User-Centered Design Practice
**DocuTAP’s User-Centered Design Process**

User-centered design (UCD) has been an integral part of DocuTAP’s design process since inception. DocuTAP’s initial design was created by spending extensive time in clinics. Research was conducted around clinic workflow by observing real users complete their work. As the electronic health record (EHR) software has changed, the UCD process has become more formalized.

The goal of the UCD process is to ensure that the EHR software is effective, efficient, and satisfies the end-user. This aligns with ISO 9421-11 which defines usability as “the effectiveness, efficiency, and satisfaction with which the intended users can achieve their tasks in the intended context of product use.”

The UCD process has been applied to the EHR software, including the following areas, prior to certification testing. The area for inpatient setting only, §170.314(a)(16) electronic medication administration record, was not included. DocuTAP software is only used in ambulatory care settings.

- §170.314(a)(1) Computerized provider order entry
- §170.314(a)(2) Drug-drug, drug-allergy interaction checks
- §170.314(a)(6) Medication list
- §170.314(a)(7) Medication allergy list
- §170.314(a)(8) Clinical decision support
- §170.314(b)(3) Electronic prescribing
- §170.314(b)(4) Clinical information reconciliation

**UCD Process Flow**

Typically when a new feature request or project is presented, it is determined if any user interface (UI) changes are needed. If UI changes are required, the project begins down the UCD process flow.

Research is conducted around requirements and user needs. This research, as well as internal UI standards, influences the UI prototype design. The initial prototype is reviewed with our internal EMR (electronic medical record) and UCD Analysts. Updates, if needed, are completed. The prototype and approach is reviewed with users. This review process includes usability research methods like expert interviews and formative usability tests. Results from the usability research are fed forward into the prototype design. If findings required significant changes to the prototype, further usability research is conducted. The prototype and all applicable user research findings are fed forward to the specification and/or user stories for the development teams.

If a software change is a significant change or critical function that could affect patient safety, summative testing plans are formulated and preparations are made for user testing near the end of development. The summative testing targets user groups who are the typically users of the feature (i.e., provider or nurse). Performance and subjective metrics are used to determine

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the usability of the feature as well as determine if the needs and goals of the user were met. Depending upon the severity of the findings, immediate updates to the software will be completed prior to the software release. Otherwise, new projects are created to modify the feature.

Typically, summative testing is not conducted on smaller software changes. Results from formative testing and expert reviews are relied upon for those updates.
EHR Usability Test Report of DocuTAP Software


Date of Usability Studies: October 2013 – November 2013; April 2014
Date of Report: April 2014
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Chapter 1: Provider Study A

Executive Summary

A remote usability study of the DocuTAP software, version 4.1 was conducted via remote sessions between October 2013 and November 2013 by DocuTAP’s User-Centered Design (UCD) Team. The purpose of the study was to test and validate the usability of the current user interface (UI) and provide evidence of usability in the EHR Under Test (EHRUT). During the usability study, five healthcare providers (e.g., MD, PA) matching the target demographic criteria served as participants and used the EHRUT in simulated, but representative tasks.

The study collected performance data on several tasks. The tasks include:

- **Computerized Provider Order Entry (CPOE; 314.a.1)**
  - Order medication and view drug-allergy interaction
  - View medication order and electronic prescribe
  - Edit medication order
  - Order lab test
  - View and change lab test
  - Order x-ray
  - View and change x-ray

- **Drug-drug, drug-allergy interaction checks (314.a.2)**
  - Adjust drug-drug interaction checking
  - Order medication and view drug-allergy interaction
  - Order medication and view drug-drug interaction

- **Electronic Prescribing (314.b.3)**
  - Create medication order
  - View medication order and electronic prescribe (i.e., send electronically to pharmacy)

During the hour-long one-on-one remote usability session, each participant was greeted by the moderator. An informed consent document (included in Appendix B) was reviewed and participants were informed that they could withdraw at any time. All participants had prior experience with the EHRUT. The moderator introduced the study and instructed participants to complete a series of tasks, given one at a time, using the EHRUT. During the testing session, the moderator timed the test and recorded user performance data on paper and electronically. The moderator did not give the participants assistance in how to complete the tasks. Participant screens and audio were recorded for subsequent analysis.

The following types of data were collected for each participant:

- Number of tasks successfully completed within the allotted time without assistance
- Ease in which task was completed (e.g., easily completed, completed with difficulty)
- Time on task
- Perceived difficulty of task on 5-point Likert scale
- Number and types of errors
- Path deviations
- Participant’s comments
- Participant’s satisfaction ratings of the system (i.e., System Usability Scale (SUS) ratings)

All participant data was de-identified – no correspondence could be made from the identity of the participant to the collected data. Following the conclusion of the testing, participants were asked to complete a post-test questionnaire and were compensated with an American Express gift card for their time. Various recommended metrics, in accordance with the examples set forth in the NIST Guide to the Process Approach for Improving Usability of Electronic Health Records, were used to evaluate the usability of the EHRUT. Following is a summary of the performance and rating data collected for the Provider tasks on the EHRUT.

<table>
<thead>
<tr>
<th>Task</th>
<th>N</th>
<th>Task Success</th>
<th>Path Deviation</th>
<th>Task Time (in seconds)</th>
<th>Errors</th>
<th>Task Ratings 5 = easy</th>
<th>Risk Rating 4 = Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPOE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Create med order</td>
<td>5</td>
<td>100</td>
<td>1.0</td>
<td>15.6 [3.6]</td>
<td>1.0 [0.2]</td>
<td>0.0</td>
<td>4.8 [0.4]</td>
</tr>
<tr>
<td>2. View med order &amp; electronic prescribe</td>
<td>5</td>
<td>100</td>
<td>1.0</td>
<td>27.2 [7.9]</td>
<td>0.8 [0.2]</td>
<td>0.0</td>
<td>View: 4.6 [0.5] Send: 4.6 [0.5]</td>
</tr>
<tr>
<td>3. Edit med order</td>
<td>5</td>
<td>100</td>
<td>1.1</td>
<td>60.6 [16.4]</td>
<td>1.0 [0.3]</td>
<td>0.0</td>
<td>4.6 [0.5]</td>
</tr>
<tr>
<td>4. Order lab test</td>
<td>5</td>
<td>80</td>
<td>1.0</td>
<td>8.5 [0.5]</td>
<td>1.1 [0.1]</td>
<td>0.0</td>
<td>4.8 [0.4]</td>
</tr>
<tr>
<td>5. View &amp; change lab test</td>
<td>5</td>
<td>100</td>
<td>1.2</td>
<td>32.8 [4.9]</td>
<td>1.4 [0.2]</td>
<td>0.0</td>
<td>View: 4.4 [0.8] Change: 4.4 [0.8]</td>
</tr>
<tr>
<td>6. Order x-ray</td>
<td>5</td>
<td>100</td>
<td>1.0</td>
<td>9.2 [1.9]</td>
<td>1.0 [0.2]</td>
<td>0.0</td>
<td>4.8 [0.4]</td>
</tr>
<tr>
<td>7. View &amp; change x-ray</td>
<td>5</td>
<td>100</td>
<td>1.1</td>
<td>16.0 [2.2]</td>
<td>1.0 [0.1]</td>
<td>0.0</td>
<td>View: 4.4 [0.8] Change: 4.4 [0.8]</td>
</tr>
</tbody>
</table>

