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Tenzing VistA EHR Usability Test Clinical Decision Support (CDS)/Clinical Information Reconciliation (CIR)/Problem List EHR Capabilities

Tenzing VistA – tVistA V2

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EXECUTIVE SUMMARY

Usability testing of the Clinical Decision Support (CDS), Clinical Information Reconciliation (CIR), and Problem List capabilities of Tenzing VistA – tVistA V2 was conducted June 21 through July 14, 2019 at Trenner Medical Offices, Oroville, CA. The purpose of the testing was to validate the usability of the CDS, CIR, and Problem List capabilities of tVistA V2 graphical user interface (GUI) and provide the opportunity for user feedback on desired changes or improvement for future development. During the usability test 10 healthcare providers matching the target demographic criteria served as participants and used the tVistA EHR in simulated, but representative tasks.

The study collected performance data on four tasks related to Clinical Decision Support, three tasks related to Clinical Information Reconciliation, and three tasks related to Problem List functionality. These tasks are designed to support the certification criteria under ONC 2015 Edition Health Information Technology (Health IT) Certification Criteria. The tasks are categorized as follows:

Clinical Decision Support

- Review Evidence Based Clinical Decision Support attributes and Clinical Reminder Logic.

- Trigger Clinical Decision Support tool through EHR data entry.

- Trigger Clinical Decision Support tool through Clinical Information Reconciliation.

- Resolve Clinical Reminder/Reset Clinical Decision Support tool.

Clinical Information Reconciliation

- Electronically and simultaneously display a problem list, create a single problem list, review, and submit a final reconciled problem list.

- Electronically and simultaneously display an allergy list, create a single allergy list, review, and submit a final reconciled allergy list

- Electronically and simultaneously display a medication list, create a single medication list, review, and submit a final reconciled medication list.

Problem List

- Access Problem List

- Record Problem

- Change Problem

During the one-hour usability test, each participant was greeted, asked to sign a consent (Appendix 1) and informed they could withdraw at any time. Participants had prior tVistA EHR experience. All participants had used clinical decision support tools including clinical reminders and order checks, but no participant had regularly used the clinical information reconciliation capabilities. All participants had used problem list, but not all participants use problem list regularly. Participants were informed of the purpose of the usability testing and the type of data the team was gathering.

Participants were provided with a demonstration on the CDS, CIR and problem list capabilities via a WebEx presentation. The presentation was also printed and provided to each participant for reference while they completed the tasks. After the demonstration the administrator introduced the test, and instructed participants to complete a series of tasks (one at a time) using the EHR. During the test the administrator timed each task while the data logger recorded user performance. The administrator did not provide assistance on how to complete a task, but asked participants to demonstrate how they thought they would complete the task based on the instruction provided and instinct.

The Following data was collected for each participant:

- Number of tasks successfully completed without assistance

- Time to Complete Tasks

- Types of Errors

- Path deviations

- Providers' verbalizations

- Providers reported workload level

- Provider's satisfaction rating of the system

All participant data was de-identified to eliminate correspondence made between participant identity and the data collected. Following the conclusion of the testing, participants were asked to complete post-test questionnaires. Various recommended metrics, in accordance with the examples set forth in the *NIST Guide to the Process Approach for Improving the Usability of Electronic Health Records*, were used to evaluate the usability of the EHR. Following is a summary of the performance and rating data collected on the usability of the CDS/CIR/Problem List capabilities of the tVistA EHR.

Major findings (1)(2)(3)(4)

The results of the NASA Task Load Index (LTX) – a measure of the subjective workload, or demand the task places on the user during execution- was: 47.80 for CDS which is a substantial improvement over previous testing (72.27) and indicates this capability did not place significant demand on users attempting the associated tasks. CIR NASA-TLX score was 47.87 which is a slight improvement over previous testing (48.07) and indicates this previously available capability did not place significant subjective workload or demand on the participants. Problem list, which was not tested in earlier usability, but has been available to users also did not place significant subjective workload burden on the participants as indicated by a NASA-TLX score of 47.84.

The results from the Post Study System Usability Questionnaire (PSSQU) – a measure of user satisfaction post participation in scenario based usability studies-for the tVista EHR capabilities were: 2.87 overall, 2.90 for System Usefulness, 2.96 for Information Quality, 2.40 for Interface Quality (4; 5). Generally, users responded favorably to the CDS, CIR and Problem List tVista capabilities. Making changes as indicated in the areas for improvement should increase usability and lead to greater system satisfaction.

Areas for improvement

- User Training
- Clear indication of CIR status on button
- Ability to complete reconciliation in phases.
- Better matching of medications
- More intuitive buttons

-
1. **Hart, S. G., & Staveland, L.E.** Development of NASA-TLX (Task Load Index): Results of empirical and theoretical research. [ed.] P. A. Hancock and N. Meshkati. *Human mental Workload*. Amsterdam: North Holland Press., 1988, pp. 139-183. Scores greater than 60 are interpreted to place a higher task load on users.
 2. *NASA-Task Load Index (NASA-TLX); 20 Years Later.* **Hart, S. G.** Santa Monica: HFEW, 2006. Proceedings of the Human Factors and Ergonomics Society 50th Annual Meeting. pp. 904-908.
 3. Administrator of the National Aeronautics and Space Administration of the United States Government. *NASA TLX App*. Apple App Store, Vers. 1.0.3 (2016).
 4. *IBM computer usability satisfaction questionnaires: Psychometric evaluation and instructions for use.* **Lewis, J. R.** 1, 1995, International Journal of Human-Computer Interaction, Vol. 7, pp. 57-78. Scores range from 1-5. Lower scores indicate higher level of satisfaction.
 5. *Psychometric Evaluation of the PSSUQ Using Data from Five Years of Usability Studies.* **Lewis, J. R.** 3 & 4, s.l.: Lawrence Erlbaum Associates, Inc., 2002, International Journal of Human-Computer Interaction, Vol. 14, pp. 463-488.

INTRODUCTION

The tVista EHR Clinical decision support, Clinical information reconciliation and Problem list capabilities tested for this study including; review of evidence based CDS attributes and clinical reminders logic, trigger CDS tool through EHR data entry as well as through CIR, resolve clinical reminder to reset CDS tool, electronically and simultaneously display a medication list, a problem list, and a medication allergy list. Display and create a single medication list, a single problem list, and a single medication allergy list, display a view to review, submit a final reconciled medication list, problem list, and medication allergy list, access the problem list and enter and change a problem. The usability testing presented realistic exercises and conditions as defined in ONC 2015 certification requirements:

§170.315(a)(9) Clinical decision support (CDS)

§170.315(b)(2) Clinical information reconciliation and incorporation

§170.315(a)(6) Problem list

Purpose

The purpose of this study was to test and validate the usability of the current user interface for tVista EHR and provide evidence of usability in the EHR. This study was conducted to meet the requirements for ONC 2015 Edition Health Information Technology (Health IT) Certification Criteria indicating that User Centered Design (UCD) should be conducted when developing EHR technology. The intended outcome of implementing User Center Design in coordination with quality system management is improved patient safety. To this end User Center Design identifies user tasks and goals that can then be incorporated into the EHR development to improve efficiency, effectiveness and user satisfaction. In order to satisfy the ONC requirement for §170.315(g)(3) Safety-enhanced design this study was designed to test Clinical Decision Support, Clinical Information Reconciliation and Problem List tVista EHR functionality. Data was collected to measure effectiveness, efficiency, and user satisfaction, using metrics of time on task, task completion, task deviation, user task load and user satisfaction. As defined in the Safety-enhanced design test procedure the *National Institute of Standards and Technology Internal Reports (NISTIR) 7742* was used as the basis of format for this final report. The usability testing was conducted by the vendor team with guidance from the NISTIR 7741 - *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records*

VHA User-Centered Design Approach

tVistA EHR consists of a suite of applications developed by the Veteran Health Administration (VHA), made available through the freedom of information act (FOIA), adopted by OSEHRA and shared with the Open source EHR community. The VHA development of the EHR is the result of collaboration of VHA HIT staff and VA Clinicians. This collaboration created the VHA legacy of user centered design. VHA utilized the technology of the time and in 1982 launched Decentralized Hospital Computer Program (DHCP) a character-based application. The patient centric EHR evolved as geographically and organizationally diverse, user-defined, clinical workflows were incorporated into the Veterans Health Information System and Technology Architecture (VistA) information system. VistA was then alpha and beta tested in hospitals and clinics throughout the US. Although VistA was built on the character-based foundation of DHCP, it has a modern browser-enabled interface, the Computerized Patient Record System (CPRS). CPRS is a Graphical User Interface (GUI) which incorporates both the requirements for Promoting Interoperability and the requests and recommendations from clinical advisors. Thus, formal user-centered design principles have varied over the development lifecycle of tVistA EHR but have not been absent.

(<https://www.voa.va.gov/documentlistpublic.aspx?NodeID=27>).

Tenzing Medical LLC User-Centered Design Approach (6) (7) (8) (9) (10) (11)

Tenzing Medical, LLC incorporated the concepts of Cognitive System Engineering (CSE), User Centered Design approach in a Decision-Centered Design (DCD) framework as described below. “CSE is an approach to the design of technology, training, and processes intended to manage cognitive complexity in sociotechnical systems” (10). Users engage in cognitively complex activities such as identifying, judging, attending, perceiving, remembering, deciding, problem solving and planning when interacting with a system.

User-Centered Design approach to system engineering encompasses 6 key principles:

- The design is based upon an explicit understanding of users, tasks and environments.
- Users are involved throughout design and development.
- The design is driven and refined by user-centered evaluation.
- The process is iterative.
- The design addresses the whole user experience.
- The design team includes multidisciplinary skills and perspectives.

tVistA EHR system design addresses the cognitive complexities associated with managing complex decision-making and the key principles of User Centered Design through the use of a Decision Centered Design (DCD) Framework. In DCD the software development involves task

analysis, design, and evaluation that focuses on describing, analyzing, understanding, and supporting complex perceptual and cognitive activities (11)

Task Analysis is used to identify key decisions and requirements. Task analysis involves identifying the cognitive activities involved in a task, how the task is performed and where the task is performed so that an understanding of the requirements of the system is complete and addresses and supports the strengths and weakness of existing cognitive tasks. Subject Matter Experts (SME) assist in identifying these key decisions and requirements and continue their involvement throughout the development process. The SME work closely with the Health Information Technology (HIT) team of designers, programmers, network specialist, pharmacist, physicians, nurses, and ancillary service specialists to provide input on development, design, workflows, and system testing. Having user input in the earliest phases of development allows for better understanding of the skills and knowledge users possess, the mental models used to develop expectation for functionality, the objectives and tasks the application will be used to complete, and the decisions users must make that the application should support.

- **Design** phase of development aims to utilize the insights gained in task analysis to create a system that reduces cognitive challenge, improves error management, and increases performance. SME provide ongoing feedback on individual packages and interoperability between packages. Requirements can be established from the elicitation of this information and conceptual designs created. The most common user activities are identified and made most prominent within the system. Eventually

6. **Armijo, D., McDonnell, C., Werner, K.** *Electronic Health Record Usability: Evaluation and Use Case Framework*. Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. Rockville : Agency for Healthcare Research and Quality, 2009. 09(10)-0091-1-EF.
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8. *Cognitive and usability engineering methods for the evaluation*. **Kushniruk, A. W., Patel, V. L.** s.l. : Elsevier Inc., 2004, Journal of Biomedical Informatics, Vol. 37, pp. 56-76.
9. **McDermott, P., Klien, G., Thordsen, M.** *Representing the Cognitive Demands of New Systems: A DecisionCentered Design Approach*. s.l. : US Air Force Research Laboratory, 2000. AFRL-HE-WP-TR-2000-0023.
10. **Militello, L. G., Domingues, C. O., Litern, G. & Klein, G.** The Role of Cognitive Systems Engineering in the System Engineering Design Process. *Systems Engineering*. May 7, 2009, p. 13. 11. **Thordsen, M. L., Hutton, R. J., Miller, T. E.** Decision centered design: Leveraging cognitive task analysis in design. [ed.] E. Hollnagel. *Handbook of Cognitive Task Analysis*. 2010, pp. 383-416.

a prototype is created, and implementation planning begins. The goal is to optimize the system.

- **Evaluation** involves continuous formative as well as summative usability testing. Decision Centered Design approach to software development incorporates users testing and feedback from the design phase. This type of development captures the unseen aspects of the system, the potential errors, evolving technology and human interaction with this technology. Usability testing demonstrates user system interaction and further defines necessary adjustments needed immediately and long term to further optimize the system. A broader range of users with diverse requirements, experiences, and work environments are recruited for summative usability testing. These users provide evaluation and feedback the HIT team uses to reevaluate and reengineer the EHR.

The DCD process is iterative. As problems are identified, options are evaluated and systems modeled, integrated, and launched and performance is assessed. The HIT team continually aims to meet customer and users' needs, utilize available technology, and evaluate priorities, limitations and tradeoffs that must be made. Dialog is continuous and frequent among all stakeholders and team members. This allows for generation of new ideas, refinement of old ideas, conceptual changes and/or rejection. This process involves many organizational entities and all parties contribute to the discussion providing input, recommendations, and knowledge exchange. The team analyzes the information provided and makes decisions about design, budget, priorities, testing, redesign and roll-out. The healthcare industry is constantly in flux requiring ongoing and often immediate changes to EHRs. As an iterative and heuristic approach to development DCD bodes well in this environment.

Although change is constant, it is important to design and implement systems that build on current user mental models. This is accomplished by reimagining the same workflow in another format or utilizing existing mental models in another application. Redundancy of function within tVistA EHR, such as right click access to action menus, as well as reusing existing technology common keyboard functions and short cuts facilitate learning and usability.

tVistA EHR is a complex system which requires the user to use complex decision making at times while only simple decision making at others, and users vary in how they practice, how they interact with the EHR, and their individual abilities. Therefore, a broad representative base of users is required to elicit meaningful evaluation of the EHR. Complex but specific user test scripts are designed, and minimal instruction is provided to users in order to elicit maximum evaluation of the EHR during usability testing. The HIT team aims to generate unforeseen

possibilities the variety of users may unfold as well as maximal feedback on user experience of the EHR.

Focusing on the intended users of a new or modified technology maximizes benefit for the user and adoptability. The Primary users are given priority over other users who may have competing or irreconcilable preferences.

Primary Users: The primary users for the clinical decision support, clinical information reconciliation and problem list capabilities are providers. Providers in both inpatient and outpatient settings specializing in various areas of medicine and whose interactions with patients require clinical decision support at the point of contact as well as the ability to reconcile medications, problems, and allergies prior to or during clinical evaluation and access and update problem lists.

Secondary Users: Secondary users of the CDS and CIR capabilities include nursing, pharmacy and ancillary service staff that may interact with patient directly while using the EHR and may assist with clinical information reconciliation and utilize clinical decision support tools and problem list for their area of expertise.

Sociotechnical systems are complex, and users have to find ways to manage the complexities. DCD approach assist users through the use of cognitive support strategies focused on decision support tools that reinforce users' natural decision-making processes. The cognitive support elements outlined below and later used in addressing recommendations help to manage complexity when designing the new software. The recommendations made later will impact future cognitive support strategies.

- **Supporting Decision Making:** Refers to decisions support tools designed to provide context specific information when needed and reduce task load.
- **Reducing Errors:** Refers both to system error reduction functionality as well as user's awareness, trust and understanding of error reduction functionality. Users must be aware of where error reduction functionality exists and where it does not so they can adjust their expectations and trust the system when appropriate thus reducing cognitive load.
- **Facilitating Scanning:** Refers to placement, amount and type of information on a screen and how well this placement allows a user to find information quickly and accurately and how well a user can return to their place in a screen after an interruption.

- **Creating Affordance:** Refers to design features that help, aid, support, facilitate or enable thinking, knowing, perceiving, or doing something. For example; words on a button indicating the meaning of the button.
- **Illustrating Perceived Benefit:** Refers to users' belief that their day-to-day activities will benefit from using the system. Lack of perceived benefit can result in lack of motivation to learn or use the system and possibly reject the system entirely
- **Supporting Mental Models:** Refers to building upon users' mental models. Designing applications that utilize common language and functionality such as windows standard or previous version functionality.

The clinical decision support, clinical information reconciliation and problem list EHR capabilities are new methods for old processes. Clinical Decision Support refers to tools used to assist providers in the patient specific care decisions based on the patient's existing medications, allergies, problems and other health care status. Clinical Decision Support takes place at the point of care. Patient data in the EHR triggers decision support tools that can then be addressed by the provider immediately with the most current information available. Clinical Information Reconciliation is the process of reconciling patient medications, allergies and problems from external sources with the patient data in the medical record. The EHR facilitates this by presenting the external data with internal data for comparison, incorporation or deletion and review of the newly reconciled medical record. Primary users' main concerns for CDS is that support tools are accurate and presented at point of care. Primary users' main concern with CIR is that the data is presented accurately and clearly for comparison, and is easily incorporated, and reviewed. Problem list involves the maintenance of an accurate list of the patients current and previous medical, social and surgical problems. The problem list is maintained through entry of coded diagnosis, options to change or update existing entries and access to the completed lists in accurate and useful displays. Finally, all tasks should be completed with a minimal number of key strokes.

Tenzing Medical, LLC practices the user center design and testing outlined above on an ongoing basis, but this document specifically focuses on the usability testing conduct over several days.

METHOD

PARTICIPANTS

A total of 10 participants were tested on the tVistA EHR CDS, CIR, Problem list capabilities. Participants in the test were physicians, nurses and ancillary staff from varied backgrounds. The participants were recruited by Denise Lefevre, the Chief Information Officer (CIO). The participants volunteered and were, therefore, not compensated for their participation. Participants had no direct connection to the development of or organization producing tVistA EHR nor the testing or supplier organization. All participants had previous experience with tVistA EHR capabilities. Most participants had used clinical reminders; however few participants had used Clinical Information Reconciliation. Participants were instructed on the CDS and CIR capabilities via WebEx presentation. The presentation was also printed and provided to each participant for reference while they completed the tasks.

Participants were from varied backgrounds and experience as outline in the table below. Participants were provided a participant ID upon arrival for testing thus de-identifying individuals.

Participants were scheduled for 60 minute sessions which included introductions and background, Clinical Decision Support tasks, Clinical Information Reconciliation task, and metrics. Between sessions the data logger, administrator and other team members debriefed and prepared for the next participant. A demographic spreadsheet with participant's information from the recruiting team and schedule of testing appointments was kept to track participation.

Participant ID	Gender	Age	Education	Occupation/Role	Professional Experience	Computer Experience	Product Experience	Assistive Technology Needed
1	Female	30-39	Some College	CAC Integrations lead	180	120	36	No
2	Female	30-39	Some College	Medical Assistant	180	180	24	No
3	Male	50-59	Doctorate	Pharmacist	240	120	120	No
4	Male	40-49	Doctorate	MD	180	84	84	No
5	Female	30-39	Bachelor's	Nurse	120	72	72	No
6	Male	20-29	Doctorate	MD	24	6	24	No
7	Male	50-59	Doctorate	MD	360	180	132	No
8	Female	40-49	Some College	Medical Assistant	216	144	144	No
9	Male	70-79	Doctorate	MD	564	132	132	No
10	Female	40-49	Bachelor's	Registered Nurse	360	144	144	No

Table 1. Demographic characteristics

STUDY DESIGN

The overall objective of this test was to determine if the application performed effectively, efficiently, and to the satisfaction of the users, and if the application failed to meet the needs of the participants what issues were encountered and how can they be mediated. This testing is also designed to satisfy the Clinical Decision Support, Clinical Information Reconciliation, and Problem List requirements of the ONC 2015 Edition Health Information Technology (Health IT) Certification Criteria. The data obtained from this testing is expected to generate recommendation and discussion for future development of the CDS, CIR and Problem List capabilities of tVistA EHR, and identify possible requirements for immediate modifications to facilitate patient safety and/or user adoption.

All participants interacted with tVistA EHR in the same location, provided with the same instruction, asked to complete the same tasks and used the same evaluation tools. Data was collected during testing by the data logger and administrator to evaluate the system for effectiveness, efficiency and satisfaction as defined by measures collected and analyzed for each participant:

- Number of tasks successfully completed within the allotted time without assistance
- Time to complete the tasks
- Number and types of errors
- Path deviations
- Participant's verbalizations (comments)
- Participant's satisfaction ratings of the system

More information about the various measures is provided below in the Usability Metrics section

TASKS

A number of tasks were constructed that would be realistic and representative of the kinds of activities a user might do with this EHR, including:

Clinical Decision Support

1. Review Evidence Based Clinical Decision Support attributes and Clinical Reminder Logic.
2. Trigger Clinical Decision Support tool through EHR data entry.
3. Trigger Clinical Decision Support tool through Clinical Information Reconciliation.
4. Resolve Clinical Reminder/Reset Clinical Decision Support tool.

Clinical Information Reconciliation

1. Electronically and simultaneously display a problem list, create a single problem list, review, and submit a final reconciled problem list.
2. Electronically and simultaneously display an allergy list, create a single allergy list, review, and submit a final reconciled allergy list
3. Electronically and simultaneously display a medication list, create a single medication list, review, and submit a final reconciled medication list.

Problem List

1. Access Problem List
2. Record Problem
3. Change Problem

Tasks were selected based on frequency of use, criticality of function for ONC 2015 Edition Health Information Technology (Health IT) Certification Criteria (sections §170.315(a)(9) Clinical decision support (CDS), §170.315(b)(2) Clinical information reconciliation and incorporation, §170.315(a)(6) Problem list), and tasks that could be foreseen as being most troublesome for users.

PROCEDURES

Upon arrival, participants were greeted; their identity was verified and matched with the name on the participant schedule. Participants were then assigned a participant ID. Each participant was made aware their performance on the upcoming tasks would be recorded for subsequent analysis. The participant was asked to sign the Informed Consent Form (Appendix 1).

First off, we would like to thank you for taking the time to provide us with feedback on the EHR capabilities being tested today. We are executing these sessions as part of the Office of the National Coordinator's certifications requirements. This usability study will help ensure that Tenzing Medical, LLC meets their certification requirements and Promoting Interoperability standards. We are asking EHR users to provide usability input to the Demographic, Implantable Device List, Drug-related, Clinical Decision Support (CDS) and Clinical Information Reconciliation (CIR) capabilities of tVistA EHR. We would like to record your performance on today's session so that we may use it for subsequent usability analysis after we end the session. Do you give your permission for these recordings?

To ensure the usability testing ran smoothly, an administrator and a data logger were present for the testing: the testing team members have 20 years of experience in psychological and clinical research and RPMS, CPRS, and commercial medical hardware and software design, development and testing. The team included experienced hardware and software developers with experience in usability testing and user-centered design programs. Also included on the

sessions were several stakeholders who were available to observe the user interaction with the system, respond to questions after completion of formal testing and elicit feedback relevant to future development.

The administrator moderated the session, administered instructions and tasks, obtained post-task rating data, and took notes on participant comments. The data logger monitored task times, and took notes on task success, path deviations, number and type of errors, and comments.

Background information was asked of each participant prior to engaging in the tasks. The data was logged by the administrator and data logger. The participant was situated at the computer, provided with log on information, and allowed time to orient themselves to the EHR and the expected tasks.

Participants were instructed to perform the tasks (see specific *instructions in Appendix 3: Moderator's guide*):

- As quickly as possible making as few errors and deviations as possible.
- Without assistance; administrators were allowed to give immaterial guidance and clarification on tasks, but not instructions on use.
- Without using a think aloud technique.

For each task, the participants were given a written copy of the task. Task time began once the administrator said begin. The task time was stopped once the participant indicated he had successfully completed the task (e.g. reconciled patient record).

Following each task, the participant was asked to complete the NASA-TASK LOAD INDEX (Appendix 4). At the completion of the session, the administrator gave the participant the POST STUDY SYSTEM USABILITY QUESTIONNAIRE (Appendix 5).

Participants were asked if they had any additional comments or questions for the group which were logged by the data logger and thanked for their participation.

Participants' demographic information, task success rate, time on task, errors, deviations, verbal responses, and post-test questionnaire were recorded into a spreadsheet.

TEST LOCATION

Usability testing took place in a small conference room. A user laptop computer and mouse were set up on a table. The Administrator sat next to the user. The user's screen was redisplayed for the data logger and observers on computers in a separate training room via

WebEx session. Stakeholders observed from the data logger's location or listened and viewed via the WebEx session. To ensure that the environment was comfortable for users, noise levels were kept to a minimum with the ambient temperature within a normal range. All of the safety instruction and evacuation procedures were valid, in place, and visible to the participants.

TEST ENVIRONMENT

Clinical Decision Support, Clinical Information reconciliation and Problem list capabilities would typically be used in a healthcare office or facility. In this instance, the testing was conducted in a small conference room in the Trenner Medical offices building. For testing a Dell Latitude 7480 laptop running Windows 7 operating system was used with an external mouse. The participants used both keyboard and mouse to navigate and interact with the tVistA EHR. A 14-inch monitor was used with a screen resolution of 1920 x 1080. The application was set up according to vendor specifications and the application was running on a Linux/GTM platform using a test database on a LAN connection. The performance of the test system was comparable to what users experience in production environments on site at hospitals and clinics. Participants were asked not to change any of the setting defaults to insure conformity

TEST FORMS AND TOOLS

During the usability test various documents and instruments were used, including:

1. Informed Consent
2. Moderator Guide
3. NASA-TLX
4. PPSSUQ

Examples of these documents can be found in the Appendices.

The participant's interaction with the EHR was captured through recording of WebEx session for each participant's test.

The test sessions were transmitted via WebEx screen sharing to a nearby observation room where the data logger observed the test session.

PARTICIPANT INSTRUCTION

The administrator read the following instructions aloud to each participant (also see the full moderator's guide in Appendix 3):

During this session, you will be asked to complete tasks using Tenzing VistA EHR then provide feedback on the CDS, CIR and problem list capabilities.

I will provide you with a list of tasks and associated data. You will be asked to complete these tasks as quickly as possible with the fewest errors or deviations. Do not try to do anything other than what is asked. We cannot assist you in accomplishing your tasks. Please save comments and question until the end of each section.

We would like you to give us feedback on the capabilities used. We would like to know how easy or difficult the system is to use, how useful the capabilities are, and what improvement we can make. The best help you can give us is to be critical. We may not be able to fix everything you mention, but it is still beneficial for us to know what issues you feel are important. Your honest feedback is what we are after. Your feedback will be used to help make the CDS CIR and Problem list capabilities better, so please do not worry about offending anyone with your comments. Your feedback as well as any questions the usability team is unable to answer will be shared with developers and stakeholders.

We have this interview divided into several parts. I'd like to start by just getting some background information; then I am going to ask some questions about if/how you currently use the EHR functions, then I will provide an introductory overview of each capability being tested. In the last part, we'll have you log in as a test user and complete tasks associated with each capability. Do you have any questions for us before we get started?

Following the procedural instructions, participants were shown the EHR and given time to explore tVistA EHR and make comments. Once complete the administrator gave the following instructions:

"I will say "Begin." At that point, please perform the task and say "Done" when you believe you have successfully completed the task. Please refrain from talking while doing the task. We will have time to discuss the task and answer questions when the task is complete."

Participants were given 10 tasks to complete. Tasks are listed Tables 3a-c below.

USABILITY METRICS

According to the *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records*, EHRs should support a process that provides a high level of usability for all users. The goal is for users to interact with the system effectively, efficiently, and with an acceptable level of satisfaction. To this end, metrics for effectiveness, efficiency and user satisfaction were captured during the usability testing. The goals of the test were to assess:

1. Effectiveness by measuring participant success rates and errors
2. Efficiency by measuring the average task time and path deviations
3. Satisfaction by measuring ease of use ratings

DATA SCORING

The following table (Table 2) details how tasks were scored, errors evaluated, and the time data analyzed.

Measures	Rationale and Scoring
<p>Effectiveness: Task Success</p>	<p>A task was counted as a “Success” if the participant was able to achieve the correct outcome, without assistance, within the time allotted on a per task basis.</p> <p>The number of successes were calculated for each task and then divided by the total number of times that task was attempted. The results are provided as a percentage.</p> <p>If the participant abandoned the task, did not reach the correct answer or performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as an “Failures.” No task times were taken for errors.</p>
<p>Efficiency: Task</p>	<p>Task times were recorded for tasks successfully completed then divided by the number of participants who completed the task successfully. The average task time is reported. Variance measures (standard deviation and standard error) were also calculated.</p>
<p>Efficiency: Task Deviations</p>	<p>The participant’s path (i.e., steps) through the application was recorded. Deviations occur if the participant, for example, varied the order of the steps, failed to sign orders, or interacted incorrectly with an onscreen prompt. This path was compared to the minimum number of steps possible per task (optimal path) established by the team and developers. The number of steps in the observed path is divided by the optimal number of steps and presented as a ratio of path deviation</p>
<p>Satisfaction: Task Load</p>	<p>Participant’s subjective impression of the workload or cost of accomplishing the task requirements were obtained through the administration of the NASA Task Load Index (NASA-TLX) after each task set. The participant was asked to complete the six subscales representing different variables including: Mental, Physical, and Temporal Demands, Frustration, Effort, and Performance. See Appendix 4.</p> <p>A high level of burden on the participants is indicated by a score of 60 or greater.</p>

<p>Satisfaction: Task Rating</p>	<p>To measure the participant's satisfaction of the CDS, CIR and Problem list capabilities the team administrated the Post Study System Usability Questionnaire (PSSUQ) at the completion of all the tasks. The PSSUQ consists of 19 items such as "it was simple to use the system" and "It was easy to find the information I needed" that the participant rates using a 7 point Likert scale ranging from 1=strongly agree to 7= strongly disagree. The PSSQU is designed to assess overall user satisfaction through perceived system usefulness, Information Quality and Interface quality.</p> <p>See Appendix 5 for a copy of the questionnaire.</p>
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Table [2]. Details of how observed data were scored.

RESULTS

DATA ANALYSIS AND REPORTING

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above. There were no participants who failed to follow session and task instructions or had their data excluded from the analyses.

The usability testing results for the CDS, CIR and Problem list capabilities of tVistA EHR are detailed below in Tables 3a-c. The results should be seen in light of the objectives and goals outlined in the Study Design section above. The data should yield actionable results. If corrected, within the CDS, CIR and Problem list tVistA EHR capabilities these will have a positive impact on user performance.

Qualitative feedback from the participants was transcribed by team members and compiled in an Excel spreadsheet. The team met to discuss all potential issues particularly those items noted as significant for consideration. Each issue was listed as verbalized by the participant and the team evaluated the issue asking questions such as: *What might cause the participant to have this issue? What cognitive support element does this issue violate? What can be done/changed to support the cognitive support element?* Recommendations intended to rectify the identified issue were recorded.

Issues were coded according to the cognitive element that led to the underlying issue, issue class, and time frame.

Issue Class

Each issue was classified into an "issue class." This classification scheme represents our understanding of the potential impact of each issue if left unaddressed.

- **Type 1** issues are those we anticipate will create an *individual error risk*. These issues may directly introduce a specific health risk. For example, a new health system that somehow allowed treatment plans to be mistakenly associated with

multiple EHRs. Some patients would be placed at significant health risk because of the design flaw.

- **Type 2** issues are those we anticipate will create an *aggregate error risk*. These issues may introduce error through cumulative effects. An example of this would be a new system that failed to capture some important paper-based function that was used in conjunction with the old system. The loss of low-tech, but high-value information can eventually lead to a problem.
- **Type 3** issues are those that we anticipate will create *adoption and long-term use risk*. These issues may negatively influence acceptance of the software. In the extreme, ignoring these issues may result in software that is rejected by the intended users. If use is mandated, users may find ways to “game” the system, distorting or circumventing the intent of the software. This is less troubling from a health risk standpoint, but could still create a long-term failure of a system in which much has been invested.

Timeframe

Recommendations are also made according to the timeframe in which issues should be addressed. Four timeframes are considered: urgent, quick fix, near-term, and long-term.

- **Urgent:** lead to significant medical error and/or patient risk, need to be fixed before next release/patch.
- **Quick fix:** These issues that we believe can be fixed "in-house" in a relatively short time frame (e.g. several weeks). These are issues that we believe will positively influence user acceptance with little development effort.
- **Near-term issue:** These issues are those that we believe will positively influence user acceptance. Can be completed in 12 months or less, but may require extra development time and effort.
- **Long-term issue:** These issues do not present significant risk in their current form. These recommendations, however, have the potential for significant, high impact benefit if resources can be found to address them over time. These fixes will take more than 12 months, contain interoperability issues and may require overhauls of existing systems, introductions of new functionality, and require extended development efforts.

Task #	Task Description	N	Task Success - Mean (%)	Task Success - Standard Deviation (%)	Task Path Deviation - Observed #	Task Path Deviation - Optimal #	Task Time - Mean (seconds)	Task Time - Standard Deviation (seconds)	Task Time Deviation - Mean Observed Seconds	Task Time Deviation - Mean Optimal Seconds	Task Errors - Mean(%)	Task Errors - Standard Deviation (%)	Task Rating - Scale Type	Task Rating (Overall)	Task Rating (Overall) - Standard Deviation	System Usefulness rating	Information Quality rating	Interface Rating	Task Load
1	Review Evidence Based CDS attributes and Clinical Reminder Logic	10	100.0	0.0	6	6	145	68	1.66	88	0.0	0.0	PSSUQ	2.87	1.49	2.90	2.96	2.40	47.80
2	Trigger Clinical Decision Support tool through EHR data entry	10	100.0	0.0	13	8	204	163	1.68	122	0.0	0.0							
3	Trigger Clinical Decision Support tool through Clinical Information Reconciliation	10	95.0	0.0	2	2	70	64	0.62	112	0.5	30.0							
4	Resolve Clinical Reminder/Reset Clinical Decision Support tool	10	100.0	0.0	27	24	301	119	1.48	202	0.0	0.0							

Table 3a: Clinical Decision Support Data

Task #	Task Description	N	Task Success - Mean (%)	Task Success - Standard Deviation (%)	Task Path Deviation - Observed #	Task Path Deviation - Optimal #	Task Time - Mean (seconds)	Task Time - Standard Deviation (seconds)	Task Time Deviation - Mean Observed Seconds	Task Time Deviation - Mean Optimal Seconds	Task Errors - Mean(%)	Task Errors - Standard Deviation (%)	Task Rating - Scale Type	Task Rating (Overall)	Task Rating (Overall) - Standard Deviation	System Usefulness rating	Information Quality rating	Interface Rating	Task Load
1	Electronically and simultaneously display a problem list, identify the source , create a single problem list, review, validate, confirm and submit a final reconciled problem list.	10	100.0	0.0	15	15	223	162	1.36	164	0.0	0.0	PSSUQ	2.87	1.49	2.90	2.96	2.40	47.87
2	Electronically and simultaneously display a allergy list, identify the source , create a single allergy list, review, validate, confirm and submit a final reconciled allergy list.	10	100.0	0.0	6	3	99	51	1.42	70	0.0	0.0							
3	Electronically and simultaneously display a medication list, identify the source , create a single medication list, review, validate, confirm and submit a final reconciled medication list.	10	90.0	30.0	14	14	280	230	1.24	226	10.0	30.0							

Table 3b: Clinical Information Reconciliation Data

Task #	Task Description	N	Task Success - Mean (%)	Task Success - Standard Deviation (%)	Task Path Deviation - Observed #	Task Path Deviation - Optimal #	Task Time - Mean (seconds)	Task Time - Standard Deviation (seconds)	Task Time Deviation - Mean Observed Seconds	Task Time Deviation - Mean Optimal Seconds	Task Errors - Mean(%)	Task Errors - Standard Deviation (%)	Task Rating - Scale Type	Task Rating (Overall)	Task Rating (Overall) - Standard Deviation	System Usefulness rating	Information Quality rating	Interface Rating	Task Load
1	Access Problem List	10	100.0	0.0	5	3	72	50	3.98	18	0.0	0.0	PSSUQ	2.87	1.49	2.90	2.96	2.40	47.84
2	Record Poble	10	100.0	0.0	11	7	165	143	2.65	26	0.0	0.0							
3	Change Poble	10	100.0	0.0	3	3	24	25	1.12	22	0.0	0.0							

Table 3c: Problem List Data

DISCUSSION OF THE FINDINGS

Effectiveness

Effectiveness was measured by task completion or failure to complete task. We asked providers to complete CDS, CIR and Problem list tasks using tVistA EHR capabilities that demonstrate the required functionality. These tasks are derived from the ONC 2015 Edition Health Information Technology (Health IT) Certification Criteria requirements. The task completion data indicates that providers were able to complete most the tasks that they were asked to execute. There are notable differences between the participants in how they completed each task. These variations are due to subject characteristics, not issues regarding the functionality of the application. These subject variables include not assigning a problem type which resulted in difficulty viewing problem, discontinuation of medication which caused some medication to not display in medication reconciliation and using reminder clock rather than cover sheet reminders for review of CDS attributes. One user was unable to complete the medication reconciliation task and part of triggering the CDS tool from CIR because the imported CCDA did not contain medications.

Efficiency

Efficiency was measured by time on task and task deviations. We asked providers to complete representative tasks of the CDS, CIR and Problem list tVistA EHR capabilities that demonstrate the required functionality. These tasks are derived from the ONC 2015 Edition Health Information Technology (Health IT) Certification Criteria requirements. We did not instruct participants to complete tasks in one specific manner but provided an overview of how tasks could be completed via one path. Any path variation causes deviation in both time on task and path deviation. The data indicates that most providers were able to complete all the tasks in a standard manner and deviations were due to thoroughness as much as user error. There were deviations in the order in which tasks were completed, 2 users had trouble locating the reconciliation action button, entering vitals proved difficult for providers for whom it is not part of their regular responsibilities, and multiple signature code entry attempts caused completion delays all of which resulted in increased time on task.

Satisfaction

Satisfaction was measured by two subjective questionnaires, the NASA TLX and the PSSUQ. Overall workload ratings indicate that the users are not overly burdened by the CDS, CIR or Problem list capabilities. The results from the NASA TLX were: 47.80 for CDS, 47.87 for CIR and 47.84 for Problem list. The results of the PSSUQ was 2.87 overall; indicating overall favorable results for all areas of the CDS, CIR and Problem list tVistA EHR capabilities. Below is a complete

list of written comments (duplicates omitted) articulated by participants in response to question items.

- *Reminder drawer terminology was confusing*
- *Training would be beneficial*
- Sometimes windows need adjustments
- Not excessive color or pictures on screen
- System kept up with movement
- System was simple click and go functions
- With training I will do much better job
- User friendly with simple tasks

This list of comments includes positive, neutral, and negative comments illustrating that there are areas of the EHR that providers find easy to use and areas of the EHR that will benefit from design enhancements. Additional training to improve or maintain skills could be effective in reinforcing the data entry methods user indicated they are unaware or unfamiliar with.

