The Fall 2018 issue of the Human Factors Quarterly discusses various methods human factors professionals use to learn about, evaluate, and direct work in health care settings. In the first article, Jolie Dobrue describes how heuristic evaluation and usability testing were employed to understand user challenges and evaluate potential solutions for a web application that clinicians use to view electronic health records. In the next article, Tim Arnold, Scott Wood, and I show how viewing patient safety reports through a human factors lens can help us understand the connection between product changes — even ostensible improvements — and safety risks. The third article, by Jeanie Scott, focuses on translating knowledge about safety concerns into actions for the field, in the form of standards for health information technology (HIT) safety and usability.

In this issue’s interview, Robin Mickelson describes some fascinating techniques she has used in her research to understand the motivations and beliefs behind patient actions. Finally, Jane Robbins, Ross Speir, and Thomas Callaghan introduce a toolkit based on knowledge gained from five years of usability evaluations to provide usability guidance for the development of Computerized Patient Record System (CPRS) templates.

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

From the Editor-in-Chief, Helen J.A. Fuller, PhD, VA National Center for Patient Safety
From Study to Software: Implementing Human Factors Recommendations in the Joint Legacy Viewer (JLV)

Jolie M. Dobre, Human Factors Engineering (HFE), Office of Health Informatics (OHI)

The Joint Legacy Viewer (JLV) is a web application co-developed by the Department of Veterans Affairs (VA) and Department of Defense (DoD) for viewing electronic health records from DoD, VA, and Health Information Exchange Partners in near real time. The VHA Office of Health Informatics Human Factors Engineering (HFE) Office and JLV teams have been working together since June 2016 to improve the user experience for JLV users in VHA, DoD, and the Veterans Benefits Administration (VBA)...

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Jeanie Scott, MS, CPHIMS, Informatics Patient Safety, OHI

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Spotlight: Usability Toolkit for CPRS Clinical Reminder Dialogue Templates Is Coming!
Robbins, Jane, Speir, Ross, and Callaghan, Thomas, HFE, OHI

Over the past five years, HFE has performed usability evaluations on over 30 Computerized Patient Record System (CPRS) templates. This work ranged from a suite of Tele-dermatology templates, used by clinicians to support dermatology for Veterans in remote areas, to the Gateway to Healthy Living template, used by VA staff to encourage...

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From Study to Software: Implementing Human Factors Recommendations in the Joint Legacy Viewer (JLV)
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Over the past five years, use of JLV has grown exponentially. Rapid growth of a health Information Technology (IT) product often results in the identification of areas for improvement. With JLV, users were frequently affected by system performance challenges or felt overwhelmed by the amount of data available to accommodate the information needs and workflows of both VA and DoD. In addition, as JLV continuously evolved, users had trouble staying abreast of new features and capabilities.

To help alleviate these growing pains, HFE performed four heuristic evaluations and ten usability studies with
JLV end users across VHA, VBA, and DoD. The studies focused on understanding current user challenges and testing possible improvements. Ten unique application features were studied, with two studies centered around the Report Builder feature. This article focuses on HFE findings related to Report Builder with emphasis on VBA workflows and related changes already made in JLV (with others in the pipeline) to address HFE recommendations.

VBA staff began to use JLV in the fall of 2014 and have come to rely on it to meet evidence requirements for claims processes ranging from claims development to rating decisions to quality reviews and appeals. As of end of the third quarter of fiscal year 2018, more than 95% (16,481 of 17,294) of authorized VBA JLV users had used JLV at least once. JLV enables VBA staff to locate quickly and download DoD treatment records on-demand to support Veteran benefits claims rather than relying on the old, slower methods of requesting and waiting for hard copies or visiting military facilities to obtain records. According to VBA users interviewed (Carter & Dobre, 2017; Dobre & Herout, 2017; Carter & Dobre, 2018), JLV has revolutionized the claims process, greatly reducing the time and effort needed to assemble records and evaluate a claim.