**Drug-Drug, Drug-Allergy Interaction Checks**

<table>
<thead>
<tr>
<th>Task</th>
<th>N</th>
<th>Task Success</th>
<th>Path Deviation</th>
<th>Task Time (in seconds)</th>
<th>Errors</th>
<th>Task Ratings 5 = easy</th>
<th>Risk Rating 4 = Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Adjust drug-drug interaction checking</td>
<td>5</td>
<td>20</td>
<td>1.1</td>
<td>13.5 [0.0]</td>
<td>1.1 [0.0]</td>
<td>1.0</td>
<td>4.6 [0.5]</td>
</tr>
<tr>
<td>2. Order med &amp; view drug-allergy interaction</td>
<td>5</td>
<td>100</td>
<td>1.0</td>
<td>12.6 [4.8]</td>
<td>0.8 [0.3]</td>
<td>0.0</td>
<td>5.0 [0.0]</td>
</tr>
<tr>
<td>3. Order med &amp; view drug-drug interaction</td>
<td>5</td>
<td>100</td>
<td>1.1</td>
<td>16.0 [1.5]</td>
<td>1.1 [0.1]</td>
<td>0.0</td>
<td>4.6 [0.8]</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Measure</th>
<th>N</th>
<th>Task Success</th>
<th>Path Deviation</th>
<th>Task Time (in seconds)</th>
<th>Error</th>
<th>Task Ratings</th>
<th>Risk Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Task</td>
<td></td>
<td>% of successful attempts</td>
<td>Deviations (Observed / Optimal)</td>
<td>Mean (SD)</td>
<td>Deviations (Observed / Optimal)</td>
<td>Mean (SD)</td>
<td>5 = easy</td>
</tr>
<tr>
<td>1. Create med order</td>
<td>5</td>
<td>100</td>
<td>1.0</td>
<td>15.6 (3.6)</td>
<td>1.0 (0.2)</td>
<td>0.0</td>
<td>4.8 (0.4)</td>
</tr>
<tr>
<td>2. View med order &amp; electronic prescribe</td>
<td>5</td>
<td>100</td>
<td>1.0</td>
<td>27.2 (7.9)</td>
<td>0.8 (0.2)</td>
<td>0.0</td>
<td>View: 4.6 (0.5) Send: 4.6 (0.5)</td>
</tr>
</tbody>
</table>

Table 1: Provider Summary Data

The results from the System Usability Scale scored the subjective satisfaction with the system based on performance with the tasks performed in the entire session to be 88.5. Common convention suggests that scores under 60 represent systems with poor usability; scores over 80 would be considered above average.

Major Findings

In addition to the performance data, the following qualitative observations were made:

When evaluating the effectiveness, efficiency, and satisfaction of the tasks, it is evident that the majority of the task areas do not need much for changes. Yet, some like the viewing and ordering of labs and x-rays features, could benefit from additional nice-to-have features that would create even more user satisfaction with the software.

Additionally, considering only 20% of the participants in the study completed the drug-drug interaction check task within the allotted time and that it is considered a task that is high-risk, this feature should be reviewed. The time in which it takes to complete the task and how often it is completed should be analyzed and compared with how frequently this option is completed. Each install of the DocuTAP software includes the complete list of drug-drug interactions from the drug database. Clinics have the ability to go in to add and adjust any current drug-drug interaction check and it needs to be determined how frequently this occurring. Editing a drug-drug interaction incorrectly, could potentially create a dangerous situation that could affect patient safety.

Participants were more than or just as efficient as the optimal task time for all but three tasks. The tasks where participants were not as efficient include viewing and changing a lab test, adjusting drug-drug interaction checking, and viewing the drug-drug interaction.

Of all the tasks that participants completed, there was only one task in which participants committed errors. All but one participant made errors when completing the adjusting the drug-drug interaction check task.

In general, participants commented that the overall prescription process is easy to do within the software. They were excited to see the new electronic prescribing process. They commented
that it appears it will provide great time savings. Some were even asking if the transition to the new process could happen faster for their clinics.

Areas for improvement

Additional research and usability studies should be considered around editing drug-drug interaction checks, and viewing and ordering labs and x-rays. Further research to determine how frequently clinics are updating the drug-drug checks and user studies could provide guidance on how to best make the changes to make it easier and faster for users to complete the task.

Participants were happy with the tabs and organization of the software, but would like more flexibility in how items are arranged under labs. A couple participants mentioned that it would be nice to have labs that are most ordered to be grouped together. Further, labs that are similar could be organized together. For example, when ordering individual thyroid labs like TSH or T4, they could be next to each other rather than appearing in a list organized alphabetically. Participants perceived that it takes longer to search through the alphabetized list than it would if the labs were organized by similarity.

Depending on a clinic’s workflow, some may require that lab and x-ray requests be sent via an HL7 message to both internal and external labs. The user must then select the lab(s) and then click a “Send Lab Request” or “Send X-ray Request” button. Some of the participants mentioned that they forget to click this button. They would like to see it closer to the lab name itself or in a different location on the page rather than the bottom. Participants also mentioned that it would be beneficial to able to cancel a lab by utilizing a cancel button instead of having to contact the lab.

Several participants commented that they suffered from alert fatigue related to all of the drug-drug interaction messages. Due to the number of drug-drug interactions that can pop-up, participants admit that they begin to ignore them. The disregard the participants have for these warnings can and will lead to them missing important warning information. One participant even admitted that he completely ignores them and relies on his Epocrates app on his smartphone and his own judgment. A related issue is that the pop-ups for drug-drug interaction, drug-allergy interaction, duplicate therapy, etc. all have the same aesthetic appearance. Participants commented that it’s easy to overlook something like an allergy because it doesn’t stick out. Some even admitted that they have mistakenly clicked through it.

When prescribing, participants commented that it can be difficult, at times, to find a new medication. The brand name may be missing from the list, but the generic name will be available. Some admitted that it’s difficult to recall the generic names if they don’t use them frequently. They refer to other resources like the Internet or other medical apps to obtain the generic name.