AREAS FOR IMPROVEMENT

As a result of this set of usability interviews we determined that the CDS, CIR, and Problem list tVista EHR capabilities violate a set of cognitive support elements. Relevant issues gleaned from these usability sessions are listed in the following section. The resulting issues are grouped with respect to the cognitive element that the usability team believes led to the underlying issue. Each issue that was uncovered during the usability interviews is listed as it relates to the cognitive element that is being violated. As a reminder, these elements include:

- *Support Decision Making*
- *Reduce Errors*
- *Facilitate Scanning*
- *Create Affordances*
- *Illustrate Perceived Benefit*
- *Support Mental Models*

Recommendations are made to encourage a design enhancement that creates support for the relevant cognitive requirement. Recommendations should be adopted and implemented only in ways that support the cognitive elements. When reviewing the issues and recommendations the HIT team should consider questions such as:

1. *Why are participants having this issue?*

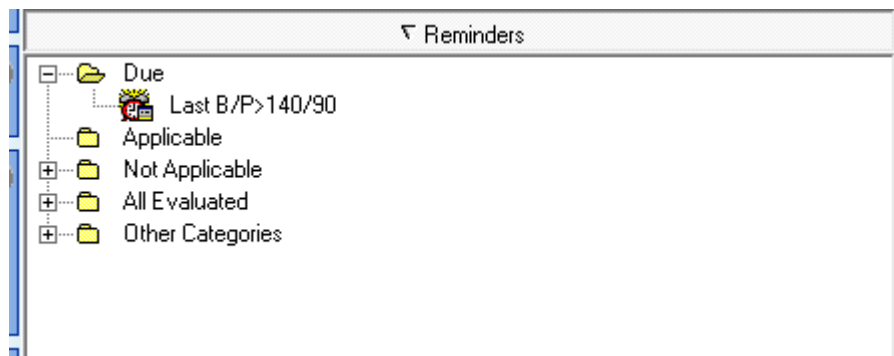
2. *What cognitive support element does this issue violate?*

3. *What can we do within the design process to facilitate the cognitive support requirement?*

Issues and Recommendations

Issue 1: CDS reminders drawer terminology is confusing

- Cognitive Support Element: Support Mental Models. Only 1 users found the terminology problematic so we believe this is a quick fix that requires additional training and logic explanation
 - Consideration:
 - How can we quickly and easily facilitate an understanding of the meaning of the clinical reminder drawer terminology

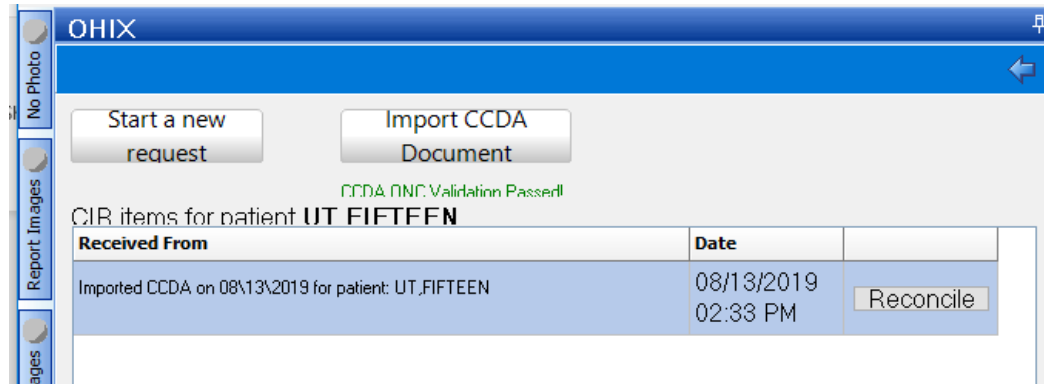


R-1 We recommend training users on clinical reminder functionality and the meaning of each reminder drawer folder and the associated reminder icons.

Issue 2: CIR Display issue due to user preference setting to extra large display.

- Cognitive Support Element: Supporting Mental Models: We believe this is a near term fix as this functionality requires development.
 - Consideration:
 - How can we allow for display sizing to accommodate for user preferences?

R-2 We recommend sizing CIR display to accommodate user changes in font preferences.



Issue 3: CIR reconciliation action button difficult to locate.

- Cognitive Support Element: Facilitating scanning. We believe this is a quick fix that requires training and familiarity with the new functionality. Increasing the Size of the Action button is a near term fix as it will require development.
 - Consideration:
How do facilitate efficient location of buttons on display?

CCDA Problem List							
Finish Problem Reconciliation		Source: Community Health And Hospitals		Problem Count: 3		Unreconciled Count: 3	
Category	Problem	Status	SNOMED-CT	ICD-9	Date	Reconcile Action	Reconcile Status
Med/Surg	Condition - Pneumonia	Active	233604007		Aug 6, 2012	Action	
Med/Surg	Condition - Asthma	Active	195967001		Jan 3, 2007	Action	
Social	Tobacco smoking status NHIS - Smokes tobacco daily		449868002		Feb 27, 2011	Action	

- R-3 Training users on the CIR functionality should facilitate locating of action button
- R-4 Increase size of Action button to make it more visible

Issue 4: CIR medications difficult to find and determine which to add. We believe this is a near term issue as it will minimize confusion, assist the users in accurately entering data and adopting the new technology.

- Cognitive Support Element: Facilitating scanning.
 - Consideration:
How can we assist users in understanding the significance of the data displayed and what it means to take action on it?

Patient: Jones, Myra

Source: Community Health And Hospitals
1002 Healthcare Drive Portland, OR 97266
tel:+1(530)533-8500

Addr: 1357 Amber Drive
Beaverton, OR 97006

Tel: tel:+1(816)-276-6909
(Home)

DOB: 05/01/1947

Sex: FEMALE

Race: White

Ethn: Not Hispanic Or Latino

Doc Type: HL7 CCDA

Finish Medication Reconciliation

TENZING Active Patient Meds	Patient Meds from: Community Health and Hospitals	Status
CV800 - ACE INHIBITORS		
LISINAPRIL 2.5MG TAB Qty: 30 for 30 days Sig: TAKE ONE TABLET BY MOUTH DAILY Ordered: Jul 30,2019@11:33 EndDate: Aug 29,2019 Status: Active Refills: 0 IVFluid: Yes Last Fill: Jul 30,2019 Provider: CRAWLEY,ROBERT RxNorm: 311353	DC	Reviewed
LISINAPRIL 2.5MG TAB Qty: 30 for 30 days Sig: TAKE ONE TABLET BY MOUTH DAILY Ordered: Jul 30,2019@11:33 EndDate: Aug 29,2019 Status: Active Refills: 0 IVFluid: Yes Last Fill: Jul 30,2019 Provider: CRAWLEY,ROBERT RxNorm: 311353	DC	Reviewed
Unassigned Drug Class		
	ALBUTEROL 90MCG 200D ORAL PWD INHL INHALE 2 INHALATIONS INHL FOUR TIMES DAILY, Oct 03, 2018, active, Fills allowed: 0, RxNorm: 1649560	Ignore Add New
	FLUTICASON PROP 110MCG 120D ORAL INHL INHALE 1 PUFF INHL DAILY BRONCHITIS (32398004), Oct 03, 2018, active, Fills allowed: 0, RxNorm: 896001	Ignore Add New

- R-5 Training users on the CIR functionality should facilitate better understanding of the meaning, design and layout of the medication reconciliation window.
- R-6 Additional display modification can be as needed based on user feedback port training and use.

Table 4 represents the issues, the associated cognitive support element, issue class and anticipated timeframe

Issue	Description	Cognitive Support Element	Issue Class	Timeframe
1	CDS reminders drawer terminology is confusing	Support Mental Models	III	Quick Fix
2	CIR Display issue due to user preference setting to extra large display	Facilitating scanning	III	Near-term
3	CIR reconciliation action button difficult to locate.	Facilitating scanning	III	Quick Fix
4	CIR medications difficult to find and determine which to add.	Creating Affordance	I	

Table 4: Issue and Recommendations by Cognitive Support Element, Issue Class and Timeframe

Areas for Improvement: Global Recommendations

To further improve usability and adoptability of tVista EHR the following recommendations are made regarding the EHR as a whole. These recommendations reflect standard windows functionality that utilize existing mental models.

1. **Gray-out visualization:** When a function is not available it should be grayed out. By graying out functions that are not available it provides the user with a visual cue that those options are not available at the present time, while still allowing them to know these features exist and may be available in other circumstances.
2. **Tool tips/instructions:** All buttons, icons, and right click options in the GUI should include tool tips describing their name and function when the user hovers the mouse over them. These tool tips allow the user to learn what various buttons in the software do on their own as they are using the software application.
3. **Window size:** Expand default screen size for pop-up dialogue windows. Pop-up dialogues should be maximized to prevent scrolling when possible if screen real estate is available. The dialogues should remain centered on the screen, with width and height adjusted to provide maximum visibility of all content.
4. **Auto-close:** Close previous windows where an action has been executed and is no longer relevant. By closing previous windows that have completed their actions you remove the need for the user to close unnecessary windows to continue using the software after they have completed a set of actions.
5. **Asterisks:** Indicate required fields with asterisks throughout the interface. By standardizing this throughout the interface users are aware of what is necessary for them to complete various tasks. This visual indicator also allows users to ensure all necessary information has been entered rather than relying on error messages which interrupt the workflow and require backtracking to complete a task.
6. **Training:** It is our belief that with an ideal interface, one that is intuitive to end users and incorporates as much usability as possible, the amount of necessary training should be minimal. This is why we often recommend streamlining processes for task completion within the EHR. We realize that while minimal training is ideal, it is not always achievable, at least not right away. By completing user testing and incorporating the feedback into the system little by little it will hopefully reduce the required amount of training required.

APPENDICES

The following appendices include supplemental data for this usability test report.

Following is a list of the appendices provided:

- 1: Informed Consent
- 2: Participant demographics
- 3: Moderator's Guide
- 4: NASA-Task Load Index
- 5: Post Study System Usability Questionnaire

Appendix 1: Informed Consent

Informed Consent

Tenzing Medical, LLC would like to thank you for participating in this study. The purpose of this study is to evaluate an electronic health records system. If you decide to participate, you will be asked to perform several tasks using the prototype and give your feedback. The study will last about 60 minutes.

Agreement

I understand and agree that as a voluntary participant in the present study conducted by Tenzing Medical, LLC I am free to withdraw consent or discontinue participation at any time. I understand and agree to participate in the study conducted and videotaped by the Tenzing Medical, LLC.

I understand and consent to the use and release of the videotape by Tenzing Medical, LLC. I understand that the information and videotape is for research purposes only and that my name and image will not be used for any purpose other than research. I relinquish any rights to the videotape and understand the videotape may be copied and used by Tenzing Medical, LLC without further permission.

I understand and agree that the purpose of this study is to make software applications more useful and usable in the future.

I understand and agree that the data collected from this study may be shared outside of Tenzing Medical, LLC and Tenzing Medical, LLC's client. I understand and agree that data confidentiality is assured, because only de-identified data – i.e., identification numbers not names – will be used in analysis and reporting of the results.

I agree to immediately raise any concerns or areas of discomfort with the study administrator. I understand that I can leave at any time.

Please check one of the following:

- YES, I have read the above statement and agree to be a participant.
- NO, I choose not to participate in this study.

Signature: _____ **Date:**

Appendix 2: Participant Demographics

Gender

Men	[5]
Women	[5]
Total (participants)	[10]

Occupation/Role

Physician	[4]
RN/BSN	[2]
MA	[2]
Clinical Applications staff	[1]
Pharmacist	[1]
Total (participants)	[10]

Years of Experience (months)

Professional	[186]
tVistA EHR	[78]

Appendix 3: Moderator's Guide

Introduction/Orientation:

First off, we would like to thank you for taking the time to provide us with feedback on the EHR capabilities being tested today. We are executing these sessions as part of the Office of the National Coordinator's certifications requirements. This usability study will help ensure that Tenzing Medical, LLC meets their certification requirements and Promoting Interoperability standards. We are asking EHR users to provide usability input to the Demographic, Implantable Device List, Drug-related, Clinical Decision Support (CDS) and Clinical Information Reconciliation (CIR) capabilities of tVista EHR. We would like to record your performance on today's session so that we may use it for subsequent usability analysis after we end the session. Do you give your permission for these recordings?

Sign Informed consent

During this session, you will be asked to complete tasks using Tenzing Vista EHR then provide feedback on the Clinical Decision Support and Clinical Information Reconciliation capabilities.

I will provide you with a list of tasks and associated data. You will be asked to complete these tasks as quickly as possible with the fewest errors or deviations. Do not try to do anything other than what is asked. We cannot assist you in accomplishing your tasks. Please save comments and question until the end of each section.

We would like you to give us feedback on the capabilities used. We would like to know how easy or difficult the system is to use, how useful the capabilities are, and what improvement we can make. The best help you can give us is to be critical. We may not be able to fix everything you mention, but it is still beneficial for us to know what issues you feel are important. Your honest feedback is what we are after. Your feedback will be used to help make the Clinical Decision Support and Clinical Information Reconciliation capabilities better, so please do not worry about offending anyone with your comments. Your feedback as well as any questions the usability team is unable to answer will be shared with developers and stakeholders.

We have this interview divided into several parts. I'd like to start by just getting some background information; then I am going to ask some questions about if/how you currently use the EHR functions, then I will provide an introductory overview of each capability being tested. In the last part, we'll have you log in as a test user and complete tasks associated with each capability. Do you have any questions for us before we get started?

Complete Participant Information & Background Information

Clinical Decision Support (CDS) and Clinical Information Reconciliation (CIR) - This section asks a user to review evidence base CDS attributes and clinical reminder logic, trigger CDS tool through EHR data entry and clinical information reconciliation, resolve clinical reminder to reset CDS tool; electronically and simultaneously display a problem, allergy and medication list, then create single lists for review and submission: access, record, and change a problem.

Participant Background Information

Moderator/Administrator:

Data Logger:

Date/Time:

Location of Testing:

Participant #

Gender:

- Male
- Female
- Unknown

Age:

- <19
- 20-29
- 30-39
- 40-49
- 50-59
- 60-69
- 70-79
- 80-89
- >89

Level of Education:

- No high school degree
- High school graduate, diploma or the equivalent (for example: GED)
- Some college credit, no degree
- Trade/technical/vocational training
- Associate degree
- Bachelor's degree
- Master's degree
- Doctorate degree (e.g., MD, DNP, DMD, PhD)

Provider Occupation/Role:

Years of professional experience:

Years of experience with EHR (rounded to the nearest half year):

Years of experience with VistA EHR (rounded to the nearest half year):

Any Assistive Technology Needs (screen readers or magnifiers, large-print or tactile keyboard):

Use

What do you think is the purpose of CDS?

Do you expect CDS tools to be useful and to improve patient care?

What, if any, Clinical Decision support tools do you currently use? (order checks, Clinical reminders,...)

At what point during a visit is Clinical Decision Support most useful? (How does it fit into the visit workflow?)

Who typically address Clinical Decision Support tools/Clinical Reminders?

What do you think is the purpose of CIR?

How do you currently complete clinical information reconciliation?

What type of incoming CIR formats are employees working with (e.g. emails, mail, scans, and papers?)

Who typically handles CIR?

At what point during a visit, where in workflow, is CIR completed for a patient?

How would you like to see Clinical Information Reconciliation (CIR) integrated into the EHR?

Show Participant section intro & Begin WebEx Recording**Provide User Test script and read**

I will say "Begin." At that point, please perform the task and say "Done" when you believe you have successfully completed the task. Please refrain from talking while doing the task. We will have time to discuss the task and answer questions when the task is complete.

Pause WebEx when User states "Done"**Read the NASA Tlx instructions to the User****Provide iPad to User to complete Nasa Tlx**

Appendix 4: NASA-Task Load Index (sample)

---NASA TLX V1.0.3 SINGLE TRIAL PAIRWISE ANSWERS---		
STUDY NAME:	SAMPLE	
STUDY GROUP:	SAMPLE	
SUBJECT ID:	S1	
TRIAL:		1
TRIAL DATE TIME:	6/21/2019 16:35	
---DATA---		
PAIRWISE CHOICES	SELECTION	
Effort vs. Physical Demand	Effort	
Physical Demand vs. Performance	Performance	
Temporal Demand vs. Mental Demand	Temporal Demand	
Physical Demand vs. Frustration	Physical Demand	
Mental Demand vs. Physical Demand	Mental Demand	
Temporal Demand vs. Frustration	Temporal Demand	
Temporal Demand vs. Effort	Effort	
Frustration vs. Effort	Effort	
Physical Demand vs. Temporal Demand	Temporal Demand	
Performance vs. Frustration	Performance	
Performance vs. Temporal Demand	Performance	
Performance vs. Mental Demand	Performance	
Effort vs. Performance	Effort	
Frustration vs. Mental Demand	Mental Demand	
Mental Demand vs. Effort	Mental Demand	

---NASA TLX V1.0.3 SINGLE TRIAL RATING SCALE ANSWERS---		
STUDY NAME:	SAMPLE	
STUDY GROUP:	SAMPLE	
SUBJECT ID:	S1	
TRIAL:		1
TRIAL DATE TIME:	6/21/2019 16:35	
---DATA---		
PAIRWISE ASKED WITH TRIAL:	TRUE	
PAIRWISE ANSWERS TO USE:	SAMPLE_S1_001_PW_06-21-2019_16-35.csv	
RATING SCALE:	RAW RATING	
Mental Demand		60
Physical Demand		15
Temporal Demand		60
Performance		20
Effort		60
Frustration		50

Weighted Rating: 46.33

Appendix 5: Post Study System Usability Questionnaire

Instructions: This questionnaire gives you an opportunity to tell us your reactions to the system you used. Your responses will help us understand what aspects of the system you are particularly concerned about and the aspects that satisfy you.

To as great a degree as possible, think about all the tasks that you have done with the system while you answer these questions.

Please read each statement and indicate how strongly you agree or disagree with the statement by circling a number on the scale.

Please write comments to elaborate on your answers.

After you have completed this questionnaire, I'll go over your answers with you to make sure I understand all of your responses. Thank you!

1. Overall, I am satisfied with how easy it is to use this system.

Strongly									Strongly
Agree	1	2	3	4	5	6	7		Disagree
Comments:									

2. It was simple to use this system.

Strongly									Strongly
Agree	1	2	3	4	5	6	7		Disagree
Comments:									

3. I could effectively complete the tasks and scenarios using this system.

Strongly									Strongly
Agree	1	2	3	4	5	6	7		Disagree
Comments:									

4. I was able to complete the tasks and scenarios quickly using this system.

Strongly									Strongly
Agree	1	2	3	4	5	6	7		Disagree
Comments:									

5. I was able to efficiently complete the tasks and scenarios using this system.

Strongly									Strongly
Agree	1	2	3	4	5	6	7	Disagree	
Comments:									

6. I felt comfortable using this system.

Strongly									Strongly
Agree	1	2	3	4	5	6	7	Disagree	
Comments:									

7. It was easy to learn to use this system.

Strongly									Strongly
Agree	1	2	3	4	5	6	7	Disagree	
Comments:									

8. I believe I could become productive quickly using this system.

Strongly									Strongly
Agree	1	2	3	4	5	6	7	Disagree	
Comments:									

9. The system gave error messages that clearly told me how to fix problems.

Strongly									Strongly
Agree	1	2	3	4	5	6	7	Disagree	
Comments:									

10. Whenever I made a mistake using the system, I could recover easily and quickly.

Strongly									Strongly
Agree	1	2	3	4	5	6	7	Disagree	
Comments:									

11. The information (such as on-line help, on-screen messages and other documentation) provided with this system was clear.

Strongly									Strongly
Agree	1	2	3	4	5	6	7	Disagree	

Comments:

12. It was easy to find the information I needed.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
-------------------	---	---	---	---	---	---	---	----------------------

Comments:

13. The information provided for the system was easy to understand.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
-------------------	---	---	---	---	---	---	---	----------------------

Comments:

14. The information was effective in helping me complete the tasks and scenarios.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
-------------------	---	---	---	---	---	---	---	----------------------

Comments:

15. The organization of information on the system screens was clear.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
-------------------	---	---	---	---	---	---	---	----------------------

Comments:

Note: The interface includes those items that you use to interact with the system. For example, some components of the interface are the keyboard, the mouse, the screens (including their use of graphics and language).

16. The interface of this system was pleasant.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
-------------------	---	---	---	---	---	---	---	----------------------

Comments:

17. I liked using the interface of this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
-------------------	---	---	---	---	---	---	---	----------------------

Comments:

18. This system has all the functions and capabilities I expect it to have.

Strongly								Strongly
Agree	1	2	3	4	5	6	7	Disagree
Comments:								

19. Overall, I am satisfied with this system.

Strongly								Strongly
Agree	1	2	3	4	5	6	7	Disagree
Comments:								

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Tenzing VistA EHR Usability Test Report of Demographics tVistA EHR Capabilities

Tenzing VistA – tVistA V2

Date of Usability Test: June 21 – July 19, 2019

Date of Report: August 31, 2019

Report Prepared By: Tenzing Medical, LLC

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EXECUTIVE SUMMARY

Usability testing of the demographic capabilities of Tenzing VistA Electronic Health Record (tVistA EHR) was conducted June 21 through July 19, 2019 at Trenner Medical Offices, Oroville, CA. The purpose of the testing was to validate the usability of the tVistA V2 and provide evidence of usability for the demographic capabilities. During the usability test 10 healthcare providers matching the target demographic criteria served as participants and used tVistA EHR in simulated but representative tasks.

The study collected performance data on multiple demographic tasks. These tasks are designed to support the certification criteria under ONC 2015 Edition Health Information Technology (Health IT) Certification Criteria. The tasks are categorized as follows:

- Access patient demographics
- Record patient demographics
- Change patient demographics

During the 30 minute usability test, each participant was greeted, asked to sign a consent (Appendix 1), and informed they could withdraw at any time. Participants had prior Tenzing VistA EHR experience. Participants were informed of the purpose of the usability testing and the type of data the testing team was gathering, but they were not instructed on how to complete the tasks. The administrator introduced the test, and instructed participants to complete a series of tasks (one at a time) using tVistA EHR. The administrator did not provide assistance on how to complete a task, but asked participants to complete it as they normally would. When a task was new to a participant, they were asked to demonstrate how they thought they would complete the task. During the test the data logger timed the task and recorded user performance.

The following data was collected for each participant:

- Number of tasks successfully completed without assistance
- Time to Complete Task
- Types of Errors
- Path deviations
- Provider's verbalizations
- Provider's reported workload level
- Provider's satisfaction rating of the system

All participant data was de-identified to eliminate correlation made between participant identity

and data collected. Following the conclusion of the testing, participants were asked to complete two post-test questionnaires. Various recommended metrics, in accordance with the examples set forth in the *NIST Guide to the Process Approach for Improving the Usability of Electronic Health Records*, were used to evaluate the usability of tVistA EHR. Following is a summary of the performance and rating data collected on the usability of the demographic capabilities of the tVistA EHR.

Major findings

The results of the NASA Task Load Index (LTX) – a measure of the subjective workload or demand the task places on the user during execution was: 50.27 Overall, workload ratings indicate the tasks presented did not place a significant workload burden on the participants (1; 2; 3). The ability of participants to complete tasks in new or different ways created minimal workload burden which may be due to participant familiarity with EHR functionality generally or tVistA EHR specifically and regular use of demographics functionality

The results from the Post Study System Usability Questionnaire (PSSQU) – a measure of user satisfaction post participation in scenario-based usability studies-for the tVistA EHR capabilities were: 2.76 overall, 2.73 for System Usefulness, 2.91 for Information Quality, 2.29 for Interface Quality (4; 5). Generally, users responded favorably to the demographics tVistA capabilities. Making changes as indicated in the areas for improvement should increase usability and lead to greater system satisfaction.

Areas for Improvement

- Make data entry format (All CAPS v Mixed Case) consistent
- Clarify prompts that are multiples versus Singular entry
- Simplify look-up

-
1. **Hart, S. G., & Staveland, L.E.** Development of NASA-TLX (Task Load Index): Results of empirical and theoretical research. [ed.] P. A. Hancock and N. Meshkati. *Human mental Workload*. Amsterdam : North Holland Press., 1988, pp. 139-183. Scores greater than 60 are interpreted to place a higher task load on users.
 2. *NASA-Task Load Index (NASA-TLX); 20 Years Later*. **Hart, S. G.** Santa Monica : HFEW, 2006. Proceedings of the Human Factors and Ergonomics Society 50th Annual Meeting. pp. 904-908.
 3. Administrator of the National Aeronautics and Space Administration of the United States Government. *NASA TLX App*. Apple App Store, Vers. 1.0.3 (2016).
 4. *IBM computer usability satisfaction questionnaires: Psychometric evaluation and instructions for use*. **Lewis, J. R.** 1, 1995, International Journal of Human-Computer Interaction, Vol. 7, pp. 57-78. Scores range from 1-5. Lower scores indicate higher level of satisfaction.
 5. *Psychometric Evaluation of the PSSUQ Using Data from Five Years of Usability Studies*. **Lewis, J. R.** 3 & 4, s.l. : Lawrence Erlbaum Associates, Inc., 2002, International Journal of Human-Computer Interaction, Vol. 14, pp. 463-488.

- Additional Training needed
- Include synonym with every option list

INTRODUCTION

The tVistA EHR demographics capabilities are designed to allow access, entry and changes to patient demographic information. The usability testing presented realistic exercises and conditions as defined in ONC 2015 certification requirements:

§ 170.315 (a)(5) Demographics

Purpose

The purpose of this study was to test and validate the usability of the current user interface for tVistA EHR and provide evidence of usability in the EHR. This study was conducted to meet the requirements for ONC 2015 Edition Health Information Technology (Health IT) Certification Criteria indicating that User Centered Design (UCD) should be conducted when developing EHR technology. The intended outcome of implementing User Center Design in coordination with quality system management is improved patient safety. To this end User Center Design identifies user tasks and goals that can then be incorporated into the EHR development to improve efficiency, effectiveness and user satisfaction. In order to satisfy the ONC requirement for §170.315 (g)(3) Safety-enhanced design this study was designed to test demographic tVistA EHR functionality. Data was collected to measure effectiveness, efficiency, and user satisfaction, using metrics of time on task, task completion, task deviation, user task load and user satisfaction. As defined in the Safety-enhanced design test procedure the *National Institute of Standards and Technology Internal Reports (NISTIR) 7742* was used as the basis of format for this final report. The usability testing was conducted by the vendor team with guidance from the *NISTIR 7741 - NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records*

VHA User-Centered Design Approach

tVistA EHR consists of a suite of applications developed by the Veteran Health Administration (VHA), made available through the freedom of information act (FOIA), adopted by Open Source Electronic Health Record Association (OSEHRA) and shared with the Open source EHR community. The VHA development of the EHR is the result of collaboration of VHA HIT staff and VA Clinicians. This collaboration created the VHA legacy of user centered design. VHA utilized the technology of the time and in 1982 launched Decentralized Hospital Computer Program (DHCP) a character-based application. The patient centric EHR evolved as geographically and

organizationally diverse, user-defined, clinical workflows were incorporated into the Veterans Health Information System and Technology Architecture (VistA) information system. VistA was then alpha and beta tested in hospitals and clinics throughout the US. Although VistA was built on the character based foundation of DHCP, it has a modern browser-enabled interface, the Computerized Patient Record System (CPRS). CPRS is a Graphical User Interface (GUI) which incorporates both the requirements for Promoting Interoperability and the requests and recommendations from clinical advisors. Thus, formal user-centered design principles have varied over the development lifecycle of tVistA EHR but have not been absent. The VA used a homegrown quality system called the Project Management Accountability System (PMAS). PMAS was supplemented by ProPath, a repository of artifacts, processes and procedures including usability testing. (<https://www.voa.va.gov/DocumentListPublic.aspx?NodeId=27>).

Tenzing Medical LLC User-Centered Design Approach (6) (7) (8) (9) (10) (11)

Tenzing Medical, LLC incorporated the concepts of Cognitive System Engineering (CSE), User-Centered Design approach in a Decision-Centered Design (DCD) framework as described below. “CSE is an approach to the design of technology, training, and processes intended to manage cognitive complexity in sociotechnical systems” (10). Users engage in cognitively complex activities such as identifying, judging, attending, perceiving, remembering, deciding, problem solving and planning when interacting with a system.

User-Centered Design approach to system engineering encompasses 6 key principles:

- The design is based upon an explicit understanding of users, tasks and environments.
- Users are involved throughout design and development.
- The design is driven and refined by user-centered evaluation.
- The process is iterative.
- The design addresses the whole user experience.
- The design team includes multidisciplinary skills and perspectives.

tVistA EHR system design addresses the cognitive complexities associated with managing complex decision-making and the key principles of User Centered Design through the use of a Decision Centered Design Framework. In DCD the software development involves task analysis, design, and evaluation that focuses on describing, analyzing, understanding, and supporting complex perceptual and cognitive activities (11)

- **Task Analysis** is used to identify key decisions and requirements. Task analysis involves identifying the cognitive activities involved in a task, how the task is performed and where the task is performed so that an understanding of the requirements of the system is

complete and addresses and supports the strengths and weakness of existing cognitive tasks. Subject Matter Experts (SME) assist in identifying these key decisions and requirements and continue their involvement throughout the development process. The SME work closely with the Health Information Technology (HIT) team of designers, programmers, network specialist, pharmacist, physicians, nurses, and ancillary service specialists to provide input on development, design, workflows, and system testing. Having user input in the earliest phases of development allows for better understanding of the skills and knowledge users possess, the mental models used to develop expectation for functionality, the objectives and tasks the application will be used to complete, and the decisions users must make that the application should support.

- **Design** phase of development aims to utilize the insights gained in task analysis to create a system that reduces cognitive challenge, improves error management, and increases performance. SME provide ongoing feedback on individual packages and interoperability between packages. Requirements can be established from the elicitation of this information and conceptual designs created. The most common user activities are identified and made most prominent within the system. Eventually a prototype is created and implementation planning begins. The goal is to optimize the system.
- **Evaluation** involves continuous formative as well as summative usability testing. Decision Centered Design approach to software development incorporates users testing and feedback from the design phase. This type of development captures the unseen aspects of the system, the potential errors, evolving technology and human interaction a with this technology. Usability testing demonstrates user system interaction and further defines necessary adjustments needed immediately and long term to further optimize the system. A broader range of users with diverse requirements, experiences, and work

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6. **Armijo, D., McDonnell, C., Werner, K.** *Electronic Health Record Usability: Evaluation and Use Case Framework*. Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. Rockville : Agency for Healthcare Research and Quality, 2009. 09(10)-0091-1-EF.
7. *Analysis of Complex Decision-Making Processes in Health Care*:. **Kushniruk, A. W.** s.l. : Elsevier Science, May 9, 2002, Journal of Biomedical Informatics, Vol. 34, pp. 365-376.
8. *Cognitive and usability engineering methods for the evaluation*. **Kushniruk, A. W., Patel, V. L.** s.l. : Elsevier Inc., 2004, Journal of Biomedical Informatics, Vol. 37, pp. 56-76.
9. **McDermott, P., Klien, G., Thordsen, M.** *Representing the Cognitive Demands of New Systems: A Decision-Centered Design Approach*. s.l. : US Air Force Research Laboratory, 2000. AFRL-HE-WP-TR-2000-0023.
10. **Militello, L. G., Domingues, C. O., Litern, G. & Klein, G.** The Role of Cognitive Systems Engineering in the System Engineering Design Process. *Systems Engineering*. May 7, 2009, p. 13.
11. **Thordsen, M. L., Hutton, R. J., Miller, T. E.** Decision centered design: Leveraging cognitive task analysis in design. [ed.] E. Hollnagel. *Handbook of Cognitive Task Analysis*. 2010, pp. 383-416.

environments are recruited for summative usability testing. These users provide evaluation and feedback the HIT team uses to reevaluate and reengineer the EHR.

The DCD process is iterative. Problems are identified. Options are evaluated and systems are modeled, integrated, and launched. Performance is then assessed. The HIT team continually aims to meet customer and users' needs, utilize available technology, and evaluate priorities, limitations, and tradeoffs that must be made. Dialog is continuous and frequent among all stakeholders and team members. This allows for generation of new ideas, refinement of old ideas, conceptual changes and/or rejection. This process involves many organizational entities and all parties contribute to the discussion providing input, recommendations, and knowledge exchange. The team analyzes the information provided and makes decisions about design, budget, priorities, testing, redesign and roll-out. The healthcare industry is constantly in flux requiring ongoing and often immediate changes to EHRs. As an iterative and heuristic approach to development DCD bodes well in this environment.

Although change is constant, it is important to design and implement systems that build on current user mental models. This is accomplished by reimagining the same workflow in another format or utilizing existing mental models in another application. Redundancy of function within tVistA EHR, such as right click access to action menus, as well as reusing existing technology common keyboard functions and short cuts facilitate learning and usability.

tVistA EHR is a complex system which requires the user to use complex decision making at times while only simple decision making at others, and users vary in how they practice, how they interact with the EHR, and their individual abilities. Therefore, a broad representative base of users is required to elicit meaningful evaluation of the EHR. Complex but specific user test scripts are designed, and minimal instruction is provided to users in order to elicit maximum evaluation of the EHR during usability testing. The HIT team aims to generate unforeseen possibilities the variety of users may unfold as well as maximal feedback on user experience of the EHR.

Focusing on the intended users of a new or modified technology maximizes benefit for the user and adoptability. The Primary users are given priority over other users who may have competing or irreconcilable preferences.

Primary Users: The primary users for the demographic capabilities are Registrars. Registrars in both inpatient and outpatient settings access, enter and update patient records on a regular basis.

Secondary Users: Secondary users of the demographic capabilities include health information management and billing staff that regularly access the information. As well as

nursing, pharmacy and ancillary service staff that may review patient demographics as related to patient care.

Sociotechnical systems are complex, and users have to find ways to manage the complexities. DCD approach assist users through the use of cognitive support strategies focused on decision support tools that reinforce users' natural decision making processes. The cognitive support elements outlined below and later used in addressing recommendations help to manage complexity when designing the new software. The recommendations made later will impact future cognitive support strategies.

- **Supporting Decision Making:** Refers to decisions support tools designed to provide context specific information when needed and reduce task load.
- **Reducing Errors:** Refers both to system error reduction functionality as well as user's awareness, trust and understanding of error reduction functionality. Users must be aware of where error reduction functionality exists and where it does not so they can adjust their expectations and trust the system when appropriate thus reducing cognitive load.
- **Facilitating Scanning:** Refers to placement, amount and type of information on a screen and how well this placement allows a user to find information quickly and accurately and how well a user can return to their place in a screen after an interruption.
- **Creating Affordance:** Refers to design features that help, aid, support, facilitate or enable thinking, knowing, perceiving, or doing something. For example; words on a button indicating the meaning of the button.
- **Illustrating Perceived Benefit:** Refers to users' belief that their day-to-day activities will benefit from using the system. Lack of perceived benefit can result in lack of motivation to learn or use the system and possibly reject the system entirely
- **Supporting Mental Models:** Refers to building upon users' mental models. Designing applications that utilize common language and functionality such as windows standard or previous version functionality.

The demographic capabilities are new methods for old processes. Accessing, entering and changing new and newly configured demographic information in a simple entry template are user tasks that require a simple, manageable, well understood process within the EHR. Primary user's main concerns for demographic capabilities include simple access, entry and edit of information. Also all tasks should be completed with a minimal number of key strokes.

Tenzing Medical, LLC practices the user center design and testing outlined above on an ongoing basis, but this document specifically focuses on the usability testing conduct over several weeks.

METHOD

PARTICIPANTS

A total of 10 participants were tested on the tVistA EHR demographic capabilities. Participants in the test were registration, health information management, and ancillary staff from varied backgrounds. The participants were recruited by Denise Lefevre, the Chief Information Officer (CIO). The participants volunteered and were, therefore, not compensated for their participation. Participants had no direct connection to the development of or organization producing tVistA EHR nor the testing or supplier organization. Some participants had previous experience with demographic tVistA EHR capabilities. All participants were given the same overview of the new demographic functionality for this testing as they had little or no prior knowledge.

Participants were from varied backgrounds and experience as outline in the table below.

Participant ID	Gender	Age	Education	Occupation/Role	Professional Experience	Computer Experience	Product Experience	Assistive Technology Needed
1	Female	30-39	Some college, no degree	Clinical Application Coordinator Integrations lead	180	120	36	No
2	Female	30-39	Some college, no degree	MA/Clinical Application Coordinator integrations	180	180	24	No
3	Male	50-59	Doctorate	Pharmacist	240	120	120	No
4	Male	40-49	Doctorate	MD/Health Informatist	180	84	84	No
5	Female	30-39	Bachelor's	Nurse/BCMA coordinator	120	72	72	No
6	Male	20-29	Doctorate	MD/Medical Informaticist Support specialist	24	6	24	No
8	Female	40-49	Some college, no degree	MA/Clinical Application Coordinator	216	144	144	No
10	Female	40-49	Bachelor's	Registered Nurse/Director of Education	360	144	144	No
11	Female	40-49	Some college, no degree	MA/Clinical Application Coordinator integrations	168	182	182	No
12	Female	30-39	Trade/technical/vocational training	Lead Clinical Application Coordinator	144	78	78	No

Table 1. Demographic characteristics

Participants were provided a participant ID upon arrival for testing thus de-identifying individuals. Participants were scheduled for 30 minute sessions which included introductions and background, demographic tasks, and metrics. Between sessions the data logger, moderator and other team members debriefed and prepared for the next participant. A demographic spreadsheet with participant's background information and a schedule of testing appointments was kept to track participation.

STUDY DESIGN

The overall objective of this test was to determine if the application performed effectively, efficiently, and to the satisfaction of the users. Also, if the application failed to meet the needs of the participants what issues were encountered and how can they be mediated. This testing was also designed to satisfy the demographic capability requirements of the Safety Enhanced Design criteria for ONC 2015 Edition Health Information Technology (Health IT) Certification Criteria. The data obtained from this testing is expected to generate recommendation and discussion for future development of the demographic capabilities of tVistA EHR and identify possible requirements for immediate modifications to facilitate patient safety and/or user adoption.

All participants interacted with tVistA EHR in the same location, provided with the same instructions, asked to complete the same tasks and used the same evaluation tools. Data was collected during testing by the data logger and administrator to evaluate the system for effectiveness, efficiency and satisfaction as defined by measures collected and analyzed for each participant:

- Number of tasks successfully completed within the allotted time without assistance
- Time to complete the tasks
- Number and types of errors
- Path deviations
- Participant's verbalizations (comments)
- Participant's satisfaction ratings of the system

More information about the various measures is provided below in the Usability Metrics section.