In July 2016, JLV introduced the Report Builder Feature, which enables users to select documents and data items displayed in JLV and compile them for export in a single formatted PDF file. There are many uses for this feature, including in clinical and health care operations workflows. VBA staff workflows require assembling claim documentation in a separate application called the Veterans Benefits Management System or VBMS. Before the Report Builder in JLV, VBA users would open and print individual records to PDF, then upload each one to VBMS. Report Builder automated much of that manual effort by enabling users to generate a custom report by selecting any items or combination of supported documents and details from the summary or expanded views of widgets.

With the release of Report Builder, usage of the feature by VBA JLV users increased quickly, as did the volume of records they sought to add to reports and to download. Users began reporting issues with performance speed and reliability as well as frequent system crashes and errors followed by loss or failure of the report, which might have taken several hours to assemble. In 2017, JLV engaged HFE to study how users engage with the Report Builder and to gather feedback on planned enhancements. The study team’s goals were to understand current context of use for both VHA and VBA users, as well as their understanding of current functionality and their opinion of future enhancements in the development backlog.

HFE found important differences between VBA users and VHA clinical users. While clinical users prefer line items (e.g., a lab result from a list), VBA users are interested in complete details (e.g., all content of a clinical note or report). Clinical users select a dozen or fewer items, while VBA users select dozens, even hundreds, of records to add to the Report Builder. Because of the volume of records, VBA users had developed workarounds when adding items to Report Builder to avoid problems building the report. For example, some created small reports of 10 or fewer records then used Adobe Acrobat to assemble them into one larger report. Others had a mental list of system cues (i.e., an attachment type, description, or file size) that might help indicate a corrupt file (which caused the Report Builder to not compile or to crash).

The first enhancement to the Report Builder to address some HFE findings came in April 2017. JLV added cues to the Report Builder interface to convey the success or failure of the ability to add each item prior to generating the report. This revealed corrupted data in advance so it could be removed from the build to increase report build success. In May 2018, a major technical redesign of the Report Builder was completed to improve performance speed and usability as well as reliability of report generation. The redesign established dedicated server resources to support the feature and changed the approach from synchronous to asynchronous, enabling users to build reports in the background and to be notified when the reports are ready, as well as to access their previously built reports for 72 hours.

"I eat sleep and preach JLV...[it] has been a lifesaver in the claims development process, especially being able to go straight to DoD to get documents. You heard the horror stories in the past from claims being a year, two years old; a lot of that was because of
Did making the changes in response to HFE recommendations work? What do VBA users think of the changes to Report Builder thus far? To start answering these questions, we interviewed a Rating Veterans Service Representative who used Report Builder extensively from the time it was introduced and following the changes. He shared that before the improvements, it was “clunky” and slow or performance would vary based on how busy the system was. He often experienced “freezing” of his reports in the middle of building them because too many documents or documents that were too large were included. This required him to create multiple smaller reports as a workaround. Since the May 2018 changes, he had not experienced freezing of reports or errors, even with very large and/or numerous documents included. Instead of an afternoon trying to get all the records he needs to upload to VBMS, the same work is taking 30-45 minutes, with most of that time spent reviewing the record to identify and add needed items to the Report Builder. In addition to improved performance speed and reliability, he appreciates how reports build in the background while he moves to another task instead of sitting and waiting for it to finish like he used to. Finally, our VBA interviewee observed that the evolution and progress with JLV over several years have made JLV much more effective and useful in his role.

How Product Changes Influence Use and Patient Safety

Fuller, Helen J.A., PhD, National Center for Patient Safety (NCPS), Arnold, Timothy J., PharmD, NCPS, and Wood, Scott D., PhD, Knowledge Based Systems, OHI

Changes in the design of medical products and devices can affect how a clinician interacts with a device, even if the underlying functionality of the device is the same. When a new device is brought into a health care setting, there is the potential to identify and address issues at various stages in the product use cycle, including acquisition, initial education, deployment, maintenance, and continuing education. However, the earlier issues are detected in the acquisition process, the greater the opportunity to make positive change and avoid risk to patients. In this piece, we argue that human factors and patient safety should be an integral part of any clinical acquisition, using examples identified from the literature and from VHA reporting systems of patient safety adverse events or near misses specific to the introduction of new or changed devices into the health care environment.