Many participants complained that when creating a prescription they always have to select the method in which the prescription should be taken. The majority of the medications prescribed in urgent cares are taken orally. Participants would like to see oral set as the default option or have it appear higher in the list of options. Currently, the list of options is in alphabetical order. Further studies in to the options would provide information on how to best resolve this issue.
Introduction

The EHRUT tested for this study was DocuTAP version 4.1. Designed to present medical information to the healthcare providers in Urgent Care Clinics, the EHRUT consists of an EMR where clinic staff can document and review an entire visit from start-to-finish. The usability study attempted to represent realistic exercises and conditions.

The purpose of this study was to test and validate the usability of the current UI, and provide evidence of usability in the EHRUT. Measures of effectiveness, efficiency, and user satisfaction (e.g., time on task, number of steps to complete task) were captured during the sessions.

Method

Participants

A total of five participants were tested on the EHRUT. Participants in the study were providers (e.g., medical doctor, physician assistant). Participants were recruited by DocuTAP’s UCD Team and were compensated with American Express gift cards for their time. All were existing users of the DocuTAP software. In addition, participants had no direct connection to the development of the EHRUT nor were participants employees of DocuTAP.

Recruited participants had a mix of backgrounds and demographic characteristics conforming to standard research methods and principles. The following is a table of participants by characteristics, including demographics, professional experience, and computing experience. Participant names were replaced with Participant IDs so that an individual’s data cannot be linked back to the individual identities.

<table>
<thead>
<tr>
<th>ID</th>
<th>Gender</th>
<th>Highest Level of Education</th>
<th>Current Occupation/Role</th>
<th>Professional Experience in Current Role (years)</th>
<th>Experience with EHR Technology (years)</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>Female</td>
<td>PhD</td>
<td>Physician Assistant</td>
<td>0.4</td>
<td>9</td>
</tr>
<tr>
<td>2</td>
<td>Male</td>
<td>MD</td>
<td>Staff Physician</td>
<td>11</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>Male</td>
<td>MD</td>
<td>Staff Physician</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>4</td>
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<td>NP</td>
<td>Nurse Practitioner</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>5</td>
<td>Male</td>
<td>MD</td>
<td>Staff Physician</td>
<td>5</td>
<td>8</td>
</tr>
</tbody>
</table>

Table 2: Provider Participant Demographic Data

Seven participants were recruited and five participated in the usability study. Two participants declined to partake in the study.

Participants were scheduled for one hour sessions with at least 30 minutes between each session for debrief by the administrator, and to reset the systems to proper test conditions. A spreadsheet was used to track the participant recruitment and schedule.
Study Design

Overall, the objective of the study was to uncover areas where the application performed well (i.e., effectively, efficiently, and with satisfaction) and areas where the application failed to meet the needs of the participants. The data from this study may serve as a baseline for future studies with an updated version of the same EHR and/or comparison with other EHRs provided the same tasks are used. In short, this study serves as both a means to record or benchmark current usability, but to also identify areas where improvements must be made.

During the usability study, participants interacted with the EHR. Each participant used the same system in his or her remote clinic or home location, and was provided the same instructions. The system was evaluated 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
- Ease in which task was completed (e.g., easily completed, completed with difficulty)
- Time on task
- Perceived difficulty of task on 5-point Likert scale
- Number and types of errors
- Path deviations
- Participant’s comments
- Participant’s satisfaction ratings of the system (i.e., System Usability Scale (SUS) ratings)

Additional information about the various measures can be found in the section for Usability Metrics below.

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. The tasks include:

**CPOE**

1. Order medication and view drug-allergy interaction
2. View medication order and electronic prescribe
3. Edit medication order
4. Order lab test
5. View and change lab test
6. Order x-ray
7. View and change x-ray

**Drug-drug, drug-allergy interaction checks**

1. Adjust drug-drug interaction checking
2. Order medication and view drug-allergy interaction
3. Order medication and view drug-drug interaction

**Electronic Prescribing**

1. Create medication order
2. View medication order and electronic prescribe (i.e., send electronically to pharmacy)
Tasks were selected based on their frequency of use, criticality of function, and those that may be most troublesome for users.

**Procedure**

Upon arrival, participants were greeted and their identity verified with the participant schedule. Participants were then assigned a random participant ID. Each participant reviewed and verbally consented to the consent form (see Appendix B). The verbal consent was recorded and witnessed by the test team.

To ensure the session ran smoothly, an experienced usability administrator facilitated the study. The usability administrator has seven years of experience and a master's degree in Human Factors Psychology.

The administrator moderated the session including providing instructions and tasks. The administrator also monitored task times, obtained post-task rating data, and took notes on participant comments. The sessions were recorded to review and compute additional findings (e.g., task success, path deviations, etc.).

Participants were instructed to perform the tasks (see specific instructions below):

- As they normally would and as quickly as possible
- Without assistance; administrator could provide clarification, but not instruction

For each task, task timing began once the administrator finished reading the question. The task time stopped once the participant indicated they had successfully completed the task. Scoring is discussed in the Data Scoring section below.

Following the session, the administrator gave the participant the post-test questionnaire (i.e., System Usability Scale, see Appendix F), requested their mailing address to send compensation, and thanked them for their time and participation.

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

**Test Location**

The test facility consisted of the administrator's computer workstation and the participants' personal workstations at home or clinic, as the study was completed remotely. Only the administrator and the participant were connected to the remote session.

**Test Environment**

The EHRUT would be typically used in an urgent care clinic. In this instance, testing was conducted either in participants' homes or clinics. For testing, the moderator and participant connected via GoToMeeting software. The participants used a mouse and keyboard to interact with the EHRUT.

The EMR was set up by the test team according to new installation documentation. The application itself was running in a Citrix environment using a test database on a LAN connection. Technically, the system performance (i.e., response time) was representative to what actual
users would experience in a field implementation. Additionally, participants were instructed not to change any of the default system settings.

Test Forms and Tools

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

1. Informed Consent Form
2. Moderator’s Guide – Provider Study A
3. System Usability Scale (SUS)

Examples of these documents can be found in Appendices Appendix B, Appendix C, and Appendix F, respectively. The Moderator’s Guide was devised so as to be able to capture required data.

The participant’s interaction with the EHRUT and verbal comments were recorded digitally with GoToMeeting software running on the moderator’s test machine.

Participant Instructions

The administrator read the following instructions to each of the participants (full moderator’s guide is available in Appendix C):

Thank you for helping us with this study. Our session today will last approximately one hour. We are conducting research around prescribing medications and ordering labs and x-rays. I will ask you to perform a few tasks. I want you to use the software like you normally would and then I will ask you some specific questions around your experience today.