TASKS

A number of tasks were constructed that would be realistic and representative of the kinds of

activities a user might do with this EHR, including:

1. Access patient demographics
2. Record patient demographics
3. Change patient demographics

Tasks were selected based on ONC 2015 Certification test protocol § 170.315 (a)(5) Demographics, frequency of use, criticality of function for Promoting Interoperability, and tasks that could be foreseen as being most troublesome for users

PROCEDURES

Upon arrival, participants were greeted; their identity was verified and matched with the name on the participant schedule. Participants were then assigned a participant ID. Each participant was made aware their performance on the upcoming tasks would be recorded for subsequent analysis. The participant was asked to sign the Informed Consent Form (Appendix 1).

First off we would like to thank you for taking the time to provide us with feedback on the EHR capabilities being tested today. We are executing these sessions as part of the Office of the National Coordinator's certifications requirements. This usability study will help ensure that Tenzing Medical, LLC meets their certification requirements and Promoting Interoperability standards. We are asking EHR users to provide usability input to the Demographic capabilities of tVistA EHR. We would like to record your performance on today's session so that we may use it for subsequent usability analysis after we end the session. Do you give your permission for these recordings?

To ensure the usability testing ran smoothly, an administrator and a data logger were present for the testing: the testing team members have 20 years of experience in psychological and clinical research and RPMS, CPRS, and commercial medical hardware and software design, development and testing. The team included experienced hardware and software developers with experience in usability testing and user-centered design programs. Also included on the sessions were several stakeholders who were available to observe the user interaction with the system, respond to questions after completion of formal testing and elicit feedback relevant to future development.

The administrator moderated the session, administered instructions and tasks, obtained post-task rating data, and took notes on participant comments. The data logger monitored task times, and took notes on task success, path deviations, number and type of errors, and comments.

Background information was asked of each participant prior to engaging in the tasks. The data was logged by the administrator and data logger. The participant was situated at the computer, provided

with log on information, and allowed time to orient themselves to the EHR and the expected tasks.

Participants were instructed to perform the tasks (see specific instructions in Appendix 3: Moderator's guide):

- As quickly as possible making as few errors and deviations as possible.
- Without assistance; administrators were allowed to give immaterial guidance and clarification on tasks, but not instructions on use.
- Without using a think aloud technique.

For each task, the participants were given a written copy of the tasks. Task timing began once the administrator said “begin”. The task time was stopped once the participant indicated he had successfully completed the task (e.g. said “done”, signed the order, etc.).

Following each task the participant was asked to complete the NASA-TASK LOAD INDEX (Appendix 4). At the completion of the session, the administrator gave the participant the POST STUDY SYSTEM USABILITY QUESTIONNAIRE (Appendix 5).

Participants were asked if they had any additional comments or questions for the group, which were logged by the data logger, and thanked for their participation.

Participants' demographic information, task success rate, time on task, errors, deviations, verbal responses, and post-test questionnaire were recorded into a spreadsheet.

TEST LOCATION

Usability testing took place in a small conference room. A user laptop computer and mouse were set up on a table. The Administrator sat next to the user. The user's screen was redisplayed for the data logger and observers on computers in a separate training room via WebEx session. Stakeholders observed from the data logger's location or listened and viewed via the WebEx session. To ensure that the environment was comfortable for users, noise levels were kept to a minimum with the ambient temperature within a normal range. All the safety instructions and evacuation procedures were valid, in place, and visible to the participants.

TEST ENVIRONMENT

Demographic EHR capabilities would typically be used in a healthcare office or facility. In this instance, the testing was conducted in a small conference room in the Trenner Medical offices

building. For testing a Dell Latitude 7480 laptop running Windows 7 operating system was used with an external mouse. The participants used both keyboard and mouse to navigate and interact with the tVista EHR. A 14-inch monitor was used with a screen resolution of 1920 x 1080. The application was set up according to vendor specifications and the application was running on a Linux/GTM platform using a test database on a LAN connection. The performance of the test system was comparable to what users experience in production environments on site at hospitals and clinics. Participants were asked not to change any of the setting defaults to insure conformity.

TEST FORMS AND TOOLS

During the usability test various documents and instruments were used, including:

1. Informed Consent
2. Moderator Guide w/ Patient Demographics
3. NASA-TLX
4. PPSSUQ

Examples of these documents can be found in the Appendices. The Moderator's Guide was devised so as to be able to capture required data.

The participant's interaction with the EHR was captured through recording of WebEx session for each participant's test.

The test sessions were transmitted via WebEx screen sharing to a nearby observation room where the data logger observed the test session.

PARTICIPANT INSTRUCTIONS

The administrator read the following instructions aloud to each participant (also see the full moderator's guide in Appendix 3):

During this session, you will be asked to complete tasks using Tenzing Vista EHR then provide feedback on the Demographic capabilities.

I will provide you with a list of tasks and associated data. You will be asked to complete these tasks as quickly as possible with the fewest errors or deviations. Do not try to do anything other than what is asked. We cannot assist you in accomplishing your tasks. Please save comments and question until the end of each section.

We would like you to give us feedback on the capabilities used. We would like to know how easy or difficult the system is to use, how useful the capabilities are, and what improvement we can make.

The best help you can give us is to be critical. We may not be able to fix everything you mention, but it is still beneficial for us to know what issues you feel are important. Your honest feedback is what we are after. Your feedback will be used to help make the Demographic capabilities better, so please do not worry about offending anyone with your comments. Your feedback as well as any questions the usability team is unable to answer will be shared with developers and stakeholders.

We have this interview divided into several parts. I'd like to start by just getting some background information; then I am going to ask some questions about if/how you currently use the EHR functions, then I will provide an introductory overview of each capability being tested. In the last part, we'll have you log in as a test user and complete tasks associated with each capability. Do you have any questions for us before we get started?

Following the procedural instructions, participants were shown the EHR and given time to explore tVista EHR and make comments. Once complete the administrator gave the following instructions:

I will say "Begin." At that point, please perform the task and say "Done" when you believe you have successfully completed the task. Please refrain from talking while doing the tasks. We will have time to discuss the tasks and answer questions when all the tasks are completed.

Participants were given 3 tasks to complete. Tasks are listed Tables 3a below.

USABILITY METRICS

According to the *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records*, EHRs should support a process that provides a high level of usability for all users.

The goal is for users to interact with the system effectively, efficiently, and with an acceptable level of satisfaction. To this end, metrics for effectiveness, efficiency and user satisfaction were captured during the usability testing. The goals of the test were to assess:

1. Effectiveness by measuring participant success rates and errors
2. Efficiency by measuring the average task time and path deviations
3. Satisfaction by measuring ease of use ratings

DATA SCORING

The following table (Table 2) details how tasks were scored, errors evaluated, and the time data analyzed.

Measures	Rationale and Scoring
<p>Effectiveness: Task Success</p>	<p>A task was counted as a “Success” if the participant was able to achieve the correct outcome, without assistance, within the time allotted on a per task basis.</p> <p>The number of successes were calculated for each task and then divided by the total number of times that task was attempted. The results are provided as a percentage.</p> <p>If the participant abandoned the task, did not reach the correct answer or performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as an “Failures.” No task times were taken for errors.</p>
<p>Efficiency: Task Time</p>	<p>Task times were recorded for tasks successfully completed then divided by the number of participants who completed the task successfully. The average task time is reported. Variance measures (standard deviation and standard error) were also calculated.</p>
<p>Efficiency: Task Deviations</p>	<p>The participant’s path (i.e., steps) through the application was recorded. Deviations occur if the participant, for example, skipped a prompt, made an incorrect entry, or interacted incorrectly with an on-screen prompt. This path was compared to the minimum number of steps possible per task (optimal path) established by the team and developers. The number of steps in the observed path is divided by the optimal number of steps and presented as a ratio of path deviation</p>
<p>Satisfaction: Task Load</p>	<p>Participant’s subjective impression of the workload or cost of accomplishing the task requirements were obtain through the administration of the NASA Task Load Index (NASA-TLX) after each task set. The participant was asked to complete the six subscales representing different variables including: Mental, Physical, and Temporal Demands, Frustration, Effort, and Performance. See Appendix 4 for a copy of the questionnaire.</p> <p>A high level of burden on the participants is indicated by a score of 60 or greater.</p>
<p>Satisfaction: Task Rating</p>	<p>To measure the participant’s satisfaction of the demographic capabilities the team administrated the Post Study System Usability Questionnaire (PSSUQ) at the completion of all the tasks. The PSSUQ consists of 19 items such as “it was simple to use the system” and “It was easy to find the information I needed” that the participant rates using a 7-point Likert scale ranging from 1=strongly agree to 7= strongly disagree. The PSSQU is designed to assess overall user satisfaction through perceived system usefulness, Information Quality and Interface quality.</p> <p>See Appendix 5 for a copy of the questionnaire.</p>

Table 2. Details of how observed data were scored.

RESULTS

DATA ANALYSIS AND REPORTING

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above. There were no participants who failed to follow session and task instructions or had their data excluded from the analyses.

The usability testing results for the Demographic capabilities of tVistA EHR are detailed below in Tables 3. The results should be seen in light of the objectives and goals outlined in the Study Design section above. The data should yield actionable results. If corrected, the demographic tVistA EHR capabilities will have a positive impact on user performance.

Qualitative feedback from the participants was transcribed by team members and compiled in an Excel spreadsheet. The team met to discuss all potential issues particularly those items noted as significant for consideration. Each issue was listed as verbalized by the participant and the team evaluated the issue asking questions such as: *What might cause the participant to have this issue? What cognitive support element does this issue violate? What can be done/changed to support the cognitive support element?* Recommendations intended to rectify the identified issue were recorded.

Issues were coded according to the cognitive element that led to the underlying issue, issue class, and time frame

Issue Class

Each issue was classified into an “issue class.” This classification scheme represents our understanding of the potential impact of each issue if left unaddressed.

- **Type 1** issues are those we anticipate will create an *individual error risk*. These issues may directly introduce a specific health risk. For example, a new health system that somehow allowed treatment plans to be mistakenly associated with multiple EHRs. Some patients would be placed at significant health risk because of the design flaw.
- **Type 2** issues are those we anticipate will create an *aggregate error risk*. These issues may introduce error through cumulative effects. An example of this would be a new system that failed to capture some important paper- based function that was used in conjunction with the old system. The loss of low-tech, but high-value information can eventually lead to a problem.
- **Type 3** issues are those that we anticipate will create *adoption and long-term use risk*. These issues may negatively influence acceptance of the software. In the extreme, ignoring these issues may result in software that is rejected by the intended users. If use is mandated, users may find ways to “game” the system, distorting or circumventing the intent of the software. This is less troubling from a health risk standpoint but could still create a long-term failure of a system in which much has been invested.

Timeframe

Recommendations are also made according to the timeframe in which issues should be addressed.

Four timeframes are considered: urgent, quick fix, near-term, and long-term.

- **Urgent:** lead to significant medical error and/or patient risk, need to be fixed before next release/patch.
- **Quick fix:** These issues that we believe can be fixed "in-house" in a relatively short time frame (e.g. several weeks). These are issues that we believe will positively influence user acceptance with little development effort.
- **Near-term issue:** These issues are those that we believe will positively influence user acceptance. Can be completed in 12 months or less but may require extra development time and effort.
- **Long-term issue:** These issues do not present significant risk in their current form. These recommendations, however, have the potential for significant, high impact benefit if resources can be found to address them over time. These fixes will take more than 12 months, contain interoperability issues and may require overhauls of existing systems, introductions of new functionality, and require extended development efforts.

Task #	Task Description	N	Task Success - Mean (%)	Task Success - Standard Deviation (%)	Task Path Deviation Observed #	Task Path Deviation Optimal #	Task Time - Mean (seconds)	Task Time Standard Deviation (seconds)	Task Time Deviation - Mean Observed Seconds	Task Time Deviation - Mean Optimal Seconds	Task Errors - Mean (%)	Task Errors - Standard Deviation (%)	Task Rating Scale Type	Task Rating (Overall)	Task Rating (Overall) - Standard Deviation	System Usefulness rating	Information Quality rating	Interface Rating	Task Load
1	Record Demographics	10	91.4	18.4	31	20	291	185	2.02	144	8.8	18.6	PSSUQ	2.76	1.50	2.73	2.91	2.29	50.27
2	Access Patient Demographics	10	93.3	13.3	5	3	73	39	1.67	44	6.7	13.3							
3	Change Patient Demographics	10	87.5	25.0	40	28	296	126	1.70	194	12.5	25.0							

Table 3: Demographic data

DISCUSSION OF THE FINDINGS

Effectiveness

Effectiveness was measured by task completion or failure to complete task. We asked providers to complete tasks of demographic tVista EHR capabilities that demonstrate the required functionality. These tasks are derived from the ONC 2015 Edition Health Information Technology (Health IT) Certification Criteria. The task completion data indicates that providers were able to complete the tasks that they were asked to execute. There are notable differences between the participants who completed each task. These variations are due to subject characteristics, not issues regarding the functionality of the system. These subject variables include not following the test script, failing to enter data in some fields, or imposing current system/organization restrictions on task. For example, entering data different than that provided in the test script or not changing an entry entered in error as this is a function restricted to certain organizational users and even when granted the privilege for this test purpose users resisted.

Efficiency

Efficiency was measured by time on task and task deviations. We asked providers to complete representative tasks of the demographic capabilities that demonstrate the required functionality. These tasks are derived from the ONC 2015 Edition Health Information Technology (Health IT) Certification Criteria. The data indicates that most providers were able to complete all the tasks in a standard manner. However, there were deviations with respect to repeated attempted entry of data due to incorrect entry form (mixed case versus all caps or incorrect spelling). Multiple users paused at prompts they did not find in the test script or did not know how to complete. A couple users skipped fields that had data required data entry per the test script. A few users entered an edit mode not commonly used and not required for the test script that required specialty keystrokes to exit. Some user failed to follow on screen prompts.

Satisfaction

Satisfaction was measured by two subjective questionnaires, the NASA TLX and the PSSUQ. Overall workload ratings indicate that the users are not overly burdened by the software. The results from the NASA TLX was 50.27. PSSUQ results indicated overall favorable results for all areas of the demographics tVista EHR capabilities. Below is a complete list of written comments (duplicates omitted) articulated by participants in

- *I hate that this has to be exact typed out.*
- *I should be able to type in “eng” and it pops up English or something like that.*
- *I'm okay with it being typed out as long as it is consistent. If it's all lower case, then all lower case if it's all caps then all caps but don't tell me to do a capital letter then all lower case and some of it is and some of it is not.*
- *I don't know the Tenzing VistA Shortcuts.*
- *I didn't know the @ sign or the ? mark gave options.*
- *You gave me instructions, but I had no idea what they mean.*
- *Need more information/instruction to start.*
- *You need a quick overview.*
- *I didn't understand the race and the ethnicity. It asked if I wanted to make it a new race or ethnicity and I didn't understand that. It didn't make sense.*
- *The hard thing is that if you don't know what's there and what's available you have to get the list but then you can't type out the word until you go back out and then you need to know how it is specifically spelled and case.*
- *Sometimes an option list has abbreviation or number to select and sometimes they don't, so you have to type it all out.*
- *Because you can't ask a question you're just stuck unless you have something there to tell you how to do it.*

This list of comments includes positive, neutral, and negative comments illustrating that there are areas of the EHR that providers find easy to use and areas of the EHR that will benefit from design enhancements. Additional training to improve or maintain skills could be effective in reinforcing the data entry methods user indicated they are unaware or unfamiliar with. Multiple users complained of a high level of testing anxiety.

AREAS FOR IMPROVEMENT

As a result of this set of usability interviews we determined that the demographic tVistA EHR capabilities violate a set of cognitive support elements. Relevant issues gleaned from these usability sessions are listed in the following section. The resulting issues are grouped with respect to the cognitive element that the usability team believes led to the underlying issue. Each issue that was uncovered during the usability interviews is listed as it relates to the cognitive element that is being violated. As a reminder, these elements include:

- *Support Decision Making*
- *Reduce Errors*

- *Facilitate Scanning*
 - *Create Affordances*
 - *Illustrate Perceived Benefit*
 - *Support Mental Models*

Recommendations are made to encourage a design enhancement that creates support for the relevant cognitive requirement. Recommendations should be adopted and implemented only in ways that support the cognitive elements. When reviewing the issues and recommendations the HIT team should consider questions such as:

1. *Why are participants having this issue?*
2. *What cognitive support element does this issue violate?*
3. *What can we do within the design process to facilitate the cognitive support requirement?*

Issues and Recommendations

Issue 1: Provider frustrated by non-standard data entry requirements; Mixed Case, All Capitals and abbreviations

- Cognitive Support Element: Supporting Mental Models. We believe this is a quick fix that could be rectified by additional explanation of the new standards being implemented and an overall change from using all capital letters to mixed case entry
 - Consideration:
 - *How can we facilitate provider quick consistent data entry format?*
- R-1 We recommend additional training on new standards being implemented and data entry formats.

```

CERT
LANGUAGE PREFERENCE:      3  English, Old (ca.450-1100)??
LANGUAGE PREFERENCE: CHOOSE 1-3:??
LANGUAGE PREFERENCE:
SEX: FEMALE// ^

Select PATIENT NAME:
  UT,CIR SAMPLE          <A>    F 02-01-1963 444223587          000448135

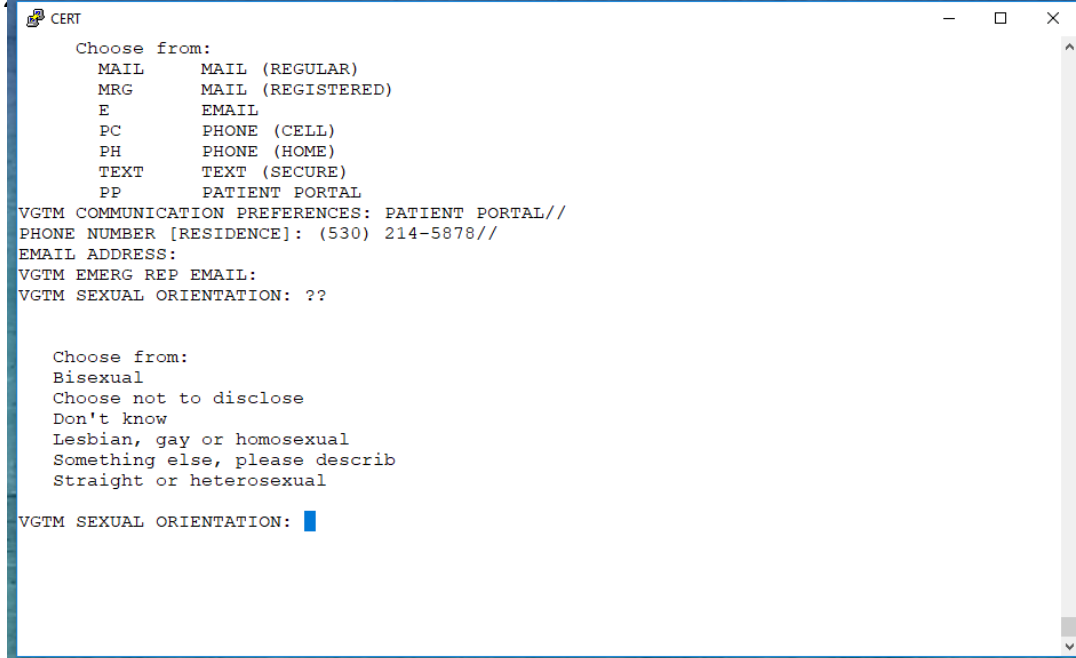
LANGUAGE PREFERENCE: EN??
LANGUAGE PREFERENCE: ENG??
LANGUAGE PREFERENCE: ENGLISH??
LANGUAGE PREFERENCE: english??
LANGUAGE PREFERENCE: eng??
LANGUAGE PREFERENCE: en
  1  en  English
  2  enm English, Middle (1100-1500)
CHOOSE 1-2: ??
LANGUAGE PREFERENCE: En
  1  English
  2  English, Middle (1100-1500)
  3  English, Old (ca.450-1100)
CHOOSE 1-3: ??
LANGUAGE PREFERENCE: Eng
  1  English
  2  English, Middle (1100-1500)
  3  English, Old (ca.450-1100)
CHOOSE 1-3: ??
LANGUAGE PREFERENCE: English
  1  English
  2  English, Middle (1100-1500)
  3  English, Old (ca.450-1100)
CHOOSE 1-3: ??
LANGUAGE PREFERENCE:

```

Examples: Entry formats that do NOT work and a few that do

Issue 2: Some prompts provide a synonym for selection list others do not. When presented with a list of options to choose from to complete an entry at a prompt some prompts provide a synonym with the list and others do not.

- Cognitive Support Element: Supporting Mental Models. The variability of prompt options causes unnecessary confusion and complicates data entry
 - Consideration:
 - *How can we standardize prompt entry options?*
 - R-2 Adding Synonyms to option list on Sexual Orientation and Gender Identity so they conform to data entry norm.



Example: Prompt with synonyms and prompt without synonyms

Issue 3: Provider not familiar with Tenzing VistA options, shortcuts, standards.

Providers stated they were unfamiliar with some or many of the entry options, shortcuts and standards.

- Cognitive Support Element: Creating Affordance
 - Consideration
 - *How can we facilitate understanding of Tenzing VistA entry options, Shortcuts and standards?*
- R-3 We recommend additional training on basic Tenzing VistA functionality so users are aware of entry options that will facilitate efficient and accurate data entry
- R-4 We recommend focused training on specific user ask so that learned functionality if meaningful, helpful and reduces entry errors.

```

LANGUAGE PREFERENCE: ?
Answer with VGTM LANGUAGE Language Name(English), or ISO 639-1 Code
Do you want the entire 487-Entry VGTM LANGUAGE List?
LANGUAGE PREFERENCE:
SEX: FEMALE// ??
Enter 'M' if this applicant is a male, or 'F' if female.

Choose from:
M          MALE
F          FEMALE
U          UNKNOWN
SEX: FEMALE//

```

```

PRELIMINARY CAUSE OF DEATH:
  Edit? NO// YES

==[ WRAP ]==[INSERT ]=====< PRELIMINARY CAUSE OF DEATH[Press <PF1>H for help]=====
Entry into a screenman prompt allows for extended text entry. <PF1>E is
used to exit.

DATE OF DEATH:
VGTM COMMUNICATION PREFERENCES: PP PATIENT PORTAL
PHONE NUMBER [RESIDENCE]: (530) 214-5878//

```

Examples: various Tenzing VistA options, standards and shortcut

Issue 4: Providers had difficulty with the Race and Ethnicity prompts. Providers found the allowed multiple entries confusing language. One provider interpreted the text confirming desire to add a Race as adding a Race to the system not the patient file.

- Cognitive Support Element: Supporting mental models
 - Consideration
 - *How can we facilitate use of multiple data entry points?*
 - *How can we clarify prompt text to make it understandable to users?*
- R-5 We could display existing entries prior to prompt for additional entry.
- R-6 We could modify text for clarification: *Are you adding 'WHITE' as a new RACE INFORMATION for this PATIENT?*

```

LANGUAGE PREFERENCE:
SEX: FEMALE//
Select RACE INFORMATION: AMERICAN INDIAN OR ALASKA NATIVE
//
RACE INFORMATION: AMERICAN INDIAN OR ALASKA NATIVE
//
METHOD OF COLLECTION: UNKNOWN//
Select RACE INFORMATION: BLACK
1 BLACK Black or African American
2 BLACK OR AFRICAN AMERICAN B Black or African American
3 BLACKFEET American Indian or Alaska Native
4 BLACKFOOT SIOUX American Indian or Alaska Native
CHOOSE 1-4: 1 BLACK Black or African American
Are you adding 'BLACK' as a new RACE INFORMATION (the 2ND for this PATIENT)?
No// Y (Yes)
METHOD OF COLLECTION: SELF IDENTIFICATION//
Select RACE INFORMATION:

```

Example: Current Display

```

RACE INFORMATION:
AMERICAN INDIAN OR ALASKA NATIVE
BLACK
Select RACE INFORMATION: BLACK// WHITE|
1 WHITE W WHITE
2 WHITE EARTH American Indian or Alaska Native
3 WHITE MOUNTAIN American Indian or Alaska Native
4 WHITE MOUNTAIN APACHE American Indian or Alaska Native
5 WHITE MOUNTAIN INUPIAT American Indian or Alaska Native
CHOOSE 1-5: 1 WHITE W WHITE
Are you adding 'WHITE' as a new RACE INFORMATION for this PATIENT?
No// Y

```

Example: Suggested Display

Table 4 represents the issues, the associated cognitive support element, issue class and anticipated timeframe

Issue	Description	Cognitive Support Element	Issue Class	Timeframe
1	Provider frustrated by non-standard data entry requirements	Supporting Mental Models	III	Quick Fix
2	Supporting mental models	Supporting Mental Models	III	Near-term
3	Provider not familiar with Tenzing VistA options, shortcuts, standards	Creating Affordance	III	Quick Fix
4	Providers had difficulty with the Race and Ethnicity prompts.	Supporting Decision Making	I	Long-term

Table 4: Issue and Recommendations by Cognitive Support Element, Issue Class and Timeframe

The following appendices include supplemental data for this usability test report. Following is a list of the appendices provided:

- 1: Informed Consent
- 2: Participant Demographics
- 3: Moderator's Guide
- 4: NASA-Task Load Index
- 5: Post Study System Usability Questionnaire

Informed Consent

Tenzing Medical, LLC would like to thank you for participating in this study. The purpose of this study is to evaluate an electronic health records system. If you decide to participate, you will be asked to perform several tasks using the prototype and give your feedback. The study will last about 30 minutes.

Agreement

I understand and agree that as a voluntary participant in the present study conducted by Tenzing Medical, LLC I am free to withdraw consent or discontinue participation at any time. I understand and agree to participate in the study conducted and videotaped by the Tenzing Medical, LLC.

I understand and consent to the use and release of the videotape by Tenzing Medical, LLC. I understand that the information and videotape is for research purposes only and that my name and image will not be used for any purpose other than research. I relinquish any rights to the videotape and understand the videotape may be copied and used by Tenzing Medical, LLC without further permission.

I understand and agree that the purpose of this study is to make software applications more useful and usable in the future.

I understand and agree that the data collected from this study may be shared outside of Tenzing Medical, LLC and Tenzing Medical, LLC's client. I understand and agree that data confidentiality is assured, because only de-identified data – i.e., identification numbers not names – will be used in analysis and reporting of the results.

I agree to immediately raise any concerns or areas of discomfort with the study administrator. I understand that I can leave at any time.

Please check one of the following:

- YES, I have read the above statement and agree to be a participant.
- NO, I choose not to participate in this study.

Signature: _____ **Date:** _____

Appendix 2: Participant Demographics

Gender	
Men	3
Women	7
Total (participants)	10
Occupation/Role	
Clinical Applications	3
Medical Assistant	3
Nurse	2
Physician	2
Total (participants)	10
Average Years of Experience (months)	
Professional	181
VistA EHR	91

Introduction/Orientation:

First off we would like to thank you for taking the time to provide us with feedback on the EHR capabilities being tested today. We are executing these sessions as part of the Office of the National Coordinator's certifications requirements. This usability study will help ensure that Tenzing Medical, LLC meets their certification requirements and Promoting Interoperability standards. We are asking EHR users to provide usability input to the Demographic, Implantable Device List, Drug-related, Clinical Decision Support (CDS) and Clinical Information Reconciliation (CIR) capabilities of tVistA EHR. We would like to record your performance on today's session so that we may use it for subsequent usability analysis after we end the session. Do you give your permission for these recordings?

Sign Informed consent

During this session, you will be asked to complete tasks using Tenzing VistA EHR then provide feedback on the Demographic capabilities.

I will provide you with a list of tasks and associated data. You will be asked to complete these tasks as quickly as possible with the fewest errors or deviations. Do not try to do anything other than what is asked. We cannot assist you in accomplishing your tasks. Please save comments and question until the end of each section.

We would like you to give us feedback on the capabilities used. We would like to know how easy or difficult the system is to use, how useful the capabilities are, and what improvement we can make. The best help you can give us is to be critical. We may not be able to fix everything you mention, but it is still beneficial for us to know what issues you feel are important. Your honest feedback is what we are after. Your feedback will be used to help make the demographic capabilities better, so please do not worry about offending anyone with your comments. Your feedback as well as any questions the usability team is unable to answer will be shared with developers and stakeholders.

We have this interview divided into several parts. I'd like to start by just getting some background information; then I am going to ask some questions about if/how you currently use the EHR functions, then I will provide an introductory overview of each capability being tested. In the last part, we'll have you log in as a test user and complete tasks associated with each capability. Do you have any questions for us before we get started?

Complete Participant Information & Background Information

Demographics – This section asks a user to record, change, and access patient demographic data including race, ethnicity, preferred language, sex, sexual orientation, gender identity, and date of birth. Basic fileman knowledge is necessary to complete this task. A Fileman shortcut list and user guide is provided for your reference.

Moderator/Administrator:

Data Logger:

Date/Time:

Location of Testing:

Participant #

Gender:

- Male
- Female
- Unknown

Age:

- <19
- 20-29
- 30-39
- 40-49
- 50-59
- 60-69
- 70-79
- 80-89
- >89

Level of Education:

- No high school degree
- High school graduate, diploma or the equivalent (for example: GED)
- Some college credit, no degree
- Trade/technical/vocational training
- Associate degree
- Bachelor's degree
- Master's degree
- Doctorate degree (e.g., MD, DNP, DMD, PhD)

Provider Occupation/Role:

Years of professional experience:

Years of experience with EHR (rounded to the nearest half year):

Years of experience with VistA EHR (rounded to the nearest half year):

Any Assistive Technology Needs (screen readers or magnifiers, large-print or tactile keyboard):

Use

How do you currently complete patient demographic entry/updates?

Are there any functions in the version that you interact with that you do not use often?

Are there any functions you see as less important than others?

Provider Fileman Shortcut list to User and read Fileman Basics

Show Participant section intro & Begin WebEx Recording

Provide User Test script and read

I will say "Begin." At that point, please perform the task and say "Done" when you believe you have successfully completed the task. Please refrain from talking while doing the task. We will have time to discuss the task and answer questions when the task is complete.

Pause WebEx when User states "Done"

Read the NASA Tlx instructions to the User

Provide iPad to User to complete Nasa Tlx

Set up Nasa Tlx for next section evaluation

Appendix 4: NASA-Task Load Index (sample)

---NASA TLX V1.0.3 SINGLE TRIAL PAIRWISE ANSWERS---	
STUDY NAME:	SAMPLE
STUDY GROUP:	SAMPLE
SUBJECT ID:	S1
TRIAL:	1
TRIAL DATE TIME:	6/21/2019 16:35
---DATA---	
PAIRWISE CHOICES	SELECTION
Effort vs. Physical Demand	Effort
Physical Demand vs. Performance	Performance
Temporal Demand vs. Mental Demand	Temporal Demand
Physical Demand vs. Frustration	Physical Demand
Mental Demand vs. Physical Demand	Mental Demand
Temporal Demand vs. Frustration	Temporal Demand
Temporal Demand vs. Effort	Effort
Frustration vs. Effort	Effort
Physical Demand vs. Temporal Demand	Temporal Demand
Performance vs. Frustration	Performance
Performance vs. Temporal Demand	Performance
Performance vs. Mental Demand	Performance
Effort vs. Performance	Effort
Frustration vs. Mental Demand	Mental Demand
Mental Demand vs. Effort	Mental Demand

---NASA TLX V1.0.3 SINGLE TRIAL RATING SCALE ANSWERS---	
STUDY NAME:	SAMPLE
STUDY GROUP:	SAMPLE
SUBJECT ID:	S1
TRIAL:	1
TRIAL DATE TIME:	6/21/2019 16:35
---DATA---	
PAIRWISE ASKED WITH TRIAL:	TRUE
PAIRWISE ANSWERS TO USE:	SAMPLE_S1_001_PW_06-21-2019_16-35.csv
RATING SCALE:	RAW RATING
Mental Demand	60
Physical Demand	15
Temporal Demand	60
Performance	20
Effort	60
Frustration	50

Weighted Rating: 46.33

Appendix 5: Post Study System Usability Questionnaire

Instructions: This questionnaire gives you an opportunity to tell us your reactions to the system you used. Your responses will help us understand what aspects of the system you are particularly concerned about and the aspects that satisfy you.

To as great a degree as possible, think about all the tasks that you have done with the system while you answer these questions.

Please read each statement and indicate how strongly you agree or disagree with the statement by circling a number on the scale.

Please write comments to elaborate on your answers.

After you have completed this questionnaire, I'll go over your answers with you to make sure I understand all of your responses.

Thank you!

1. Overall, I am satisfied with how easy it is to use this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

2. It was simple to use this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

3. I could effectively complete the tasks and scenarios using this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

4. I was able to complete the tasks and scenarios quickly using this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

5. I was able to efficiently complete the tasks and scenarios using this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

6. I felt comfortable using this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
----------------	---	---	---	---	---	---	---	-------------------

Comments:

7. It was easy to learn to use this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
----------------	---	---	---	---	---	---	---	-------------------

Comments:

8. I believe I could become productive quickly using this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
----------------	---	---	---	---	---	---	---	-------------------

Comments:

9. The system gave error messages that clearly told me how to fix problems.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
----------------	---	---	---	---	---	---	---	-------------------

Comments:

10. Whenever I made a mistake using the system, I could recover easily and quickly.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
----------------	---	---	---	---	---	---	---	-------------------

Comments:

11. The information (such as on-line help, on-screen messages and other documentation) provided with this system was clear.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
----------------	---	---	---	---	---	---	---	-------------------

Comments:

12. It was easy to find the information I needed.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
----------------	---	---	---	---	---	---	---	-------------------

Comments:

13. The information provided for the system was easy to understand.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
----------------	---	---	---	---	---	---	---	-------------------

Comments:

14. The information was effective in helping me complete the tasks and scenarios.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

15. The organization of information on the system screens was clear.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

Note: The interface includes those items that you use to interact with the system. For example, some components of the interface are the keyboard, the mouse, the screens (including their use of graphics and language).

16. The interface of this system was pleasant.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

17. I liked using the interface of this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

18. This system has all the functions and capabilities I expect it to have.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

19. Overall, I am satisfied with this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

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Tenzing VistA EHR Usability Test Report of Drug-Related tVistA EHR Capabilities: Computerized Provider Order Entry, Drug-Drug/Drug-Allergy Interaction Checks, Medication List, & Medication Allergy List

Tenzing VistA – tVistA V2

Date of Usability Test: June 21 – July 11, 2019

Date of Report: August 31, 2019

Report Prepared By: Tenzing Medical, LLC

Denise Lefevre, CIO

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EXECUTIVE SUMMARY

Usability testing of the drug-related capabilities of Tenzing VistA Electronic Health Record (tVistA EHR) was conducted June 21 through July 11, 2019 at Trenner Medical Offices, Oroville, CA. The purpose of the testing was to validate the usability of the tVistA V2 graphical user interface (GUI) and provide evidence of usability for the drug-related EHR capabilities including: Medication list, computerized provider order entry (CPOE), Drug-drug/drug-allergy interaction checks, and Medication allergy list. During the usability test 10 healthcare providers matching the target demographic criteria served as participants and used tVistA EHR in simulated but representative tasks.

The study collected performance data on multiple drug-related EHR tasks. These drug-related tasks are designed to support the certification criteria under ONC 2015 Edition Health Information Technology (Health IT) Certification Criteria. The tasks are categorized as follows:

Adverse Reaction:

- Record adverse reactions
- Change adverse reactions
- Access adverse reactions

Medication List:

- Enter medications
- Access/review medications
- Change medications
- Electronically perform interaction checks

Order Entry:

- Electronically order lab and radiology exam
- Electronically change lab and radiology exam order
- Access lab and radiology exam orders

During the one hour usability test, each participant was greeted, asked to sign a consent (Appendix 1), and informed they could withdraw at any time. Participants had prior Tenzing VistA EHR experience. Participants were informed of the purpose of the usability testing and the type of data the testing team was gathering, but they were not instructed on how to complete the tasks. The administrator introduced the test, and instructed participants to complete a series of tasks (one at a time) using tVistA EHR. The administrator did not provide assistance on how to complete a task, but asked participants to complete it as they

normally would. When a task was new to a participant, they were asked to demonstrate how they thought they would complete the task. During the test the data logger timed the task and recorded user performance.

The following data was collected for each participant:

- Number of tasks successfully completed without assistance
- Time to Complete Task
- Types of Errors
- Path deviations
- Provider's verbalizations
- Provider's reported workload level
- Provider's satisfaction rating of the system

All participant data was de-identified to eliminate correlation made between participant identity and data collected. Following the conclusion of the testing, participants were asked to complete two post-test questionnaires. Various recommended metrics, in accordance with the examples set forth in the *NIST Guide to the Process Approach for Improving the Usability of Electronic Health Records*, were used to evaluate the usability of tVistA EHR. Following is a summary of the performance and rating data collected on the usability of the drug-related capabilities of the tVistA EHR. The summary is broken down into three segments: 1) Adverse Reactions, 2) Medication List and Interactions 3) Order Entry.

Major findings

The results of the NASA Task Load Index (LTX) – a measure of the subjective workload, or demand the task places on the user during execution was: 29.70 for Adverse Reaction which is a considerable improvement from previous testing (38.20); 38.80 for Medication List and Interactions which is also an improvement from previous testing (49.86); and 27.67 for Order Entry which is similar to earlier testing (27.50). Overall, workload ratings indicate the tasks presented did not place a significant workload burden on the participants (1; 2; 3).

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1. **Hart, S. G., & Staveland, L.E.** Development of NASA-TLX (Task Load Index): Results of empirical and theoretical research. [ed.] P. A. Hancock and N. Meshkati. *Human mental Workload*. Amsterdam : North Holland Press., 1988, pp. 139-183. Scores greater than 60 are interpreted to place a higher task load on users.
 2. *NASA-Task Load Index (NASA-TLX); 20 Years Later*. **Hart, S. G.** Santa Monica : HFEW, 2006. Proceedings of the Human Factors and Ergonomics Society 50th Annual Meeting. pp. 904-908.
 3. Administrator of the National Aeronautics and Space Administration of the United States Government. *NASA TLX App*. Apple App Store, Vers. 1.0.3 (2016).

The ability of participants to complete tasks in new or different ways created minimal workload burden which may be due to participant familiarity with EHR functionality generally or tVistA EHR specifically and regular use of drug-related functionality.

The results from the Post Study System Usability Questionnaire (PSSQU) – a measure of user satisfaction post participation in scenario based usability studies-for the tVistA EHR capabilities were: 2.87 overall, 2.90 for System Usefulness, 2.96 for Information Quality, 2.40 for Interface Quality (4; 5). Generally, users responded favorably to the drug-related tVistA capabilities. Making changes as indicated in the areas for improvement should increase usability and lead to greater system satisfaction.

Areas for Improvement

- Customization of order entry menus
- Additional training of quick orders.

INTRODUCTION

The tVistA EHR drug-related capabilities are designed to electronically present medical information, facilitate adverse reaction management, allow for electronic provider order entry and generate and present drug interaction checks to healthcare providers in ambulatory and inpatient medical care facilities. The usability testing presented realistic exercises and conditions as defined in ONC 2015 certification requirements:

§ 170.315 (a)(8) Medication allergy list

§ 170.315 (a)(7) Medication list

§ 170.315 (a)(4) Drug-drug, drug-allergy interaction checks for CPOE

§ 170.315 (a)(1) Computerized provider order entry (CPOE) – medications

§ 170.315 (a)(2) Computerized provider order entry (CPOE) – laboratory

§ 170.315 (a)(3) Computerized provider order entry (CPOE) – diagnostic imaging

4. *IBM computer usability satisfaction questionnaires: Psychometric evaluation and instructions for use.* Lewis, J. R. 1, 1995, International Journal of Human-Computer Interaction, Vol. 7, pp. 57-78. Scores range from 1-5. Lower scores indicate higher level of satisfaction.

5. *Psychometric Evaluation of the PSSUQ Using Data from Five Years of Usability Studies.* Lewis, J. R. 3 & 4, s.l. : Lawrence Erlbaum Associates, Inc., 2002, International Journal of Human-Computer Interaction, Vol. 14, pp. 463-488.

Purpose

The purpose of this study was to test and validate the usability of the current user interface for tVistA EHR and provide evidence of usability in the EHR. This study was conducted to meet the requirements for ONC 2015 Edition Health Information Technology (Health IT) Certification Criteria indicating that User Centered Design (UCD) should be conducted when developing EHR technology. The intended outcome of implementing User Center Design in coordination with quality system management is improved patient safety. To this end User Center Design identifies user tasks and goals that can then be incorporated into the EHR development to improve efficiency, effectiveness and user satisfaction. In order to satisfy the ONC requirement for §170.315 (g)(3) Safety-enhanced design this study was designed to test drug-related tVistA EHR functionality including Allergy list, Medication list, Drug-drug and Drug-allergy interactions, and CPOE. Data was collected to measure effectiveness, efficiency, and user satisfaction, using metrics of time on task, task completion, task deviation, user task load and user satisfaction. As defined in the Safety-enhanced design test procedure the *National Institute of Standards and Technology Internal Reports* (NISTIR) 7742 was used as the basis of format for this final report. The usability testing was conducted by the vendor team with guidance from the NISTIR 7741 - *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records*.

VHA User-Centered Design Approach

tVistA EHR consists of a suite of applications developed by the Veteran Health Administration (VHA), made available through the freedom of information act (FOIA), adopted by OSEHRA and shared with the Open source EHR community. The VHA development of the EHR is the result of collaboration of VHA HIT staff and VA Clinicians. This collaboration created the VHA legacy of user centered design. VHA utilized the technology of the time and in 1982 launched Decentralized Hospital Computer Program (DHCP) a character-based application. The patient centric EHR evolved as geographically and organizationally diverse, user-defined, clinical workflows were incorporated into the Veterans Health Information System and Technology Architecture (VistA) information system. VistA was then alpha and beta tested in hospitals and clinics throughout the US. Although VistA was built on the character based foundation of DHCP, it has a modern browser-enabled interface, the Computerized Patient Record System (CPRS). CPRS is a Graphical user Interface (GUI) which incorporates both the requirements for Promoting Interoperability and the requests and recommendations from clinical advisors. Thus, formal

user-centered design principles have varied over the development lifecycle of tVista EHR but have not been absent. (<https://www.voa.va.gov/DocumentListPublic.aspx?NodId=27>).

Tenzing Medical LLC User-Centered Design Approach (6) (7) (8) (9) (10) (11)

Tenzing Medical, LLC incorporated the concepts of Cognitive System Engineering (CSE), User-Centered Design approach in a Decision-Centered Design (DCD) framework as described below. “CSE is an approach to the design of technology, training, and processes intended to manage cognitive complexity in sociotechnical systems” (10). Users engage in cognitively complex activities such as identifying, judging, attending, perceiving, remembering, deciding, problem solving and planning when interacting with a system.

User-Centered Design approach to system engineering encompasses 6 key principles:

- The design is based upon an explicit understanding of users, tasks and environments.
- Users are involved throughout design and development.
- The design is driven and refined by user-centered evaluation.
- The process is iterative.
- The design addresses the whole user experience.
- The design team includes multidisciplinary skills and perspectives.

tVista EHR system design addresses the cognitive complexities associated with managing complex decision-making and the key principles of User Centered Design through the use of a Decision Centered Design Framework. In DCD the software development involves task analysis, design, and evaluation that focuses on describing, analyzing, understanding, and supporting complex perceptual and cognitive activities (11).

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6. **Armijo, D., McDonnell, C., Werner, K.** *Electronic Health Record Usability: Evaluation and Use Case Framework*. Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. Rockville : Agency for Healthcare Research and Quality, 2009. 09(10)-0091-1-EF.
7. *Analysis of Complex Decision-Making Processes in Health Care*:. **Kushniruk, A. W.** s.l. : Elsevier Science, May 9, 2002, Journal of Biomedical Informatics, Vol. 34, pp. 365-376.
8. *Cognitive and usability engineering methods for the evaluation*. **Kushniruk, A. W., Patel, V. L.** s.l. : Elsevier Inc., 2004, Journal of Biomedical Informatics, Vol. 37, pp. 56-76.
9. **McDermott, P., Klien, G., Thordsen, M.** *Representing the Cognitive Demands of New Systems: A Decision-Centered Design Approach*. s.l. : US Air Force Research Laboratory, 2000. AFRL-HE-WP-TR-2000-0023.
10. **Militello, L. G., Domingues, C. O., Litern, G. & Klein, G.** The Role of Cognitive Systems Engineering in the System Engineering Design Process. *Systems Engineering*. May 7, 2009, p. 13.
11. **Thordsen, M. L., Hutton, R. J., Miller, T. E.** Decision centered design: Leveraging cognitive task analysis in design. [ed.] E. Hollnagel. *Handbook of Cognitive Task Analysis*. 2010, pp. 383-416.

- **Task Analysis** is used to identify key decisions and requirements. Task analysis involves identifying the cognitive activities involved in a task, how the task is performed and where the task is performed so that an understanding of the requirements of the system is complete and addresses and supports the strengths and weakness of existing cognitive tasks. Subject Mater Experts (SME) assist in identifying these key decisions and requirements and continue their involvement throughout the development process. The SME work closely with the Health Information Technology (HIT) team of designers, programmers, network specialist, pharmacist, physicians, nurses, and ancillary service specialists to provide input on development, design, workflows, and system testing. Having user input in the earliest phases of development allows for better understanding of the skills and knowledge users possess, the mental models used to develop expectation for functionality, the objectives and tasks the application will be used to complete, and the decisions users must make that the application should support.
- **Design** phase of development aims to utilize the insights gained in task analysis to create a system that reduces cognitive challenge, improves error management, and increases performance. SME provide ongoing feedback on individual packages and interoperability between packages. Requirements can be established from the elicitation of this information and conceptual designs created. The most common user activities are identified and made most prominent within the system. Eventually a prototype is created, and implementation planning begins. The goal is to optimize the system.
- **Evaluation** involves continuous formative as well as summative usability testing. Decision Centered Design approach to software development incorporates users testing and feedback from the design phase. This type of development captures the unseen aspects of the system, the potential errors, evolving technology and human interaction with this technology. Usability testing demonstrates user system interaction and further defines necessary adjustments needed immediately and long term to further optimize the system. A broader range of users with diverse requirements, experiences, and work environments are recruited for summative usability testing. These users provide evaluation and feedback the HIT team uses to reevaluate and reengineer the EHR.

The DCD process is iterative. As problems are identified, options are evaluated and systems modeled, integrated, and launched and performance is assessed. The HIT team continually aims to meet customer and users' needs, utilize available technology, and evaluate priorities, limitations and tradeoffs that must be made. Dialog is continuous and frequent among all stakeholders and team members. This allows for generation of new ideas, refinement of old ideas, conceptual changes and/or rejection. This process involves many organizational entities and all parties contribute to the discussion providing input, recommendations, and knowledge exchange. The team analyzes the information provided and makes decisions about design, budget, priorities, testing, redesign and roll-out. The healthcare industry is constantly in flux requiring ongoing and often immediate changes to EHRs. As an iterative and heuristic approach to development DCD bodes well in this environment.

Although change is constant, it is important to design and implement systems that build on current user mental models. This is accomplished by reimagining the same workflow in another format or utilizing existing mental models in another application. Redundancy of function within tVistA EHR, such as right click access to action menus, as well as reusing existing technology common keyboard functions and short cuts facilitate learning and usability.

tVistA EHR is a complex system which requires the user to use complex decision making at times while only simple decision making at others, and users vary in how they practice, how they interact with the EHR, and their individual abilities. Therefore, a broad representative base of users is required to elicit meaningful evaluation of the EHR. Complex but specific user test scripts are designed, and minimal instruction is provided to users in order to elicit maximum evaluation of the EHR during usability testing. The HIT team aims to generate unforeseen possibilities the variety of users may unfold as well as maximal feedback on user experience of the EHR.

Focusing on the intended users of a new or modified technology maximizes benefit for the user and adoptability. The Primary users are given priority over other users who may have competing or irreconcilable preferences.

Primary Users: The primary users for the drug-related capabilities are ordering Providers. Providers in both inpatient and outpatient settings specializing in various areas of medicine that order a medication, lab or radiology for most every patient they see, and who address the drug-drug and drug-allergy alerts on a regular basis.

Secondary Users: Secondary users of the drug-related capabilities include

nursing, pharmacy and ancillary service staff that may enter, review or complete orders and review and/or update adverse reactions. Also, health information management and billing staff that access the information.

Sociotechnical systems are complex, and users have to find ways to manage the complexities. DCD approach assist users through the use of cognitive support strategies focused on decision support tools that reinforce users' natural decision making processes. The cognitive support elements outlined below and later used in addressing recommendations help to manage complexity when designing the new software. The recommendations made later will impact future cognitive support strategies.

- **Supporting Decision Making:** Refers to decisions support tools designed to provide context specific information when needed and reduce task load.
- **Reducing Errors:** Refers both to system error reduction functionality as well as user's awareness, trust and understanding of error reduction functionality. Users must be aware of where error reduction functionality exists and where it does not so they can adjust their expectations and trust the system when appropriate thus reducing cognitive load.
- **Facilitating Scanning:** Refers to placement, amount and type of information on a screen and how well this placement allows a user to find information quickly and accurately and how well a user can return to their place in a screen after an interruption.
- **Creating Affordance:** Refers to design features that help, aid, support, facilitate or enable thinking, knowing, perceiving, or doing something. For example; words on a button indicating the meaning of the button.
- **Illustrating Perceived Benefit:** Refers to users' belief that their day-to-day activities will benefit from using the system. Lack of perceived benefit can result in lack of motivation to learn or use the system and possibly reject the system entirely
- **Supporting Mental Models:** Refers to building upon users' mental models. Designing applications that utilize common language and functionality such as windows standard or previous version functionality.

The Drug-related EHR capabilities are new methods for old processes. Ordering and monitoring adverse reactions are user tasks that require a simple, manageable, well understood process within the EHR. Primary user's main concerns for drug-related capabilities include simple order entry, adverse reaction tracking and interaction checks, as

well as medication and order visualization. Finally, all tasks should be completed with a minimal number of keystrokes.

Tenzing Medical, LLC practices the user center design and testing outlined above on an ongoing basis, but this document specifically focuses on the usability testing conduct over several weeks.

METHOD

PARTICIPANTS

A total of 10 participants were tested on the tVistA EHR drug-related capabilities.

Participants in the test were ordering providers from varied backgrounds. The participants were recruited by Denise Lefevre, the Chief Information Officer (CIO). The participants volunteered and were, therefore, not compensated for their participation. Participants had no direct connection to the development of or organization producing tVistA EHR nor the testing or supplier organization. All participants had previous experience with drug-related tVistA EHR capabilities. Participants were given no additional training for this testing as they had prior knowledge.

Participants were from varied backgrounds and experience as outline in the table below.

Participant ID	Gender	Age	Education	Occupation/Role	Professional Experience	Computer Experience	Product Experience	Assistive Technology Needed
1	Female	30-39	Some College	CAC Integrations lead	180	120	36	No
2	Female	30-39	Some College	Medical Assistant	180	180	24	No
3	Male	50-59	Doctorate	Pharmacist	240	120	120	No
4	Male	40-49	Doctorate	MD	180	84	84	No
5	Female	30-39	Bachelor's	Nurse	120	72	72	No
6	Male	20-29	Doctorate	MD	24	6	24	No
7	Male	50-59	Doctorate	MD	360	180	132	No
8	Female	40-49	Some College	Medical Assistant	216	144	144	No
9	Male	70-79	Doctorate	MD	564	132	132	No
10	Female	40-49	Bachelor's	Registered Nurse	360	144	144	No

Table 1. Demographic characteristics

Participants were provided a participant ID upon arrival for testing thus de-identifying individuals.

Participants were scheduled for 60 minute sessions which included introductions and background, adverse reactions tasks, medication list and interactions tasks, order entry tasks, and metrics. Between sessions the data logger, moderator and other team members debriefed and prepared for the next participant. A demographic spreadsheet with participant's background information and a schedule of testing appointments was kept to track participation.

STUDY DESIGN

The overall objective of this test was to determine if the application performed effectively, efficiently, and to the satisfaction of the users. Also, if the application failed to meet the needs of the participants what issues were encountered and how can they be mediated. This testing was also designed to satisfy the drug-related capability requirements of the Safety Enhanced Design criteria for ONC 2015 Edition Health Information Technology (Health IT) Certification Criteria. The data obtained from this testing is expected to generate recommendation and discussion for future development of the drug-related capabilities of tVistA EHR and identify possible requirements for immediate modifications to facilitate patient safety and/or user adoption.

All participants interacted with tVistA EHR in the same location, provided with the same instructions, asked to complete the same tasks and used the same evaluation tools. Data was collected during testing by the data logger and administrator to evaluate the system for effectiveness, efficiency and satisfaction as defined by measures collected and analyzed for each participant:

- Number of tasks successfully completed within the allotted time without assistance
- Time to complete the tasks
- Number and types of errors
- Path deviations
- Participant's verbalizations (comments)
- Participant's satisfaction ratings of the system

More information about the various measures is provided below in the Usability Metrics section.

TASKS

A number of tasks were constructed that would be realistic and representative of the kinds of activities a user might do with this EHR, including:

1. Adverse Reaction
 - a. Enter adverse reaction
 - b. Change adverse reaction
 - c. Access adverse reaction
2. Medication list
 - a. Enter medications
 - b. Change medications
 - c. Review medications
 - d. Electronically perform interaction checks
3. Order Entry
 - a. Order a lab and radiology exam
 - b. Change lab and radiology exam
 - c. Review lab and radiology exam orders

Tasks were selected based on frequency of use, criticality of function for Promoting Interoperability, availability of ONC 2015 Certification test protocols § 170.315 (a)(8) Medication allergy list, § 170.315 (a)(7) Medication list, § 170.315 (a)(4) Drug-drug, drug-allergy interaction checks for CPOE, § 170.315 (a)(1) Computerized provider order entry (CPOE) – medications, § 170.315 (a)(2) Computerized provider order entry (CPOE) – laboratory, § 170.315 (a)(3) Computerized provider order entry (CPOE) – diagnostic imaging), and tasks that could be foreseen as being most troublesome for users.

PROCEDURES

Upon arrival, participants were greeted; their identity was verified and matched with the name on the participant schedule. Participants were then assigned a participant ID. Each participant was made aware their performance on the upcoming tasks would be recorded for subsequent analysis. The participant was asked to sign the Informed Consent Form (Appendix 1).

First off we would like to thank you for taking the time to provide us with feedback on the EHR capabilities being tested today. We are executing these sessions as part of the Office of the National Coordinator's certifications requirements. This usability study will help ensure that Tenzing Medical, LLC meets their certification requirements and Promoting

Interoperability standards. We are asking EHR users to provide usability input to the Demographic, Implantable Device List, Drug-related, Clinical Decision Support (CDS) and Clinical Information Reconciliation (CIR) capabilities of tVistA EHR. We would like to record your performance on today's session so that we may use it for subsequent usability analysis after we end the session. Do you give your permission for these recordings?

To ensure the usability testing ran smoothly, an administrator and a data logger were present for the testing: the testing team members have 20 years of experience in psychological and clinical research and RPMS, CPRS, and commercial medical hardware and software design, development and testing. The team included experienced hardware and software developers with experience in usability testing and user-centered design programs. Also included on the sessions were several stakeholders who were available to observe the user interaction with the system, respond to questions after completion of formal testing and elicit feedback relevant to future development.

The administrator moderated the session, administered instructions and tasks, obtained post-task rating data, and took notes on participant comments. The data logger monitored task times, and took notes on task success, path deviations, number and type of errors, and comments.

Background information was asked of each participant prior to engaging in the tasks. The data was logged by the administrator and data logger. The participant was situated at the computer, provided with log on information, and allowed time to orient themselves to the EHR and the expected tasks.

Participants were instructed to perform the tasks (see specific instructions in Appendix 3: Moderator's guide):

- As quickly as possible making as few errors and deviations as possible.
- Without assistance; administrators were allowed to give immaterial guidance and clarification on tasks, but not instructions on use.
- Without using a think aloud technique.

For each task, the participants were given a written copy of the task. Task timing began once the administrator said begin. The task time was stopped once the participant indicated he had successfully completed the task (e.g. said "done", signed the order, etc.).

Following each task (Medication allergy list, Medication list and Drug-drug, drug-allergy interaction checks, and computerized provider order entry) the participant was asked to complete the NASA-TASK LOAD INDEX (Appendix 4). At the completion of the session, the administrator gave the participant the POST STUDY SYSTEM USABILITY

QUESTIONNAIRE (Appendix 5).

Participants were asked if they had any additional comments or questions for the group which were logged by the data logger and thanked for their participation.

Participants' demographic information, task success rate, time on task, errors, deviations, verbal responses, and post-test questionnaire were recorded into a spreadsheet.

TEST LOCATION

Usability testing took place in a small conference room. A user laptop computer and mouse were set up on a table. The Administrator sat next to the user. The user's screen was redisplayed for the data logger and observers on computers in a separate training room via WebEx session. Stakeholders observed from the data logger's location or listened and viewed via the Webex session. To ensure that the environment was comfortable for users, noise levels were kept to a minimum with the ambient temperature within a normal range. All of the safety instruction and evacuation procedures were valid, in place, and visible to the participants.

TEST ENVIRONMENT

Drug-related EHR capabilities would typically be used in a healthcare office or facility. In this instance, the testing was conducted in a small conference room in the Trenner Medical offices building. For testing a Dell Latitude 7480 laptop running Windows 7 operating system was used with an external mouse. The participants used both keyboard and mouse to navigate and interact with the tVista EHR. A 14-inch monitor was used with a screen resolution of 1920 x 1080. The application was set up according to vendor specifications and the application was running on a Linux/GTM platform using a test database on a LAN connection. The performance of the test system was comparable to what users experience in production environments on site at hospitals and clinics. Participants were asked not to change any of the setting defaults to insure conformity.

TEST FORMS AND TOOLS

During the usability test various documents and instruments were used, including:

1. Informed Consent
2. Moderator Guide w/ Patient Demographics

3. NASA-TLX
4. PPSSUQ

Examples of these documents can be found in the Appendices.

The participant's interaction with the EHR was captured through recording of WebEx session for each participant's test.

The test sessions were transmitted via WebEx screen sharing to a nearby observation room where the data logger observed the test session.

PARTICIPANT INSTRUCTIONS

The administrator read the following instructions aloud to each participant (also see the full moderator's guide in Appendix 3):

During this session, you will be asked to complete tasks using Tenzing VistA EHR then provide feedback on the Drug-related capabilities.

I will provide you with a list of tasks and associated data. You will be asked to complete these tasks as quickly as possible with the fewest errors or deviations. Do not try to do anything other than what is asked. We cannot assist you in accomplishing your tasks. Please save comments and question until the end of each section.

We would like you to give us feedback on the capabilities used. We would like to know how easy or difficult the system is to use, how useful the capabilities are, and what improvement we can make. The best help you can give us is to be critical. We may not be able to fix everything you mention, but it is still beneficial for us to know what issues you feel are important. Your honest feedback is what we are after. Your feedback will be used to help make the Drug-related capabilities better, so please do not worry about offending anyone with your comments. Your feedback as well as any questions the usability team is unable to answer will be shared with developers and stakeholders.

We have this interview divided into several parts. I'd like to start by just getting some background information; then I am going to ask some questions about if/how you currently use the EHR functions, then I will provide an introductory overview of each capability being tested. In the last part, we'll have you log in as a test user and complete tasks associated with each capability. Do you have any questions for us before we get started?

Following the procedural instructions, participants were shown the EHR and given time to explore tVistA EHR and make comments. Once complete the administrator gave the following instructions:

"I will say "Begin." At that point, please perform the task and say "Done" when you believe you have successfully completed the task. Please refrain from talking while doing the tasks. We will have time to discuss the tasks and answer questions when all the tasks are completed."

Participants were given 10 tasks to complete. Tasks are listed Tables 3a-c below.

USABILITY METRICS

According to the *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records*, EHRs should support a process that provides a high level of usability for all users. The goal is for users to interact with the system effectively, efficiently, and with an acceptable level of satisfaction. To this end, metrics for effectiveness, efficiency and user satisfaction were captured during the usability testing. The goals of the test were to assess:

1. Effectiveness by measuring participant success rates and errors
2. Efficiency by measuring the average task time and path deviations
3. Satisfaction by measuring ease of use ratings

DATA SCORING

The following table (Table 2) details how tasks were scored, errors evaluated, and the time data analyzed.

Measures	Rationale and Scoring
Effectiveness: Task Success	<p>A task was counted as a "Success" if the participant was able to achieve the correct outcome, without assistance, within the time allotted on a per task basis.</p> <p>The number of successes were calculated for each task and then divided by the total number of times that task was attempted. The results are provided as a percentage.</p> <p>If the participant abandoned the task, did not reach the correct answer or performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as an "Failures." No task times were taken for errors.</p>
Efficiency: Task Time	<p>Task times were recorded for tasks successfully completed then divided by the number of participants who completed the task successfully. The average task time is reported. Variance measures (standard deviation and standard error) were also calculated.</p>
Efficiency: Task Deviations	<p>The participant's path (i.e., steps) through the application was recorded. Deviations occur if the participant, for example, went to a wrong screen, clicked on an incorrect menu item, or interacted incorrectly with an on-screen prompt. This path was compared to the optimal path established by the team and developers. The number of steps in the observed path is divided by the optimal number of steps and presented as a ratio of path deviation</p>

<p>Satisfaction: Task Load</p>	<p>Participant's subjective impression of the workload or cost of accomplishing the task requirements were obtain through the administration of the NASA Task Load Index (NASA-TLX) after each task set, Adverse Reactions, Medication List and Order Entry. The participant was asked to complete the six subscales representing different variables including: Mental, Physical, and Temporal Demands, Frustration, Effort, and Performance. See Appendix 4.</p> <p>A high level of burden on the participants is indicated by a score of 60 or greater.</p>
<p>Satisfaction: Task Rating</p>	<p>To measure the participant's satisfaction of the drug-related capabilities the team administrated the Post Study System Usability Questionnaire (PSSUQ) at the completion of all the tasks. The PSSUQ consists of 19 items such as "it was simple to use the system" and "It was easy to find the information I needed" that the participant rates using a 7 point Likert scale ranging from 1=strongly agree to 7= strongly disagree. The PSSQU is designed to assess overall user satisfaction through perceived system usefulness, information quality and interface quality.</p> <p>See Appendix 5 for a copy of the questionnaire.</p>

Table 2. Details of how observed data were scored.

RESULTS

DATA ANALYSIS AND REPORTING

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above. There were no participants who failed to follow session and task instructions or had their data excluded from the analyses.

The usability testing results for the Drug-related capabilities of tVistA EHR are detailed below in Tables 3a-c. The results should be seen in light of the objectives and goals outlined in the Study Design section above. The data should yield actionable results. If corrected, within the drug-related tVistA EHR capabilities these will have a positive impact on user performance.

Qualitative feedback from the participants was transcribed by team members and compiled in an Excel spreadsheet. The team met to discuss all potential issues particularly those items noted as significant for consideration. Each issue was listed as verbalized by the participant and the team evaluated the issue asking questions such as: *What might cause the participant to have this issue? What cognitive support element does this issue violate? What can be done/changed to support the cognitive support element?* Recommendations intended to rectify the identified issue were recorded.

Issues were coded according to the cognitive element that led to the underlying issue, issue class, and time frame.

Issue Class

Each issue was classified into an “issue class.” This classification scheme represents our understanding of the potential impact of each issue if left unaddressed.

- **Type 1** issues are those we anticipate will create an *individual error risk*. These issues may directly introduce a specific health risk. For example, a new health system that somehow allowed treatment plans to be mistakenly associated with multiple EHRs. Some patients would be placed at significant health risk because of the design flaw.
- **Type 2** issues are those we anticipate will create an *aggregate error risk*. These issues may introduce error through cumulative effects. An example of this would be a new system that failed to capture some important paper-based function that was used in conjunction with the old system. The loss of low-tech, but high-value information can eventually lead to a problem.
- **Type 3** issues are those that we anticipate will create *adoption and long-term use risk*. These issues may negatively influence acceptance of the software. In the extreme, ignoring these issues may result in software that is rejected by the intended users. If use is mandated, users may find ways to “game” the system, distorting or circumventing the intent of the software. This is less troubling from a health risk standpoint but could still create a long-term failure of a system in which much has been invested.

Timeframe

Recommendations are also made according to the timeframe in which issues should be addressed. Four timeframes are considered: urgent, quick fix, near-term, and long-term.

- **Urgent:** lead to significant medical error and/or patient risk, need to be fixed before next release/patch.
- **Quick fix:** These issues that we believe can be fixed "in-house" in a relatively short time frame (e.g. several weeks). These are issues that we believe will positively influence user acceptance with little development effort.
- **Near-term issue:** These issues are those that we believe will positively influence user acceptance. Can be completed in 12 months or less but may require extra development time and effort.
- **Long-term issue:** These issues do not present significant risk in their current form. These recommendations, however, have the potential for significant, high impact benefit if resources can be found to address them over time. These fixes will take more than 12 months, contain interoperability issues and may require overhauls of existing systems, introductions of new functionality, and require extended development efforts.

Task #	Task Description	N	Task Success - Mean (%)	Task Success - Standard Deviation (%)	Task Path Deviation - Observed #	Task Path Deviation - Optimal #	Task Time - Mean (seconds)	Task Time - Standard Deviation (seconds)	Task Time Deviation - Mean Observed Seconds	Task Time Deviation - Mean Optimal Seconds	Task Errors - Mean (%)	Task Errors - Standard Deviation (%)	Task Rating - Scale Type	Task Rating (Overall)	Task Rating (Overall) - Standard Deviation	System Usefulness rating	Information Quality rating	Interface Rating	Task Load
1	Enter ADR	10	100	0.0	20	18	127	48	0.99	128	0.0	0.0	PSSUQ	2.87	1.49	2.90	2.96	2.40	29.70
2	Change ADR	10	100	0.0	11	13	47	19	1.35	66	0.0	0.0							
3	Access ADR	10	100	0.0	4	4	43	16	1.02	42	0.0	0.0							

Table 3a: Data from Adverse Reaction Tasks

Task #	Task Description	N	Task Success - Mean (%)	Task Success - Standard Deviation (%)	Task Path Deviation - Observed #	Task Path Deviation - Optimal #	Task Time - Mean (seconds)	Task Time - Standard Deviation (seconds)	Task Time Deviation - Mean Observed Seconds	Task Time Deviation - Mean Optimal Seconds	Task Errors - Mean (%)	Task Errors - Standard Deviation (%)	Task Rating - Scale Type	Task Rating (Overall)	Task Rating (Overall) - Standard Deviation	System Usefulness rating	Information Quality rating	Interface Rating	Task Load
1	Enter Medication order	10	100	0.0	22	18	218	73	0.79	276	0.0	0.0	PSSUQ	2.87	1.49	2.90	2.96	2.40	29.70
2	Access Medication orders	10	100	0.0	5	5	89	44	1.44	62	0.0	0.0							
3	Change Medication order	10	100	0.0	10	15	93	40	0.82	114	0.0	0.0							
4	Electronically perform interaction checks	10	100	0.0	4	4	26	13	1.63	16	0.0	0.0							

Table 3b: Data from Medication list and Interactions

Task #	Task Description	N	Task Success - Mean (%)	Task Success - Standard Deviation (%)	Task Path Deviation - Observed #	Task Path Deviation - Optimal #	Task Time - Mean (seconds)	Task Time - Standard Deviation (seconds)	Task Time Deviation - Mean Observed Seconds	Task Time Deviation - Mean Optimal Seconds	Task Errors - Mean (%)	Task Errors - Standard Deviation (%)	Task Rating - Scale Type	Task Rating (Overall)	Task Rating (Overall) - Standard Deviation	System Usefulness rating	Information Quality rating	Interface Rating	Task Load
1	Order a lab and radiology exam	10	100	0.0	27	15	242	98	1.11	218	0.0	0.0	PSSUQ	2.87	1.49	2.90	2.96	2.40	29.70
2	Change a lab and radiology exam order	10	100	0.0	16	27	124	94	0.50	246	0.0	0.0							
3	Access lab and radiology exam Orders	10	100	0.0	5	16	37	24	0.92	22	0.0	0.0							

Table 3c: Data from Order Entry Tasks

DISCUSSION OF THE FINDINGS

Effectiveness

Effectiveness was measured by task completion or failure to complete task. We asked providers to complete tasks of drug-related tVista EHR capabilities that demonstrate the required functionality. These tasks are derived from the ONC 2015 Edition Health Information Technology (Health IT) Certification Criteria. The task completion data indicates that most providers were able to complete all the tasks that they were asked to execute. There are notable differences between the participants who completed each task. These variations are due to subject characteristics, not issues regarding the functionality of the GUI. These subject variables include selecting allergy rather than pharmacology as Nature of reaction for Adverse reaction, using meds tab rather than orders tab to order medications and accessing meds on meds tab and labs on lab tab.

Efficiency

Efficiency was measured by time on task and task deviations. We asked providers to complete representative tasks of the drug-related tVista EHR capabilities that demonstrate the required functionality. These tasks are derived from the ONC 2015 Edition Health Information Technology (Health IT) Certification Criteria. We did not instruct participants to complete tasks in one specific manner, because there are multiple, valid paths to task completion for any given task. This variation causes deviation in both time on task and path. Nevertheless, the data indicates that most providers were able to complete all the tasks in a standard manner. However, there were deviations with respect to misspelling of allergy causing difficulty finding a match, entering then changing individual orders rather than entering all order then changing all orders, using various menus to search for med, lab and rad orders, and having difficulty deciding to cancel order or override interactions and what reason to use for an override.

Satisfaction

Satisfaction was measured by two subjective questionnaires, the NASA TLX and the PSSUQ. Overall workload ratings indicate that the users are not overly burdened by the software. The results from the NASA TLX were: 29.70 for Adverse Reaction; 38.80 for Medication List and Interactions; and 27.67 for Order Entry. PSSUQ results indicated overall favorable results for all areas of the drug-related tVista EHR capabilities. Below is a complete list of written comments (duplicates omitted) articulated by participants in response to question items.

- *Geez there's a lot of Cholesterol orders*
- *Are we treating an ambulatory of inpatient?*
- *Keep going through drug-drug and drug-allergy checks*
- *I have to double and triple check because the font is so small.*
- *Pop-up reminders for missing data in order are helpful in completing order.*

This list of comments includes positive, neutral, and negative comments illustrating that there are areas of the EHR that providers find easy to use and areas of the EHR that will benefit from design enhancements. Additional training to improve or maintain skills could be effective in reinforcing the data entry methods user indicated they are unaware or unfamiliar with.

AREAS FOR IMPROVEMENT

As a result of this set of usability interviews we determined that most users are now familiar with and comfortable working with the drug-related tVista EHR capabilities. There are still drug-related capabilities that violate a set of cognitive support elements. Relevant issues gleaned from these usability sessions are listed in the following section. The resulting issues are grouped with respect to the cognitive element that the usability team believes led to the underlying issue. Each issue that was uncovered during the usability interviews is listed as it relates to the cognitive element that is being violated. As a reminder, these elements include:

- *Support Decision Making*
- *Reduce Errors*
- *Facilitate Scanning*
- *Create Affordances*
- *Illustrate Perceived Benefit*
- *Support Mental Models*

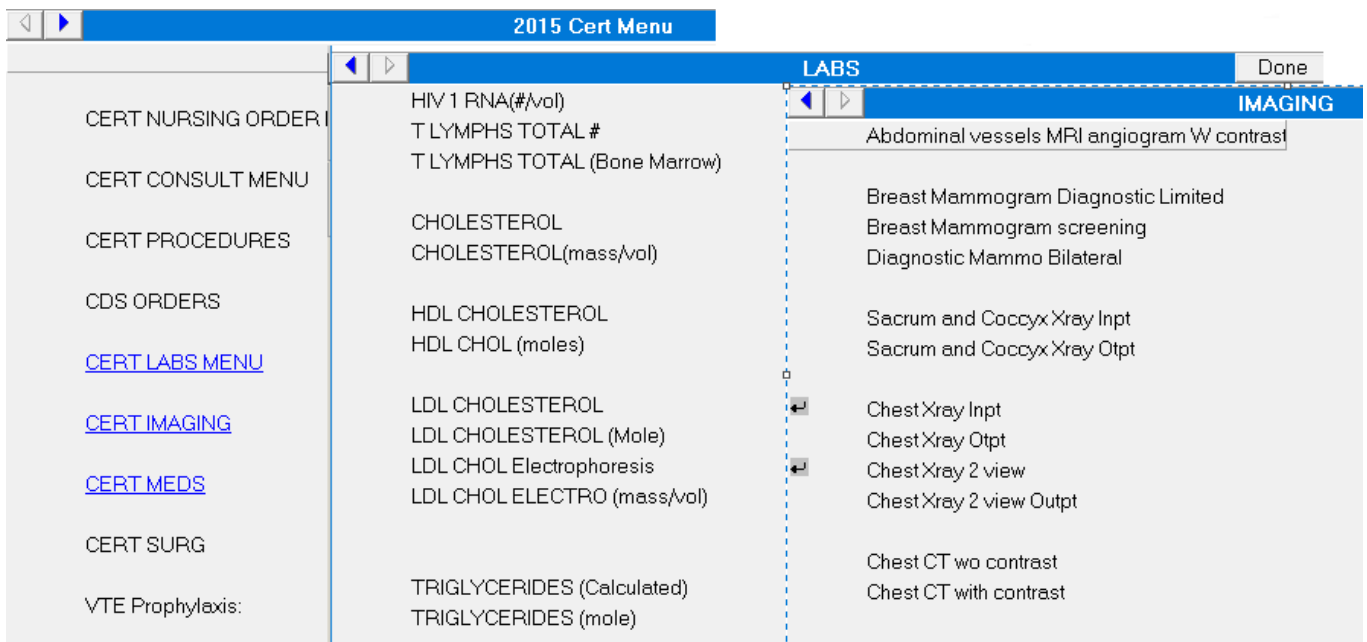
Recommendations are made to encourage a design enhancement that creates support for the relevant cognitive requirement. Recommendations should be adopted and implemented only in ways that support the cognitive elements. When reviewing the issues and recommendations the HIT team should consider questions such as:

1. *Why are participants having this issue?*
2. *What cognitive support element does this issue violate?*
3. *What can we do within the design process to facilitate the cognitive support requirement?*

Issues and Recommendations

Issue 1: Provider had difficulty finding Medication, Lab and Imaging orders in menus.

- Cognitive Support Element: Reducing errors: We believe this is a quick fix that could be rectified with additional user training and configuration of custom order menus. Although many of the order entry issues from this usability test were due to test script and CERT environment specificity, we believe the continuously changing requirements of health care and providers preferences dictate ongoing evaluation and configuration of order menus.
 - Consideration:
 - *How can we facilitate provider quick and accurate data entry?*
- R-1 We recommend additional training of providers on how to quickly and accurately add, edit and sign orders.
- R-2 We recommend working with providers to improve and update order menus to meet changing clinical requirements and user preferences.

**Issue 2: Provider has difficulty reading order details because font is too small.**

- Cognitive Support Element: Reducing errors: We believe this is a quick fix that requires training providers how to set the font preference to display larger text.
 - Consideration:

- How can we display order details more clearly?
- R-1 Train providers to set user preferences to increase display font.

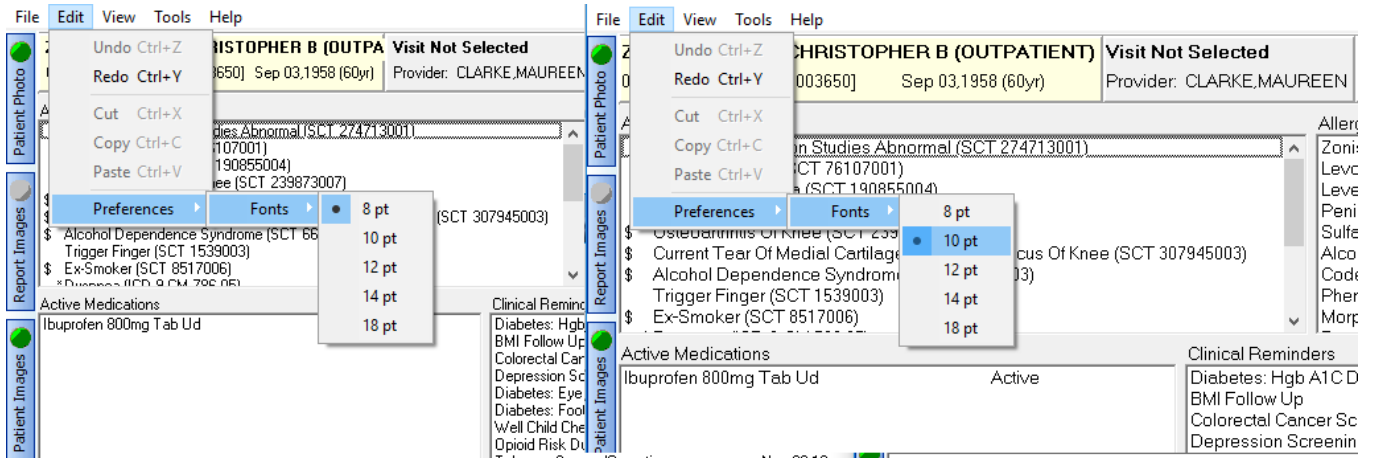


Table 4 represents the issues, the associated cognitive support element, issue class and anticipated timeframe

Issue	Description	Cognitive Support Element	Issue Class	Timeframe
1	Provider had difficulty finding Medication, Lab and Imaging orders in menus	Reducing errors	I	Near term
2	Provider has difficulty reading order details because font is too small.	Reducing errors	III	Quick Fix

Table 4: Issue and Recommendations by Cognitive Support Element, Issue Class and Timeframe

Areas for Improvement: Global Recommendations

To further improve usability and adoptability of tVista EHR the following recommendation are made regarding the EHR as a whole. These recommendations reflect standard windows functionality that utilize existing mental models.

1. **Gray-out visualization:** When a function is not available it should be grayed out. By graying out functions that are not available it provides the user with a visual cue that those options are not available at the present time, while still allowing them to know these features exist and may be available in other circumstances.
2. **Tool tips/instructions:** All buttons, icons, and right click options in the GUI should include tool tips describing their name and function when the user hovers the mouse over them. These tool tips allow the user to learn what various buttons in the software do on their own as they are using the software application.

3. **Window size:** Expand default screen size for pop-up dialogue windows. Pop-up dialogues should be maximized to prevent scrolling when possible if screen real estate is available. The dialogues should remain centered on the screen, with width and height adjusted to provide maximum visibility of all content.
4. **Auto-close:** Close previous windows where an action has been executed and is no longer relevant. By closing previous windows that have completed their actions you remove the need for the user to close unnecessary windows to continue using the software after they have completed a set of actions.
5. **Asterisks:** Indicate required fields with asterisks throughout the interface. By standardizing this throughout the interface users are aware of what is necessary for them to complete various tasks. This visual indicator also allows users to ensure all necessary information has been entered rather than relying on error messages which interrupt the workflow and require backtracking to complete a task.
6. **Training:** It is our belief that with an ideal interface, one that is intuitive to end users and incorporates as much usability as possible, the amount of necessary training should be minimal. This is why we often recommend streamlining processes for task completion within the EHR. We realize that while minimal training is ideal, it is not always achievable, at least not right away. By completing user testing and incorporating the feedback into the system little by little it will hopefully reduce the required amount of training required.

APPENDICES

The following appendices include supplemental data for this usability test report.

Following is a list of the appendices provided:

- 1: Informed Consent
- 2: Participant Demographics
- 3: Moderator's Guide
- 4: NASA-Task Load Index
- 5: Post Study System Usability Questionnaire

Appendix 1: Informed Consent

Informed Consent

Tenzing Medical, LLC would like to thank you for participating in this study. The purpose of this study is to evaluate an electronic health records system. If you decide to participate, you will be asked to perform several tasks using the prototype and give your feedback. The study will last about 60 minutes.

Agreement

I understand and agree that as a voluntary participant in the present study conducted by Tenzing Medical, LLC I am free to withdraw consent or discontinue participation at any time. I understand and agree to participate in the study conducted and videotaped by the Tenzing Medical, LLC.

I understand and consent to the use and release of the videotape by Tenzing Medical, LLC. I understand that the information and videotape is for research purposes only and that my name and image will not be used for any purpose other than research. I relinquish any rights to the videotape and understand the videotape may be copied and used by Tenzing Medical, LLC without further permission.

I understand and agree that the purpose of this study is to make software applications more useful and usable in the future.

I understand and agree that the data collected from this study may be shared outside of Tenzing Medical, LLC and Tenzing Medical, LLC's client. I understand and agree that data confidentiality is assured, because only de-identified data – i.e., identification numbers not names – will be used in analysis and reporting of the results.

I agree to immediately raise any concerns or areas of discomfort with the study administrator. I understand that I can leave at any time.

Please check one of the following:

- YES, I have read the above statement and agree to be a participant.
- NO, I choose not to participate in this study.

Signature: _____ **Date:**

August 31, 2019

Appendix 2: Participant Demographics

Gender	
Men	[5]
Women	[5]
Total (participants)	[10]

Occupation/Role	
Physician	[4]
RN/BSN	[2]
MA	[2]
Clinical Applications staff	[1]
Pharmacist	[1]
Total (participants)	[10]

Years of Experience (months)	
Professional	[186]
tVistA EHR	[78]

Appendix 3: Moderator's Guide

Introduction/Orientation:

First off, we would like to thank you for taking the time to provide us with feedback on the EHR capabilities being tested today. We are executing these sessions as part of the Office of the National Coordinator's certifications requirements. This usability study will help ensure that Tenzing Medical, LLC meets their certification requirements and Promoting Interoperability standards. We are asking EHR users to provide usability input to the Demographic, Implantable Device List, Drug-related, Clinical Decision Support (CDS) and Clinical Information Reconciliation (CIR) capabilities of tVistA EHR. We would like to record your performance on today's session so that we may use it for subsequent usability analysis after we end the session. Do you give your permission for these recordings?

Sign Informed consent

During this session, you will be asked to complete tasks using Tenzing VistA EHR then provide feedback on the Drug-related capabilities.

I will provide you with a list of tasks and associated data. You will be asked to complete these tasks as quickly as possible with the fewest errors or deviations. Do not try to do anything other than what is asked. We cannot assist you in accomplishing your tasks. Please save comments and question until the end of each section.

We would like you to give us feedback on the capabilities used. We would like to know how easy or difficult the system is to use, how useful the capabilities are, and what improvement we can make. The best help you can give us is to be critical. We may not be able to fix everything you mention, but it is still beneficial for us to know what issues you feel are important. Your honest feedback is what we are after. Your feedback will be used to help make the Drug-related capabilities better, so please do not worry about offending anyone with your comments. Your feedback as well as any questions the usability team is unable to answer will be shared with developers and stakeholders.

We have this interview divided into several parts. I'd like to start by just getting some background information; then I am going to ask some questions about if/how you currently use the EHR functions, then I will provide an introductory overview of each capability being tested. In the last part, we'll have you log in as a test user and complete tasks associated with each capability. Do you have any questions for us before we get started?

Complete Participant Information & Background Information

Drug Related (CPOE, allergy and medication lists and drug interactions) – This section asks a user to enter, change and access allergies and medications, lab and radiology orders. Drug- drug and drug-allergy Interaction will appear as a result of the data entered. The interaction will require your acknowledgement and/or intervention. For the purposes of this exercise you may decide on an appropriate response or simple you "Test" when prompted.

Participant Background Information

Moderator/Administrator:

Data Logger:

Date/Time:

Location of Testing:

Participant #

Gender:

- Male
- Female
- Unknown

Age:

- <19
- 20-29
- 30-39
- 40-49
- 50-59
- 60-69
- 70-79
- 80-89
- >89

Level of Education:

- No high school degree
- High school graduate, diploma or the equivalent (for example: GED)
- Some college credit, no degree
- Trade/technical/vocational training
- Associate degree
- Bachelor's degree
- Master's degree
- Doctorate degree (e.g., MD, DNP, DMD, PhD)

Provider Occupation/Role:

Years of professional experience:

Years of experience with EHR (rounded to the nearest half year):

Years of experience with VistA EHR (rounded to the nearest half year):

Any Assistive Technology Needs (screen readers or magnifiers, large-print or tactile keyboard):

Use

How do you currently complete orders now? (Include meds, Rad and labs)

How do you manage your patients' medications?

How do you check for adverse reactions currently?

What tabs do you use to manage your patients' meds, labs & imaging orders?

Are there any functions in the version that you interact with that you do not use often?

Are there any functions you see as less important than others?

Show Participant section intro & Begin Webex Recording

Provide Patient with CPRS user guide and review drug related slides

Provide User Test script

I will say "Begin." At that point, please perform the task and say "Done" when you believe you have successfully completed the task. Please refrain from talking while doing the task. We will have time to discuss the task and answer questions when the task is complete.

Pause Webex when User states "Done"

Read the NASA Tix instructions to the User

Provide iPad to User to complete Nasa Tix

Set up Nasa Tix for next section evaluation

Appendix 4: NASA-Task Load Index (sample)

---NASA TLX V1.0.3 SINGLE TRIAL PAIRWISE ANSWERS---	
STUDY NAME:	SAMPLE
STUDY GROUP:	SAMPLE
SUBJECT ID:	S1
TRIAL:	1
TRIAL DATE TIME:	6/21/2019 16:35
---DATA---	
PAIRWISE CHOICES	SELECTION
Effort vs. Physical Demand	Effort
Physical Demand vs. Performance	Performance
Temporal Demand vs. Mental Demand	Temporal Demand
Physical Demand vs. Frustration	Physical Demand
Mental Demand vs. Physical Demand	Mental Demand
Temporal Demand vs. Frustration	Temporal Demand
Temporal Demand vs. Effort	Effort
Frustration vs. Effort	Effort
Physical Demand vs. Temporal Demand	Temporal Demand
Performance vs. Frustration	Performance
Performance vs. Temporal Demand	Performance
Performance vs. Mental Demand	Performance
Effort vs. Performance	Effort
Frustration vs. Mental Demand	Mental Demand
Mental Demand vs. Effort	Mental Demand

---NASA TLX V1.0.3 SINGLE TRIAL RATING SCALE ANSWERS---	
STUDY NAME:	SAMPLE
STUDY GROUP:	SAMPLE
SUBJECT ID:	S1
TRIAL:	1
TRIAL DATE TIME:	6/21/2019 16:35
---DATA---	
PAIRWISE ASKED WITH TRIAL:	TRUE
PAIRWISE ANSWERS TO USE:	SAMPLE_S1_001_PW_06-21-2019_16-35.csv
RATING SCALE:	RAW RATING
Mental Demand	60
Physical Demand	15
Temporal Demand	60
Performance	20
Effort	60
Frustration	50

Weighted Rating: 46.33

Appendix 5: Post Study System Usability Questionnaire

Instructions: This questionnaire gives you an opportunity to tell us your reactions to the system you used. Your responses will help us understand what aspects of the system you are particularly concerned about and the aspects that satisfy you.

To as great a degree as possible, think about all the tasks that you have done with the system while you answer these questions.

Please read each statement and indicate how strongly you agree or disagree with the statement by circling a number on the scale.

Please write comments to elaborate on your answers.

After you have completed this questionnaire, I'll go over your answers with you to make sure I understand all of your responses.

Thank you!

1. Overall, I am satisfied with how easy it is to use this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

2. It was simple to use this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

3. I could effectively complete the tasks and scenarios using this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

4. I was able to complete the tasks and scenarios quickly using this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

5. I was able to efficiently complete the tasks and scenarios using this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

6. I felt comfortable using this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

7. It was easy to learn to use this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

8. I believe I could become productive quickly using this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

9. The system gave error messages that clearly told me how to fix problems.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

10. Whenever I made a mistake using the system, I could recover easily and quickly.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

11. The information (such as on-line help, on-screen messages and other documentation) provided with this system was clear.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

12. It was easy to find the information I needed.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

13. The information provided for the system was easy to understand.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

14. The information was effective in helping me complete the tasks and scenarios.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

15. The organization of information on the system screens was clear.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

Note: The interface includes those items that you use to interact with the system. For example, some components of the interface are the keyboard, the mouse, the screens (including their use of graphics and language).

16. The interface of this system was pleasant.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

17. I liked using the interface of this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

18. This system has all the functions and capabilities I expect it to have.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

19. Overall, I am satisfied with this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

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Tenzing VistA EHR Usability Test Report of Implantable Device List tVistA EHR Capabilities

Tenzing VistA – tVistA V2

Date of Usability Test: June 21 – July 19, 2019

Date of Report: August 31, 2019

Report Prepared By: Tenzing Medical, LLC

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EXECUTIVE SUMMARY

Usability testing of the implantable device list capabilities of Tenzing VistA Electronic Health Record (tVistA EHR) was conducted June 21 through July 19, 2019 at Trenner Medical Offices, Oroville, CA. The purpose of the testing was to validate the usability of the tVistA V2 and provide evidence of usability for the implantable device list capabilities. During the usability test 10 healthcare providers matching the target implantable device list criteria served as participants and used tVistA EHR in simulated but representative tasks.

The study collected performance data on multiple implantable device list tasks. These tasks are designed to support the certification criteria under ONC 2015 Edition Health Information Technology (Health IT) Certification Criteria. The tasks are categorized as follows:

- Record UDI for patient's Implantable Device
- Verify Parse Identifiers for UDI
- Obtain and associate description and database attributes
- Obtain Implantable Device List
- Access UDI
- Change Status of UDI

During the 30 minute usability test, each participant was greeted, asked to sign a consent (Appendix 1), and informed they could withdraw at any time. Participants had prior Tenzing VistA EHR experience. Participants were informed of the purpose of the usability testing and the type of data the testing team was gathering, but they were not instructed on how to complete the tasks. The administrator introduced the test, and instructed participants to complete a series of tasks (one at a time) using tVistA EHR. The administrator did not provide assistance on how to complete a task, but asked participants to complete it as they normally would. When a task was new to a participant, they were asked to demonstrate how they thought they would complete the task. During the test the data logger timed the task and recorded user performance.

The following data was collected for each participant:

- Number of tasks successfully completed without assistance
- Time to Complete Task

Types of Errors

Path deviations

Provider's verbalizations

Provider's reported workload level

Provider's satisfaction rating of the system

All participant data was de-identified to eliminate correlation made between participant identity and data collected. Following the conclusion of the testing, participants were asked to complete two post-test questionnaires. Various recommended metrics, in accordance with the examples set forth in the *NIST Guide to the Process Approach for Improving the Usability of Electronic Health Records*, were used to evaluate the usability of tVistA EHR. Following is a summary of the performance and rating data collected on the usability of the implantable device list capabilities of the tVistA EHR.

Major findings

The results of the NASA Task Load Index (TLX) – a measure of the subjective workload or demand the task places on the user during execution was: 51.43. Overall, workload ratings indicate the tasks presented did not place a significant workload burden on the participants. The ability of participants to complete tasks in new or different ways created minimal workload burden which may be due to participant familiarity with EHR functionality generally or tVistA HER (1; 2; 3).

The results from the Post Study System Usability Questionnaire (PSSQU) – a measure of

-
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 5. *Psychometric Evaluation of the PSSUQ Using Data from Five Years of Usability Studies.* **Lewis, J. R.** 3 & 4, s.l. : Lawrence Erlbaum Associates, Inc., 2002, International Journal of Human-Computer Interaction, Vol. 14, pp. 463-488.

capabilities were: 2.76 overall, 2.73 for System Usefulness, 2.91 for Information Quality, 2.29 for Interface Quality (4; 5). Generally, users responded favorably to the implantable device list tVistA capabilities. Making changes as indicated in the areas for improvement should increase usability and lead to greater system satisfaction.

Areas for Improvement

- Additional training to familiarize user with entry process
- Clarify menu options and their purpose
- Clarify print option and procedure for printing reports

INTRODUCTION

The tVistA EHR implantable device list capabilities are designed to use bar code scanner to record a patient's unique device identifier, parse the identifiers and use programmed call to issuing agency to obtain UDI description and database attributes. Users also obtain lists of implantable devices, change device status, and access UDI information. The usability testing presented realistic exercises and conditions as defined in ONC 2015 certification requirements:

§ 170.315 (a)(14)

Purpose

The purpose of this study was to test and validate the usability of the current user interface for tVistA EHR and provide evidence of usability in the EHR. This study was conducted to meet the requirements for ONC 2015 Edition Health Information Technology (Health IT) Certification Criteria indicating that User Centered Design (UCD) should be conducted when developing EHR technology. The intended outcome of implementing User Center Design in coordination with quality system management is improved patient safety. To this end User Center Design identifies user tasks and goals that can then be incorporated into the EHR development to improve efficiency, effectiveness and user satisfaction. In order to satisfy the ONC requirement for §170.315 (g)(3) Safety-enhanced design this study was designed to test implantable device list tVistA EHR functionality. Data was collected to measure effectiveness, efficiency, and user satisfaction, using metrics of time on task, task completion, task deviation, user task load and user satisfaction. As defined in the Safety-enhanced design test procedure the *National Institute of Standards and Technology Internal Reports* (NISTIR) 7742 was used as the basis of format for this final report. The

usability testing was conducted by the vendor team with guidance from the NISTIR 7741 - *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records*.

VHA User-Centered Design Approach

tVistA EHR consists of a suite of applications developed by the Veteran Health Administration (VHA), made available through the freedom of information act (FOIA), adopted by Open Source Electronic Health Record Association (OSEHRA) and shared with the Open source EHR community. The VHA development of the EHR is the result of collaboration of VHA HIT staff and VA Clinicians. This collaboration created the VHA legacy of user centered design. VHA utilized the technology of the time and in 1982 launched Decentralized Hospital Computer Program (DHCP) a character-based application. The patient centric EHR evolved as geographically and organizationally diverse, user-defined, clinical workflows were incorporated into the Veterans Health Information System and Technology Architecture (VistA) information system. VistA was then alpha and beta tested in hospitals and clinics throughout the US. Although VistA was built on the character-based foundation of DHCP, it has a modern browser-enabled interface, the Computerized Patient Record System (CPRS). CPRS is a Graphical user Interface (GUI) which incorporates both the requirements for Promoting Interoperability and the requests and recommendations from clinical advisors. Thus, formal user-centered design principles have varied over the development lifecycle of tVistA EHR but have not been absent. (<https://www.voa.va.gov/documentlistpublic.aspx?NodeID=27>).

Tenzing Medical LLC User-Centered Design Approach (6) (7) (8) (9) (10) (11)

Tenzing Medical, LLC incorporated the concepts of Cognitive System Engineering (CSE), User-Centered Design approach in a Decision-Centered Design (DCD) framework as described below. “CSE is an approach to the design of technology, training, and processes intended to manage cognitive complexity in sociotechnical systems” (10). Users engage in cognitively complex activities such as identifying, judging, attending, perceiving, remembering, deciding, problem solving and planning when interacting with a system.

User-Centered Design approach to system engineering encompasses 6 key principles:

- The design is based upon an explicit understanding of users, tasks and environments.
- Users are involved throughout design and development.

- The design is driven and refined by user-centered evaluation.
- The process is iterative.
- The design addresses the whole user experience.
- The design team includes multidisciplinary skills and perspectives.

tVistA EHR system design addresses the cognitive complexities associated with managing complex decision-making and the key principles of User Centered Design through the use of a Decision Centered Design Framework. In DCD the software development involves task analysis, design, and evaluation that focuses on describing, analyzing, understanding, and supporting complex perceptual and cognitive activities (11)

- **Task Analysis** is used to identify key decisions and requirements. Task analysis involves identifying the cognitive activities involved in a task, how the task is performed and where the task is performed so that an understanding of the requirements of the system is complete and addresses and supports the strengths and weakness of existing cognitive tasks. Subject Matter Experts (SME) assist in identifying these key decisions and requirements and continue their involvement throughout the development process. The SME work closely with the Health Information Technology (HIT) team of designers, programmers, network specialist, pharmacist, physicians, nurses, and ancillary service specialists to provide input on development, design, workflows, and system testing. Having user input in the earliest phases of development allows for better understanding of the skills and knowledge users possess, the mental models used to develop expectation for functionality, the objectives and tasks the application will be used to complete,

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6. **Armijo, D., McDonnell, C., Werner, K.** *Electronic Health Record Usability: Evaluation and Use Case Framework*. Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. Rockville : Agency for Healthcare Research and Quality, 2009. 09(10)-0091-1-EF.
7. *Analysis of Complex Decision-Making Processes in Health Care*:. **Kushniruk, A. W.** s.l. : Elsevier Science, May 9, 2002, Journal of Biomedical Informatics, Vol. 34, pp. 365-376.
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10. **Militello, L. G., Domingues, C. O., Litern, G. & Klein, G.** The Role of Cognitive Systems Engineering in the System Engineering Design Process. *Systems Engineering*. May 7, 2009, p. 13.
11. **Thordsen, M. L., Hutton, R. J., Miller, T. E.** Decision centered design: Leveraging cognitive task analysis in design. [ed.] E. Hollnagel. *Handbook of Cognitive Task Analysis*. 2010, pp. 383-416.

and the decisions users must make that the application should support.

- **Design** phase of development aims to utilize the insights gained in task analysis to create a system that reduces cognitive challenge, improves error management, and increases performance. SME provide ongoing feedback on individual packages and interoperability between packages. Requirements can be established from the elicitation of this information and conceptual designs created. The most common user activities are identified and made most prominent within the system. Eventually a prototype is created, and implementation planning begins. The goal is to optimize the system.
- **Evaluation** involves continuous formative as well as summative usability testing. Decision Centered Design approach to software development incorporates users testing and feedback from the design phase. This type of development captures the unseen aspects of the system, the potential errors, evolving technology and human interaction with this technology. Usability testing demonstrates user system interaction and further defines necessary adjustments needed immediately and long term to further optimize the system. A broader range of users with diverse requirements, experiences, and work environments are recruited for summative usability testing. These users provide evaluation and feedback the HIT team uses to reevaluate and reengineer the EHR.

The DCD process is iterative. As problems are identified, options are evaluated and systems modeled, integrated, and launched and performance is assessed. The HIT team continually aims to meet customer and users' needs, utilize available technology, and evaluate priorities, limitations and tradeoffs that must be made. Dialog is continuous and frequent among all stakeholders and team members. This allows for generation of new ideas, refinement of old ideas, conceptual changes and/or rejection. This process involves many organizational entities and all parties contribute to the discussion providing input, recommendations, and knowledge exchange. The team analyzes the information provided and makes decisions about design, budget, priorities, testing, redesign and roll-out. The healthcare industry is constantly in flux requiring ongoing and often immediate changes to EHRs. As an iterative and heuristic approach to development DCD bodes well in this environment.

Although change is constant, it is important to design and implement systems that build on current user mental models. This is accomplished by reimagining the same workflow in

another format or utilizing existing mental models in another application. Redundancy of function within tVistA EHR, such as right click access to action menus, as well as reusing existing technology common keyboard functions and short cuts facilitate learning and usability.

tVistA EHR is a complex system which requires the user to use complex decision making at times while only simple decision making at others, and users vary in how they practice, how they interact with the EHR, and their individual abilities. Therefore, a broad representative base of users is required to elicit meaningful evaluation of the EHR.

Complex but specific user test scripts are designed, and minimal instruction is provided to users in order to elicit maximum evaluation of the EHR during usability testing. The HIT team aims to generate unforeseen possibilities the variety of users may unfold as well as maximal feedback on user experience of the EHR.

Focusing on the intended users of a new or modified technology maximizes benefit for the user and adoptability. The Primary users are given priority over other users who may have competing or irreconcilable preferences.

Primary Users: The primary users for the implantable device list capabilities are surgical staff and patient safety staff. Surgical staff in both inpatient and outpatient settings access, enter, verify, and update a patient's implantable device record. Patient safety personnel use implantable device reports to investigate patient safety issue associate with implantable devices.

Secondary Users: Secondary users of the implantable device list capabilities include health information management and billing staff that regularly access the information. As well as nursing, pharmacy and ancillary service staff that may review patient implantable device list as related to patient care.

Sociotechnical systems are complex, and users have to find ways to manage the complexities. DCD approach assist users through the use of cognitive support strategies focused on decision support tools that reinforce users' natural decision-making processes. The cognitive support elements outlined below and later used in addressing recommendations help to manage complexity when designing the new software. The recommendations made later will impact future cognitive support strategies.

- **Supporting Decision Making:** Refers to decisions support tools designed to provide context specific information when needed and reduce task load.
- **Reducing Errors:** Refers both to system error reduction functionality as well as

user's awareness, trust and understanding of error reduction functionality. Users must be aware of where error reduction functionality exists and where it does not so they can adjust their expectations and trust the system when appropriate thus reducing cognitive load.

- **Facilitating Scanning:** Refers to placement, amount and type of information on a screen and how well this placement allows a user to find information quickly and accurately and how well a user can return to their place in a screen after an interruption.
- **Creating Affordance:** Refers to design features that help, aid, support, facilitate or enable thinking, knowing, perceiving, or doing something. For example; words on a button indicating the meaning of the button.
- **Illustrating Perceived Benefit:** Refers to users' belief that their day-to-day activities will benefit from using the system. Lack of perceived benefit can result in lack of motivation to learn or use the system and possibly reject the system entirely
- **Supporting Mental Models:** Refers to building upon users' mental models. Designing applications that utilize common language and functionality such as windows standard or previous version functionality.

The implantable device list capabilities are new methods for old processes. Accessing, recording and updating new and newly configured implantable device list information in a simple entry template are user tasks that require a simple, manageable, well understood process within the EHR. Primary user's main concerns for implantable device list capabilities include simple access, entry and edit of information and quick reliable retrieval of implantable device information. Also, all tasks should be completed with a minimal number of key strokes.

Tenzing Medical, LLC practices the user center design and testing outlined above on an ongoing basis, but this document specifically focuses on the usability testing conduct over several weeks.

METHOD

PARTICIPANTS

A total of 10 participants were tested on the tVistA EHR implantable device list capabilities. Participants in the test were nurses and physician that work with implantable devices as well as health information management, and ancillary staff from varied backgrounds. The participants were recruited by Denise Lefevre, the Chief Information Officer (CIO). The participants volunteered and were, therefore, not compensated for their participation. Participants had no direct connection to the development of or organization producing tVistA EHR nor the testing or supplier organization. Participants had no previous experience with implantable device list capabilities, but they had tVistA EHR experience. All participants were given the same overview of the new implantable device list functionality for this testing.

Participants were from varied backgrounds and experience as outline in the table below. Participants were provided a participant ID upon arrival for testing thus de-identifying individuals.

Participants were scheduled for 30 minute sessions which included introductions and background, implantable device list tasks, and metrics. Between sessions the data logger, moderator and other team members debriefed and prepared for the next participant. An implantable device list spreadsheet with participant's background information and a schedule of testing appointments was kept to track participation

Participant ID	Gender	Age	Education	Occupation/Role	Professional Experience	Computer Experience	Product Experience	Assistive Technology Needed
1	Female	30-39	Some college, no degree	Clinical Application Coordinator Integrations lead	180	120	36	No
2	Female	30-39	Some college, no degree	MA/Clinical Application Coordinator integrations	180	180	24	No
3	Male	50-59	Doctorate	Pharmacist	240	120	120	No
4	Male	40-49	Doctorate	MD/Health Informatist	180	84	84	No
5	Female	30-39	Bachelor's	Nurse/BCMA coordinator	120	72	72	No
6	Male	20-29	Doctorate	MD/Medical Informaticist Support specialist	24	6	24	No
8	Female	40-49	Some college, no degree	MA/Clinical Application Coordinator	216	144	144	No
10	Female	40-49	Bachelor's	Registered Nurse/Director of Education	360	144	144	No
11	Female	40-49	Some college, no degree	MA/Clinical Application Coordinator integrations	168	182	182	No
12	Female	30-39	Trade/technical/vocational training	Lead Clinical Application Coordinator	144	78	78	No

Table 1. Implantable device list characteristics

STUDY DESIGN

The overall objective of this test was to determine if the application performed effectively, efficiently, and to the satisfaction of the users. Also, if the application failed to meet the needs of the participants what issues were encountered and how can they be mediated. This testing was also designed to satisfy the implantable device list capability requirements of the Safety Enhanced Design criteria for ONC 2015 Edition Health Information Technology (Health IT) Certification Criteria. The data obtained from this testing is expected to generate recommendation and discussion for future development of the implantable device list capabilities of tVistA EHR and identify possible requirements for immediate modifications to facilitate patient safety and/or user adoption.

All participants interacted with tVistA EHR in the same location, provided with the same instructions, asked to complete the same tasks and used the same evaluation tools. Data was collected during testing by the data logger and administrator to evaluate the system for effectiveness, efficiency and satisfaction as defined by measures collected and analyzed for each participant:

- Number of tasks successfully completed within the allotted time without assistance
- Time to complete the tasks
- Number and types of errors
- Path deviations
- Participant's verbalizations (comments)
- Participant's satisfaction ratings of the system

More information about the various measures is provided below in the Usability Metrics section.

TASKS

A number of tasks were constructed that would be realistic and representative of the kinds of activities a user might do with this EHR, including:

1. Record UDI for patient's Implantable Device

2. Verify Parse Identifiers for UDI
3. Obtain and associate description and database attributes
4. Obtain Implantable Device List
5. Access UDI
6. Change Status of UDI

Tasks were selected based on ONC 2015 Certification test protocol § 170.315 (a)(14) Implantable device list, frequency of use, criticality of function for Promoting Interoperability, and tasks that could be foreseen as being most troublesome for users.

PROCEDURES

Upon arrival, participants were greeted; their identity was verified and matched with the name on the participant schedule. Participants were then assigned a participant ID. Each participant was made aware their performance on the upcoming tasks would be recorded for subsequent analysis. The participant was asked to sign the Informed Consent Form (Appendix 1).

“First off we would like to thank you for taking the time to provide us with feedback on the EHR capabilities being tested today. We are executing these sessions as part of the Office of the National Coordinator’s certifications requirements. This usability study will help ensure that Tenzing Medical, LLC meets their certification requirements and Promoting Interoperability standards. We are asking EHR users to provide usability input to the Implantable device list capabilities of tVista EHR. We would like to record your performance on today’s session so that we may use it for subsequent usability analysis after we end the session. Do you give your permission for these recordings?”

To ensure the usability testing ran smoothly, an administrator and a data logger were present for the testing: the testing team members have 20 years of experience in psychological and clinical research and RPMS, CPRS, and commercial medical hardware and software design, development and testing. The team included experienced hardware and software developers with experience in usability testing and user-centered design programs. Also included on the sessions were several stakeholders who were available to observe the user interaction with the system, respond to questions after completion of formal testing and elicit feedback relevant to future development.

The administrator moderated the session, administered instructions and tasks, obtained post-task rating data, and took notes on participant comments. The data logger monitored

task times, and took notes on task success, path deviations, number and type of errors, and comments.

Background information was asked of each participant prior to engaging in the tasks. The data was logged by the administrator and data logger. The participant was situated at the computer, provided with log on information, and allowed time to orient themselves to the EHR and the expected tasks.

Participants were instructed to perform the tasks (see specific instructions in Appendix 3: Moderator's guide):

- As quickly as possible making as few errors and deviations as possible.
- Without assistance; administrators were allowed to give immaterial guidance and clarification on tasks, but not instructions on use.
- Without using a think aloud technique.

For each task, the participants were given a written copy of the tasks. Task timing began once the administrator said "begin". The task time was stopped once the participant indicated he had successfully completed the task (e.g. said "done", etc.).

Following each the task the participant was asked to complete the NASA-TASK LOAD INDEX (Appendix 4). At the completion of the session, the administrator gave the participant the POST STUDY SYSTEM USABILITY QUESTIONNAIRE (Appendix 5).

Participants were asked if they had any additional comments or questions for the group which were logged by the data logger and thanked for their participation.

Participants' implantable device list information, task success rate, time on task, errors, deviations, verbal responses, and post-test questionnaire were recorded into a spreadsheet.

TEST LOCATION

Usability testing took place in a small conference room. A user laptop computer and mouse were set up on a table. The Administrator sat next to the user. The user's screen was redisplayed for the data logger and observers on computers in a separate training room via WebEx session. Stakeholders observed from the data logger's location or listened and viewed via the WebEx session. To ensure that the environment was

comfortable for users, noise levels were kept to a minimum with the ambient temperature within a normal range. All of the safety instruction and evacuation procedures were valid, in place, and visible to the participants.

TEST ENVIRONMENT

Implantable device list EHR capabilities would typically be used in a healthcare office or facility. In this instance, the testing was conducted in a small conference room in the Trenner Medical offices building. For testing a Dell Latitude 7480 laptop running Windows 7 operating system was used with an external mouse. The participants used both keyboard and mouse to navigate and interact with the tVista EHR. A 14-inch monitor was used with a screen resolution of 1920 x 1080. The application was set up according to vendor specifications and the application was running on a Linux/GTM platform using a test database on a LAN connection. The performance of the test system was comparable to what users experience in production environments on site at hospitals and clinics. Participants were asked not to change any of the setting defaults to insure conformity.

TEST FORMS AND TOOLS

During the usability test various documents and instruments were used, including:

1. Informed Consent
2. Moderator Guide w/ Patient Implantable device list
3. NASA-TLX
4. PPSSUQ

Examples of these documents can be found in the Appendices. The Moderator's Guide was devised so as to be able to capture required data.

The participant's interaction with the EHR was captured through recording of WebEx session for each participant's test.

The test sessions were transmitted via WebEx screen sharing to a nearby observation room where the data logger observed the test session.

PARTICIPANT INSTRUCTIONS

The administrator read the following instructions aloud to each participant (also see the full

moderator's guide in Appendix 3):

During this session, you will be asked to complete tasks using Tenzing VistA EHR then provide feedback on the Implantable device list capabilities.

I will provide you with a list of tasks and associated data. You will be asked to complete these tasks as quickly as possible with the fewest errors or deviations. Do not try to do anything other than what is asked. We cannot assist you in accomplishing your tasks. Please save comments and question until the end of each section.

We would like you to give us feedback on the capabilities used. We would like to know how easy or difficult the system is to use, how useful the capabilities are, and what improvement we can make. The best help you can give us is to be critical. We may not be able to fix everything you mention, but it is still beneficial for us to know what issues you feel are important. Your honest feedback is what we are after. Your feedback will be used to help make the Implantable device list capabilities better, so please do not worry about offending anyone with your comments. Your feedback as well as any questions the usability team is unable to answer will be shared with developers and stakeholders. We have this interview divided into several parts. I'd like to start by just getting some background information; then I am going to ask some questions about if/how you currently use the EHR functions, then I will provide an introductory overview of each capability being tested. In the last part, we'll have you log in as a test user and complete tasks associated with each capability. Do you have any questions for us before we get started?

Following the procedural instructions, participants were shown the EHR and given time to explore tVistA EHR and make comments. Once complete the administrator gave the following instructions:

"I will say "Begin." At that point, please perform the task and say "Done" when you believe you have successfully completed the task. Please refrain from talking while doing the tasks. We will have time to discuss the tasks and answer questions when all the tasks are completed."

Participants were given 6 tasks to complete. Tasks are listed Tables 3 below.

USABILITY METRICS

According to the *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records*, EHRs should support a process that provides a high level of usability for all users. The goal is for users to interact with the system effectively, efficiently, and with an acceptable level of satisfaction. To this end, metrics for effectiveness, efficiency and user satisfaction were captured during the usability testing. The goals of the test were to assess:

1. Effectiveness by measuring participant success rates and errors

2. Efficiency by measuring the average task time and path deviations
3. Satisfaction by measuring ease of use ratings

DATA SCORING

The following table (Table 2) details how tasks were scored, errors evaluated, and the time data analyzed.

Measures	Rationale and Scoring
<p>Effectiveness: Task Success</p>	<p>A task was counted as a “Success” if the participant was able to achieve the correct outcome, without assistance, within the time allotted on a per task basis.</p> <p>The number of successes were calculated for each task and then divided by the total number of times that task was attempted. The results are provided as a percentage.</p> <p>If the participant abandoned the task, did not reach the correct answer or performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as a “Failures.” No task times were taken for errors.</p>
<p>Efficiency: Task Time</p>	<p>Task times were recorded for tasks successfully completed then divided by the number of participants who completed the task successfully. The average task time is reported. Variance measures (standard deviation and standard error) were also calculated.</p>
<p>Efficiency: Task Deviations</p>	<p>The participant’s path (i.e., steps) through the application was recorded. Deviations occur if the participant, for example, skipped a prompt, made an incorrect entry, or interacted incorrectly with an on-screen prompt. This path was compared to the optimal path established by the team and developers. The number of steps in the observed path is divided by the optimal number of steps and presented as a ratio of path deviation</p>
<p>Satisfaction: Task Load</p>	<p>Participant’s subjective impression of the workload or cost of accomplishing the task requirements were obtain through the administration of the NASA Task Load Index (NASA-TLX) after each task set. The participant was asked to complete the six subscales representing different variables including: Mental, Physical, and Temporal Demands, Frustration, Effort, and Performance. See Appendix.</p> <p>A high level of burden on the participants is indicated by a score of 60 or greater.</p>

<p>Satisfaction: Task Rating</p>	<p>To measure the participant's satisfaction of the demographic capabilities the team administrated the Post Study System Usability Questionnaire (PSSUQ) at the completion of all the tasks. The PSSUQ consists of 19 items such as "it was simple to use the system" and "It was easy to find the information I needed" that the participant rates using a 7-point Likert scale ranging from 1=strongly agree to 7= strongly disagree. The PSSQU is designed to assess overall user satisfaction through perceived system usefulness, Information Quality and Interface quality.</p> <p>See Appendix 5 for a copy of the questionnaire.</p>
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Table 2. Details of how observed data were scored.

RESULTS

DATA ANALYSIS AND REPORTING

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above. There were no participants who failed to follow session and task instructions or had their data excluded from the analyses.

The usability testing results for the Implantable device list capabilities of tVista EHR are detailed below in Table 3. The results should be seen in light of the objectives and goals outlined in the Study Design section above. The data should yield actionable results. If corrected, the implantable device list tVista EHR capabilities will have a positive impact on user performance.

Qualitative feedback from the participants was transcribed by team members and compiled in an Excel spreadsheet. The team met to discuss all potential issues particularly those items noted as significant for consideration. Each issue was listed as verbalized by the participant and the team evaluated the issue asking questions such as: *What might cause the participant to have this issue? What cognitive support element does this issue violate? What can be done/changed to support the cognitive support element?* Recommendations intended to rectify the identified issue were recorded.

Issues were coded according to the cognitive element that led to the underlying issue, issue class, and time frame

Issue Class

Each issue was classified into an "issue class." This classification scheme represents our understanding of the potential impact of each issue if left unaddressed.

- **Type 1** issues are those we anticipate will create an *individual error risk*. These issues may directly introduce a specific health risk. For example, a new health system that somehow allowed treatment plans to be mistakenly associated with multiple EHRs. Some patients would be placed at significant health risk because of the design flaw.
- **Type 2** issues are those we anticipate will create an *aggregate error risk*. These issues may introduce error through cumulative effects. An example of this would be a new system that failed to capture some important paper- based function that was used in conjunction with the old system. The loss of low-tech, but high-value information can eventually lead to a problem.
- **Type 3** issues are those that we anticipate will create *adoption and long-term use risk*. These issues may negatively influence acceptance of the software. In the extreme, ignoring these issues may result in software that is rejected by the intended users. If use is mandated, users may find ways to “game” the system, distorting or circumventing the intent of the software. This is less troubling from a health risk standpoint but could still create a long-term failure of a system in which much has been invested.

Timeframe

Recommendations are also made according to the timeframe in which issues should be addressed. Four timeframes are considered: urgent, quick fix, near-term, and long-term.

- **Urgent:** lead to significant medical error and/or patient risk, need to be fixed before next release/patch.
- **Quick fix:** These issues that we believe can be fixed "in-house" in a relatively short time frame (e.g. several weeks). These are issues that we believe will positively influence user acceptance with little development effort.
- **Near-term issue:** These issues are those that we believe will positively influence user acceptance. Can be completed in 12 months or less but may require extra development time and effort.
- **Long-term issue:** These issues do not present significant risk in their current form. These recommendations, however, have the potential for significant, high impact benefit if resources can be found to address them over time. These fixes will take more than 12 months, contain interoperability issues and may require overhauls of existing systems, introductions of new functionality, and require extended development efforts.

Task #	Task Description	N	Task Success - Mean (%)	Task Success - Standard Deviation (%)	Task Path Deviation - Observed #	Task Path Deviation - Optimal #	Task Time - Mean (seconds)	Task Time - Standard Deviation (seconds)	Task Time Deviation - Mean Observed Seconds	Task Time Deviation - Mean Optimal Seconds	Task Errors Mean (%)	Task Errors - Standard Deviation (%)	Task Rating - Scale Type	Task Rating (Overall)	Task Rating (Overall) - Standard Deviation	System Usefulness rating	Information Quality rating	Interface Rating	Task Load	
1	Record UDI for patient's Implantable Device	10	100.0	0.0	10	6	170	65	2.50	68	0.0	0.0	PSSUQ	2.76	1.50	2.73	2.91	2.29	51.43	
2	Verify Parse Identifiers for UDI	10	100.0	0.0	5	5	34	18	1.22	28	0.0	0.0								
3	Obtain and associate description and database attributes	10	100.0	0.0	15	14	123	52	2.09	82	0.0	0.0								
4	Obtain Implantable Device List	10	60.0	49.0	5	4	96	74	1.61	62	40.0	49.0								
5	Acces UDI	10	90.0	30.0	16	7	120	115	2.00	60	10.0	30.0								
6	Change Status os UDI	10	100.0	0.0	9	6	52	52	2.22	24	0.0	0.0								

Table 3: Implantable Device data

DISCUSSION OF THE FINDINGS

Effectiveness

Effectiveness was measured by task completion or failure to complete task. We asked providers to complete tasks of implantable device list tVistA EHR capabilities that demonstrate the required functionality. These tasks are derived from the ONC 2015 Edition Health Information Technology (Health IT) Certification Criteria. The task completion data indicates that most providers were able to complete most tasks that they were asked to execute. There are notable differences between the participants who completed each task. These variations are due to subject characteristics, not issues regarding the functionality of the system. These subject variables include not entering patient name when first prompted but entering at second prompt and using enter/edit to inquire to UDI as opposed to using separate menu. Four providers failed to obtain the implantable device list. This was the last task on the test script. Users stated they did not see the task or thought they had completed it elsewhere in the test script. One user failed to access the implantable device also stated he thought he had completed this task. The confusion for the users thinking similar tasks are the same reflects the lack of familiarity with the new functionality.

Efficiency

Efficiency was measured by time on task and task deviations. We asked providers to complete representative tasks of the implantable device list capabilities that demonstrate the required functionality. These tasks are derived from the ONC 2015 Edition Health Information Technology (Health IT) Certification Criteria. We did not instruct participants to complete tasks in one specific manner, because there are multiple, valid paths to task completion for any given task. This variation causes deviation in both time on task and path. Nevertheless, the data indicates that most providers were able to complete all the tasks in a standard manner. However there were deviations with respect to repeatedly scanning device bar code but not answer “Yes” when prompted “Are you adding ‘Implantable device UDI’ as a new VGTM IMPANTABLE DEVICE?”, time spent verifying parsed data and UDI descriptions and using enter/edit option to activate the UDI and inquire to UDI as opposed to using separate menu options

Satisfaction

Satisfaction was measured by two subjective questionnaires, the NASA TLX and the PSSUQ. Overall workload ratings indicate that the users are not overly burdened by the software. The results from the NASA TLX were: 51.43. PSSUQ scores indicated overall favorable results for all areas of the implantable device list tVistA EHR capabilities. Below is a complete list of written comments (duplicates omitted) articulated by participants in response to question items.

- *This is where I get confused; Am I adding this?*
- *Is this another Step" - Asked by participant regarding inquiry to implantable device task.*
- *If we had a proper procedure in place and time to navigate Tenzing VistA generally, it would be much easier.*
- *I would like a little user training to familiarize myself for future use.*
- *With use it will be easy to navigate.*
- *Nicely gave clear format for answers.*

This list of comments includes positive, neutral, and negative comments illustrating that there are areas of the EHR that providers find easy to use and areas of the EHR that will benefit from design enhancements. Additional training to improve skills could be effective in reinforcing the data entry methods user indicated they are unaware or unfamiliar with.

AREAS FOR IMPROVEMENT

As a result of this set of usability interviews we determined that the implantable device list tVistA EHR capabilities violate a set of cognitive support elements. Relevant issues gleaned from these usability sessions are listed in the following section. The resulting issues are grouped with respect to the cognitive element that the usability team believes led to the underlying issue. Each issue that was uncovered during the usability interviews is listed as it relates to the cognitive element that is being violated. As a reminder, these elements include:

- *Support Decision Making*
- *Reduce Errors*
- *Facilitate Scanning*
- *Create Affordances*
- *Illustrate Perceived Benefit*
- *Support Mental Models*

Recommendations are made to encourage a design enhancement that creates support for the relevant cognitive requirement. Recommendations should be adopted and implemented only in

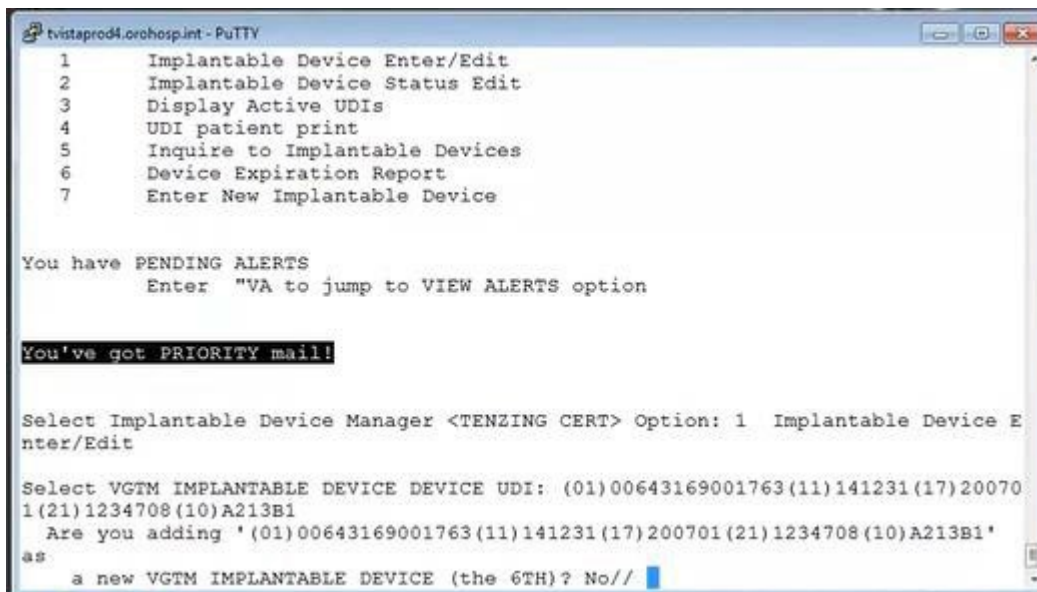
ways that support the cognitive elements. When reviewing the issues and recommendations the HIT team should consider questions such as:

1. *Why are participants having this issue?*
2. *What cognitive support element does this issue violate?*
3. *What can we do within the design process to facilitate the cognitive support requirement?*

Issues and Recommendations

Issue 1: User tentative about adding device to system.

- Cognitive Support Element: Supporting Decision Making. We believe this is a quick fix that could be rectified with user training on implantable device list
 - Consideration:
 - *How can we facilitate provider confidence in adding implantable device data to the system?*
- R-1 We recommend evaluation of the verbiage that asks provider if they want to add the implantable device so that it is clear to users the results of their actions.
- R-2 We recommend additional training on addition of implantable device.



```

tvistaprod4.orohosp.int - PuTTY
1  Implantable Device Enter/Edit
2  Implantable Device Status Edit
3  Display Active UDIs
4  UDI patient print
5  Inquire to Implantable Devices
6  Device Expiration Report
7  Enter New Implantable Device

You have PENDING ALERTS
   Enter "VA to jump to VIEW ALERTS option

You've got PRIORITY mail!

Select Implantable Device Manager <TENZING CERT> Option: 1  Implantable Device E
nter/Edit

Select VGTm IMPLANTABLE DEVICE DEVICE UDI: (01)00643169001763(11)141231(17)20070
1(21)1234708(10)A213B1
Are you adding ' (01)00643169001763(11)141231(17)200701(21)1234708(10)A213B1'
as
a new VGTm IMPLANTABLE DEVICE (the 6TH)? No//
  
```

Issue 2: User confused by DEVICE: prompt referring to printer device as opposed to the implantable device.

Cognitive Support Element: Supporting Mental Models. Users were asked to obtain an implantable device list which required printing the list to the screen, but they were confused by DEVICE prompt that referred to print device as opposed to implantable device.

- Consideration:
 - *How can we clarify differences between implantable device entry and system devices?*
- R-3 We recommend training to familiarize users with menu options, functionality and meaning of prompts.

```

tvistaprod4.oro.hosp.int - PuTTY
Aortic heart valve bioprosthesis

1   Implantable Device Enter/Edit
2   Implantable Device Status Edit
3   Display Active UDIs
4   UDI patient print
5   Inquire to Implantable Devices
6   Device Expiration Report
7   Enter New Implantable Device

You have PENDING ALERTS
Enter "VA to jump to VIEW ALERTS option

You've got PRIORITY mail!

Select Implantable Device Manager <TENZING CERT> Option: 3 Display Active UDIs
Start with PATIENT: UT,TWO//
Go to PATIENT: LAST//
DEVICE: █
  
```

Issue 3: Users had trouble deciding which menu option to use

- Cognitive Support Element: Creating Affordance. Users took considerable time selecting which menu option to use for a given task or used the same menu option for multiple task rather than choosing the option specific for task.
 - Consideration
 - *How can we facilitate understanding of which option to access for specific tasks?*
- R-4 We recommend reviewing and modifying menu description, so they are more meaningful to users for option specific tasks.
- R-5 We recommend additional training on the implantable device capabilities to familiarize user with all the options and the benefit of using specific options for specific tasks.

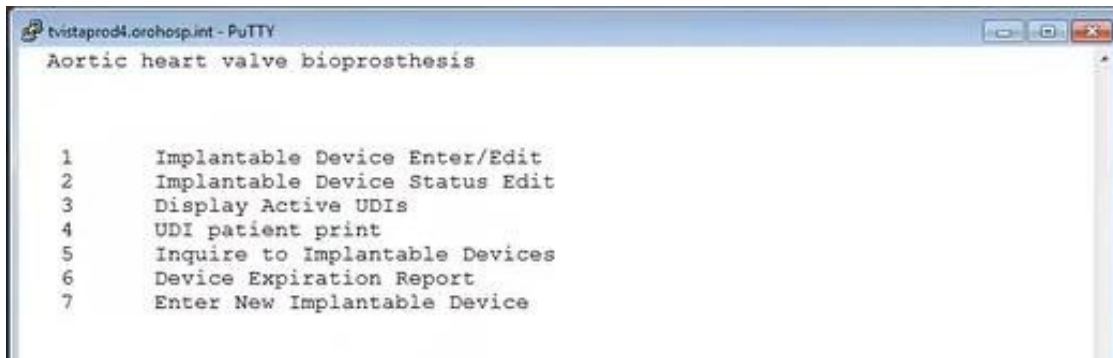


Table 4 represents the issues, the associated cognitive support element, issue class and anticipated timeframe

Issue	Description	Cognitive Support Element	Issue Class	Timeframe
1	User tentative about adding device to system.	Supporting Decision Making	III	Quick Fix
2	User confused by DEVICE: prompt referring to printer device as opposed to the implantable device.	Supporting Mental Models	III	Quick Fix
3	Users had trouble deciding which menu option to use	Creating Affordance	III	Quick Fix

Table 4: Issue and Recommendations by Cognitive Support Element, Issue Class and Timeframe

APPENDICES

The following appendices include supplemental data for this usability test report.

Following is a list of the appendices provided:

- 1: Informed Consent
- 2: Participant Implantable device list
- 3: Moderator's Guide
- 4: NASA-Task Load Index
- 5: Post Study System Usability Questionnaire

Appendix 1: Informed Consent

Informed Consent

Tenzing Medical, LLC would like to thank you for participating in this study. The purpose of this study is to evaluate an electronic health records system. If you decide to participate, you will be asked to perform several tasks using the prototype and give your feedback. The study will last about 30 minutes.

Agreement

I understand and agree that as a voluntary participant in the present study conducted by Tenzing Medical, LLC I am free to withdraw consent or discontinue participation at any time. I understand and agree to participate in the study conducted and videotaped by the Tenzing Medical, LLC.

I understand and consent to the use and release of the videotape by Tenzing Medical, LLC. I understand that the information and videotape is for research purposes only and that my name and image will not be used for any purpose other than research. I relinquish any rights to the videotape and understand the videotape may be copied and used by Tenzing Medical, LLC without further permission.

I understand and agree that the purpose of this study is to make software applications more useful and usable in the future.

I understand and agree that the data collected from this study may be shared outside of Tenzing Medical, LLC and Tenzing Medical, LLC's client. I understand and agree that data confidentiality is assured, because only de-identified data – i.e., identification numbers not names – will be used in analysis and reporting of the results.

I agree to immediately raise any concerns or areas of discomfort with the study administrator. I understand that I can leave at any time.

Please check one of the following:

- YES, I have read the above statement and agree to be a participant.
- NO, I choose not to participate in this study.

Signature: _____ **Date:**

Appendix 2: Participant Demographics

Gender

Men	3
Women	7
Total (participants)	10

Occupation/Role

Clinical Applications	3
Medical Assistant	3
Nurse	2
Physician	2
Total (participants)	10

Average Years of Experience (months)

Professional	181
VistA EHR	91

Appendix 3: Moderator's Guide

Introduction/Orientation:

First off we would like to thank you for taking the time to provide us with feedback on the EHR capabilities being tested today. We are executing these sessions as part of the Office of the National Coordinator's certifications requirements. This usability study will help ensure that Tenzing Medical, LLC meets their certification requirements and Promoting Interoperability standards. We are asking EHR users to provide usability input to the Demographic, Implantable Device List, Drug-related, Clinical Decision Support (CDS) and Clinical Information Reconciliation (CIR) capabilities of tVistA EHR. We would like to record your performance on today's session so that we may use it for subsequent usability analysis after we end the session. Do you give your permission for these recordings?

Sign Informed consent

During this session, you will be asked to complete tasks using Tenzing VistA EHR then provide feedback on the Implantable Device capabilities.

I will provide you with a list of tasks and associated data. You will be asked to complete these tasks as quickly as possible with the fewest errors or deviations. Do not try to do anything other than what is asked. We cannot assist you in accomplishing your tasks. Please save comments and question until the end of each section.

We would like you to give us feedback on the capabilities used. We would like to know how easy or difficult the system is to use, how useful the capabilities are, and what improvement we can make. The best help you can give us is to be critical. We may not be able to fix everything you mention, but it is still beneficial for us to know what issues you feel are important. Your honest feedback is what we are after. Your feedback will be used to help make the implantable device capabilities better, so please do not worry about offending anyone with your comments. Your feedback as well as any questions the usability team is unable to answer will be shared with developers and stakeholders.

We have this interview divided into several parts. I'd like to start by just getting some background information; then I am going to ask some questions about if/how you currently use the EHR functions, then I will provide an introductory overview of each capability being tested. In the last part, we'll have you log in as a test user and complete tasks associated with each capability. Do you have any questions for us before we get started?

Complete Participant Information & Background Information

Implantable Devices – This section asks a user to record, change, and access patient implantable device data including race, ethnicity, preferred language, sex, sexual orientation, gender identity, and date of birth. Basic fileman knowledge is necessary to complete this task. A Fileman shortcut list and user guide is provided for your reference.

Participant Background Information

Moderator/Administrator:

Data Logger:

Date/Time:

Location of Testing:

Participant #

Gender:

- Male
- Female
- Unknown

Age:

- <19
- 20-29
- 30-39
- 40-49
- 50-59
- 60-69
- 70-79
- 80-89
- >89

Level of Education:

- No high school degree
- High school graduate, diploma or the equivalent (for example: GED)
- Some college credit, no degree
- Trade/technical/vocational training
- Associate degree
- Bachelor's degree
- Master's degree
- Doctorate degree (e.g., MD, DNP, DMD, PhD)

Provider Occupation/Role:

Years of professional experience:

Years of experience with EHR (rounded to the nearest half year):

Years of experience with VistA EHR (rounded to the nearest half year):

Any Assistive Technology Needs (screen readers or magnifiers, large-print or tactile keyboard):

Use

How do you currently complete patient implantable device entry/updates?

Are there any functions in the version that you interact with that you do not use often?

Are there any functions you see as less important than others?

Provider Fileman Shortcut list to User and read Fileman Basics

Show Participant section intro & Begin WebEx Recording

Provide User Test script and read

I will say "Begin." At that point, please perform the task and say "Done" when you believe you have successfully completed the task. Please refrain from talking while doing the task. We will have time to discuss the task and answer questions when the task is complete.

Pause WebEx when User states "Done"

Read the NASA Tlx instructions to the User

Provide iPad to User to complete Nasa Tlx

Set up Nasa Tlx for next section evaluation

Appendix 4: NASA-Task Load Index (sample)

---NASA TLX V1.0.3 SINGLE TRIAL PAIRWISE ANSWERS---		
STUDY NAME:	SAMPLE	
STUDY GROUP:	SAMPLE	
SUBJECT ID:	S1	
TRIAL:		1
TRIAL DATE TIME:		6/21/2019 16:35
---DATA---		
PAIRWISE CHOICES	SELECTION	
Effort vs. Physical Demand	Effort	
Physical Demand vs. Performance	Performance	
Temporal Demand vs. Mental Demand	Temporal Demand	
Physical Demand vs. Frustration	Physical Demand	
Mental Demand vs. Physical Demand	Mental Demand	
Temporal Demand vs. Frustration	Temporal Demand	
Temporal Demand vs. Effort	Effort	
Frustration vs. Effort	Effort	
Physical Demand vs. Temporal Demand	Temporal Demand	
Performance vs. Frustration	Performance	
Performance vs. Temporal Demand	Performance	
Performance vs. Mental Demand	Performance	
Effort vs. Performance	Effort	
Frustration vs. Mental Demand	Mental Demand	
Mental Demand vs. Effort	Mental Demand	

---NASA TLX V1.0.3 SINGLE TRIAL RATING SCALE ANSWERS---		
STUDY NAME:	SAMPLE	
STUDY GROUP:	SAMPLE	
SUBJECT ID:	S1	
TRIAL:		1
TRIAL DATE TIME:		6/21/2019 16:35
---DATA---		
PAIRWISE ASKED WITH TRIAL:	TRUE	
PAIRWISE ANSWERS TO USE:	SAMPLE_S1_001_PW_06-21-2019_16-35.csv	
RATING SCALE:	RAW RATING	
Mental Demand		60
Physical Demand		15
Temporal Demand		60
Performance		20
Effort		60
Frustration		50

Weighted Rating: 46.33

Appendix 5: Post Study System Usability Questionnaire

Instructions: This questionnaire gives you an opportunity to tell us your reactions to the system you used. Your responses will help us understand what aspects of the system you are particularly concerned about and the aspects that satisfy you.

To as great a degree as possible, think about all the tasks that you have done with the system while you answer these questions.

Please read each statement and indicate how strongly you agree or disagree with the statement by circling a number on the scale.

Please write comments to elaborate on your answers.

After you have completed this questionnaire, I'll go over your answers with you to make sure I understand all of your responses.

Thank you!

1. Overall, I am satisfied with how easy it is to use this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

2. It was simple to use this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

3. I could effectively complete the tasks and scenarios using this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

4. I was able to complete the tasks and scenarios quickly using this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

5. I was able to efficiently complete the tasks and scenarios using this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

6. I felt comfortable using this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

7. It was easy to learn to use this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

8. I believe I could become productive quickly using this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

9. The system gave error messages that clearly told me how to fix problems.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

10. Whenever I made a mistake using the system, I could recover easily and quickly.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

11. The information (such as on-line help, on-screen messages and other documentation) provided with this system was clear.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

12. It was easy to find the information I needed.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

13. The information provided for the system was easy to understand.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

14. The information was effective in helping me complete the tasks and scenarios.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

15. The organization of information on the system screens was clear.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

Note: The interface includes those items that you use to interact with the system. For example, some components of the interface are the keyboard, the mouse, the screens (including their use of graphics and language).

16. The interface of this system was pleasant.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

17. I liked using the interface of this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

18. This system has all the functions and capabilities I expect it to have.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

19. Overall, I am satisfied with this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

2767 Olive Highway
Oroville, CA 95966-6185

Tenzing VistA EHR Usability Test of Electronic Prescribing tVistA EHR Capabilities

Tenzing VistA – tVistA V2.1

Date of Usability Test: Aug 24, 2023 – Aug 1, 2024

Date of Report: September 30, 2024

Report Prepared By: Tenzing Medical, LLC

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EXECUTIVE SUMMARY

Usability testing of the electronic prescribing (e-Rx) capabilities of Tenzing VistA – tVistA V2.1 was conducted August 24, 2023 through September 29, 2023 and July 29 through August 1, 2024 at Oroville Hospital. The purpose of the testing was to validate the usability of the e-Rx capabilities of tVistA V2.1 graphical user interface (GUI) and provide the opportunity for user feedback on desired changes or improvement for future development. During the usability test 11 healthcare providers matching the target demographic criteria served as participants and used the tVistA EHR in simulated, but representative tasks.

The study collected performance data on six tasks related to electronic prescribing functionality. These tasks are designed to support the ONC Health IT Certification Program. The tasks are categorized as follows:

- Prescribe and transmit medications electronically
- Discontinue a medication using e-prescribing tool
- Deny Renewal Request
- Approve Renewal (refill) request
- Approve change request for therapeutic substitution
- Approve change request for generic substitution

During the one hour usability test, each participant was greeted and informed they could withdraw at any time. Participants had prior TVistA EHR experience, but did not have experience with the e-prescribe package being tested. Ten of the participants had used electronic prescribing functionality previously, but none had used the e-Rx being tested for tVistA EHR. Participants were informed of the purpose of the usability testing and the type of data the team was gathering. Participants were provided with a demonstration on the electronic prescribing capabilities. The presentation was printed and provided to each participant for reference while they completed the tasks. After demonstrating the e-Rx capabilities the administrator introduced the test, and instructed participants to complete a series of tasks (one at a time) using the EHR. During the test the administrator timed each task while the data logger recorded user performance. The administrator did not provide assistance on how to complete a task, but asked participants to demonstrate how they thought they would complete the task based on the instruction provided and instinct.

The Following data was collected for each participant:

Number of task successfully completed without assistance
Time to Complete Tasks
Types of Errors
Path deviations
Provider's verbalizations
Provider's reported workload level
Provider's satisfaction rating of the system

All participant data was de-identified to eliminate correspondence made between participant identity and the data collected. Following the conclusion of the testing, participants were asked to complete post-test questionnaires. Various recommended metrics, in accordance with the examples set forth in the *NIST Guide to the Process Approach for Improving the Usability of Electronic Health Records*, were used to evaluate the usability of the EHR. Following is a summary of the performance and rating data collected on the usability of the Electronic Prescribing capabilities of the tVista EHR.

Major findings⁽¹⁾⁽²⁾⁽³⁾⁽⁴⁾

The results of the NASA Task Load Index (LTX) – a measure of the subjective workload, or demand the task places on the user during execution- was: 10.32 (SD = 3.85) which indicates this new capability did not placed significant demand on users attempting the associated tasks. The results from the Post Study System Usability Questionnaire (PSSUQ) – a measure of user satisfaction post participation in scenario based usability studies-for the e-Rx tVista EHR capabilities was 3.05 (SD = 1.48) overall. Generally users responded favorably to the e-Rx tVista capabilities. Making changes as indicated in the areas for improvement should increase usability and lead to greater system satisfaction.

1. **Hart, S. G., & Staveland, L.E.** Development of NASA-TLX (Task Load Index): Results of empirical and theoretical research. [ed.] P. A. Hancock and N. Meshkati. *Human mental Workload*. Amsterdam : North Holland Press., 1988, pp. 139-183. Scores greater than 60 are interpreted to place a higher task load on users.

2. *NASA-Task Load Index (NASA-TLX); 20 Years Later*. **Hart, S. G.** Santa Monica : HFEW, 2006. Proceedings of the Human Factors and Ergonomics Society 50th Annual Meeting. pp. 904-908.

3. *IBM computer usability satisfaction questionnaires: Psychometric evaluation and instructions for use*. **Lewis, J. R.** 1, 1995, International Journal of Human-Computer Interaction, Vol. 7, pp. 57-78. Scores range from 1-5. Lower scores indicate higher level of satisfaction.

4. *Psychometric Evaluation of the PSSUQ Using Data from Five Years of Usability Studies*. **Lewis, J. R.** 3 & 4, s.l. : Lawrence Erlbaum Associates, Inc., 2002, International Journal of Human-Computer Interaction, Vol. 14, pp. 463-488.

Areas for improvement

- User Training
- Improved readability of Graphical User Interface
- More prevalent display of New Medication entry point
- Minimize scrolling
- Minimize word crowding
- Clearly identify errors and missing or required information

INTRODUCTION

The tVista EHR electronic prescribing capabilities tested for this study include; Prescribing and transmitting medications electronically, discontinuing a medication using e-prescribing tool, denying a renewal request, approving a renewal (refill) request, approving a change request for a therapeutic substitution and approving a change request for a generic substitution. The usability testing presented realistic exercises and conditions as defined in ONC Health IT Certification Program requirements:

§170.315(b)(3) Electronic prescribing

Purpose

The purpose of this study was to test and validate the usability of the current user interface for tVista EHR and provide evidence of usability in the EHR. This study was conducted to meet the requirements ONC Health IT Certification Program and the recommendation indicating that User Centered Design (UCD) should be conducted when developing EHR technology. The intended outcome of implementing User Center Design in coordination with quality system management is improved patient safety. To this end User Center Design identifies user tasks and goals that can then be incorporated into the EHR development to improve efficiency, effectiveness and user satisfaction. In order to satisfy the ONC requirement for §170.315(b)(3), Safety-enhanced design, this study was designed to test tVista EHR electronic prescribing functionality. Data was collected to measure effectiveness, efficiency, and user satisfaction, using metrics of time on task, task completion, task deviation, user task load and user satisfaction. As defined in the Safety-enhanced design test procedure the *National Institute of Standards and Technology Internal Reports (NISTIR) 7742* was used as the basis of format for this final report. The usability testing was conducted by the vendor team with guidance from the NISTIR 7741 - *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records*

Tenzing Medical LLC User-Centered Design Approach (5) (6) (7) (8) (Militelto L. G., 2009) (10)

Tenzing Medical, LLC incorporated the concepts of Cognitive System Engineering (CSE), User-Centered Design approach in a Decision-Centered Design (DCD) framework as described below. “CSE is an approach to the design of technology, training, and processes intended to manage cognitive complexity in sociotechnical systems” (Militelto L. G., 2009). Users engage in cognitively complex activities such as identifying, judging, attending, perceiving, remembering, deciding, problem solving and planning when interacting with a system.

User-Centered Design approach to system engineering encompasses 6 key principles:

- The design is based upon an explicit understanding of users, tasks and environments.
- Users are involved throughout design and development.
- The design is driven and refined by user-centered evaluation.
- The process is iterative.
- The design addresses the whole user experience.
- The design team includes multidisciplinary skills and perspectives.

tVistA EHR system design addresses the cognitive complexities associated with managing complex decision-making and the key principles of User Centered Design through the use of a Decision Centered Design (DCD) Framework. In DCD the software development involves task analysis, design, and evaluation that focuses on describing, analyzing, understanding, and supporting complex perceptual and cognitive activities (10)

Task Analysis is used to identify key decisions and requirements. Task analysis involves identifying the cognitive activities involved in a task, how the task is performed and where the task is performed so that an understanding of the

-
5. **Armijo, D., McDonnell, C., Werner, K.** *Electronic Health Record Usability: Evaluation and Use Case Framework*. Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. Rockville : Agency for Healthcare Research and Quality, 2009. 09(10)-0091-1-EF.
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requirements of the system is complete and addresses and supports the strengths and weakness of existing cognitive tasks. Subject Mater Experts (SME) assist in identifying these key decisions and requirements and continue their involvement throughout the development process. The SME work closely with the Health Information Technology (HIT) team of designers, programmers, network specialist, pharmacist, physicians, nurses, and ancillary service specialists to provide input on development, design, workflows, and system testing. Having user input in the earliest phases of development allows for better understanding of the skills and knowledge users possess, the mental models used to develop expectation for functionality, the objectives and tasks the application will be used to complete, and the decisions users must make that the application should support.

Design phase of development aims to utilize the insights gained in task analysis to create a system that reduces cognitive challenge, improves error management, and increases performance. SME provide ongoing feedback on individual packages and interoperability between packages. Requirements can be established from the elicitation of this information and conceptual designs created. The most common user activities are identified and made most prominent within the system. Eventually a prototype is created and implementation planning begins. The goal is to optimize the system.

Evaluation involves continuous formative as well as summative usability testing. Decision Centered Design approach to software development incorporates users testing and feedback from the design phase. This type of development captures the unseen aspects of the system, the potential errors, evolving technology and human interaction with this technology. Usability testing demonstrates user system interaction and further defines necessary adjustments needed immediately and long term to further optimize the system. A broader range of users with diverse requirements, experiences, and work environments are recruited for summative usability testing. These users provide evaluation and feedback the HIT team uses to reevaluate and reengineer the EHR.

The DCD process is iterative. As problems are identified, options are evaluated and systems modeled, integrated, and launched and performance is accessed. The HIT team continually aims to meet customer and users' needs, utilize available technology, and assess and understand priorities, limitations and tradeoffs that must be made. Dialog is continuous and frequent among all stakeholders and team members. This allows for generation of new ideas, refinement of old ideas, conceptual changes and/or rejection. This process involves many organizational entities

and all parties contribute to the discussion providing input, recommendations, and knowledge exchange. The team analyzes the information provided and makes decisions about design, budget, priorities, testing, redesign and roll-out. The healthcare industry is constantly in flux requiring ongoing and often immediate changes to EHRs. As an iterative and heuristic approach to development DCD bodes well in this environment.

Although change is constant, it is important to design and implement systems that build on current user mental models. This is accomplished by reimagining the same workflow in another format or utilizing existing mental models in another application. Redundancy of function within tVistA EHR, such as right click access to action menus, as well as reusing existing technology common keyboard functions and short cuts facilitate learning and usability.

tVistA EHR is a complex system which requires the user to use complex decision making at times while only simple decision making at others, and users vary in how they practice, how they interact with the EHR, and their individual abilities. Therefore, a broad representative base of users is required to elicit meaningful evaluation of the EHR. Complex but specific user test scripts are designed and minimal instruction is provided to users in order to elicit maximum evaluation of the EHR during usability testing. The HIT team aims to generate unforeseen possibilities the variety of users may unfold as well as maximal feedback on user experience of the EHR.

Focusing on the intended users of a new or modified technology maximizes benefit for the user and adoptability. The Primary users are given priority over other users who may have competing or irreconcilable preferences.

Primary Users: The primary users for the electronic prescribing capabilities are prescribing providers. Providers in both inpatient and outpatient settings specializing in various areas of medicine and whose interactions with patients require prescribing medications at discharge or during a clinical encounters.

Secondary Users: Secondary users of electronic prescribing capabilities include nursing, pharmacy and ancillary service staff that may complete medication distribution, review prescribed medication, provide assistance in using e-prescribing technologies or assist patient with medication related questions.

Sociotechnical systems are complex and users have to find ways to manage the complexities. DCD approach assist users through the use of cognitive support strategies focused on decision support tools that reinforce users' natural decision making processes. The cognitive support elements outlined below and later used in addressing recommendations help to manage complexity when designing the new software. The recommendations made later will impact

future cognitive support strategies.

- **Supporting Decision Making:** refers to decisions support tools designed to provide context specific information when needed and reduce task load.
- **Reducing Errors:** refers both to system error reduction functionality as well as user's awareness, trust and understanding of error reduction functionality. Users must be aware of where error reduction functionality exists and where it does not so they can adjust their expectations and trust the system when appropriate thus reducing cognitive load.
- **Facilitating Scanning:** Refers to placement, amount and type of information on a screen and how well this placement allows a user to find information quickly and accurately and how well a user can return to their place in a screen after an interruption.
- **Creating Affordance:** Refers to design features that help, aid, support, facilitate or enable thinking, knowing, perceiving, or doing something. For example; words on a button indicating the meaning of the button.
- **Illustrating Perceived Benefit:** Refers to users belief that their day-to-day activities will benefit from using the system. Lack of perceived benefit can result in lack of motivation to learn or use the system and possibly reject the system entirely
- **Supporting Mental Models:** Refers to building upon users mental models. Designing applications that utilize common language and functionality such as windows standard or previous version functionality.

The electronic prescribing (e-Rx) tVistA EHR capabilities are new methods for old processes. Electronic prescribing refers to tools used to assist providers in managing and prescribing medications. All medication prescribed to a patient in the system are displayed for the provider to review during the patient assessment and prescribing process. Providers can transmit prescription electronically including controlled substance. Providers can also discontinue previously prescribed medication, respond to refill/renewal and change requests and reconcile the medication list to keep patient medications accurate and up to date. Primary users' main concerns for electronic prescribing is maintaining an accurate medication list and transmitting medication quickly and accurately to the patients chosen pharmacy. Finally, all tasks should be completed with a minimal number of key strokes.

Tenzing Medical, LLC practices the user center design and testing outlined above on an ongoing basis, but this document specifically focuses on the usability testing conduct over two separate weeks of development.

METHOD

PARTICIPANTS

A total of 11 participants were tested on the tVistA EHR e-Rx capabilities. Participants in the test were physicians, Nurse Practitioner, pharmacists, and e-prescribing application specialist. The participants were recruited by Dr Narinder Singh, the Chief Medical Information Officer (CMIO). The participants volunteered and were, therefore, not compensated for their participation. Participants had no direct connection to the development of or organization producing tVistA EHR nor the testing or supplier organization. All participants had previous experience with tVistA EHR capabilities, but had never used the tVistA EHR e-Rx capabilities being tested. Ten participants had used electronic prescribing software, however no participant had ever seen or used tVistA electronic prescribing. Participants were provided a brief orientation to the e-Rx capabilities prior to testing, and the presentation was printed and provided to each participant for reference while they completed the tasks.

Participants were from varied backgrounds and experience as outline in the table below. Participants where provided a participant ID upon arrival for testing thus de-identifying individuals.

Participants were scheduled for 60 minute sessions which included introductions and background, electronic prescribing orientation, e-Rx tasks, and metrics. Between sessions the data logger, moderator and other team members debriefed and prepared for the next participant. A demographic sheet with participant's information and metrics were compiled for evaluation

Participant ID	Gender	Age	Education	Occupation/ Role	Professional Experience (months)	Computer Experience (months)	Product Experience (months)	Assistive Technology Needed? (YES/NO)
1	Male	60-69	Doctorate	Pharmacist/ Developer	360	360	204	NO
2	Male	60-69	Doctorate	CMIO/Internist	360	360	204	NO
3	Female	40 - 49	Doctorate	Director of Pharmacy	204	200	180	NO
4	Female	50 - 59	Associate	Clinical coordinator e-Rx specialist	96	396	96	NO
5	Male	60-69	Doctorate	Chief Medical Officer - Outpatient (Primary Care Medicine)	420	180	180	NO
6	Female	60-69	Master's	Director of Clinical Services (Allied Health)	456	240	180	NO
7	Male	40 - 49	Doctorate	Hospitalist (Family Medicine)	216	204	180	NO
8	Female	40 - 49	Master's	ER Manager	168	240	168	NO
9	Male	70-79	Doctorate	Hospitalist (Antimicrobial Stewardship Director)	540	240	204	NO
10	Male	40 - 49	Doctorate	Hospitalist	96	240	36	NO
11	Male	70-79	Doctorate	CMO (internal & Pulmonary Medicine)	360	230	204	NO

Table 1. Demographic characteristics

The overall objective of this test was to determine if the application performed effectively, efficiently, and to the satisfaction of the users, and if the application failed to meet the needs of the participants what issues were encountered and how can they be mediated. This testing is also designed to satisfy the electronic prescribing requirements of the Safety Enhanced Design criteria for ONC Health IT Certification Program. The data obtained from this testing is expected to establish a baseline of the e-Rx capabilities of tVistA EHR, generate recommendation and discussion for future development of the e-Rx capabilities of tVistA EHR, and identify possible requirements for immediate modifications to facilitate user adoption and/or patient safety.

All participants interacted with tVistA EHR in the same location, provided with the same instruction, asked to complete the same tasks and used the same evaluation tools. Data was collected during testing by the data logger and administrator to evaluate the system for effectiveness, efficiency and satisfaction as defined by measures collected and analyzed for each participant:

- Number of tasks successfully completed within the allotted time without assistance
- Time to complete the tasks
- Number and types of errors
- Path deviations
- Participant's verbalizations (comments)
- Participant's satisfaction ratings of the system

More information about the various measures is provided below in the Usability Metrics section

TASKS

A number of tasks were constructed that would be realistic and representative of the kinds of activities a user might do with this EHR, including:

1. Prescribe and Transmit medications electronically
2. Cancel an e-prescribed medication transmitting a cancel message to the pharmacy
3. Electronically Denying a refill/renewal request for a medication
4. Electronically Approving refill/renewal request for a medication
5. Electronically Approve a change requests for a therapeutic substitution
6. Electronically Approve a change requests a generic substitution

Tasks were selected based on frequency of use, criticality of function for ONC Health IT Certification Program, availability of ONC Health IT Certification Program test protocols (sections §170.315(b)(3) Electronic prescribing), and tasks that could be foreseen as being most troublesome for users.

PROCEDURES

Upon arrival, participants were greeted and assigned a participant ID. Each participant was made aware their performance on the upcoming tasks would be voluntary and used for subsequent analysis.

“First off we would like to thank you for taking the time to provide us with feedback on the EHR capabilities being tested today. We are executing these sessions as part of ONC Health IT Certification Program requirements, this usability study in electronic prescribing will help ensure that Tenzing Medical, LLC meets their Certification standards. We are asking EHR users to provide usability input to the e-prescribing capabilities of Tenzing VistA EHR.”

To ensure the usability testing ran smoothly, an administrator and a data logger were present for the testing: the testing team members have back grounds in psychological research with 25 years of experience in psychological and clinical research and RPMS, CPRS, and private medical hardware and software design, development and testing. The team included experienced hardware and software developers with experience in usability testing and user-centered design programs. Also included on the sessions were several stakeholders who were available to observe the user interaction with the system, respond to questions after completion of formal testing and elicit feedback relevant to future development.

The administrator moderated the session, administered instructions and tasks, obtained post-task rating data, and took notes on participant comments. The data logger monitored task times, and took notes on task success, path deviations, number and type of errors, and comments.

Back ground information was asked of each participant prior to engaging in the tasks. The data was logged by the administrator and data logger. The participant was situated at the computer, and provided with a demonstration on the e-prescribing capabilities. The participants were then shown that a printed copy of the presentation was next to the laptop and available for their reference while they completed the tasks. The participant was allowed time to orient themselves on the EHR and the expected tasks.

Participants were instructed to perform the tasks (see specific instructions in Appendix 2: Moderator's guide):

- As quickly as possible making as few errors and deviations as possible.
- Without assistance; administrators were allowed to give immaterial guidance and clarification on tasks, but not instructions on use.
- Without using a think aloud technique.

The participants were given a written copy of the task. Task time began once the administrator said begin. The task time was stopped once the participant indicated he had successfully

completed the tasks.

Following task completion the participant was asked to complete the NASA-TASK LOAD INDEX (Appendix 4) and the POST STUDY SYSTEM USABILITY QUESTIONNAIRE (Appendix 5).

Participants were asked if they had any additional comments or questions for the group which were logged by the data logger and thanked for their participation.

Participants' demographic information, task success rate, time on task, errors, deviations, verbal responses, and post-test questionnaire were recorded on a spreadsheet.

TEST LOCATION

Usability testing took place in a small conference room. A user laptop computer and mouse were set up on a table. The Administrator sat next to the user. The user's screen was redisplayed for the data logger and observers. Stakeholders observed from the data logger's location. To ensure that the environment was comfortable for users, noise levels were kept to a minimum with the ambient temperature within a normal range. All of the safety instruction and evacuation procedures were valid, in place, and visible to the participants.

TEST ENVIRONMENT

Electronic prescribing capabilities would typically be used in a healthcare office or facility. In this instance, the testing was conducted in a small conference room on Oroville Hospital campus. For testing a Dell Latitude 5401 laptop running Windows 10 Pro operating system was used with an external mouse. The participants used both keyboard and mouse to navigate and interact with the tVistA EHR. A 14 inch monitor was used with a screen resolution of 1920 x 1080. The application was set up according to vendor specifications and the application was running on a Linux/GTM platform using a test database on a LAN connection. The performance of the test system was comparable to what users experience in production environments on site at clinics and hospitals. Participants were asked not to change any of the setting defaults to insure conformity.

TEST FORMS AND TOOLS

During the usability test various documents and instruments were used, including:

1. Moderator Guide
2. NASA-TLX
3. PPSSUQ

Examples of these documents can be found in the Appendices. The Moderator's Guide was devised so as to be able to capture required data.

PARTICIPANT INSTRUCTION

The administrator read the following instructions aloud to each participant (also see the full moderator's guide in Appendix 2):

“During this session, you will be asked to complete tasks using the Tenzin VistA EHR then provide feedback on the e-prescribing capabilities.

I will provide you with a list of tasks and associated data. You will be asked to complete these tasks as quickly as possible with the fewest errors or deviations. Do not try to do anything other than what is asked. I cannot assist you in accomplishing your tasks. Please save comments and question until the end of the session.

We would like you to give us feedback on the e-prescribing capabilities used. We would like to know how easy or difficult the system is to use, how useful the capabilities are, and what improvement we can make. The best help you can give us is to be critical. We may not be able to fix everything you mention, but it is still beneficial for us to know what issues you feel are important. Your honest feedback is what we are after. Your feedback will be used to help make the electronic prescribing capabilities better, so please do not worry about offending anyone with your comments. Your feedback as well as any questions the usability team is unable to answer will be shared with developers and stakeholders.

We have this interview divided into several parts. I'd like to start by just getting some background information; then I am going to ask some questions about if/how you currently use e-prescribing functions. You will be given an introductory overview of the new electronic prescribing software. In the last part, we'll have you log in as a test user and attempt to electronically prescribe a medication, Cancel/ discontinue a medication, Respond to/process Renewal Request and Change Request. Do you have any questions for us before we get started?”

Following the procedural instructions, participants were provided a brief overview of the e-prescribing capabilities, informed a reference guide was available on the table next to the laptop, and asked to make comments. Once complete the administrator gave the following instructions:

I will say “Begin.” At that point, please perform the task and say “Done” when you believe you have successfully completed the task. Please refrain from talking while doing the task. We will have time to discuss the task and answer questions when the task is complete.

Participants were given 6 tasks to complete.

USABILITY METRICS

According to the *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records*, EHRs should support a process that provides a high level of usability for all users. The goal is for users to interact with the system effectively, efficiently, and with an acceptable level of satisfaction. To this end, metrics for effectiveness, efficiency and user satisfaction were captured during the usability testing. The goals of the test were to assess:

1. Effectiveness by measuring participant success rates and errors
2. Efficiency by measuring the average task time and path deviations
3. Satisfaction by measuring ease of use ratings

DATA SCORING

The following table (Table 2) details how tasks were scored, errors evaluated, and the time data analyzed.¹⁰

Measures	Rationale and Scoring
Effectiveness: Task Success	A task was counted as a “Success” if the participant was able to achieve the correct outcome, without assistance, within the time allotted on a per task basis.
Effectiveness: Task Failures	A task was counted as a “Failure” if the participant was unable to achieve the correct outcome, without assistance, within the time allotted on a per task basis (i.e. incomplete/unsigned prescription)
Efficiency: Task Deviations	The participant’s path (i.e., steps) through the application was recorded. Deviations occur if the participant, for example, went to a wrong screen, clicked on an incorrect menu item, or interacted incorrectly with an on-screen prompt. This path was compared to the optimal path established by the team and developers. Because the e-prescribing capability tasks being measured are so variable the optimal number of steps cannot be defined and only qualitative deviations were noted.
Efficiency: Task Time	Task times were recorded for tasks successfully completed then divided by the number of participants who completed the task successfully. The average task time is reported.
Satisfaction: Task Load	Participant’s subjective impression of the workload or cost of accomplishing the task requirements were obtain through the administration of the NASA Task Load Index (NASA-TLX) after the task set. The participant was asked to complete the six subscales representing different variables including: Mental, Physical, and Temporal Demands, Frustration, Effort, and Performance. See Appendix 3 for a copy of the questionnaire. A high level of burden on the participants is indicated by a score of 60 or greater.
Satisfaction: Task Rating	To measure the participant’s satisfaction of the e-prescribing capabilities the team administrated the Post Study System Usability Questionnaire (PSSUQ) at the completion of all the tasks. The PSSUQ consists of 19 items such as “it was simple to use the system” and “It was easy to find the information I needed” that the participant rates using a 7 point Likert scale ranging from 1=strongly agree to 7= strongly disagree. The PSSQU is designed to assess overall user satisfaction through perceived system usefulness, Information Quality and Interface quality. See Appendix 4 for a copy of the questionnaire.

Table [2]. Details of how observed data were score

RESULTS

DATA ANALYSIS AND REPORTING

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above. There were no participants who failed to follow session and task instructions or had their data excluded from the analyses.

The usability testing results for the Electronic prescribing capabilities of tVistA EHR are detailed below in Tables 3a. The results should be seen in light of the objectives and goals outlined in the Study Design section above. The data should yield actionable results. If corrected, within the tVistA EHR Electronic prescribing capabilities these will have a positive impact on user performance.

Qualitative feedback from the participants was transcribed by team members and compiled in an Excel spreadsheet. The team met to discuss all potential issues, particularly those items noted as significant for consideration. Each issue was listed as verbalized by the participant and the team evaluated the issue asking questions such as: *What might cause the participant to have this issue? What cognitive support element does this issue violate? What can be done/changed to support the cognitive support element?* Recommendations intended to rectify the identified issue were recorded.

Issues were coded according to the cognitive element that led to the underlying issue, issue class, and time frame

Issue Class

Each issue was classified into an “issue class.” This classification scheme represents our understanding of the potential impact of each issue if left unaddressed.

- **Type 1** issues are those we anticipate will create an *individual error risk*. These issues may directly introduce a specific health risk. For example, a new health system that somehow allows treatment plans to be mistakenly associated with multiple EHRs. Some patients would be placed at significant health risk because of the design flaw.
- **Type 2** issues are those we anticipate will create an *aggregate error risk*. These issues may introduce error through cumulative effects. An example of this would be a new system that failed to capture some important paper- based function that was used in conjunction with the old system. The loss of low-tech, but high-value information can eventually lead to a problem.
- **Type 3** issues are those that we anticipate will create *adoption and long-term use risk*. These issues may negatively influence acceptance of the software. In the extreme, ignoring these issues may result in software that is rejected by the intended users. If use is mandated, users may find ways to “game” the system, distorting or circumventing the intent of the software. This is less troubling from a health risk standpoint, but could still create a long-term failure of a system in which much has been invested.

Timeframe

Recommendations are also made according to the timeframe in which issues should be addressed. Four timeframes are considered: urgent, quick fix, near-term, and long-term.

- **Urgent:** lead to significant medical error and/or patient risk, need to be fixed before next release/patch.
- **Quick fix:** These issues that we believe can be fixed "in-house" in a relatively short time frame (e.g. several weeks). These are issues that we believe will positively influence user acceptance with little development effort.
- **Near-term issue:** These issues are those that we believe will positively influence user acceptance. Can be completed in 12 months or less, but may require extra development time and effort.
- **Long-term issue:** These issues do not present significant risk in their current form. These recommendations, however, have the potential for significant, high impact benefit if resources can be found to address them over time. These fixes will take more than 12 months, contain interoperability issues and may require overhauls of existing systems, introductions of new functionality, and require extended development efforts.

	Task	N	Task success	Path Deviations	Time on Task		Errors	Task Ratings
Task #		#	Mean (SD)	Deviations (observed/optimal)	Mean (SD)	Deviations (observed/optimal)	Mean (SD)	Mean (SD)
ERX-1	Prescribe and transmit medications electronically	11	90.9 (0.30)	31/19	358 (144)	547/128	9.0(0.30)	3.05 (1.48)
ERX-2	Cancel a medication using e-prescribing tool	11	90.9 (0.30)	8/3	66 (36)	143/25	9.0(0.30)	3.05 (1.48)
ERX-3	Deny Renewal Request	11	100 (0.00)	13/7	131 (63)	257/51	0.00 (0.00)	3.05 (1.48)
ERX-4	Approve Renewal (refill) request	11	100 (0.00)	10/6	96 (58)	214/22	0.00 (0.00)	3.05 (1.48)
ERX-5	Approve change request for therapeutic substitution	11	100 (0.00)	20/9	304 (98)	526/195	0.00 (0.00)	3.05 (1.48)
ERX-6	Approve change request for generic substitution	11	100 (0.00)	20/12	180 (72)	341/85	0.00 (0.00)	3.05 (1.48)

Table 3: Data from e-Rx

DISCUSSION OF THE FINDINGS

Effectiveness

Effectiveness was measured by task completion or failure to complete task. We asked providers to complete Electronic prescribing tasks using tVista EHR capabilities that demonstrate the required functionality. These tasks are derived from the ONC Health IT Certification Program requirements. The task completion data indicates that providers were able to complete all the tasks that they were asked to execute. There were no notable differences between the participants who completed each task excepting the order in which the tasks were completed. One participant failed to sign oe-Rx orders thus preventing their transmission and completion of the task.

Efficiency

Efficiency was measured by time on task and task deviations. We asked providers to complete representative tasks of the e-Rx tVista EHR capabilities that demonstrate the required functionality. These tasks are derived from the ONC Health IT Certification Program requirements. We did not instruct participants to complete tasks in one specific manner, but provided an overview of how tasks could be completed via one path. Any path variation causes deviation in both time on task and path deviation. The data indicates that most providers were able to complete all the tasks in a standard manner and deviations were due to thoroughness and user preference. There were deviations in the order in which tasks were completed and options used to complete prescriptions. For example, some providers wrote all the prescriptions then signed and transmitted while others signed and transmitted each prescription individually.

Satisfaction

Satisfaction was measured by two subjective questionnaires, the NASA TLX and the PSSUQ. Overall workload ratings indicate that the users are not overly burdened by the e-Rx capabilities. The results from the NASA TLX was: 10.32. The results of the PSSUQ was 3.05 indicating overall favorable results for all areas of the e-Rx tVista EHR capabilities. Below is a complete list of written comments (duplicates omitted) articulated by participants in response to:

What changes would you like to see to your current e-prescribing functionality?

- *I would like to see a simplified layout. Our current screens are too busy.*
- *Current e-prescribe workflow is not apparent I would like it to be more intuitive*
- *Data does not cross over to EHR appropriately so needs to be better integrated with EHR*
- *I would like to see patient's out-of-pocket cost of medications at time of prescription*

- *I would like to go to one screen to do everything rather than multiple. Having to go to different screens for different options it is hard to remember where to go to do what I needed to do*
- *What's really frustrating is having to delete out meds when patient shows up in the ER and meds are not accurate*
- *I would like to work in one system and not have to go to another for e-prescribing meds*

What do you think of the e-prescribing product you just tested?

- *Useability test instructions are confusing - last name first in EHR, but first name first on test script*
- *If there are zero requests the RX should be Green not Red*
- *The New button does not stand out; needs to be bigger, bolder or with more color*
- *Refill could be more intuitive*
- *Need a que to scroll down to complete or default to bottom button*
- *The drop down list made it hard to find the patient quickly*
- *A lot of words makes it get crowded [prescription window and change screen]]*
- *Took a bit to find where things were located*
- *It is similar to current e-rx product, but formats are different*
- *I saw the quick order, but I was not sure if it was exactly same as test script, Med was completely spelled out on menus but it was confusing*
- *I didn't know how to use the med order template*
- *With an hour of use It would be easy to master*
- *A little training and I think providers would have no problem using it*
- *I like it*
- *Shows a lot more info*
- *Once everyone understands it they will be pretty good quickly*
- *I didn't feel frustrated*
- *I just wanted to get it done to see how long it will take in LIVE*
- *I will love it to have Faxes gone*
- *Diagnosis Code search is clunky with all the SNOMED code*
- *So the Renewal and Change request come straight from the Pharmacies*
- *The Need Appointment concept for denials is great*
- *The Sign button is helpful knowing you have prscriptions to sign.*
- *Great for continuity of care*
- *The actions were familiar as a tVista user, but not similar to current e-prescribe product*
- *I think the Provider Notification Box is beautiful. Especially for outpatient*

- *It is much smoother and intuitive than current e-prescribe product*
- *I like that you don't have to change patients to see Pharmacy requests*

This list of comments are mostly positive or neutral and illustrate that there are areas of the e-Rx product that providers find easy to use. A few negative comments illustrate that there are areas of the e-Rx product that will benefit from design enhancements. Additional training to improve skills will be effective in reinforcing the data entry methods users indicated they are unaware or unfamiliar with.

AREAS FOR IMPROVEMENT

As a result of this set of usability interviews we determined that the e-Rx tVistA EHR capabilities violate a set of cognitive support elements. Relevant issues gleaned from these usability sessions are listed in the following section. The resulting issues are grouped with respect to the cognitive element that the usability team believes led to the underlying issue. Each issue that was uncovered during the usability interviews is listed as it relates to the cognitive element that is being violated. As a reminder, these elements include:

- *Support Decision Making*
- *Reduce Errors*
- *Facilitate Scanning*
- *Create Affordances*
- *Illustrate Perceived Benefit*
- *Support Mental Models*

Recommendations are made to encourage a design enhancement that creates support for the relevant cognitive requirement. Recommendations should be adopted and implemented only in ways that support the cognitive elements. When reviewing the issues and recommendations the HIT team should consider questions such as:

- 1. Why are participants having this issue?*
- 2. What cognitive support element does this issue violate?*
- 3. What can we do within the design process to facilitate the cognitive support requirement?*

Issues and Recommendations

Issue 1: If there are zero request the Rx button should be Green not Red

- Cognitive Support Element: Facilitating scanning. We believe this is a quick fix as the development effort is minimal.
 - Consideration:
How can we make the requests on Rx button more clear?

R-1 We recommend the button display black when there are zero requests to be consistent with system color signal.

R-2 We recommend increasing the font size of the button display and/or adding a tool tip.

Issue 2: The drop down lists made it hard to find the patients quickly

- Cognitive Support Element: Facilitating scanning. We believe this is a Near-term issue as the functionality will impact usability and adoption of the technology.
 - Consideration:
How can we present the information so it is easily readable and easily navigable?

R-1 We believe test script listing the patient first name then last (i.e John Smith) while the request panel lists patient last name, first name (i.e. Smith,John) caused some of the confusion and is a reflection on the test rather than the e-prescribe product.

R-2 We recommend training users to expand the column width so each patient appears on one line in alphabetical order by last name as displayed in the HER for ease of scanning for patient

Issue 3: The Refill could be more intuitive

- Cognitive Support Element: Creating Affordances. We believe this is a quick fix as the development effort would be minimal.
 - Consideration:
How can we make clear the purpose of the Renewal and options to act on it?

R-1 We recommend removing refill option from order drop down action list as meds will be renewed not refilled and the verbiage needs to be consistent with Change action options.

Issue 4: There needs to be a reminder to scroll through the prescription display before you can accept when screen is constricted.

- Cognitive Support Element: Creating Affordances. We believe this is a near term issue as the functionality will impact usability and adoption of the technology.
 - Consideration:
How can we present information and allow data entry in a way that does not require excessive scrolling or provides prompt when scrolling is required?

R-1 We recommend increasing full prescription display window so need to scroll is minimized

R-2 We recommend increasing the size of the Accept Order button

R-3 We recommend training user to review the entire prescription window as is the requirement that necessitates the scrolling.

Issue 5: So many words in the prescription window make it crowded

- Cognitive Support Element: Reducing Errors We believe this is a near term issue as it will minimize errors, confusion, and assist the users in accurately entering data and adopting the new technology.
 - Consideration:
How can we assist users in understanding the new technology at point of use?
Can we use existing functionality to add the new assistive information?

R-1 The display includes all required standards. We will maximize prescriber education to better understand requirements.

R-2 Add asterisk / highlight in front of required data fields as is standard throughout tVistA

Issue 6: Medication order menu and quick order are new concept and formats unfamiliar to and not yet trusted.

- Cognitive Support Element: Supporting Decision Making. We believe this is a near-term fix as it will facilitate usability and adoption of the new technology
 - Consideration:
How can we create order dialog and menus that meet the users need for clarity and accuracy?

R -1 Create order dialogs defined by prescribers and categorize on menus for quick, accurate ordering of most commonly prescribed medications and quick, easy editing of commonly prescribed medications.

R-2 Create order menu to be similar to currently utilized inpatient medication order menus

R-3 Train users to review quick orders for completeness and accuracy on entry

Issue 7: Diagnosis Code search is clunky with all the SNOMED code

- Cognitive Support Element: Supporting Decision Making. We believe this is a near-term fix as it will facilitate usability and adoption of the new technology
 - Consideration:
How can we facilitate selection of clinical indications to minimize searching of thousands of possible choices?

R -1 Create order dialogs defined by prescribers and categorize on menus for quick with common clinical indication

R-2 Present list of patient diagnosis and common clinical indications for the medications when available to remove necessity to search for clinical indications

R-3 Train users to use search terms that will facilitate finding desired / appropriate clinical indication when other options are not presented.

R-4 Educate users on the value of inclusion of appropriate clinical indication.

Table 4 represents the issues, the associated cognitive support element, issue class and anticipated timeframe

Issue	Description	Cognitive Support Element	Issue Class	Timeframe
1	The Rx button appearance if zero requests	Facilitating scanning	III	Quick Fix
2	The Patient Drop down list	Facilitating scanning	III	Near-term
3	The refill could be more intuitive	Creating Affordance	III	Quick Fix
4	The scrolling necessary to see full prescription details in order to accept order.	Creating Affordance	III	Near-term
5	Crowded prescription window	Reducing Errors	III	Near-term
6	Unfamiliar with medication order menu and quick orders new concept and formats	Support Decision making	III	Near-term
7	Proper and efficient use of clinical indications	Support Decision making	III	Near-term

Table 4: Issue and Recommendations by Cognitive Support Element, Issue Class and Timeframe

Areas for Improvement: Global Recommendations

To further improve usability and adoptability of tVista EHR the following recommendations are made regarding the EHR as a whole. These recommendations reflect standard windows functionality that utilize existing mental models.

1. **Gray-out visualization:** When a function is not available it should be grayed out. By graying out functions that are not available it provides the user with a visual cue that those options are not available at the present time, while still allowing them to know these features exist and may be available in other circumstances.
2. **Tool tips/instructions:** All buttons, icons, and right click options in the GUI should include tool tips describing their name and function when the user hovers the mouse over them. These tool tips allow the user to learn what various buttons in the software do on their own as they are using the software application.
3. **Window size:** Expand default screen size for pop-up dialogue windows. Pop-up dialogues should be maximized to prevent scrolling when possible if screen real estate is available. The dialogues should remain centered on the screen, with width and height adjusted to provide maximum visibility of all content.
4. **Auto-close:** Close previous windows where an action has been executed and is no longer relevant. By closing previous windows that have completed their actions you remove the need for the user to close unnecessary windows to continue using the software after they have completed a set of actions.

5. **Asterisks:** Indicate required fields with asterisks throughout the interface. By standardizing this throughout the interface users are aware of what is necessary for them to complete various tasks. This visual indicator also allows users to ensure all necessary information has been entered rather than relying on error messages which interrupt the workflow and require backtracking to complete a task.
6. **Training:** It is our belief that with an ideal interface, one that is intuitive to end users and incorporates as much usability as possible, the amount of necessary training should be minimal. This is why we often recommend streamlining processes for task completion within the EHR. We realize that while minimal training is ideal, it is not always achievable, at least not right away. By completing user testing and incorporating the feedback into the system little by little it will reduce the required amount of training required.

APPENDICES

The following appendices include supplemental data for this usability test report.

Following is a list of the appendices provided

- 1: Participant demographics
- 2: Moderator's Guide
- 3: Test Scenarios
4. NASA-Task Load Index
- 5: Post Study System Usability Questionnaire

Appendix 1: Participant Demographics

Gender

Men	[7]
Women	[4]
Total (participants)	[11]

Occupation/Role

Pharmacist	[2]
Prescriber	[8]
e-Rx specialist	[1]
Total (participants)	[11]

Provider Type

Hospitalist	[3]
Internist	[2]
Primary Care	[1]
Physician Assistant/ER Manager	[1]
Nurse Practitioner/Clinical Services	[1]
Pharmacist	[2]
Application coordinator	[1]
Total (participants)	[11]

Years of Experience

Professional	[24.8]
EHR	[16.3]
VistA EHR	[15.1]
e-Prescribing	[10.5]

Appendix 2: Moderator's Guide

Introduction/Orientation:

First off we would like to thank you for taking the time to provide us with feedback on the EHR capabilities being tested today. We are executing these sessions as part of ONC Health IT Certification Program requirements, this usability study in electronic prescribing will help ensure that Tenzing Medical, LLC meets their Certification standards. We are asking EHR users to provide usability input to the e-prescribing capabilities of Tenzing VistA HER

Sign Informed consent

During this session, you will be asked to complete tasks using the tVistA EHR then provide feedback on the e-prescribing capabilities.

I will provide you with a list of tasks and associated data. You will be asked to complete these tasks as quickly as possible with the fewest errors or deviations. Do not try to do anything other than what is asked. I cannot assist you in accomplishing your tasks. Please save comments and question until the end of the session.

We would like you to give us feedback on the e-prescribing capabilities used. We would like to know how easy or difficult the system is to use, how useful the capabilities are, and what improvement we can make. The best help you can give us is to be critical. We may not be able to fix everything you mention, but it is still beneficial for us to know what issues you feel are important. Your honest feedback is what we are after. Your feedback will be used to help make the electronic prescribing capabilities better, so please do not worry about offending anyone with your comments. Your feedback as well as any questions the usability team is unable to answer will be shared with developers and stakeholders.

We have this interview divided into several parts. I'd like to start by just getting some background information; then I am going to ask some questions about if/how you currently use e-prescribing functions. You will be given an introductory overview of the new electronic prescribing software. In the last part, we'll have you log in as a test user and attempt to electronically prescribe a medication, transmit the medication, prescribe and transmit a medication with a complex dose, prescribe and print a prescription for a medication, and discontinue a medication electronically. Do you have any questions for us before we get started?

Complete Background Information

Show Participant BCMA, Scanner, and CPRS & Begin Camtasia Recording

I will say "Begin." At that point, please perform the task and say "Done" when you believe you have successfully completed the task. Please refrain from talking while doing the task. We will have time to discuss the task and answer questions when the task is complete.

Provide Test Script

Administrator:

Data Logger:

Date/Time:

Participant #

Background

Gender:

Age range: 23 to 39 40 to 59 60 to 74 75 and older

Provider Type: MD DO PA NP RN:

Provider Occupation/Role:

Years of experience:

Years of experience with EHR (rounded to the nearest half year):

Years of experience with VistA EHR (rounded to the nearest half year):

Year of experience with electronic prescribing (rounded to the nearest half year):

Tell me a little about your facility. (i.e., is it a large hospital? A smaller outpatient clinic?)

Use

What is your current role at your facility?

How do you currently write a prescription?

If currently using e-prescribing:

Are there any functions that you do not use too often?

Are there any functions you see as less important than others?

Are there any changes/improvements you would like to see to your current e-prescribing functionality?

Appendix 3: Test Scenarios

TASK	ACTION
NewRx	1. Prescribe medications below (complex dose and oral and liquid med prescribed using mL) and transmit via eRx for
	<p>Medication name: AMOXICILLIN 200MG/5ML (AMOXIL) PWDR,RENST-ORAL Directions: TAKE TWO (2) AND ONE-HALF (1/2) ML MOUTH THREE TIMES DAILY FOR 7 DAYS DISCARD REMAINDER Days Supply: 7 Quantity: 52.5 mL Refills: 0 Clinical Indication: Acute otitis media</p> <p>Medication name: Tobramycin and Dexamethasone Ophthalmic Suspension Directions: Instill 1 drop into LEFT eye every 6 hours for 7 days Quantity: 10 mL Refills: 1 Clinical Indication: Blepharitis of left upper eyelid Chronic Med? No Dispense as Written?: No</p>
CancelRx	2. Cancel Prescribed medications below
	<p>Medication name: Zestril 20 mg tablet Directions: Take 1 tablet by mouth once per day for 30 days Quantity: 30 Refills: 1 Clinical Indication: Hyperlipoproteinemia, type I Chronic Med? Yes Dispense as Written?: Yes</p>
RxRenewal Response	3. Deny Renewal Request - Deny request for additional Fill – Reason “Patient needs Appointment”
	<p>Medication name: NORTRIPTYLINE (PAMELOR SOL) SOLN,ORAL Directions: Take 10 ml by mouth four times daily Days Supply: 30 Quantity: 1200 mL Refills: 0 Clinical Indication: Depressive disorder</p> <p>Medication name: NORTRIPTYLINE (PAMELOR SOL) SOLN,ORAL Directions: Take 10 ml by mouth four times daily Days Supply: 30 Quantity: 1200 mL Refills: 1 Clinical Indication: Depressive disorder</p>

RxRenewal Response	4. Accept (Approve) Renewal (Refill) Request
	<p>Medication name: EPINEPHRINE (EPIPEN) INJ,SOLN, CONTENTS OF 1 SYRINGE 0.3MG/0.3ML</p> <p>Directions: Inject in thigh if needed for severe allergic reaction. Call 911.</p> <p>Days Supply: 30</p> <p>Quantity: 2</p> <p>Refills: 2</p> <p>Clinical Indication: Anaphylaxis due to tree nut</p> <p>Chronic Med? No</p> <p>Dispense as Written?: Yes</p>
RxChange Response	5. Replace to select dosage change and allow for 1 refill/2 Authorized Fill.
	<p>Medication name: alendronate-cholecalciferol 70 mg-5,600 unit oral tablet</p> <p>Directions: TAKE 1 TABLET BY MOUTH ONCE WEEKLY IN THE MORNING ; TAKE WITH 12+ OUNCES OF ONLY WATER AT LEAST ONE HALF-HOUR BEFORE ANY MEAL, BEVERAGE OR MEDICATION AND REMAIN STANDING UPRIGHT. DO NOT LIE DOWN OR RECLINE FOR AT LEAST 30 MINUTES AFTER ADMINISTERING</p> <p>Quantity: 1 pack</p> <p>Quantity: 4</p> <p>Refills: 1</p> <p>Clinical Indication: Osteoporosis</p> <p>Substitution Allowed?: Yes</p> <p>Medication name: alendronate-cholecalciferol 70 mg-2,800 unit oral tablet</p> <p>Directions: TAKE 2 TABLET BY MOUTH ONCE WEEKLY IN THE MORNING ; TAKE WITH 12+ OUNCES OF ONLY WATER AT LEAST ONE HALF-HOUR BEFORE ANY MEAL, BEVERAGE OR MEDICATION AND REMAIN STANDING UPRIGHT. DO NOT LIE DOWN OR RECLINE FOR AT LEAST 30 MINUTES AFTER ADMINISTERING</p> <p>Quantity: 1 pack</p> <p>Quantity: 8</p> <p>Refills: 1</p> <p>Clinical Indication: Osteoporosis</p> <p>Substitution Allowed?: Yes</p>

RxChange Response	6. Use Replace to rewrite script for new med as defined below Replace Sig (Dosage, rout, schedule), Days Supply, and Quantity
	<p>Medication name: Vibramycin 100 mg capsule Directions: Take 1 capsule orally every 12 hours for 10 days Quantity: 20 Refills: 3 Clinical Indication: Chronic urinary tract infection</p> <p>Medication name: doxycycline hyclate 100 mg capsule Directions: Take 1 capsule orally every 12 hours for 2 weeks Days Supply: 14 Quantity: 28 Refills: 3 Clinical Indication: Urinary tract infection, site not specified</p>

Appendix 4: NASA-Task Load Index

Instructions: Mark the scale that represents your experience.

Mental Demand

Low High



Physical Demand

Low High



Temporal Demand

Low High




Effort

Low High




Performance

Low High



Frustration

Low High



Appendix 5: Post Study System Usability Questionnaire

Instructions: This questionnaire gives you an opportunity to tell us your reactions to the system you used. Your responses will help us understand what aspects of the system you are particularly concerned about and the aspects that satisfy you.

To as great a degree as possible, think about all the tasks that you have done with the system while you answer these questions.

Please read each statement and indicate how strongly you agree or disagree with the statement by circling a number on the scale.

Please write comments to elaborate on your answers.

After you have completed this questionnaire, I'll go over your answers with you to make sure I understand all of your responses.

Thank you!

1. Overall, I am satisfied with how easy it is to use this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

2. It was simple to use this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

3. I could effectively complete the tasks and scenarios using this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

4. I was able to complete the tasks and scenarios quickly using this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

5. I was able to efficiently complete the tasks and scenarios using this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

6. I felt comfortable using this system.

Strongly									Strongly
Agree	1	2	3	4	5	6	7		Disagree
Comments:									

7. It was easy to learn to use this system.

Strongly									Strongly
Agree	1	2	3	4	5	6	7		Disagree
Comments:									

8. I believe I could become productive quickly using this system.

Strongly									Strongly
Agree	1	2	3	4	5	6	7		Disagree
Comments:									

9. The system gave error messages that clearly told me how to fix problems.

Strongly									Strongly
Agree	1	2	3	4	5	6	7		Disagree
Comments:									

10. Whenever I made a mistake using the system, I could recover easily and quickly.

Strongly									Strongly
Agree	1	2	3	4	5	6	7		Disagree
Comments:									

11. The information (such as on-line help, on-screen messages and other documentation) provided with this system was clear.

Strongly									Strongly
Agree	1	2	3	4	5	6	7		Disagree
Comments:									

12. It was easy to find the information I needed.

Strongly									Strongly
Agree	1	2	3	4	5	6	7		Disagree
Comments:									

13. The information provided for the system was easy to understand.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

14. The information was effective in helping me complete the tasks and scenarios.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

15. The organization of information on the system screens was clear.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

Note: The interface includes those items that you use to interact with the system. For example, some components of the interface are the keyboard, the mouse, the screens (including their use of graphics and language).

16. The interface of this system was pleasant.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

17. I liked using the interface of this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

18. This system has all the functions and capabilities I expect it to have.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

19. Overall, I am satisfied with this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
Comments:								

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Tenzing VistA EHR Usability Test of Decision Support Interventions EHR Capabilities

Tenzing VistA – tVistA V2.1

Date of Usability Test: Nov 12 – Nov 18, 2024

Date of Report: Nov 21, 2024

Report Prepared By: Tenzing Medical, LLC

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EXECUTIVE SUMMARY

Usability testing of the Decision Support Interventions (DSI) capabilities of Tenzing VistA – tVistA V2.1 was conducted Nov 12 through Nov 18, 2024 at Trenner Medical Offices, Oroville, CA. The purpose of the testing was to validate the usability of the DSI capabilities of tVistA V2.1 graphical user interface (GUI) and provide the opportunity for user feedback on desired changes or improvement for future development. During the usability test 10 healthcare providers matching the target demographic criteria served as participants and used the tVistA EHR in simulated, but representative tasks.

The study collected performance data on three tasks related to Decision Support Interventions.. These tasks are designed to support ONC Health IT Certification Program. The tasks are categorized as follows:

Decision Support Interventions

- Review Evidence Based Decision Support Intervention source attributes and intervention data using Clinical Reminder logic.

- Resolve Clinical Reminder/Reset Decision Support Intervention tool.

- Review Support Intervention made to resolve Decision Support Intervention using Clinical Maintenance.

During the thirty minute usability test, each participant was greeted and informed they could withdraw at any time. Participants had prior tVistA EHR experience. All participants had used tVistA. One participant used clinical decision support tools including clinical reminders and order checks regularly. Participants were informed of the purpose of the usability testing and the type of data the team was gathering. Participants were provided with a demonstration on the DSI capabilities. After the demonstration the administrator introduced the test, and instructed participants to complete a series of tasks (one at a time) using the EHR. During the test the administrator timed each task while the data logger recorded user performance. The administrator did not provide assistance on how to complete a task, but asked participants to demonstrate how they thought they would complete the task based on the instruction provided and instinct.

The Following data was collected for each participant:

- Number of task successfully completed without assistance

- Time to Complete Tasks

- Types of Errors

- Path deviations

- Provider's verbalizations

- Provider's reported workload level
- Provider's satisfaction rating of the system

All participant data was de-identified to eliminate correspondence made between participant identity and the data collected. Following the conclusion of the testing, participants were asked to complete post-test questionnaires. Various recommended metrics, in accordance with the examples set forth in the *NIST Guide to the Process Approach for Improving the Usability of Electronic Health Records*, were used to evaluate the usability of the EHR. Following is a summary of the performance and rating data collected on the usability of the Decision Support Intervention capabilities of the tVistA EHR.

Major findings ⁽¹⁾⁽²⁾⁽³⁾⁽⁴⁾

The results of the NASA Task Load Index (LTX) – a measure of the subjective workload, or demand the task places on the user during execution- was: 8.22 (SD = 3.3) which indicates this new capability did not placed significant demand on users attempting the associated tasks. The results from the Post Study System Usability Questionnaire (PSSUQ) – a measure of user satisfaction post participation in scenario based usability studies-for the DSI tVistA EHR capabilities was 2.64 (SD = 1.2) overall. Generally users responded favorably to the DSI tVistA capabilities. Making changes as indicated in the areas for improvement should increase usability and lead to greater system satisfaction.

Areas for improvement

- User Training
- Clear indication of workflow involved with Clinical Reminder
- Clear instructions in Reminder Dialog

-
1. **Hart, S. G., & Staveland, L.E.** Development of NASA-TLX (Task Load Index): Results of empirical and theoretical research. [ed.] P. A. Hancock and N. Meshkati. *Human mental Workload*. Amsterdam: North Holland Press., 1988, pp. 139-183. Scores greater than 60 are interpreted to place a higher task load on users.
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 3. *IBM computer usability satisfaction questionnaires: Psychometric evaluation and instructions for use*. **Lewis, J. R.** 1, 1995, International Journal of Human-Computer Interaction, Vol. 7, pp. 57-78. Scores range from 1-5. Lower scores indicate higher level of satisfaction.
 4. *Psychometric Evaluation of the PSSUQ Using Data from Five Years of Usability Studies*. **Lewis, J. R.** 3 & 4, s.l.: Lawrence Erlbaum Associates, Inc., 2002, International Journal of Human-Computer Interaction, Vol. 14, pp. 463-488.

INTRODUCTION

The tVista EHR Decision Support Interventions (DSI) capabilities tested for this study including; review of evidence based DSI and intervention data using Clinical Reminder logic, resolving clinical reminder to reset DSI, and reviewing the interventions made to process the clinical reminder and reset them. The usability testing presented realistic exercises and conditions as defined in ONC certification requirements:

§170.315(b)(11) Decision Support Interventions (DSI)

Purpose

The purpose of this study was to test and validate the usability of the current user interface for tVista EHR and provide evidence of usability in the EHR. This study was conducted to meet the requirements for the ONC Health IT Certification Program indicating that User Centered Design (UCD) should be conducted when developing EHR technology. The intended outcome of implementing User Center Design in coordination with quality system management is improved patient safety. To this end User Center Design identifies user tasks and goals that can then be incorporated into the EHR development to improve efficiency, effectiveness and user satisfaction. In order to satisfy the ONC requirement for §170.315(g)(3) Safety-enhanced design this study was designed to test Decision Support Interventions of tVista EHR functionality. Data was collected to measure effectiveness, efficiency, and user satisfaction, using metrics of time on task, task completion, task deviation, user task load and user satisfaction. As defined in the Safety-enhanced design test procedure the *National Institute of Standards and Technology Internal Reports (NISTIR) 7742* was used as the basis of format for this final report. The usability testing was conducted by the vendor team with guidance from the NISTIR 7741 - *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records*

Tenzing Medical LLC User-Centered Design Approach ^{(5) (6) (7) (8) (9) (Milittleo L. G.,2009) (10)}

Tenzing Medical, LLC incorporated the concepts of Cognitive System Engineering (CSE), User Centered Design approach in a Decision-Centered Design (DCD) framework as described below. “CSE is an approach to the design of technology, training, and processes intended to manage cognitive complexity in sociotechnical systems” (Milittleo I. g.,2009). Users engage in cognitively complex activities such as identifying, judging, attending, perceiving, remembering, deciding, problem solving and planning when interacting with a system.

User-Centered Design approach to system engineering encompasses 6 key principles:

- The design is based upon an explicit understanding of users, tasks and environments.

- Users are involved throughout design and development.
- The design is driven and refined by user-centered evaluation.
- The process is iterative.
- The design addresses the whole user experience.
- The design team includes multidisciplinary skills and perspectives.

tVista EHR system design addresses the cognitive complexities associated with managing complex decision-making and the key principles of User Centered Design through the use of a Decision Centered Design (DCD) Framework. In DCD the software development involves task analysis, design, and evaluation that focuses on describing, analyzing, understanding, and supporting complex perceptual and cognitive activities (10)

Task Analysis is used to identify key decisions and requirements. Task analysis involves identifying the cognitive activities involved in a task, how the task is performed and where the task is performed so that an understanding of the requirements of the system is complete and addresses and supports the strengths and weakness of existing cognitive tasks. Subject Matter Experts (SME) assist in identifying these key decisions and requirements and continue their involvement throughout the development process. The SME work closely with the Health Information Technology (HIT) team of designers, programmers, network specialist, pharmacist, physicians, nurses, and ancillary service specialists to provide input on development, design, workflows, and system testing. Having user input in the earliest phases of development allows for better understanding of the skills and knowledge users possess, the mental models used to develop expectation for functionality, the objectives and tasks the application will be used to complete, and the decisions users must make that the application should support.

-
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Design phase of development aims to utilize the insights gained in task analysis to create a system that reduces cognitive challenge, improves error management, and increases performance. SME provide ongoing feedback on individual packages and interoperability between packages. Requirements can be established from the elicitation of this information and conceptual designs created. The most common user activities are identified and made most prominent within the system. Eventually a prototype is created, and implementation planning begins. The goal is to optimize the system.

- **Evaluation** involves continuous formative as well as summative usability testing. Decision Centered Design approach to software development incorporates users testing and feedback from the design phase. This type of development captures the unseen aspects of the system, the potential errors, evolving technology and human interaction with this technology. Usability testing demonstrates user system interaction and further defines necessary adjustments needed immediately and long term to further optimize the system. A broader range of users with diverse requirements, experiences, and work environments are recruited for summative usability testing. These users provide evaluation and feedback the HIT team uses to reevaluate and reengineer the EHR.

The DCD process is iterative. As problems are identified, options are evaluated and systems modeled, integrated, and launched and performance is assessed. The HIT team continually aims to meet customer and users' needs, utilize available technology, and evaluate priorities, limitations and tradeoffs that must be made. Dialog is continuous and frequent among all stakeholders and team members. This allows for generation of new ideas, refinement of old ideas, conceptual changes and/or rejection. This process involves many organizational entities and all parties contribute to the discussion providing input, recommendations, and knowledge exchange. The team analyzes the information provided and makes decisions about design, budget, priorities, testing, redesign and roll-out. The healthcare industry is constantly in flux requiring ongoing and often immediate changes to EHRs. As an iterative and heuristic approach to development DCD bodes well in this environment.

Although change is constant, it is important to design and implement systems that build on current user mental models. This is accomplished by reimagining the same workflow in another format or utilizing existing mental models in another application. Redundancy of function within tVistA EHR, such as right click access to action menus, as well as reusing existing technology common keyboard functions and short cuts facilitate learning and usability.

tVistA EHR is a complex system which requires the user to use complex decision making at times while only simple decision making at others, and users vary in how they practice, how they interact with the EHR, and their individual abilities. Therefore, a broad representative base of users is required to elicit meaningful evaluation of the EHR. Complex but specific user test scripts are designed, and minimal instruction is provided to users in order to elicit maximum evaluation of the EHR during usability testing. The HIT team aims to generate unforeseen possibilities the variety of users may unfold as well as maximal feedback on user experience of the EHR.

Focusing on the intended users of a new or modified technology maximizes benefit for the user and adoptability. The Primary users are given priority over other users who may have competing or irreconcilable preferences.

Primary Users: The primary users for the Decision Support Interventions are clinical professional that use tVistA EHR. Providers in both inpatient and outpatient settings specializing in various areas of medicine and whose interactions with patients require decision support at the point of contact during clinical evaluation.

Secondary Users: Secondary users of the Decision Support Interventions capabilities include ancillary service staff and support that may interact with patient directly while or may support clinical staff that interact with patients and they may assist with clinical decision support interventions for their area of expertise.

Sociotechnical systems are complex, and users have to find ways to manage the complexities. DCD approach assist users through the use of cognitive support strategies focused on decision support tools that reinforce users' natural decision-making processes. The cognitive support elements outlined below and later used in addressing recommendations help to manage complexity when designing the new software. The recommendations made later will impact future cognitive support strategies.

- **Supporting Decision Making:** Refers to decisions support tools designed to provide context specific information when needed and reduce task load.
- **Reducing Errors:** Refers both to system error reduction functionality as well as user's awareness, trust and understanding of error reduction functionality. Users must be aware of where error reduction functionality exists and where it does not so they can adjust their expectations and trust the system when appropriate thus reducing cognitive load.
- **Facilitating Scanning:** Refers to placement, amount and type of information on a screen and how well this placement allows a user to find information quickly and

accurately and how well a user can return to their place in a screen after an interruption.

- **Creating Affordance:** Refers to design features that help, aid, support, facilitate or enable thinking, knowing, perceiving, or doing something. For example; words on a button indicating the meaning of the button.
- **Illustrating Perceived Benefit:** Refers to users' belief that their day-to-day activities will benefit from using the system. Lack of perceived benefit can result in lack of motivation to learn or use the system and possibly reject the system entirely
- **Supporting Mental Models:** Refers to building upon users' mental models. Designing applications that utilize common language and functionality such as windows standard or previous version functionality.

The decision support interventions EHR capabilities are new methods for old processes.

Decision Support Interventions (DSI) refer to tool used to assist providers in the patient specific care decisions based on the patient's existing demographics, medications, allergies, problems and other health care status. Decision Support Interventions take place at the point of care. Patient data in the EHR triggers decision support tools that can then be addressed by the provider immediately with the most current information available. Primary users' main concerns for DSI is that support tools are accurate and presented at point of care. Finally, all tasks should be completed with a minimal number of key strokes.

Tenzing Medical, LLC practices the user center design and testing outlined above on an ongoing basis, but this document specifically focuses on the usability testing conduct over several days.

METHOD

PARTICIPANTS

A total of 10 participants were tested on the tVistA EHR DSI capabilities. Participants in the test were physicians, nurses, medical scribes, and ancillary staff from varied backgrounds. The participants were recruited by Denise Lefevre, the Chief Information Officer (CIO). The participants volunteered and were, therefore, not compensated for their participation. Participants had no direct connection to the development of or organization producing tVistA EHR nor the testing or supplier organization. All participants had previous experience with tVistA EHR capabilities. One participant uses clinical reminders regularly. Most participants had not used clinical reminders. Participants were instructed on the DSI capabilities for reference which they completed the tasks.

Participants were from varied backgrounds and experience as outline in the Table 1. below.

Participants were provided a participant ID upon arrival for testing thus de-identifying individuals.

Participants were scheduled for 30 minute sessions which included introductions and background, Decision Support Intervention tasks, and metrics. Between sessions the data logger, moderator and other team members debriefed and prepared for the next participant. A demographic spreadsheet with participant's information and metrics were compiled for evaluation.

Participant ID	Gender	Age	Education	Occupation/Role	Professional Experience (months)	Computer Experience (months)	Product Experience (months)	Assistive Technology Needed? (YES/NO)
DSI-01	M	60-69	Doctorate degree (e.g., MD, DNP, DMD, PhD)	Pharmacist/Developer	360	360	280	NO
DSI-02	M	60-69	Doctorate degree (e.g., MD, DNP, DMD, PhD)	CMIO, Internist	360	240	240	NO
DSI-03	F	50-59	Associate degree	Clinical coordinator, MA	214	396	168	NO
DSI-04	F	40-49	Doctorate degree (e.g., MD, DNP, DMD, PhD)	Director of Pharmacy	221	221	168	NO
DSI-05	F	20-29	Bachelor's degree	Medical Scribe	52	52	52	NO
DSI-06	M	20-29	Associate degree	Medical Scribe	23	60	60	NO
DSI-07	F	30-39	Bachelor's degree	Medical Scribe	84	84	84	NO
DSI-08	F	30-39	Some college credit, no degree	Medical Scribe	72	144	144	NO
DSI-09	M	20-29	Bachelor's degree	Medical Scribe	244	120	244	NO
DSI-10	M	50-59	Bachelor's degree	Analyst/Developer	360	360	240	NO

Table 1. Demographic characteristics

STUDY DESIGN

The overall objective of this test was to determine if the application performed effectively, efficiently, and to the satisfaction of the users, and if the application failed to meet the needs of the participants what issues were encountered and how can they be mediated. This testing is also designed to satisfy the Decision Support Interventions requirements of the ONC Health IT Certification Program. The data obtained from this testing is expected to generate recommendations and discussion for future development of the DSI capabilities of tVistA EHR, and identify possible requirements for immediate modifications to facilitate patient safety and/or user adoption.

All participants interacted with tVistA EHR in the same location, provided with the same instruction, asked to complete the same tasks and used the same evaluation tools. Data was collected during testing by the data logger and administrator to evaluate the system for effectiveness, efficiency and satisfaction as defined by measures collected and analyzed for each participant:

- Number of tasks successfully completed within the allotted time without assistance
- Time to complete the tasks
- Number and types of errors
- Path deviations
- Participant's verbalizations (comments)
- Participant's satisfaction ratings of the system

More information about the various measures is provided below in the Usability Metrics section

TASKS

A number of tasks were constructed that would be realistic and representative of the kinds of activities a user might do with this EHR, including:

1. Review Evidence Based Decision Support Intervention source attributes and intervention data using Clinical Reminder logic.
2. Resolve Clinical Reminder/Reset Decision Support Intervention tool.
3. Review Support Intervention made to resolve Decision Support Intervention using Clinical Maintenance

Tasks were selected based on frequency of use, criticality of function for ONC Health IT Certification Program (section §170.315(b)(11) Decision Support Interventions (DSI)), and tasks that could be foreseen as being most troublesome for users.

PROCEDURES

Upon arrival, participants were greeted and assigned a participant ID. Each participant was made aware their performance on the upcoming tasks would be voluntary and used for subsequent analysis.

“First off we would like to thank you for taking the time to provide us with feedback on the EHR capabilities being tested today. We are executing these sessions as part of ONC Health IT Certification Program requirements, this usability study in decision support interventions will help ensure that Tenzing Medical, LLC meets their Certification standards. We are asking EHR users to provide usability input to the eDSI of Tenzing VistA EHR.”

To ensure the usability testing ran smoothly, an administrator and a data logger were present for the testing: the testing team members have back grounds in psychological research with 25 years of experience in psychological and clinical research and RPMS, CPRS, and private medical hardware and software design, development and testing. The team included experienced hardware and software developers with experience in usability testing and user-centered design programs. Also included on the sessions were several stakeholders who were available to observe the user interaction with the system, respond to questions after completion of formal testing and elicit feedback relevant to future development.

The administrator moderated the session, administered instructions and tasks, obtained post-task rating data, and took notes on participant comments. The data logger monitored task times, and took notes on task success, path deviations, number and type of errors, and comments.

Back ground information was asked of each participant prior to engaging in the tasks. The data was logged by the administrator and data logger. The participant was situated at the computer, and provided with a demonstration on the decision support intervention capabilities. The participant was allowed time to orient themselves on the EHR and the expected tasks.

Participants were instructed to perform the tasks (see specific instructions in Appendix 2:

Moderator's guide):

- As quickly as possible making as few errors and deviations as possible.
- Without assistance; administrators were allowed to give immaterial guidance and clarification on tasks, but not instructions on use.
- Without using a think aloud technique.

The participants were given a written copy of the task. Task time began once the administrator

said begin. The task time was stopped once the participant indicated she had successfully completed the tasks.

Following task completion the participant was asked to complete the NASA-TASK LOAD INDEX (Appendix 4) and the POST STUDY SYSTEM USABILITY QUESTIONNAIRE (Appendix 5).

Participants were asked if they had any additional comments or questions for the group which were logged by the data logger and thanked for their participation.

Participants' demographic information, task success rate, time on task, errors, deviations, verbal responses, and post-test questionnaire were recorded on a spreadsheet.

TEST LOCATION

Usability testing took place in a small conference room. A user laptop computer and mouse were set up on a table. The Administrator sat next to the user. The user's screen was redisplayed for the data logger and observers. Stakeholders observed from the data logger's location. To ensure that the environment was comfortable for users, noise levels were kept to a minimum with the ambient temperature within a normal range. All of the safety instruction and evacuation procedures were valid, in place, and visible to the participants.

TEST ENVIRONMENT

Secision Support Inteeventions capabilities would typically be used in a healthcare office or facility. In this instance, the testing was conducted in a small conference room on Oroville Hospital campus. For testing a Dell Latitude 5401 laptop running Windows 10 Pro operating system was used with an external mouse. The participants used both keyboard and mouse to navigate and interact with the tVista EHR. A 14 inch monitor was used with a screen resolution of 1920 x 1080. The application was set up according to vendor specifications and the application was running on a Linux/GTM platform using a test database on a LAN connection. The performance of the test system was comparable to what users experience in production environments on site at clinics and hospitals. Participants were asked not to change any of the setting defaults to insure conformity.

TEST FORMS AND TOOLS

During the usability test various documents and instruments were used, including:

1. Moderator Guide
2. NASA-TLX
3. PPSSUQ

Examples of these documents can be found in the Appendices.

PARTICIPANT INSTRUCTION

The administrator read the following instructions aloud to each participant (also see the full moderator's guide in Appendix 3):

During this session, you will be asked to complete tasks using the Tenzin VistA EHR then provide feedback on the Decision Support Interventions (DSI).

I will provide you with a list of tasks and associated data. You will be asked to complete these

tasks as quickly as possible with the fewest errors or deviations. Do not try to do anything other than what is asked. I cannot assist you in accomplishing your tasks. Please save comments and question until the end of the session.

We would like you to give us feedback on the Decision Support Interventions (DSI) used. We would like to know how easy or difficult the system is to use, how useful the capabilities

are, and what improvement we can make. The best help you can give us is to be critical. We may not be able to fix everything you mention, but it is still beneficial for us to know what issues you feel are important. Your honest feedback is what we are after. Your feedback will be used to help make DSI capabilities better, so please do not worry about offending anyone with your comments. Your feedback as well as any questions the usability team is unable to answer will be shared with developers and stakeholders.

We have this interview divided into several parts. I'd like to start by just getting some background information; then I am going to ask some questions about if/how you currently use the DSI functions. You will be given an introductory overview of the new Decision Support Interventions (DSI). In the last part, we'll have you log in as a test user and attempt to review evidence based DSI source attributes, intervention data and clinical reminder logic, Resolve Clinical Reminder/Reset Clinical DSI, Review Intervention made.

Do you have any questions for us before we get started? In the last part, we'll have you log in as a test

Following the procedural instructions, participants were shown the EHR and given time to explore tVistA EHR and make comments. Once complete the administrator gave the following instructions:

I will say "Begin." At that point, please perform the tasks and say "Done" when you believe you have successfully completed the tasks. Please refrain from talking while doing the tasks. We will have time to discuss the tasks and answer questions when the tasks are complete.

Participants were given 3 tasks to complete. Tasks are listed Tables 3 below.

USABILITY METRICS

According to the *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records*, EHRs should support a process that provides a high level of usability for all users. The goal is for users to interact with the system effectively, efficiently, and with an acceptable level of satisfaction. To this end, metrics for effectiveness, efficiency and user satisfaction were captured during the usability testing. The goals of the test were to assess:

1. Effectiveness by measuring participant success rates and errors
2. Efficiency by measuring the average task time and path deviations
3. Satisfaction by measuring ease of use ratings

DATA SCORING

The following table (Table 2) details how tasks were scored, errors evaluated, and the time data analyzed.

Measures	Rationale and Scoring
<p>Effectiveness: Task Success</p> <p>Task Failure</p>	<p>A task was counted as a “Success” if the participant was able to achieve the correct outcome, without assistance, within the time allotted on a per task basis.</p> <p>The number of successes were calculated for each task and then divided by the total number of times that task was attempted. The results are provided as a percentage.</p> <p>If the participant abandoned the task, did not reach the correct answer or performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as an “Failures.” No task times were taken for errors.</p>
<p>Efficiency: Task</p>	<p>Task times were recorded for tasks successfully completed then divided by the number of participants who completed the task successfully. The average task time is reported. Variance measures (standard deviation and standard error) were also calculated.</p>
<p>Efficiency: Task Deviations</p>	<p>The participant’s path (i.e., steps) through the application was recorded. Deviations occur if the participant, for example, varied the order of the steps, failed to sign orders, or interacted incorrectly with an onscreen prompt. This path was compared to the minimum number of steps possible per task (optimal path) established by the team and developers. The number of steps in the observed path is divided by the optimal number of steps and presented as a ratio of path deviation</p>

<p>Satisfaction: Task Load</p>	<p>Participant’s subjective impression of the workload or cost of accomplishing the task requirements were obtained through the administration of the NASA Task Load Index (NASA-TLX) after each task set. The participant was asked to complete the six subscales representing different variables including: Mental, Physical, and Temporal Demands, Frustration, Effort, and Performance. See Appendix 4.</p> <p>A high level of burden on the participants is indicated by a score of 60 or greater.</p>
<p>Satisfaction: Task Rating</p>	<p>To measure the participant’s satisfaction of the CDS, CIR and Problem list capabilities the team administrated the Post Study System Usability Questionnaire (PSSUQ) at the completion of all the tasks. The PSSUQ consists of 19 items such as “it was simple to use the system” and “It was easy to find the information I needed” that the participant rates using a 7 point Likert scale ranging from 1=strongly agree to 7= strongly disagree. The PSSQU is designed to assess overall user satisfaction through perceived system usefulness, Information Quality and Interface quality.</p> <p>See Appendix 5 for a copy of the questionnaire.</p>

Table [2]. Details of how observed data were scored.

RESULTS

DATA ANALYSIS AND REPORTING

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above. There were no participants who failed to follow session and task instructions or had their data excluded from the analyses.

The usability testing results for the Decision Support Interventions capabilities of tVista EHR are detailed below in Tables 3. The results should be seen in light of the objectives and goals outlined in the Study Design section above. The data should yield actionable results. If corrected, within the tVista EHR decisions support interventions capabilities these will have a positive impact on user performance.

Qualitative feedback from the participants was transcribed by team members and compiled in an Excel spreadsheet. The team met to discuss all potential issues particularly those items noted as significant for consideration. Each issue was listed as verbalized by the participant and the team evaluated the issue asking questions such as: *What might cause the participant to have this issue? What cognitive support element does this issue violate? What can be done/changed to support the cognitive support element?* Recommendations intended to rectify the identified issue were recorded.

Issues were coded according to the cognitive element that led to the underlying issue, issue class, and time frame.

Issue Class

Each issue was classified into an “issue class.” This classification scheme represents our understanding of the potential impact of each issue if left unaddressed.

- **Type 1** issues are those we anticipate will create an *individual error risk*. These issues may directly introduce a specific health risk. For example, a new health system that somehow allowed treatment plans to be mistakenly associated with multiple EHRs. Some patients would be placed at significant health risk because of the design flaw.
- **Type 2** issues are those we anticipate will create an *aggregate error risk*. These issues may introduce error through cumulative effects. An example of this would be a new system that failed to capture some important paper- based function that was used in conjunction with the old system. The loss of low-tech, but high-value information can eventually lead to a problem.
- **Type 3** issues are those that we anticipate will create *adoption and long-term use risk*. These issues may negatively influence acceptance of the software. In the extreme, ignoring these issues may result in software that is rejected by the intended users. If use is mandated, users may find ways to “game” the system, distorting or circumventing the intent of the software. This is less troubling from a health risk standpoint, but could still create a long-term failure of a system in which much has been invested.

Timeframe

Recommendations are also made according to the timeframe in which issues should be addressed. Four timeframes are considered: urgent, quick fix, near-term, and long-term.

- **Urgent:** lead to significant medical error and/or patient risk, need to be fixed before next release/patch.
- **Quick fix:** These issues that we believe can be fixed "in-house" in a relatively short time frame (e.g. several weeks). These are issues that we believe will positively influence user acceptance with little development effort.
- **Near-term issue:** These issues are those that we believe will positively influence user acceptance. Can be completed in 12 months or less, but may require extra development time and effort.
- **Long-term issue:** These issues do not present significant risk in their current form. These recommendations, however, have the potential for significant, high impact benefit if resources can be found to address them over time. These fixes will take more than 12 months, contain interoperability issues and may require overhauls of existing systems, introductions of new functionality, and require extended development efforts.

Task #	Task	N	Task success	Task success	Path Deviations	Time on Task			Errors		Task Ratings Likert Scale of 1-7 should (1=strongly agree to 7=strongly disagree)	
						Mean (Seconds)	Standard Deviation (seconds)	Deviations (observed/optimal) seconds	Mean (%)	Std Dev (%)	Mean (%)	Std Dev (%)
1	Review Evidence Based DSI source attributes and intervention data using Clinical Reminder Logic	10	90.0	0.3	39/24	80	71	70/150	0.1	0.3	2.64	1.2
2	Resolve Clinical Reminder/Reset Decision Support Intervention tool	10	100.0	0.0	56/34	158	105	96/255	0.0	0.0	2.64	1.2
3	Review Support Intervention made to resolve Decision Support Intervention using Clinical Maintenance	10	90.0	0.3	26/22	85	82	20/65	0.1	0.3	2.64	1.2

Table 3: Data from DSI

DISCUSSION OF THE FINDINGS

Major findings (1)(2)(3)(4)

The results of the NASA Task Load Index (LTX) – a measure of the subjective workload, or demand the task places on the user during execution- was: 8.22 (SD = 3.3) which indicates this new capability did not place significant demand on users attempting the associated tasks. The results from the Post Study System Usability Questionnaire (PSSUQ) – a measure of user satisfaction post participation in scenario based usability studies-for the DSI tVistA EHR capabilities was 2.64 (SD = 1.2) overall. Generally users responded favorably to the DSI tVistA capabilities. Making changes as indicated in the areas for improvement should increase usability and lead to greater system satisfaction.

Effectiveness

Effectiveness was measured by task completion or failure to complete task. We asked providers to complete Decision Support Interventions tasks using tVistA EHR capabilities that demonstrate the required functionality. These tasks are derived from the ONC Health IT Certification Program requirements. The task completion data indicates that providers were able to complete most the tasks that they were asked to execute. There are notable differences between the participants in how they completed each task. These variations are due to subject characteristics, not issues regarding the functionality of the application. These subject variables include reviewing source attributes and intervention data from different areas of tVistA EHR, Completing Task out of order of test script, duration of patient information refresh. One user completed the final review of the clinical maintenance but skipped the initial review of the source attributes and intervention data from clinical inquiry

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10. **Hart, S. G., & Staveland, L.E.** Development of NASA-TLX (Task Load Index): Results of empirical and theoretical research. [ed.] P. A. Hancock and N. Meshkati. *Human mental Workload*. Amsterdam: North Holland Press., 1988, pp. 139-183. Scores greater than 60 are interpreted to place a higher task load on users.
 11. *NASA-Task Load Index (NASA-TLX); 20 Years Later.* **Hart, S. G.** Santa Monica: HFEW, 2006. Proceedings of the Human Factors and Ergonomics Society 50th Annual Meeting. pp. 904-908.
 12. *IBM computer usability satisfaction questionnaires: Psychometric evaluation and instructions for use.* **Lewis, J. R.** 1, 1995, International Journal of Human-Computer Interaction, Vol. 7, pp. 57-78. Scores range from 1-5. Lower scores indicate higher level of satisfaction.
 13. *Psychometric Evaluation of the PSSUQ Using Data from Five Years of Usability Studies.* **Lewis, J. R.** 3 & 4, s.l.: Lawrence Erlbaum Associates, Inc., 2002, International Journal of Human-Computer Interaction, Vol. 14, pp. 463-488.

Efficiency

Efficiency was measured by time on task and task deviations. We asked providers to complete representative tasks of the DSI tVista EHR capabilities that demonstrate the required functionality. These tasks are derived from the ONC Health IT Certification Program requirements. We did not instruct participants to complete tasks in one specific manner but provided an overview of how tasks could be completed via one path. Any path variation causes deviation in both time on task and path deviation. The data indicates that most providers were able to complete all the tasks in a standard manner and deviations were due to thoroughness as much as user error. There were deviations in the order in which tasks were completed, the section of EHR used to complete and the time spent reviewing the clinical data presented and input..

Satisfaction

Satisfaction was measured by two subjective questionnaires, the NASA TLX and the PSSUQ. Overall workload ratings indicate that the users are not overly burdened by the DSI capabilities. The results from the NASA TLX was: 8.2. The results of the PSSUQ was 2.64 overall; indicating overall favorable results for all areas of the DSI EHR capabilities. Below is a complete list of written comments (duplicates omitted) articulated by participants in response to question items.

- *Check boxes allowed for selection on one or more including a none of the above, which doesn't make sense*
- *This is too easy as I am familiar with the functionality*
- *What if I did not receive any error messages*
- *That was easy*
- *I think if I read and followed the direction I would have done better*
- *That's a lot of information, but it's good to see the references and know where it comes from*
- *Red Clock makes Reminders due easy to identify*
- *Simple menu locating reminders to complete*

This list of comments includes positive and neutral comments illustrating that the providers find the DSI easy to use but some design enhancements can improve the tool. Additional training to improve or maintain skills could be effective in reinforcing the data entry methods user indicated they are unaware or unfamiliar with.

AREAS FOR IMPROVEMENT

As a result of this set of usability interviews we determined that the DSI capabilities did not violate a set of cognitive support elements. One relevant issue was gleaned from these usability sessions it is listed in the following section. The resulting issue is grouped with respect to the cognitive element that the usability team believes led to the underlying issue and the cognitive element that is being violated. As a reminder, these elements include:

- *Support Decision Making*
- *Reduce Errors*
- *Facilitate Scanning*
- *Create Affordances*
- *Illustrate Perceived Benefit*
- *Support Mental Models*

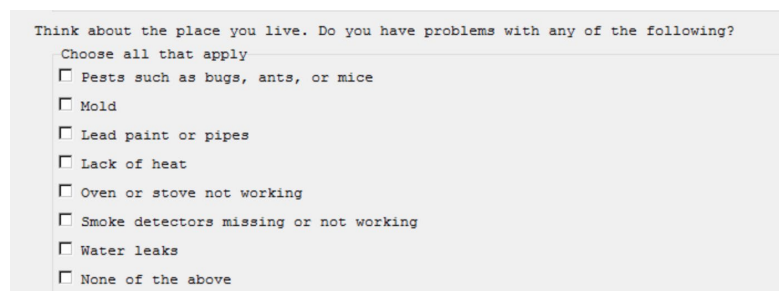
Recommendations are made to encourage a design enhancement that creates support for the relevant cognitive requirement. Recommendations should be adopted and implemented only in ways that support the cognitive elements. When reviewing the issues and recommendations the HIT team should consider questions such as:

1. *Why are participants having this issue?*
2. *What cognitive support element does this issue violate?*
3. *What can we do within the design process to facilitate the cognitive support requirement?*

Issues and Recommendations

Issue 1: Check boxes allowed for selection on one or more including a none of the above, which doesn't make sense

- Cognitive Support Element: Support Mental Models. One user found the terminology problematic so we believe this is a quick fix that requires change to display for clarity
 - Consideration:
How can we quickly and easily facilitate an understanding of the meaning of the clinical reminder drawer terminology



Think about the place you live. Do you have problems with any of the following?

Choose all that apply

- Pests such as bugs, ants, or mice
- Mold
- Lead paint or pipes
- Lack of heat
- Oven or stove not working
- Smoke detectors missing or not working
- Water leaks
- None of the above

- R-1 We recommend modifying the drop down list for clarity removing none of the above a multiple choice option and making it a stand alone option.
- R-2 Training users on the DSI functionality should facilitate better understanding of the meaning, design and layout of clinical reminders and DSI.
- R-3 Additional display modification can be as needed based on user feedback post training and use.

Table 4 represents the issues, the associated cognitive support element, issue class and anticipated timeframe

Issue	Description	Cognitive Support Element	Issue Class	Timeframe
1	Check boxes allowed for selection on one or more including a none of the above, which doesn't make sense	Support Mental Models	III	Quick Fix

Table 4: Issue and Recommendations by Cognitive Support Element, Issue Class and Timeframe

Areas for Improvement: Global Recommendations

To further improve usability and adoptability of tVistA EHR the following recommendations are made regarding the EHR as a whole. These recommendations reflect standard windows functionality that utilize existing mental models.

- Gray-out visualization:** When a function is not available it should be grayed out. By graying out functions that are not available it provides the user with a visual cue that those options are not available at the present time, while still allowing them to know these features exist and may be available in other circumstances.
- Tool tips/instructions:** All buttons, icons, and right click options in the GUI should include tool tips describing their name and function when the user hovers the mouse over them. These tool tips allow the user to learn what various buttons in the software do on their own as they are using the software application.
- Window size:** Expand default screen size for pop-up dialogue windows. Pop-up dialogues should be maximized to prevent scrolling when possible if screen real estate is available. The dialogues should remain centered on the screen, with width and height adjusted to provide maximum visibility of all content.
- Auto-close:** Close previous windows where an action has been executed and is no longer relevant. By closing previous windows that have completed their actions you remove the need for the user to close unnecessary windows to continue using the software after they have completed a set of actions.

5. **Asterisks:** Indicate required fields with asterisks throughout the interface. By standardizing this throughout the interface users are aware of what is necessary for them to complete various tasks. This visual indicator also allows users to ensure all necessary information has been entered rather than relying on error messages which interrupt the workflow and require backtracking to complete a task.
6. **Training:** It is our belief that with an ideal interface, one that is intuitive to end users and incorporates as much usability as possible, the amount of necessary training should be minimal. This is why we often recommend streamlining processes for task completion within the EHR. We realize that while minimal training is ideal, it is not always achievable, at least not right away. By completing user testing and incorporating the feedback into the system little by little it will hopefully reduce the required amount of training required.

APPENDICES

The following appendices include supplemental data for this usability test report.

Following is a list of the appendices provided:

1. Participant demographics
2. Moderator's Guide
3. Test Scenarios
4. NASA-Task Load Index
5. Post Study System Usability Questionnaire

Appendix 1: Participant Demographics

Gender

Men	[5]
Women	[5]
Total (participants)	[10]

Occupation/Role

Doctor, CMIO	[1]
Medical Scribe	[5]
Pharmacist	[1]
Director of Pharmacy	[1]
Clinical Application MA	[1]
Analyst	[1]
Total (participants)	[10]

Provider Type

Doctor	[1]
Medical Scribe	[5]
Pharmacist	[2]
Application coordinator	[1]
Analyst	[1]
Total (participants)	[10]

Years of Experience

Professional	[16.6]
EHR	[17]
VistA EHR	[12.6]

Appendix 2: Moderator's Guide

Introduction/Orientation:

First off we would like to thank you for taking the time to provide us with feedback on the EHR capabilities being tested today. We are executing these sessions as part of ONC Health IT Certification Program, this usability study in Decision Support Interventions (DSI) will help ensure that Tenzing Medical, LLC meets their Certification standards. We are asking EHR users to provide usability input to the DSI capabilities of Tenzing VistA EHR.

During this session, you will be asked to complete tasks using the Tenzin VistA EHR then provide feedback on the Decision Support Interventions (DSI).

I will provide you with a list of tasks and associated data. You will be asked to complete these tasks as quickly as possible with the fewest errors or deviations. Do not try to do anything other than what is asked. I cannot assist you in accomplishing your tasks. Please save comments and question until the end of the session.

We would like you to give us feedback on the Decision Support Interventions (DSI) used. We would like to know how easy or difficult the system is to use, how useful the capabilities are, and what improvement we can make. The best help you can give us is to be critical. We may not be able to fix everything you mention, but it is still beneficial for us to know what issues you feel are important. Your honest feedback is what we are after. Your feedback will be used to help make DSI capabilities better, so please do not worry about offending anyone with your comments. Your feedback as well as any questions the usability team is unable to answer will be shared with developers and stakeholders.

We have this interview divided into several parts. I'd like to start by just getting some background information; then I am going to ask some questions about if/how you currently use the DSI functions. You will be given an introductory overview of the new Decision Support Interventions (DSI). In the last part, we'll have you log in as a test user and attempt to review evidence based DSI source attributes, intervention data and clinical reminder logic, Resolve Clinical Reminder/Reset Clinical DSI, Review Intervention made.

Do you have any questions for us before we get started?

Complete Background Information & Show Participant introductory Presentation

I will say "Begin." At that point, please perform the tasks and say "Done" when you believe you have successfully completed the tasks. Please refrain from talking while doing the tasks. We will have time to discuss the tasks and answer questions when the tasks are complete.

Provide Test Script

Appendix 3: Test Scenario

DSI Usability Test Script

ACTION

Using the provider login provided for testing Log into the EHR

DOCTOR,CERT TESTING

ACCESS CODE: **MDTEST1**

VERIFY CODE: **MDTEST1!**

ELECTRONIC SIGNATURE CODE: **123456**

Select Patient _____

1. Verify that the Reminder Clock is Red indicating Clinical reminders are due and note the reminders due for the patient.
2. Create a New PROGRESS NOTE, open the Reminders Draw and click on the first Reminder Due to begin processing the reminders.
3. Review the *Source Attributes* and *Intervention data* for each clinical reminder using the **Reminder Inquiry** option

- Social Determinants of Health (SDOH) Screen
- Sexual Orientation and Gender Identity (SOGI) Screen
- Pregnancy Status health status
- Pacemaker Interrogation Needed (UDI)

Note that each Clinical Reminder displays a

- Description,
- Developer,
- Funding Source,
- Release/Revision date,
- Guidelines, and
- patient attributes including
 - Language
 - Race
 - Ethnicity
 - Social Determinants of Health
 - Sexual Orientation
 - Health Vital signs

4. Address/Resolve the remaining Clinical Reminders using the Reminder dialog from the Notes Tab
 - Complete Screening for **SDOH** including **Follow-up action**, and **Background** (language, race, ethnicity) review
 - Click Next > button to process the next reminder and select an appropriate option. ■■

▪ Repeat step 4 until all reminders are addressed then click Finish to close the Reminder Resolution Window

- Complete Screening for SOGI
- Complete Screening for Pregnancy Reminder
- Resolve Pacemaker Interrogation Needed Clinical Reminder by deferring for 3 months

5. Review and Sign Changes

6. Refresh Patient and Verify Clinical Reminders Clock is **Blue** indicating all reminders have been addressed.

Review *Clinical Maintenance* on of the resolved Clinical Reminders noting the Status, Last Done date, Frequency, and Resolution

Complete NASA TLX & PSSUQ

Appendix 4: NASA-Task Load Index

Instructions: Mark the scale that represents your experience.

Mental Demand



Physical Demand



Temporal Demand



Effort



Performance



Frustration



Appendix 5: Post Study System Usability Questionnaire

Instructions: This questionnaire gives you an opportunity to tell us your reactions to the system you used. Your responses will help us understand what aspects of the system you are particularly concerned about and the aspects that satisfy you.

To as great a degree as possible, think about all the tasks that you have done with the system while you answer these questions.

Please read each statement and indicate how strongly you agree or disagree with the statement by circling a number on the scale.

Please write comments to elaborate on your answers.

After you have completed this questionnaire, I'll go over your answers with you to make sure I understand all of your responses. Thank you!

1. Overall, I am satisfied with how easy it is to use this system.

Strongly									Strongly
Agree	1	2	3	4	5	6	7		Disagree
Comments:									

2. It was simple to use this system.

Strongly									Strongly
Agree	1	2	3	4	5	6	7		Disagree
Comments:									

3. I could effectively complete the tasks and scenarios using this system.

Strongly									Strongly
Agree	1	2	3	4	5	6	7		Disagree
Comments:									

4. I was able to complete the tasks and scenarios quickly using this system.

Strongly									Strongly
Agree	1	2	3	4	5	6	7		Disagree
Comments:									

5. I was able to efficiently complete the tasks and scenarios using this system.

Strongly									Strongly
Agree	1	2	3	4	5	6	7		Disagree
Comments:									

6. I felt comfortable using this system.

Strongly									Strongly
Agree	1	2	3	4	5	6	7		Disagree
Comments:									

7. It was easy to learn to use this system.

Strongly									Strongly
Agree	1	2	3	4	5	6	7		Disagree
Comments:									

8. I believe I could become productive quickly using this system.

Strongly									Strongly
Agree	1	2	3	4	5	6	7		Disagree
Comments:									

9. The system gave error messages that clearly told me how to fix problems.

Strongly									Strongly
Agree	1	2	3	4	5	6	7		Disagree
Comments:									

10. Whenever I made a mistake using the system, I could recover easily and quickly.

Strongly									Strongly
Agree	1	2	3	4	5	6	7		Disagree
Comments:									

11. The information (such as on-line help, on-screen messages and other documentation) provided with this system was clear.

Strongly									Strongly
Agree	1	2	3	4	5	6	7		Disagree

Comments:

12. It was easy to find the information I needed.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
-------------------	---	---	---	---	---	---	---	----------------------

Comments:

13. The information provided for the system was easy to understand.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
-------------------	---	---	---	---	---	---	---	----------------------

Comments:

14. The information was effective in helping me complete the tasks and scenarios.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
-------------------	---	---	---	---	---	---	---	----------------------

Comments:

15. The organization of information on the system screens was clear.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
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Comments:

Note: The interface includes those items that you use to interact with the system. For example, some components of the interface are the keyboard, the mouse, the screens (including their use of graphics and language).

16. The interface of this system was pleasant.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
-------------------	---	---	---	---	---	---	---	----------------------

Comments:

17. I liked using the interface of this system.

Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree
-------------------	---	---	---	---	---	---	---	----------------------

Comments:

18. This system has all the functions and capabilities I expect it to have.

Strongly								Strongly
Agree	1	2	3	4	5	6	7	Disagree
Comments:								

19. Overall, I am satisfied with this system.

Strongly								Strongly
Agree	1	2	3	4	5	6	7	Disagree