure Mode Effect Analysis (HFMEA) teams as well. Developed by NCPS, HFMEA is a five-step process used by interdisciplinary teams to evaluate a health care process; 1,000-plus have been conducted VA-wide.

"We want them to be part of an RCA or HFMEA team, even if it's not device-related, because it is a great learning experience," added Bauld. "They see how people in various disciplines can work together and develop a process that results in an improvement in patient safety."

"And the more who participate in these kinds of efforts, the more likely culture changes will occur," added Patail. "For NCPS, it's all about building a culture of safety at the VA."

Numerous Responsibilities

The VA issues Patient Safety Alerts or Advisories on specific issues relating to equipment, medications and procedures that might cause harm to patients: NCPS biomedical engineers play a critical role developing those related to medical devices.

Patient Safety Alerts communicate urgent notices that require immediate and specific action(s) on the part of the recipient; Advisories communicate recommendations, are more general in nature, and implementation may be subject to local judgment.

"The source for nearly half of all Alerts and Advisories we have developed have been VA facility staff members," said Joe DeRosier,

How a Local Patient Safety Initiative is Becoming a National Priority

By Joe Murphy, APR, NCPS public affairs officer

The NCPS Patient Safety Initiative (PSI) was established to stimulate creative approaches to complex patient safety issues. Many successful projects have been funded, including one that has spurred NCPS pharmacists to take on an issue that directly affects a huge portion of our Veteran population: standardization of prescription medication labeling.

The Amarillo VA Health Care System in 2007 was awarded a grant through the PSI program to evaluate a medication label design that highlighted key points of information and displayed them in varying locations on the prescription label. Veterans readily volunteered their opinions for this local quality improvement project.

"We became really interested in this PSI," said Erin Narus, NCPS pharmacist, "which was initiated by Joe Youngblood, the patient safety manager at Amarillo, based on the growing emphasis in this area. This PSI provided us with some foundational insight into how Veterans react to current VA prescription labels."

She and Keith Trettin, pharmacist and NCPS program manager, contacted Youngblood.

"Joe is also a pharmacist and has been a wonderful consultant," Narus continued. He had presented Veterans with three different label types, with data elements located in different places on each of the labels. "It turned out the current label the VA was using ended up being the least preferred by Veterans."

She and Trettin began digging into the history of what she termed "the patient-centered label movement," which began a few years ago, with support from members of the VA's Pharmacy Benefits Management Services (PBM). "Both Jeanne Tuttle and Virginia Torrise had been making significant contributions at a national level within various expert advisory panels. By closely partnering with them, we were able to very quickly get to the heart of the issue," said Narus.

"The message is clear and consistent from the literature and expert advisory panel recommendations. Certain pieces of information on the prescription label are critical for the patients: the patient name, directions for use, drug name, drug strength and the use-by date," she added.

Narus said that the questions and proposed label designs used in the study she and Trettin are developing for the VA will be grounded in the foundational work of advisory panel recommendations from the American College of Physicians, the United States Pharmacopeia, the American Foundation for the Blind®, the California State Board of Pharmacy, and the National Association of Boards of Pharmacy.

The VA Medication Labeling Project

"We're looking to do a quantitative study," said Narus. "We will be asking specific questions about preference, usability and jargon interpretation – finding out if Veterans can understand the words we use on the prescription label."

Veterans will be directly involved in the effort to develop a single standardized prescription label for use within the VA. "We have gone out to 10 sites who have agreed to partner with us in this project," said Narus. "They will be hosting staff from a marketing firm that will administer surveys to volunteers who participate – Veterans and their caregivers."

"It's very important that we generate interest in this survey," said Trettin. "We are hoping to get between 60 and 90 Veterans to participate per site, so that would give us around 900 individuals." He said they anticipate three separate administrations of the survey at each site, with about 30 volunteers per session.

"We will be testing actual, proposed labels with our Veterans," continued Narus. "The labels will have data elements in different areas. We want to ensure that the final standardized version allows individuals to readily find information and understand what it is used for."

Trettin explained that it is the Veterans' perspective they want. "While we could take the recommendations and design a label based upon advisory panel guidance, it's important that we actually test the usability of that label with the user – the Veteran and caregiver."

Narus said that there are as many as 10 different label formats currently used around the VA. "So standardizing to one specific label format would be really significant," she said.

Once the final product is approved by the VA's PBM leadership, the standardization can take place rapidly.

Reformatting for a standardized label will not require changes to the VistA software, Narus explained, as changes will be made at the dispensing system level: "We'll use the existing label sizes and the existing machines – only the placement of the data elements will change."

Having spoken to a number of manufacturers, she is confident the changes can be made smoothly. "The manufacturers' representatives had noted certain constraints, but these will be added into the final review of our recommendations." Narus said. "We'll go to each of them and make sure that the reformatting will work. We want to give the PBM a solid product."

Trettin estimates the recommendations could be forwarded to the PBM by mid-spring 2011. "We have the major stake-holders from PBM on our steering committee, so that they can review the information as it goes along," he said.

Narus closed the interview by returning to the contribution made by

Joe Youngblood: "The part that I think is most exciting is that a lot of the momentum for this project originated at the facility level with an initiative by Joe, then a new patient safety manager, who developed a team at Amarillo to start talking to Veterans about their concerns and preferences. We are committed to carrying on with this effort to come up with a standardized VA-wide prescription label that Veterans can use – which we believe can have a significant impact on minimizing the risk of medication errors."

When VA Patient Safety Professionals Need Information

By Paula Allstetter, NCPS program analyst

The NCPS Patient Safety Information System, nicknamed "SPOT," is composed of more than 700,000 patient safety reports, with narrative event descriptions, and more than 15,000 root cause analyses. The latter include event descriptions, root causes, actions, outcomes, and lessons learned, as developed by root cause analysis (RCA) teams.

The database is used regularly by patient safety managers (PSMs) when working with RCA teams, and internally by NCPS.

We use natural language processing software programs, which analyze text, to retrieve data from SPOT. Our ability to retrieve relevant information is augmented by an NCPS-developed categorization process that we apply to all RCA cases submitted into the database.

VA employees can find detailed information on the categorization online at the NCPS Intranet site. Scroll down to "Primary Analysis and Categorization (PAC)."

Since more than 95 percent of the information in the incident reports is narrative text, successful categorization and ultimate retrieval of relevant information relies on clear and specific descriptions provided by those writing and submitting the reports.

We ask PSMs to complete all the data fields, providing as much clear and concise information as possible, so that when search requests are performed and results compiled, valuable data is available to all concerned.

PSMs must also keep the entries "de-identified" by excluding information that identifies specific people or locations: All identifiers must be removed before the data can be shared with others.

Often the search requests are expanded into Topic Summaries. In some cases, the data have been used to develop articles for *TIPS* or other publications.

When requesting a search, it is important to include "key words," such as location (operating room, emergency department, etc.), event (fire, misidentification, etc.), activity or process (monitoring, medication use, etc.), and actions (work area redesign, patient scheduling, etc.) that help clarify what data is needed. Explicit names of devices, medications, processes, or activities that are of interest should also be included.

We have developed a process that can be accessed through the NCPS Intranet site to speed up the search process.

VA employees can go to the NCPS Intranet site, scroll down to the bottom of the page, and click on the "Request National RCA Database Search." As you will see, your request will be sent via email to our team of NCPS analysts. Depending on the request, or if nothing is available in the database, we may be able to recommend other sources for the information.

If you need additional help, you can contact other members of the NCPS staff, too, such as those in the recall program, our biomedical engineers or our pharmacists. If you don't have a specific name, use the general NCPS email, *ncps@va.gov*, and your request will be forwarded to the appropriate staff member. Facility suicide prevention coordinators are the best resource for information regarding the topic of patient suicide or para-suicide. You can also try searching:

- MAUDE – *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm*
- FDA – *http://www.fda.gov/Safety/Recalls/default.htm*
- Alerts and Advisories are on the NCPS Intranet site for VA employees

Some requests are simple; others more complex, requiring more time. Remember, especially if you are on a tight deadline, please allow five or more business days for search results to be completed. If it is emergent, please indicate why: Every effort will be made to get it done for you as quickly as possible.

Once pulled, the data is checked for any identifiers before it can be sent.

Data is sent to requestors using the VA's established secure methods. Data is only to be viewed by the requestor and those involved in the project. We recommend that search products be destroyed once an RCA team project is complete. Search request data, even though de-identified, is still considered very sensitive and protected under 38 U.S.C. 5705.

If you have any further questions please call your NCPS program analyst and we will be happy to point you in the right direction.

Note: I would like to thank my colleagues at NCPS, particularly the other analysts, for assistance developing and reviewing this article.

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NCPS program manager. "When people at the local level tell us about a potential problem, we act on it."

Sources for Alerts and Advisories can also come from external organizations, such as the ECRI Institute, the FDA, or from manufacturers.

"But an internally reported problem to me is a gold nugget compared to information coming from the outside," added Patail. "Finding the problem first adds to the VA's reputation for a commitment to patient safety."

"Issues identified through a VA investigation often mean the same problem is occurring around the country," said Bauld. "Even when others don't report a problem, the VA's Alerts and Advisories, published on our Internet site (*www.patientsafety.gov*), help the entire medical community."

"We have also been actively involved with the FDA," he continued. "When we were working on an Alert having to do with contamination of hemodialysis machines, we talked to the FDA. We found out they had done a similar Alert 11 years ago. Our FDA counterparts were very pleased that we were doing the new Alert, bringing the information up to date and making it public."

NCPS biomedical engineers often talk to the manufacturer to reduce or eliminate a vulnerability.

"We really do push the manufacturers," said King. "There are times we have spoken with them and they say, 'Well, that's in our instructions.' And we say, 'That's well and good, but if somebody can mistakenly do this with the device, regardless of your instructions, they will. So can you think of some design improvements to reduce the vulnerability?' "

She added that NCPS biomedical engineers often give manufacturers suggestions they think can make a device safer.

Bauld spoke of an example having to do with a hospital bed footboard that could entrap a Veteran's feet. The issue is particularly important for patients who either temporarily or permanently lack the ability to feel pain in their feet.

"In this case," Bauld said, "it was an NCPS team that took the problem on – not just us – clinicians and others had a chance to look at the footboard and come up with ideas on how to make it better. Our human factors people were really a key in this effort, too. Like an RCA team, the multi-disciplinary approach really works."

Patail noted that design problems cannot always be solved by a single manufacturer. "Sometimes the fixes mean having to write a standard,"

Bauld added, "Sometimes the problem is encountered on all devices of the same kind, regardless of who makes them, so we can become involved in developing an industry-wide standard."

"Developing a standard involves making a fundamental change in the way a device is made and produced," he continued. "Bryanne initiated an effort to develop international standards for gas and fluid connectors. A misconnection between medical device tubings can create a major risk to a patient."

Teams that work to develop standards often include a wide range of disciplines, such as medical, purchasing and legal. "We come together to find standards that are right for the VA and right for our patients," said Bauld.

NCPS biomedical engineers have also been able to work on projects centered on future advances in device technology, such as biometrics.

Biometrics is focused on developing new ways to identify patients, without relying on "proxy devices," such as wristbands or identification cards.

"We are trying to get away from things like wristbands, which have all sorts of drawbacks," said Bauld. "Biometrics can create a unique link to a patient, using methods like iris, veins, fingerprints or facial recognition."

"There is a great deal of technology out there, but using it in a medical facility creates a lot of challenges," added King. "Many of our Veterans are missing limbs, so using finger prints could be a problem. If a patient needs a medication at night, and the eyes are closed or bandaged, iris recognition would be a problem."

Biometric devices – for VA's applications – are expected to have at least two independent methods of identification and to have a bar code scanner as a backup.

"And we want to make sure the device doesn't spread contamination to another patient," Patail continued, "so touching it adds to the difficulties."

Hazard Summaries are another issue that NCPS biomedical engineers develop and disseminate. "Instead of issuing individual Patient Safety Alerts or Advisories, which are very focused, we sometimes develop a Hazard Summary," said DeRosier, "which includes a lot of different issues that can contribute to a problem."

"For instance, we are developing one on suicide risks," added Bauld, "because there are so many issues involved. We create the summaries to give PSMs and clinicians an overview of things to access in their environment."

The biomedical engineers also work with a number of organizations outside the VA. "We learn a lot that we can pass along," said Bauld. This can include making presentations at annual professional meetings. "We like to present the case that the VA is actively working on things across the nation. Attending and making presentations at these kinds of meetings is an important way to do that."

Conclusion

Regardless of the issues that NCPS biomedical engineers face, as Patail noted, the focus is on problem-solving. "In order to solve a problem," he said, "you have to define it properly first. This can easily take more time than solving it. In fact, we often spend as much as 60 percent of our time just defining a problem."