When designing software, there are always so many ideas about how it should look and work. Today, you are going to help us review prescribing and ordering labs and x-rays. I want you to work through the tasks like you normally would and try to complete them as quickly as possible without rushing. I will not be able to assist you with the tasks, but I can provide you more clarification if you need it. At the end of each task, I will ask you some questions about what you completed. Please feel free to share any thoughts or feelings you have about the features of the software – positive or negative. All of the feedback you share is important and very helpful to me. I did not have any involvement in the creation, so please be honest with your opinions.

I want to emphasize that we are not evaluating you, we are evaluating the software. We will record the session. All recordings will be kept strictly confidential. We may use footage to share with our developers and/or management the experience you have to help highlight both positive findings and areas for improvement. It also helps so that I don’t have to take as many notes during this session.

Following the procedural instructions, participants were asked a few pre-study questions for demographic information (e.g., age, degree, experience with EHRs and computers). Once this was complete, the administrator gave the following instructions:

For each task, I will read the description and say “Begin.” At that point, please start the task and say, “Done.” once you believe you have successfully completed the task. I
want you to complete the task like you normally would and as quickly as possible. Please refrain from proving your thoughts and comments until you complete the task. I will ask your impressions about the task once you are done.

Participants were then given 10 tasks to complete. Tasks are listed in the moderator’s guide in Appendix C.

Usability Metrics

According to the NIST Guide to the Process 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 of DocuTAP EMR by measuring participant success rates and errors
2. Efficiency of DocuTAP EMR by measuring average task time and path deviations
3. Satisfaction with DocuTAP EMR by measuring ease of use ratings

Data Scoring

The following table (Table 3) details how tasks were scored, errors evaluated, and time data analyzed.

<table>
<thead>
<tr>
<th>Measures</th>
<th>Rationale and Scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Effectiveness:</strong></td>
<td>A task was counted as a “Success” if the participant was able to achieve the correct outcome, without any assistance, within the time allotted on a per task basis.</td>
</tr>
<tr>
<td>Task Success</td>
<td>The total number of successes were calculated for each task and then divided by the total number of times the task was attempted. The results are provided as a percentage.</td>
</tr>
<tr>
<td></td>
<td>Task times were recorded for successes. Observed task times divided by the optimal time for each task is a measure of optimal efficiency.</td>
</tr>
<tr>
<td></td>
<td>Optimal task performance time, as benchmarked by expert performance under realistic conditions, was recorded when constructing the tasks. Target task times used for task times in the Moderator’s Guide were defined by taking multiple measurements of the optimal performance and multiplying it by 1.5 which allows some time buffer because participants were not trained to expert performance. Therefore, if expert optimal performance on a task was 60 seconds, then allotted task time performance was [60*1.5=90] seconds. This ratio was aggregated across tasks and reported with both mean and variance scores.</td>
</tr>
<tr>
<td><strong>Effectiveness:</strong></td>
<td>If the participant abandoned the task, did not reach the correct answer, performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as a “Failure.”</td>
</tr>
<tr>
<td>Task Failures</td>
<td>The total number of errors was calculated for each task and then divided by the total number of times the task was attempted. Not all deviations were counted as errors. This is the mean number of failed tasks per participant. A count of errors and error types was collected.</td>
</tr>
</tbody>
</table>
Safety-Enhanced Design Summative Usability Testing Report

<table>
<thead>
<tr>
<th>Measures</th>
<th>Rationale and Scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Efficiency:</strong></td>
<td>The participant’s path through the EHR was recorded. Deviations occur if the participant, for instance, went to a wrong screen or clicked on an incorrect menu item. This path was compared with the optimal path. The number of steps in the observed path was divided by the number of optimal steps to provide a ratio of path deviation. Optimal paths were recorded during task development.</td>
</tr>
<tr>
<td>Task Deviations</td>
<td></td>
</tr>
<tr>
<td><strong>Efficiency:</strong></td>
<td>Each task was timed from when the administrator said “Begin,” until the participant said, “Done.” If a participant failed to say, “Done,” the time was stopped when the participant stopped performing the task. Only task times for tasks that were successfully completed were included in the average task time analysis. Average time task was completed for each task. Variance measures (standard deviation and standard error) were also calculated.</td>
</tr>
<tr>
<td>Task Time</td>
<td></td>
</tr>
<tr>
<td><strong>Satisfaction:</strong></td>
<td>Participants’ subjective impression of the ease of use of the EHR was measured by administering both a simple post-task question as well as a post-session questionnaire. After each task, the participant was asked to rate “How would you rate [task] on a scale from 1 (very difficult) to 5 (very easy). These scores were averaged across participants. According to common convention, system that are judged to be easy to use are rated 3.3 or above. To measure participants’ confidence in and likeability of the DocuTAP EHR overall, the testing team administered the System Usability Scale (SUS) post-session questionnaire. See Appendix F for the full questionnaire.</td>
</tr>
<tr>
<td>Task Rating</td>
<td></td>
</tr>
</tbody>
</table>

Table 3: Details of How Observed Data Were Scored

The following table (Table 4) details the four-point risk assessment scale utilized.

<table>
<thead>
<tr>
<th>Rating</th>
<th>Risk</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Low</td>
<td>Negligible – little to no impact on patient safety.</td>
</tr>
<tr>
<td>3</td>
<td>Moderate</td>
<td>Tolerable level of risk with patient safety, no more risky than risk experienced in daily life.</td>
</tr>
<tr>
<td>2</td>
<td>High</td>
<td>Undesirable level of risk that potentially creates a dangerous situation that could affect patient safety.</td>
</tr>
<tr>
<td>1</td>
<td>Critical</td>
<td>Intolerable level of risk that creates a dangerous situation that adversely impacts patient safety.</td>
</tr>
</tbody>
</table>

Table 4: Risk Assessment Scale

Results

Data Analysis and Reporting

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

The usability study results for the EHRUT are detailed below (see Table 5). The results should be considered with the objectives and goals outlined in the Study Design section above. The data
provides actionable insights that, if corrected, could have a positive impact on user performance.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Task Success</th>
<th>Path Deviation</th>
<th>Task Time (in seconds)</th>
<th>Error s</th>
<th>Task Ratings</th>
<th>Risk Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>#</td>
<td>% of successful attempts</td>
<td>Deviations (Observed/Optimal)</td>
<td>Mean (SD)</td>
<td>Deviations (Observed/Optimal)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td><strong>Task</strong></td>
<td>N</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPOE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Create med order</td>
<td>5</td>
<td>100</td>
<td>1.0</td>
<td>15.6 (3.6)</td>
<td>1.0 (0.2)</td>
<td>0.0</td>
</tr>
<tr>
<td>2. View med order &amp; electronic prescribe</td>
<td>5</td>
<td>100</td>
<td>1.0</td>
<td>27.2 (7.9)</td>
<td>0.8 (0.2)</td>
<td>0.0</td>
</tr>
<tr>
<td>3. Edit med order</td>
<td>5</td>
<td>100</td>
<td>1.1</td>
<td>60.6 (16.4)</td>
<td>1.0 (0.3)</td>
<td>0.0</td>
</tr>
<tr>
<td>4. Order lab test</td>
<td>5</td>
<td>80</td>
<td>1.0</td>
<td>8.5 (0.5)</td>
<td>1.1 (0.1)</td>
<td>0.0</td>
</tr>
<tr>
<td>5. View &amp; change lab test</td>
<td>5</td>
<td>100</td>
<td>1.2</td>
<td>32.8 (4.9)</td>
<td>1.4 (0.2)</td>
<td>0.0</td>
</tr>
<tr>
<td>6. Order x-ray</td>
<td>5</td>
<td>100</td>
<td>1.0</td>
<td>9.2 (1.9)</td>
<td>1.0 (0.2)</td>
<td>0.0</td>
</tr>
<tr>
<td>7. View &amp; change x-ray</td>
<td>5</td>
<td>100</td>
<td>1.1</td>
<td>16.0 (2.2)</td>
<td>1.0 (0.1)</td>
<td>0.0</td>
</tr>
<tr>
<td><strong>Drug-Drug, Drug-Allergy Interaction Checks</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Adjust drug-drug interaction checking</td>
<td>5</td>
<td>20</td>
<td>1.1</td>
<td>13.5 (0.0)</td>
<td>1.1 (0.0)</td>
<td>1.0</td>
</tr>
<tr>
<td>2. Order med &amp; view drug-allergy interaction</td>
<td>5</td>
<td>100</td>
<td>1.0</td>
<td>12.6 (4.8)</td>
<td>0.8 (0.3)</td>
<td>0.0</td>
</tr>
<tr>
<td>3. Order med &amp; view drug-drug interaction</td>
<td>5</td>
<td>100</td>
<td>1.1</td>
<td>16.0 (1.5)</td>
<td>1.1 (0.1)</td>
<td>0.0</td>
</tr>
<tr>
<td><strong>Electronic Prescribing</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Create med order</td>
<td>5</td>
<td>100</td>
<td>1.0</td>
<td>15.6 (3.6)</td>
<td>1.0 (0.2)</td>
<td>0.0</td>
</tr>
<tr>
<td>2. View med order &amp; electronic prescribe</td>
<td>5</td>
<td>100</td>
<td>1.0</td>
<td>27.2 (7.9)</td>
<td>0.8 (0.2)</td>
<td>0.0</td>
</tr>
</tbody>
</table>

Table 5: Provider Summary Data
The results from the System Usability Scale scored the subjective satisfaction with the system based on performance with the tasks performed in the entire session to be 88.5. Common convention suggests that scores under 60 represent systems with poor usability; scores over 80 would be considered above average. Given the data findings related to effectiveness, efficiency, and satisfaction for the tasks evaluated, it is evident that the majority of the task areas do not require changes. Yet, some like the viewing and ordering of labs and x-rays features, could benefit from additional nice-to-have features that would enhance user satisfaction with the software. Further review around the editing of drug-drug interaction checks is recommended. Based on user comments and feedback, further investigation into alert fatigue that users feel when presented with drug-drug interaction, drug-allergy interaction, duplicate therapy, etc. warnings is warranted. Participants were more than or just as efficient as the optimal task time for all but three tasks. Of all the tasks that participants completed, there was only one task in which participants committed errors.

**Effectiveness**

The majority of the tasks were successfully completed 100% of the time by the provider participants except for ordering a lab test and adjusting a drug-drug interaction. When ordering a lab test, only 80% of the participants completed it successfully within the allotted time. The participant who failed to complete the task commented that the lab options available in the test environment were different than what is available in his current clinic layout. It should also be noted that the participant only failed the task by three seconds. The test environment consisted of the base software and what is installed at all clinics prior to any clinic customization. DocuTAP software is highly customizable down to the clinic level, so it is likely that no one clinic has the same lab options and/or layout. Only 20% of participants successfully completed the adjusting a drug-drug interaction task within the allotted time. The allotted time allowed for this task was 18 seconds. On average the participants took 34.3 seconds, which is nearly double the allotted time. All participants completed the task correctly, but the majority of them took longer to complete the task.

For the CPOE tasks, participants were able to effectively complete the tasks without many path deviations. The task with the most task deviations was viewing and changing a lab test. Three of five participants reviewed the patient’s lab history prior to viewing the labs page and changing the lab. Minor task deviations were observed for the drug-drug, drug-allergy interaction check tasks. No path deviations were observed for the electronic prescribing tasks.

Of all the tasks that participants completed, there was only one task in which participants committed errors. All but one participant made errors when completing the adjusting the drug-drug interaction check task. The most common error was after searching for a specific drug the participant did not select the desired drug from the list of search results. This caused an error message to be generated when the participants attempted to save their changes.

**Efficiency**

Participants were more than or just as efficient as the optimal task time for the majority of the tasks. The tasks where participants were not as efficient include viewing and changing a lab test, adjusting drug-drug interaction checking, and viewing the drug-drug interaction. When viewing
and changing a lab test, many of the participants viewed the additional lab history page, which was not necessary for viewing current lab orders.

Editing a medication and viewing a drug-allergy interaction tasks had the most variation when it came to task times. The variation is most likely due to the variety of paths that can be taken to complete the tasks correctly.

**Satisfaction**

Each participant completed the SUS at the end of their session and, on average, the SUS was 88.5. This score is considered above average. In addition, each of the provider scores were above average ranging from 75 to 100. Previous research utilizing the SUS dictates that the average SUS score is 68.

The tasks were, in general, rated as being easy to complete. The lowest rated tasks at 4.4 were viewing and changing both a lab and x-ray order. They also had the most variance in the ratings from three to five on a five-point scale with five equating to very easy. The highest rated task was ordering a medication and viewing the drug-allergy interaction check with a perfect rating of 5.

**Major Findings**

When evaluating the effectiveness, efficiency, and satisfaction of the tasks, it is evident that the majority of the task areas do not need much for changes. Yet, some like the viewing and ordering of labs and x-rays features, could benefit from additional nice-to-have features that would create even more user satisfaction with the software.

Additionally, considering only 20% of the participants in the study completed the drug-drug interaction check task within the allotted time and that it is considered a task that is high-risk, this feature should be reviewed. The time in which it takes to complete the task and how often it is completed should be analyzed and compared with how frequently this option is completed. Each install of the DocuTAP software includes the complete list of drug-drug interactions from the drug database. Clinics have the ability to go in to add and adjust any current drug-drug interaction check and it needs to be determined how frequently this option is completed. Editing a drug-drug interaction incorrectly, could potentially create a dangerous situation that could affect patient safety.

Participants were more than or just as efficient as the optimal task time for all but three tasks. The tasks where participants were not as efficient include viewing and changing a lab test, adjusting drug-drug interaction checking, and viewing the drug-drug interaction.

Of all the tasks that participants completed, there was only one task in which participants committed errors. All but one participant made errors when completing the adjusting the drug-drug interaction check task.

In general, participants commented that the overall prescription process is easy to do within the software. They were excited to see the new electronic prescribing process. They commented that it appears it will provide great time savings. Some were even asking if the transition to the new process could happen faster for their clinics.
Areas for Improvement

Additional research and usability studies should be considered around editing drug-drug interaction checks, and viewing and ordering labs and x-rays. Further research to determine how frequently clinics are updating the drug-drug checks and user studies could provide guidance on how to best make the changes to make it easier and faster for users to complete the task.

Participants were happy with the labs and organization of the software, but would like more flexibility in how items are arranged under labs. A couple participants mentioned that it would be nice to have labs that are most ordered to be grouped together. Further, labs that are similar could be organized together. For example, when ordering individual thyroid labs like TSH or T4, they could be next to each other rather than appearing in a list organized alphabetically. Participants perceived that it takes longer to search through the alphabetized list than it would if the labs were organized by similarity.

Depending on a clinic’s workflow, some may require that lab and x-ray requests be sent via an HL7 message to both internal and external labs. The user must then select the lab(s) and then click a “Send Lab Request” or “Send X-ray Request” button. Some of the participants mentioned that they forget to click this button. They would like to see it closer to the lab name itself or in a different location on the page rather than the bottom. Participants also mentioned that it would be beneficial to be able to cancel a lab by utilizing a cancel button instead of having to contact the lab.

Several participants commented that they suffered from alert fatigue related to all of the drug-drug interaction messages. Due to the number of drug-drug interactions that can pop-up, participants admit that they begin to ignore them. The disregard the participants have for these warnings can and will lead to them missing important warning information. One participant even admitted that he completely ignores them and relies on his Epocrates app on his smartphone and his own judgment. A related issue is that the pop-ups for drug-drug interaction, drug-allergy interaction, duplicate therapy, etc. all have the same aesthetic appearance. Participants commented that it’s easy to overlook something like an allergy because it doesn’t stick out. Some even admitted that they have mistakenly clicked through it.

When prescribing, participants commented that it can be difficult, at times, to find a new medication. The brand name may be missing from the list, but the generic name will be available. Some admitted that it’s difficult to recall the generic names if they don’t use them frequently. They refer to other resources like the internet or other medical apps to obtain the generic name.

Many participants complained that when creating a prescription they always have to select the method in which the prescription should be taken. The majority of the medications prescribed in urgent cares are taken orally. Participants would like to see oral set as the default option or have it appear higher in the list of options. Currently, the list of options is in alphabetical order. Further studies in to the options would provide information on how to best resolve this issue.
Chapter 2: Provider Study B

Executive Summary

A remote usability study of the DocuTAP software, version 5.1 was conducted via remote sessions in April 2014 by DocuTAP’s User-Centered Design (UCD) Team. The purpose of the study was to test and validate the usability of the current user interface (UI) and provide evidence of usability in the EHR Under Test (EHRUT). During the usability study, five healthcare providers (e.g., MD, PA) matching the target demographic criteria served as participants and used the EHRUT in simulated, but representative tasks.

The study collected performance data on several tasks. The tasks include:

- **Clinical Decision Support (314.a.8)**
  - Configure and activate new alert
  - Open patient record and view patient alerts for age and problem list; and vitals
  - Open med list to view patient alerts based on lab tests/results and medication list; and med allergy
  - Review diagnostic and therapeutic reference for lab tests/results
- **Clinical Information Reconciliation (314.b.4)**
  - Open received record and reconcile active med list
  - Reconcile active problem list
  - Reconcile active med allergy list

During the forty-five minute one-on-one remote usability session, each participant was greeted by the moderator. An informed consent document (included in Appendix B) was reviewed and participants were informed that they could withdraw at any time. All participants had prior experience with the EHRUT. The moderator introduced the study and instructed participants to complete a series of tasks, given one at a time, using the EHRUT. During the testing session, the moderator timed the test and recorded user performance data on paper and electronically. The moderator did not give the participants assistance in how to complete the tasks. Participant screens and audio were recorded for subsequent analysis.

The following types of data were collected for each participant:

- Number of tasks successfully completed within the allotted time without assistance
- Ease in which task was completed (e.g., easily completed, completed with difficulty)
- Time on task
- Perceived difficulty of task on 5-point Likert scale
- Number and types of errors
- Path deviations
- Participant’s comments
- Participant’s satisfaction ratings of the system (i.e., System Usability Scale (SUS) ratings)

All participant data was de-identified – no correspondence could be made from the identity of the participant to the collected data. Following the conclusion of the testing, participants were asked to complete a post-test questionnaire and were compensated with an American Express gift card for their time. Various recommended metrics, in accordance with the examples set forth in the NIST Guide to the Process Approach for Improving Usability of Electronic Health
Records were used to evaluate the usability of the EHRUT. Following is a summary of the performance and rating data collected for the Provider tasks on the EHRUT.

<table>
<thead>
<tr>
<th>Measure</th>
<th>N</th>
<th>Task Success</th>
<th>Path Deviation</th>
<th>Task Time (in seconds)</th>
<th>Errors</th>
<th>Task Ratings</th>
<th>Risk Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>#</td>
<td>% of successful attempts</td>
<td>Deviations (Observed / Optimal)</td>
<td>Mean (SD)</td>
<td>Deviations (Observed / Optimal)</td>
<td>Mean</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Task</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Configure &amp; active new alert</td>
<td>5</td>
<td>20</td>
<td>1.1</td>
<td>81.0 (0.0)</td>
<td>1.5 (0.0)</td>
<td>2.2</td>
<td>3.8 (0.4)</td>
</tr>
<tr>
<td>2. Open patient record &amp; view patient alerts for age &amp; problem list; &amp; vitals</td>
<td>5</td>
<td>100</td>
<td>1.0</td>
<td>10.4 (0.5)</td>
<td>1.0 (0.0)</td>
<td>0.0</td>
<td>5 (0.0)</td>
</tr>
<tr>
<td>3. Open med list to view patient alerts based on lab tests/results &amp; medication list; &amp; med allergy</td>
<td>5</td>
<td>100</td>
<td>1.0</td>
<td>5.0 (0.0)</td>
<td>1.0 (0.0)</td>
<td>0.0</td>
<td>5 (0.0)</td>
</tr>
<tr>
<td>4. Review diagnostic &amp; therapeutic reference for lab tests/results</td>
<td>5</td>
<td>100</td>
<td>1.0</td>
<td>5.0 (0.0)</td>
<td>1.0 (0.0)</td>
<td>0.0</td>
<td>5 (0.0)</td>
</tr>
</tbody>
</table>

**Clinical Decision Support**

<table>
<thead>
<tr>
<th>Task</th>
<th>N</th>
<th>Task Success</th>
<th>Path Deviation</th>
<th>Task Time (in seconds)</th>
<th>Errors</th>
<th>Task Ratings</th>
<th>Risk Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>#</td>
<td>% of successful attempts</td>
<td>Deviations (Observed / Optimal)</td>
<td>Mean (SD)</td>
<td>Deviations (Observed / Optimal)</td>
<td>Mean</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Configure &amp; active new alert</td>
<td>5</td>
<td>20</td>
<td>1.1</td>
<td>81.0 (0.0)</td>
<td>1.5 (0.0)</td>
<td>2.2</td>
<td>3.8 (0.4)</td>
</tr>
<tr>
<td>2. Open patient record &amp; view patient alerts for age &amp; problem list; &amp; vitals</td>
<td>5</td>
<td>100</td>
<td>1.0</td>
<td>10.4 (0.5)</td>
<td>1.0 (0.0)</td>
<td>0.0</td>
<td>5 (0.0)</td>
</tr>
<tr>
<td>3. Open med list to view patient alerts based on lab tests/results &amp; medication list; &amp; med allergy</td>
<td>5</td>
<td>100</td>
<td>1.0</td>
<td>5.0 (0.0)</td>
<td>1.0 (0.0)</td>
<td>0.0</td>
<td>5 (0.0)</td>
</tr>
<tr>
<td>4. Review diagnostic &amp; therapeutic reference for lab tests/results</td>
<td>5</td>
<td>100</td>
<td>1.0</td>
<td>5.0 (0.0)</td>
<td>1.0 (0.0)</td>
<td>0.0</td>
<td>5 (0.0)</td>
</tr>
</tbody>
</table>

**Clinical Information Reconciliation**

<table>
<thead>
<tr>
<th>Task</th>
<th>N</th>
<th>Task Success</th>
<th>Path Deviation</th>
<th>Task Time (in seconds)</th>
<th>Errors</th>
<th>Task Ratings</th>
<th>Risk Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>#</td>
<td>% of successful attempts</td>
<td>Deviations (Observed / Optimal)</td>
<td>Mean (SD)</td>
<td>Deviations (Observed / Optimal)</td>
<td>Mean</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Open received record &amp; reconcile med list</td>
<td>5</td>
<td>60</td>
<td>1.2</td>
<td>4.2 (0.4)</td>
<td>0.9 (0.1)</td>
<td>0.4</td>
<td>5 (0.0)</td>
</tr>
<tr>
<td>2. Reconcile problem list</td>
<td>5</td>
<td>80</td>
<td>1</td>
<td>11.3 (0.4)</td>
<td>1.3 (0.0)</td>
<td>0.0</td>
<td>5 (0.0)</td>
</tr>
<tr>
<td>3. Reconcile med allergy list</td>
<td>5</td>
<td>100</td>
<td>1</td>
<td>17.4 (2.2)</td>
<td>1.3 (0.2)</td>
<td>0.0</td>
<td>5 (0.0)</td>
</tr>
</tbody>
</table>

**Table 6: Provider Summary Data**

The results from the System Usability Scale scored the subjective satisfaction with the system based on performance with the tasks performed in the entire session to be: 83. Common convention suggests that scores under 60 represent systems with poor usability; scores over 80 would be considered above average.
Major Findings

In addition to the performance data, the following qualitative observations were made:

When evaluating the effectiveness, efficiency, and satisfaction of the tasks, it is evident that the majority of the task areas do not need much for changes. However, the alert creation task should be reviewed and could benefit from clarification. Considerations on how to create a new alert versus edit an existing alert should be made. It was easy for participants to attempt to overwrite an existing alert and realize their mistake later in the process. At that point they have to start over with the new alert.

It is a positive finding that the tasks rated higher on the risk rating scale, reconciling medication and medication allergy lists, were all completed successfully. The only task failure was due to taking longer than the optimal task time.

Participants were efficient or nearly efficient at completing the tasks other than for the alert creation task. Only one participant could complete the task within the time allotted.

Errors were made while completing the alerts creation task and the medication reconciliation task. Most participants attempted to overwrite and existing alert rather than creating a new one. In the medication reconciliation task, a participant cancelled out of matching up prescriptions rather than completing the step.

Overall, participants were happy with both features. Some participants did have negative comments about alert creation even though they liked the idea of having clinic-wide notifications. Many were excited about the reconciliation process and ecstatic that they could do this electronically rather than attempt to review scanned or faxed documents.

Areas for improvement

Additional research and considerations should be made around the alert creation process. More in-depth training and understanding by users would be also helpful. Further research into how many clinics utilize the alerts feature and how often they create alerts could provide guidance on how to best make the changes to make it easier and faster for users to complete the task. One other item for consideration is for the system to recognize a brand name and automatically include the generics when creating an alert, however, further research into feasibility and safety of this needs to be completed. Participants also mentioned they would appreciate the ability to access the alerts creation screen from both the Practice Management and Electronic Medical Record applications.

Introduction

The EHRUT tested for this study was DocuTAP version 5.1. Designed to present medical information to the healthcare providers in Urgent Care Clinics, the EHRUT consists of an EHR where clinic staff can document and review an entire visit from start-to-finish. The usability study attempted to represent realistic exercises and conditions.

The purpose of this study was to test and validate the usability of the current UI, and provide evidence of usability in the EHRUT. Measures of effectiveness, efficiency, and user satisfaction (e.g., time on task, number of steps to complete task) were captured during the sessions.
Method

Participants

A total of five participants were tested on the EHRUT. Participants in the study were providers (e.g., medical doctor, physician assistant). Participants were recruited by DocuTAP’s UCD Team and were compensated with American Express gift cards for their time. All were existing users of the DocuTAP software. In addition, participants had no direct connection to the development of the EHRUT nor were participants employees of DocuTAP.

Recruited participants had a mix of backgrounds and demographic characteristics conforming to standard research methods and principles. The following is a table of participants by characteristics, including demographics, professional experience, and computing experience. Participant names were replaced with Participant IDs so that an individual’s data cannot be linked back to the individual identities.

<table>
<thead>
<tr>
<th>ID</th>
<th>Gender</th>
<th>Highest Level of Education</th>
<th>Current Occupation/Role</th>
<th>Professional Experience in Current Role (years)</th>
<th>Experience with EHR Technology (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F</td>
<td>PA</td>
<td>Physician Assistant</td>
<td>0.8</td>
<td>10</td>
</tr>
<tr>
<td>2</td>
<td>F</td>
<td>NP</td>
<td>Nurse Practitioner</td>
<td>1.5</td>
<td>6</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>MD</td>
<td>Staff Physician</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>4</td>
<td>F</td>
<td>PA</td>
<td>Physician Assistant</td>
<td>3.5</td>
<td>5</td>
</tr>
<tr>
<td>5</td>
<td>F</td>
<td>NP</td>
<td>Nurse Practitioner</td>
<td>13</td>
<td>7</td>
</tr>
</tbody>
</table>

Table 7: Provider Participant Demographic Data

Five participants were recruited and five participated in the usability study.

Participants were scheduled for one hour sessions with at least 30 minutes between each session for debrief by the administrator, and to reset the systems to proper test conditions. A spreadsheet was used to track the participant recruitment and schedule.

Study Design

Overall, the objective of the study was to uncover areas where the application performed well (i.e., effectively, efficiently, and with satisfaction) and areas where the application failed to meet the needs of the participants. The data from this study may serve as a baseline for future studies with an updated version of the same EHR and/or comparison with other EHRs provided the same tasks are used. In short, this study serves as both a means to record or benchmark current usability, but to also identify areas where improvements must be made.

During the usability study, participants interacted with the EHR. Each participant used the same system in his or her remote clinic or home location, and was provided the same instructions. The system was evaluated 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
- Ease in which task was completed (e.g., easily completed, completed with difficulty)
- Time on task
Safety-Enhanced Design Summative Usability Testing Report

- Perceived difficulty of task on 5-point Likert scale
- Number and types of errors
- Path deviations
- Participant's comments
- Participant's satisfaction ratings of the system (i.e., System Usability Scale (SUS) ratings)

Additional information about the various measures can be found in the section for Usability Metrics below.

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. The tasks include:

Clinical Decision Support
1. Configure and activate new alert
2. Open patient record and view patient alerts for age and problem list; and vitals
3. Open med list to view patient alerts based on lab tests/results and medication list; and med allergy
4. Review diagnostic and therapeutic reference for lab tests/results

Clinical Information Reconciliation
1. Open received record and reconcile active med list
2. Reconcile active problem list
3. Reconcile active med allergy list

Tasks were selected based on their frequency of use, criticality of function, and those that may be most troublesome for users.

Procedure
Upon arrival, participants were greeted and their identity verified with the participant schedule. Participants were then assigned a random participant ID. Each participant reviewed and verbally consented to the consent form (see Appendix B). The verbal consent was recorded and witnessed by the test team.

To ensure the session ran smoothly, an experienced usability administrator facilitated the study. The usability administrator has seven years of experience and a master's degree in Human Factors Psychology.

The administrator moderated the session including providing instructions and tasks. The administrator also monitored task times, obtained post-task rating data, and took notes on participant comments. The sessions were recorded to review and compute additional findings (e.g., task success, path deviations, etc.).

Participants were instructed to perform the tasks (see specific instructions below):
- As they normally would and as quickly as possible
- Without assistance; administrator could provide clarification, but not instruction
For each task, task timing began once the administrator finished reading the question. The task time stopped once the participant indicated they had successfully completed the task. Scoring is discussed in the Data Scoring section below.

Following the session, the administrator gave the participant the post-test questionnaire (i.e., System Usability Scale, see Appendix F), requested their mailing address to send compensation, and thanked them for their time and participation.

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

Test Location
The test facility consisted of the administrator’s computer workstation and the participants’ personal workstations at home or clinic, as the study was completed remotely. Only the administrator and the participant were connected to the remote session.

Test Environment
The EHRUT would be typically used in an urgent care clinic. In this instance, testing was conducted either in participants’ homes or clinics. For testing, the moderator and participant connected via GoToMeeting software. The participants used a mouse and keyboard to interact with the EHRUT.

The EMR was set up by the test team according to new installation documentation. The application itself was running in a Citrix environment using a test database on a LAN connection. Technically, the system performance (i.e., response time) was representative to what actual users would experience in a field implementation. Additionally, participants were instructed not to change any of the default system settings.

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

1. Informed Consent Form
2. Moderator’s Guide – Provider Study B
3. System Usability Scale (SUS)

Examples of these documents can be found in Appendices Appendix B, Appendix C, and Appendix F, respectively. The Moderator’s Guide was devised so as to be able to capture required data.

The participant’s interaction with the EHRUT and verbal comments were recorded digitally with GoToMeeting software running on the moderator’s test machine.

Participant Instructions
The administrator read the following instructions to each of the participants (full moderator’s guide is available in Appendix D):

Thank you for helping us with this study. Our session today will last approximately one hour. We are conducting research around patient alerts and reconciling. I will ask you to
perform a few tasks. I want you to use the software like you normally would and then I will ask you some specific questions around your experience today.

When designing software, there are always so many ideas about how it should look and work. Today, you are going to help us review prescribing and ordering labs and X-rays. I want you to work through the tasks like you normally would and try to complete them as quickly as possible without rushing. I will not be able to assist you with the tasks, but I can provide you more clarification if you need it. At the end of each task, I will ask you some questions about what you completed. Please feel free to share any thoughts or feelings you have about the features of the software – positive or negative. All of the feedback you share is important and very helpful to me. I did not have any involvement in the creation, so please be honest with your opinions.

I want to emphasize that we are not evaluating you, we are evaluating the software. We will record the session. All recordings will be kept strictly confidential. We may use footage to share with our developers and/or management the experience you have to help highlight both positive findings and areas for improvement. It also helps so that I don’t have to take as many notes during this session.

Following the procedural instructions, participants were asked a few pre-study questions for demographic information (e.g., age, degree, experience with EHRs and computers). Once this was complete, the administrator gave the following instructions:

For each task, I will read the description and say “Begin.” At that point, please start the task and say, “Done,” once you believe you have successfully completed the task. I want you to complete the task like you normally would and as quickly as possible. Please refrain from proving your thoughts and comments until you complete the task. I will ask your impressions about the task once you are done.

Participants were then given seven tasks to complete. