Articles in this issue examine a broad range of human factors topics. The first article describes VA’s Purchasing for Safety Model which systematically evaluates and advises on purchases of medical devices or products to reduce potential patient safety issues. The second article explores use of human factors engineering to promote best practices in daily chlorhexidine gluconate bathing and prevent multidrug resistant organisms and healthcare-associated infections in VA. In the third article, an interview with Himalaya Patel, PhD, activities in VA’s Human–Computer Interaction and Simulation Lab which facilitate collaboration and communication around health IT projects are highlighted along with Dr. Patel’s thoughts on the future of health IT. The final article compares two usability testing models on different versions of a VA mobile application where lessons learned in the earlier study were leveraged in the later study and contributed to improved usability metrics in the resulting application. We conclude with our Spotlight series reviewing recent FDA guidance emphasizing improving the usability of medical technology.

As always, we welcome your questions, feedback, and ideas for new articles via e-mail to VHA10P2HFQ@va.gov.

From the Editor-in-Chief, Rachel Wiebe, RD, CPHS
Hospitals are realizing how important it is to consider patient safety when purchasing medical equipment and devices. Safety reports such as those filed with the Food & Drug Administration (FDA) under the Manufacturer and User Facility Device Experience Database (MAUDE) and in-house reporting systems have demonstrated that not all products are considered equal...

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mobile application (app), which VA designed for Veteran patients to schedule appointments. The evaluation included a pilot of the app in five New England VHA clinics. This version of the app, 2.1, combined the features of several previous standalone apps and allowed patients to...

FDA Releases New Recommendations for Human Factors Design and Testing of Medical Devices

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Many devices have been associated with recalls or adverse event reports in the past. VHA is getting ahead of the curve in objectively considering patient safety when purchasing medical equipment and devices in terms of usability, compatibility, and functionality as described in this issue’s article on the VA Purchasing for Safety Model. Others like the Food and Drug Administration (FDA) are thinking along the same lines.

Purchasing for Safety by Focusing on Human Factors and Performance

Helen J.A. Fuller, PhD, Office of Strategic Integration-Veterans Engineering Resource Center (OSI-VERC); Hasan Shanawani, MD, National Center for Patient Safety (NCPS); Kyle M. Maddox, BS, OSI-VERC; Nancy J. Lightner, PhD, OSI-VERC; Tandi Bagian, MS, NCPS

Introduction

The Veterans Health Administration (VHA) is the largest health care system in the United States. It possesses a great deal of purchasing power. As a government entity, VHA has a commitment to impartiality, and all purchasing decisions must be explicit and transparent. The goal is to have medical products and devices that will best serve the needs of the Veterans at the best possible cost to honor its responsibility to taxpayers.

A prototype for meeting these goals is the Purchasing for Safety Model. The model was developed as a joint effort between two VA groups: the National Center for Patient Safety (NCPS) and the Veterans Engineering Resource Center (VERC). The model and two pilot efforts that used the model are described below.

Purchasing for Safety Model

The Purchasing for Safety Model is a procedure for investigating medical devices or products with an end goal of influencing the purchasing decision. The process begins with either a concern with an existing item or the need to purchase a new type of item.

The Purchasing for Safety group begins by assembling a preliminary test team and meeting with the individual
or group that identified the need for investigation to learn about their areas of concern and start to define the scope of the project. They also review the Lessons Learned database and test plans from similar previous projects.

The first stage is data collection. The team identifies potential stakeholders and subject matter experts. After meeting with representatives from these groups, the team documents the expected use, ranges of use, and known hazards for the product. Other references include the manufacturer’s webpage, in-house reporting systems, databases of safety reports such as MAUDE and ECRI, and Internet searches. Following this, the team should identify other comparable products on the market and in use in their hospital system. They also should document the purchase and use history in their hospital system. Finally, the team identifies relevant standards for the medical product or device in question. Some possibilities are FDA, International Organization for Standardization (ISO), American Society for Testing Materials, Institute of Electrical and Electronic Engineers, American Medical Association, Code of Federal Regulations, Center for Disease Control, and Emergency Care Research Institute. The team should record any product requirements identified, including relevant testing protocols.

After scheduling a meeting with stakeholders to refine the scope of the project, the team can proceed to the testing stage. First, the team develops a list of tests with references. These may include use tests and performance tests for concerns such as material strength and fatigue testing. The team creates a test plan, acquires necessary equipment, and performs a dry run or pilot test. Finally, the team can implement the test plan, iterating as necessary, and documenting carefully. At the completion of each test session, the team conducts an internal debrief session to discuss concerns, collect feedback from testers, document lessons learned, and modify the test plan if necessary.

The next step is the reporting stage. The team drafts a report with all relevant findings and distributes it to the agreed upon stakeholders. This may result in procurement decisions, discussions with manufacturers, an in-house alert, and/or sharing information with government agencies such as the FDA. Finally, each team member completes a Lessons Learned form to facilitate future investigation efforts.

**Pilot Tests**

The VERC and NCPS conducted an investigation of bedside and leg urine collection bags after receiving reports of possible failures. The team compiled potential failure modes based on user reports from an in-house reporting system and a search of the MAUDE database. They also identified ISO standards and test protocols for urine collection bags. Based on these, the team devised a list of tests and used them to investigate performance of a subset of bags available for purchase by the VHA. The result was documentation of certain failures as well as performance differences and recommendations for purchase.

The team also used this method to investigate compatibility between integrated evacuation devices and bed/mattress combinations. In addition, this project considered compatibility with different patient characteristics such as height, weight and need for portable oxygen. For the evacuation stage after the device was removed from the bed, the team also considered compatibility with the use environment. Next steps for this project include expanding the investigation to include portable evacuation devices.

**Summary**

The Purchasing for Safety Model can help hospitals and health care systems to evaluate medical products and devices systematically for issues that may lead to patient safety concerns. It combines a search of existing databases for known problems, a compilation of current product criteria in the form of standards, and well-documented testing of products to aid users in making purchasing decisions. The greater formality will help hospitals justify purchasing decisions, and the thoroughness of the investigation will promote patient safety. By conducting careful testing and documenting methods and findings, the test team can assist stakeholders in making purchasing decisions that may ultimately result in better patient care.
Application of Human Factors Framework for the Implementation of Daily Chlorhexidine Bathing in non-ICU Settings

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The HERO Center is home to a group of core and affiliated investigators who undertake interdisciplinary research and quality improvement projects for MDRO and HAI prevention. The first project is to implement daily chlorhexidine gluconate (CHG) patient bathing in non-Intensive Care Unit (ICU) patient settings within multiple VA facilities. Daily bathing with CHG is a key proven intervention for reducing MDRO HAIs in ICU settings and there is emerging literature to support its use in non-ICU settings as well.

We are using the Systems Engineering Initiative for Patient Safety (SEIPS) as the main conceptual framework to inform both the implementation and evaluation of the intervention. The SEIPS model has been used extensively in implementing and evaluating interventions in healthcare.1-3 The SEIPS model4-9 focuses on five interacting elements of the work system—person, tasks, tools and technologies, physical environment, and organizational conditions. Interactions of these elements affect care processes (e.g., patient bathing), which result in patient outcomes such as quality of care and patient safety, and organizational outcomes such as efficiency.

SEIPS Model Applied to CHG Bathing

Figure 1 shows the conceptual model and adaptation of the SEIPS model to the process and outcomes of daily CHG bathing. In this study, we examine changes related to each aspect of the work system of the SEIPS model. For example, various people are involved in the implementation of the CHG bathing intervention including providers, nurses, nursing assistants and patients. Their perceptions about performing this daily task and engagement are critical. The main tasks are provision of the bath and adherence to the recommended daily frequency, and employment of standard bathing steps. The bathing task is performed by either the patients themselves and/or nursing staff. The requirement for daily bathing may influence nursing workload and workflow. Time management may influence the quality of bathing. Role ambiguity (uncertainty about how and when to apply CHG) may exist for patients who self-bathe compared to those where the bath is provided by a clinical team member. The tools involved with this bathing intervention are the CHG product and other bathing supplies. Technologies used include the electronic medical record (EHR) for documentation and in some facilities, electronic orders. Key members of the organizational team include both the research and field (operations) staff working closely together. The safety culture of the organization and the nursing unit are critical factors influencing uptake/fidelity of the intervention. The main hospital environment is within non-ICU patient care units. Environmental issues include laundry facilities, patient privacy concerns, and adequate room layout and temperature.
Our Experience

The HERO Center is using a stepped-wedge design to sequentially implement CHG bathing in four VA medical centers. This design allows us to learn from each implementation site before we move to the next site.

The initial site selected for implementation is a 20-bed medical-surgical unit at the William S. Middleton Memorial VA Hospital in Madison, WI. The intervention start date was Fiscal Year 2016/Quarter 3. The planning phase began with research and quality improvement staff engaging key stakeholders at the facility including nursing management, unit staff and infection control. These planning meetings addressed prioritization of the work systems needed to support facilitation of successful implementation including bathing products (tools), documentation (technology), workflow (tasks), staff training (persons), and policies/procedures (organizational).

In addition, the study team provided information on how fidelity to the intervention would be monitored (bathing observation, skin swabs to evaluate for presence of residual CHG, unit staff and patient interviews to understand acceptability). The team identified that routine daily bathing was a unit priority and substitution of CHG soap in place of the hospital-approved soap would not change the nursing workflow substantially. For this reason, unit champions were not utilized to facilitate staff engagement and implementation of intervention. Once products and policies were in place, clinical staff training was conducted with nursing management responsible for training staff that missed initial training sessions. A one-month initiation period was provided to allow staff to gain competence prior to planned observations.

Once observations started, the study team identified that CHG soap was not being used consistently. The study team held a focus group with frontline nursing staff (nursing assistants and health technicians) to discuss barriers to the intervention and brainstorm possible solutions. The focus groups revealed important barriers to implementation. The main themes identified by frontline staff were: 1) interrupted workflow during CHG bathing process; 2) inadequate educational training and tools provided; 3) concerns with CHG bathing product; and 4) miscommunication between clinical staff and patients. Staff identified that having to use both CHG on the body and hospital-approved soap for face and perineum interrupted their work flow. Staff did not recognize the intervention was intended to be a practice change, but instead thought they were testing the CHG product. Staff did not feel they were adequately trained by the study team on the rationale for CHG bathing and in turn, could not discuss adequately with their patients. Staff noticed that the CHG soap did not foam or lather and felt that it wasn’t getting the patient clean. Staff also requested better tools such as fliers and posters that would assist both staff and patient understanding of the intervention.

Another barrier to implementation we identified was varying levels of readiness at all levels of the organization —facility level, unit level and individual staff level. Themes identified include 1) costs (e.g., concern for CHG product cost), 2) resources (e.g., staffing levels, time per patient), and 3) staff preferences (e.g., use of CHG versus standard soap).
With this feedback, the study team and clinical staff members decided to “restart” the project. Since the identification of these barriers, the team has done the following: 1) Revised nursing policy to improve workflow, 2) Created additional educational sessions and posters for staff, and 3) Created posters and fliers for patient education. The unit now feels more prepared to implement the intervention.

This project illustrates the challenges of bridging the gap between evidence and practice, the need to understand barriers and address those barriers quickly. Healthcare workers often encounter organizational and other barriers after implementation of infection prevention initiatives that impede full implementation, and early and frequent evaluations are useful to devise strategies to ensure high fidelity to an intervention. We have found that application of the SEIPS model during implementation evaluation may facilitate identification of barriers.

Using our experience, we have several recommendations to enhance uptake and adoption of an intervention: 1) Assessing readiness for change at all levels of the organization. One such tool is the Organizational Readiness for Change Assessment developed and utilized by the VA that assesses organizational readiness for implementation of a specific, evidence-based clinical practice. 2) Use of a system and human factors engineering model to undertake a comprehensive assessment of barriers. 3) Using clinical unit champions to serve as key resources for education, training, content expertise and peer to peer coaching. Finally, 4) ensuring leadership support.

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Evaluating the Future of Health Information Technology: An Interview with Himalaya Patel, PhD

Helen J.A. Fuller, PhD, OSI-VERC

Himalaya Patel, PhD manages the Human–Computer Interaction (HCI) and Simulation Lab, located at the Richard L. Roudebush VA Medical Center in Indianapolis, IN. The HCI Lab increases accessibility to staff and Veteran patients. This facilitates collaboration and communication on projects. As lab manager, Dr. Patel gets a close look at the use of VA’s health information technology (HIT), sometimes before widespread implementation.

Helen J.A. Fuller: How were you introduced to the concept of human factors?

Himalaya Patel: My formal introduction to human factors, specifically human-computer interaction, was in an undergraduate elective course offered by my university’s computer science department. This exposure led me to graduate studies in informatics and human-computer interaction. As a graduate student, I learned about related topics ranging from social psychology to neuroscience. These topics influenced my research on interaction with humanlike computer interfaces.

HF: How do you use/employ human factors in your work?

HP: We use human factors approaches to evaluate various HIT staples at VHA, including the Computerized...
Patient Record System (CPRS) for clinicians and check-in kiosks for patients. We are also planning to evaluate forward-looking applications like the VA Mobile ecosystem for on-the-go clinicians and a new national telestroke program focused on Veteran patients in rural areas.

Our lab focuses on human factors research methods. In designing user studies, tradeoffs are expected. You can observe users, but that makes it difficult to ask repeatedly about their thought process; you can ask them what they’re thinking but you can’t assume they are working as they would normally. Planning observations or interventions to address the questions you’re trying to answer is a recurring challenge. However, I find it fun, and I doubt I’m alone.

HF: What human factors–based project do you feel made the biggest impact in VHA? Why?

HP: Naming a single project is difficult, as is assessing the extent of its impact. One body of work I cite frequently comes from the Health Services Research & Development Center of Innovation at DeBakey VA in Houston, TX which has improved our understanding of the sociotechnical processes shaping the use of HIT in VHA. Naturally, I should also mention the work going on at our own Center of Innovation in Indianapolis. We prototyped an evidence-based user interface for consultation orders, which increased satisfaction and decreased perceived workload amongst primary care clinicians. My colleagues have identified ways to improve the presentation of drug-drug interaction alerts.

Fortunately, the gap can be short from human factors research to implementation. Human factors projects can directly inform software projects like the Enterprise Health Management Platform, which is being primed to replace CPRS as the main entry point for patient records in VistA.

HF: Where do you see the greatest potential for the application of human factors principles in VHA?

HP: Beyond improving the efficiency, effectiveness, and satisfaction of clinicians, which is itself a big task, we could improve how patients interact with VA HIT. We could do more with patient-facing tools like My HealtheVet. For example, one of our studies relied on its Secure Messaging component, specifically its potential role during medication reconciliation.

HF: Have you seen changes in the interest in or awareness of human factors in VA? What are they?

HP: What stands out to me is the fragmentation of human factors knowledge and advocacy. For instance, consider VA’s different online venues: Discussion threads pop up at VA Pulse, a few training courses are on the Talent Management System, and in the caverns known as SharePoint sites, some are better furnished than others. (Note to self: Update the HCI Lab’s SharePoint page.)

I believe we can improve this situation through collaboration, including cross-training and joint projects. For example, researchers are not necessarily great at operations work, and vice versa. Reaching out to clinicians would also help. Ideally, the outcomes of such projects would benefit everyone involved.

Usability Examinations of Two Versions of the Veterans Appointment Request Mobile App
Jane Robbins, Human Factors Engineer, John Brown, Usability Specialist, Ashley Cook, Human Factors Engineer, and Nancy Wilck, Acting Director, Human Factors Engineering, Office of Informatics and Information Governance

In 2015, the Human Factors Engineering (HFE) team performed usability testing on the Veteran Appointment Request (VAR) mobile application (app), which VA designed for Veteran patients to schedule appointments. The evaluation included a pilot of the app in five New England VHA clinics. This version of the app, 2.1, combined the features of several previous standalone apps and allowed patients to enter information that had formerly been handled by VHA.
scheduling staff, allowing patients greater flexibility in making appointments.

After the pilot, HFE made usability improvement recommendations and subsequently the program office and development team issued a new version, VAR 3.0. HFE then performed a second round of usability testing on the new version in 2016.

This paper addresses the many challenges encountered during the VAR 2.1 study related to recruiting, participant dropout, difficult-to-analyze data, and conducting unmoderated usability testing on mobile devices. It also shows how the VAR 3.0 study took advantage of the lessons learned in the earlier study, simplified the study plan, and encountered a smoother process. Additionally, the enhancements made in the new version improved the user experience with the app. As a result, usability metrics – including patient satisfaction and task completion – improved considerably in the second version.

VAR Version 2.1 Study

For the VAR 2.1 study, HFE employed a remote unmoderated mobile usability testing tool to support testing with a representative sample of geographically-dispersed Veterans. The team also used moderated interviews and questionnaires, as detailed below:

- **Remote unmoderated mobile usability testing:** A commercially available tool was configured to allow app testing on mobile devices owned by the recruited participants. This tool managed the presentation of predefined tasks (including appropriate randomization and task counterbalancing), presented questionnaires, and captured task completion and questionnaire data along with videos of participants as they used the app.

- **Remote moderated interviews using a survey tool:** Participants were asked to interact with the Help resources developed to support the app in order to recommend improvements for Help resources. The team also set up phone interviews to capture additional information after the unmoderated use of the app. During the interviews, the HFE moderator used the survey tool to prompt for questions and to expedite reporting by structured note taking.

A vendor recruited 60 participants from a predefined user group, balancing the population to mimic the Veteran patient population by targeting half on each side of the median Veteran age (65 years old), as well as an equal distribution of mobile and desktop device ownership. Although HFE had pre-tested the study configuration, Veteran participants encountered a variety of technical issues accessing the app and using the unmoderated testing tool. These technical issues prevented HFE from collecting the amount and quality of data as called for in the original study design.

Technical issues were more common with older Veterans with a low to moderate level of technical expertise. Many of them used Android mobile devices; but the testing tool was less stable on that platform compared to the iOS (Apple) platform. This resulted in difficulty recruiting, retaining, and completing sessions with participants. The study experienced a dropout rate of 93%.

As the study progressed, the number and variety of technology compatibility issues became evident. HFE concluded that the study needed to be greatly simplified, so the study was paused. Many lessons were learned about recruiting older, less technically-savvy participants. HFE also learned which methods were best for evaluating the usability of a mobile app in conjunction with a complex live field test.

When the study restarted, the following methods were used in the redesigned study:

- **Diary study:** HFE discontinued further use of the unmoderated mobile usability testing tool. Instead, the team asked participants to use the app on their own, documenting their experience in a diary using a template provided by the study team.

- **Remote moderated interviews using a survey tool:** The team expanded the use of follow-up interviews to expand on questionnaire data that originally was collected via the unmoderated mobile usability testing tool. These surveys also supplemented diary study feedback. As before, the HFE moderator used a survey tool to prompt for questions and to take notes.

- **A communications audit and analysis:** The team performed an audit of communications between the
recruiting vendor and Veterans to expand understanding of the reasons for participant dropout.

This revised design enabled the HFE team to successfully complete the study and deliver the app improvement recommendations to the sponsoring office.

**VAR Version 3.0 Study**

After the program office and development team incorporated many of the recommended enhancements into the app, HFE conducted in-person usability testing of VAR 3.0 at its Informatics Research & Design Center using the same types of mobile and laptop devices owned by the recruited participants. The devices used by participants during the study were VA-owned and configured to reduce connectivity issues. The moderator assisted participants with technical issues as necessary.

The study design for VAR 3.0 included several of the basic tasks from the original study, but included three direct scheduling tasks so that the learning curve of the app for Veterans could be examined. The study team also included a new task to explore if Veterans could find a feature used to send feedback to the VHA about the app, a feature found on many VHA apps.

- **In-person moderated mobile and laptop usability testing:** The HFE moderator presented a set of tasks and captured videos of participants as they attempted task completion. Test data was used for all tasks.
- **Moderated use of a survey tool:** The moderator had the participants complete questionnaires before and after study completion, as well as after each task. The data was recorded on an iPad by participants using a survey tool.

The lessons learned from VAR 2.1 that were incorporated into the VAR 3.0 study resulted in a greatly reduced dropout rate. Technical issues arose early in the study due to server issues, but the development team resolved them by moving testing to a more stable, but identical, environment.

**Comparison of the Two Versions**

![Chart Data: VAR 2.1 Tasks](image)

![Chart Data: VAR 3.0 Tasks](image)

*Figure 1: Comparison of Task Success between Versions 2.1 and 3.0*

Aside from the ease of data collection and participant recruitment, the metrics for the app indicated significant improvements. Participant satisfaction with the app, as expressed in the System Usability Score (SUS), rose
from 79.3 for VAR 2.1 to 88.5 for VAR 3.0. Additionally, while 80% of participants said they would recommend VAR 2.1 to other Veterans, 100% of VAR 3.0 participants said they would recommend the app.

Most significantly, the average task success rate leapt from an average of 29% to 83% between the two versions. In VAR 2.1, Veterans using the key functionality of the app - the ability to book online appointments - completed the task only 10% of the time, whereas VAR 3.0 test participants succeeded over 93% of the time (averaged over the three tasks). Only 20% of VAR 2.1 test participants were able to view their appointment but 92% of VAR 3.0 participants were able to do so.

Additionally, by including three sequential scheduling tasks of the same type in VAR 3.0, HFE was able to examine the impact of learning by the participants. The majority of participants completed all three tasks and 84% felt that the app got easier to use with practice.

**Conclusion**

Because of the high dropout rate and technical barriers, the initial study design for the VAR 2.1 study did not allow for collection of sufficient data to analyze. Once the VAR 2.1 study was redesigned, data analysis was difficult because the methodology changes increased the amount and diversity of the data. Despite these limitations, it was apparent that Veteran participants had difficulties with the app itself. HFE made qualitative observations and provided its resulting recommendations for improvement to the sponsoring office.

For the VAR 3.0 study, HFE more carefully controlled the study scope and methodologies used, which allowed for more efficient data collection. Providing an in-person moderator also reduced the technical barriers. Therefore, HFE gained a truer picture of the user experience with the app. The app itself became easier to use due to numerous changes made between VAR 2.1 and VAR 3.0, and this was reflected in the SUS scores and success metrics received during the second round of testing. The metrics collected showed that the enhancements greatly improved the usability of the app, and provided assurance to the VHA program office that the app would be useful in helping to improve Veteran access to care.

**FDA Releases New Recommendations for Human Factors Design and Testing of Medical Devices**

Rachel Wiebe, RD, Office of Technology and Information Strategy, Veterans Health Administration

Many devices have been associated with recalls or adverse event reports in the past. VHA is getting ahead of the curve in objectively considering patient safety when purchasing medical equipment and devices in terms of usability, compatibility, and functionality as described in this issue’s article on the VA Purchasing for Safety Model. Others like the Food and Drug Administration (FDA) are thinking along the same lines.

Last year the FDA released new guidance emphasizing improving the usability of medical technology. While the recommendations and considerations are non-binding, FDA advises both industry and manufacturers to incorporate the principles of human factors to improve the design of devices and in studies to evaluate the user interface of products to eliminate or mitigate potential use-related hazards.

- Adjusting design up front to manufacture devices that provide effective displays, controls, packaging,
product labels and instructions for use is safer than relying on training or expecting users to refer back to information - Right? We agree!

- Check out the FDA final guidance document for Applying Human Factors and Usability Engineering to Medical Devices.

- Applying underlying Human Factors principles in studies during development, investigational use and marketing of devices and products offers opportunities to increase the likelihood that product interfaces will be safe and effective for use for the intended users, the intended uses and environments.
- FDA offered recommendations in February 2016 on timing and sequencing of Human Factors studies and how Human Factors studies relate to other clinical studies of new products as well as process considerations. While still draft, the Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development guidance is well worth a look.

Your VHA Human Factors Newsletter Editorial Board gives this FDA guidance two-thumbs up!