Human factors literature tells us that design changes may have impacts, both positive and negative, on usability and error tolerance (Wickens, 2004). Some changes may improve usability if, for example, they provide a better fit with the user’s physical or cognitive capabilities, allow use in a way that better fits the user’s workflow, align better with the user’s mental model, or are more error-tolerant (Weinger et al., 2010). For example, one oxygen delivery device included a thermal fuse intended to stop the flow of oxygen from an oxygen tank to a patient in the event of a fire. However, unlike most fuses, this thermal fuse only worked when installed in one direction; if installed backwards, the fuse would not work as intended, placing the patient at risk. The manufacturer changed the design of the thermal fuse to be bidirectional so that it works when inserted in either orientation.

Similarly, some design changes can improve some aspects of usability while dangerously breaking the user’s mental model in other ways. One common redesign flaw is when the new system breaks the user’s mental model by changing its behavior or how it indicates correct usage. For example, a transport monitor, which
displays patient vitals while they are being transported, added a training mode that allowed the device to display realistic patient data. This demonstration mode met an important training need, allowing users to view realistic patient data during training. However, the only indication that the device was in demonstration mode was a small, inconspicuous “D” on the screen (Gosbee, 2002). If users did not notice that signal, they would operate under an incorrect understanding of the patient’s condition. This example shows what can happen when the procurement process does not holistically consider all goals necessary for safe and effective use.

Other changes may have a negative impact that outweighs any positive benefits, sometimes in subtle, indirect ways. One such design change involved a portable oxygen tank. With the old tank, the user could start the flow of oxygen using only a valve on the top of the tank’s regulator to set the desired rate. The new tank required the user to turn a separate valve on the side of the regulator, prior to setting the flow rate with the valve on the top (Figure 1). With the new design, users may think oxygen is flowing to the patient based only on the top valve setting and fail to realize that the tank is not on. For example, if a clinician focused only on the top valve, it would be easy to miss the additional valve on the side of the regulator, which could be catastrophic. Although the company stated that the second valve was intended to improve safety when transporting and storing the tanks, they failed to recognize the need for additional training and the difficulty in forcing users to unlearn years of experience.

Figure 1. Diagram of oxygen tanks showing steps to operate. The new design requires that the user open the tank using Valve 1 and then set the desired flow of oxygen using Valve 2. The previous design only had one valve.

Another case involved a broken blade on a scalpel that was used for outpatient procedures in a health care facility. The facility had switched scalpel suppliers twice to avoid staff safety issues with other scalpel designs while working within the constraints of their existing procurement contract. It was not possible to determine whether the blade was defective, and there were no other identified problems with this lot, the surgeon reported that the scalpel felt less sturdy than the scalpel he was accustomed to using during this procedure, creating an unintended risk to the patient. In solving one problem, the facility may have introduced a different one, demonstrating what can happen when there are necessary tradeoffs between two systems goals, even when both goals emphasize safety.

In a final example, a labeling change that was likely initiated for safety reasons had an unintended consequence. One manufacturer changed their design of an IV bag containing heparin by replacing red text with black text, possibly to improve readability, as red text on a bag of clear fluid has low contrast. However, this made the IV bag look like a different, lower risk, product (Figure 2). The concern regarding the changed IV bag design was identified by a pharmacy technician during distribution. The heparin bag was stored next to normal saline in the storage area. The large block of red text, though difficult to read, was a salient characteristic of the heparin bag for individuals with normal color vision, and it is possible that clinicians, perhaps subconsciously, used it as a cue to identify the IV bag as containing a high-risk substance. By removing this cue, the manufacturer increased the design similarity between the two products and may have increased the probability of selecting an unintended product.

Figure 2. This is an illustration of the design change of an IV bag of heparin. The original design is (A), and the new design is (B). Compare each to a bag of normal saline (C). For a user selecting a bag quickly without reading the text, it may be more likely for him or her to confuse Bag B with Bag C than to confuse Bag A with Bag C.

Changes in medical product or device design can have profound human factors implications in both usability and patient safety. One way to avoid unintended consequences is to increase input from clinicians who use the devices. It is important also to document differences in product interfaces and operating instructions in order to improve end user training and point-of-use aids.
These goals can be best accomplished by including human factors and patient safety experts during product selection and deployment stages. Such inclusion in the procurement process would not only allow for a more comprehensive, holistic product evaluation, it would provide greater value to facilities, clinicians, and patients by identifying critical design flaws as early as possible.


A Different Set of Standards for Health IT Safety and Usability
Jeanie Scott, MS, CPHIMS, Informatics Patient Safety, OHI

When we discuss standards in the context of health Information Technology (IT), often the reference is to data, transport, terminology, and even security1. Messaging standards allow the exchange of data between systems. Building on data exchange are Transport standards. Fundamental to data exchange are Terminology standards.

Privacy and Security standards protect rights, access, and integrity of our health information. (See Table 1 for examples of these types of standards.) Whereas these standards are valuable for the complex, robust health information systems in use today, none have addressed effectively the concepts of safety and usability. With the introduction in 2011 of the Office of the National Coordinator for Health Information Technology (ONC) program for voluntary health IT certification came processes for implementing measures to ensure adoption of data, transport, terminology, and security standards2. The ONC Health IT certification has continued to develop with the latest 2015 edition.

<table>
<thead>
<tr>
<th>Table 1: Examples of Health IT Data Standards</th>
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<td><strong>Messaging Standards (Allow the Exchange of Data Between Systems)</strong></td>
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<td><strong>Transport Standards</strong></td>
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<tr>
<td><strong>Terminology Standards (Fundamental to Data Exchange)</strong></td>
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Health IT standards thus far have targeted the development of software products, specifically the vendor community, and ability to attest to ONC Health IT certification. To date, no single standard has taken the approach that safety and usability are a shared responsibility between the vendor and the health care delivery organization. Vendors attest under ONC Health IT certification for the quality and usability of products pre-market; however, the validity of the attestation statements is not transferrable upon actual implementation. To achieve attestation for quality management system (QMS) – how well is the system built and tested – attestation requires health IT developers to either use a recognized QMS or illustrate how their QMS maps to one or more QMS established by the federal government or a standards developing organization (SDO). Attestation for user-centered design – known as Safety-enhanced design – recommends vendors to follow NISTIR 7804 120 “Technical Evaluation, Testing, and Validation of the Usability of Electronic Health Records” with a minimum of 10 representative test participants for each category of anticipated clinical end users who conduct critical tasks where the user interface design could impact patients. Participants should not include employees of the developer company. Once deployed and implemented at a health care delivery organization (hospital or ambulatory care setting), the product(s) are often configured to meet the specific workflows and business processes unique to that institution.

In 2014, the Association for the Advancement of Medical Instrumentation (AAMI) proposed a new set of standards to address the safety concerns with the implementation of health IT. In the novel concept3, AAMI describes a set of health IT standards that address patient safety risk across the full life cycle of health IT use – from design and development to implementation, use, upgrades, and obsolescence. The Food and Drug Administration (FDA) currently recognizes AAMI/ANSI HE75:2009 for medical devices during the pre-market evaluation process. AAMI’s proposal for developing health IT standards identifies that risks for health IT do not end at the design and development stage; rather, the risks continue throughout the lifecycle. The proposed health IT1000 standard series aimed to articulate the various roles and responsibilities for quality, risk, and usability during each phase of the product lifecycle. As of October 2017, AAMI is completing the final approval for the first of four standards, health IT1000-14. The first standard aims to define fundamental concepts, principles, and roles in the health IT lifecycle. Subsequent standards are expected for Quality system principles and practices, Risk management process, and health IT usability. These standards represent a different kind of standard series: a series in which roles and responsibilities of those involved in creating, configuring, and using health IT include not only vendors but also the health IT product user community. The concept of a shared responsibility for usability continues to bring vendors, health care organizations, and professional groups together to develop better practices for design and operation of health information technology solutions.


Exploring Macrocognitive Workflow: An Interview with Robin Mickelson, PhD

Robin Mickelson, PhD, is a quality scholar with the VA Tennessee Valley Healthcare System. She comes to VA with a professional background that includes extensive experience as a clinician and informatician. After completing her PhD, she joined VA as a post-doctoral fellow in the Quality Scholar Program. Dr. Mickelson explores the cognitive and collaborative processes that unfold while emphasizing the patient’s part in medication management. She also discusses journaling as a technique for capturing user perceptions and its potential as an intervention throughout the continuum of care. At the 2018 International Symposium on Human Factors and Ergonomics in Health Care, she served as a panelist on the Patient Safety Track panel, “The Patient in Patient Safety: Starting the Conversation.”

Tim Arnold & Helen Fuller: What is your role with VA?

Robin Mickelson: As a quality scholar, we work on both VA research and quality improvement projects.

TA & HF: Can you tell us about some interesting VA projects you’ve worked on?

RM: My area of interest is the performance of patients. In other words, applying human factors methods to the understanding of what, how, and why patients do things with their health in mind, specifically medication management. During my PhD studies, I worked with Richard Holden on these patient work concepts.

TA & HF: What was the outcome of that project? What did you conclude?

RM: One thing that was very clear is patient work is very collaborative. There are many people involved in patient care and therefore it is a very macrocognitive process, but there are many barriers. Because there is such a difference between patients’ and clinicians’ knowledge and training, it makes it hard for them to come together as a team. A focus of my work is on sense-making and shared mental models. Patients do not understand the mental models of providers, and providers do not really understand the mental models of patients and these models are not adequately shared. We are doing some work now on patient-centered medication reconciliation and eliciting what medication information is important to patients to perform their medication tasks because that is what drives behavior. If providers do not understand what is driving patient behavior, then it is hard for them to support what patients do. A finding from our study is that providers do not generally ask about or verify the patient’s understanding of information. Perhaps integrating questions into nursing intake questionnaires that seek to elicit a deeper understanding into patients’ thoughts. One big takeaway from that work is that patients need more access communication and collaboration with providers. For example, improving communication channels and access to information. Provide patients with quick access to an expert because patients often will make a quick decision and feel like they cannot contact their provider.

TA & HF: What are some unique methods you often use to understand users? Can you describe these methods and how this can inform a user-centered design process?
RM: Specifically, one method I used in my dissertation work is a video diary, because it is difficult to observe a patient doing health work in their natural setting. We gave patients an iPad to record their medication activities. A video diary allows patients to document their processes without being so obtrusive. This method captured interesting aspects that could not be captured through an interview or other cross-sectional methods. We collected information on situational context and interparticipant variation over time. There is not a static way that patients manage medication, it can be variable from day to day.

RM: In an interview, patients sometimes try to sugarcoat the conversation, whereas when they are documenting their processes over the course of a week that is difficult to maintain and a truer picture is collected. Journaling worked out to be a really informative method for collecting data about what patients do to manage their medications. An unexpected finding was that patients really liked the journaling activity and they got a lot out of it personally; for example, it helped them become more aware of their medication process, and they felt good about helping other people and perhaps their provider also.

RM: One interesting finding was the emotional meaning of medications. Having a chronic life-threatening disease is highly emotional and emotions can drive medication management behaviors in a positive or negative way.

RM: The biggest drawback was that the technology itself was a little difficult for some of the patients to use. If I had it to do over, I would give the iPad to the patient for a week before actually collecting the data. I would have the patients document a fun project for a week so that they could get use to the technology, because 30% of the patients had never used a computer. I felt we spent a lot of energy just getting up to speed with the technology.

RM: Another method we are using with an upcoming Indianapolis VA study is card sorting, looking at cognitive requirements to organize medication for providers and I am going to use card-sorting to look at the information requirements of patients. With patients, you really have to come up with unique methods to gather data.

TA & HF: How can these methods inform the user-centered design process?

RM: These methods are useful in discovering what patients need to support their health work. I am always interested when I speak to providers about patients, “We all know what patients do,” It is just assumed: “They do this and this and this.” But patients really have unique requirements for tools and technology. For example, just a medication list, a provider likes it in a certain order by medication name or when the last thing that was prescribed. They then give this list to a patient and invariably the patient will redo the list and make it more user friendly to them, so they will organize the medications by time, because that is what is important to them: “Ok, when do I have to take this?” So, you’ll see these patient lists where they have everything listed by time and how much: “How many of these pills do I have to take and when do I have to take it?”

RM: So, we give them this list and we do not organize it that way to make it useful for them, so that is an example about what we don’t understand about what patients do and what they need in a tool.

RM: The team cognition concept is team members with individual roles and knowledge come together and create a shared understanding and that is one of the big challenges in the medication reconciliation study. Patients understand medication differently than providers. A lot of patients know the name of their medications, but a lot of them don’t, but they know what they look like, when they take them, how many they take, and they might know what it does. But the difference between the generic and the brand name is all very confusing. There is this difficult communication that goes on between providers and patients when they are trying to talk about medications because there is not an artifact that brings those two things together to make it easier for both people. That is one example about how this whole process could be made better if there were some tool or technique to facilitate communication between each other about medications.

TA & HF: What other techniques have you used in projects to understand how users think and make decisions?

RM: I hear of and look at studies and ask the question: How can we use those methods or how would that work
with patients? I think patients are part of the team but a very unexploited resource to improve the delivery of health care that is going to become really important in the future.

**TA & HF:** One opportunity to improve health IT systems is to enhance capabilities that promote a “shared cognition” across the care team. What are some knowledge elicitation techniques that could help articulate the needs of users as a team?

**RM:** There is a lot of work by Nancy Cooke about team cognition. Shared cognition can really be best studied by looking at communication. This is one way to capture team interaction. I think looking at communication—which in some ways is accessible—I think that is an interesting way to look at interactions between patients and providers. We used these techniques in the Caring Heart Study. We recorded appointments and wished we had more time to consider the flow and content of information through discourse analysis. Now with secure messaging, many patients interact electronically with providers. I think that is an exciting thing to think about.

**RM:** We are also doing a project on ICU diaries. In the ICU, when a patient is intubated or unresponsive in some way, the nurse primarily will document events that happen during the ICU stay. The family also adds to this diary. The diary helps the patient recover and can reduce anxiety in family members. We are looking at that process from a work systems perspective and studying how the diary fits into that recovery process.

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**Spotlight: Usability Toolkit for CPRS Clinical Reminder Dialogue Templates Is Coming!**

Robbins, Jane, Speir, Ross, and Callaghan, Thomas, HFE, OHI

Over the past five years, HFE has performed usability evaluations on over 30 Computerized Patient Record System (CPRS) templates. This work ranged from a suite of Tele-dermatology templates, used by clinicians to support dermatology for Veterans in remote areas, to the Gateway to Healthy Living template, used by VA staff to encourage healthy living habits for Veterans, to the Life-Sustaining Treatment template, which documents life-sustaining treatment decisions. Hundreds of potential usability problems were uncovered and subsequently addressed.

Now, HFE wants to leverage this knowledge to provide usability guidance for Clinical Applications Coordinators (CACs), Health Information Specialists (HISs) and others who develop and maintain CPRS templates. The aim of this new toolkit is to incorporate usability best practices so that developers can make CPRS templates consistent in design and so that templates can be used more efficiently and accurately.

HFE has been developing this guidance into a toolkit, by:

- Identifying the most common (and most critical) usability problems.
- Reviewing related research papers to identify best practices.
- Collecting existing materials on improving template usability.
- Collaborating with end users to organize and present the guidance in a way that aligns with the template design process.

The CPRS usability guidance toolkit will provide user interface design guidance and tools for assessing
template usability. We plan to:

- Pilot the toolkit with one or more sites.
- Encourage participation from the VA community.

HFE depends on input from template users like you, so if you would like to get involved with the CPRS template toolkit project in an advisory role, please contact HFE at VHA10P2AHFManagers@va.gov.

Keep updated & let us know how we're doing.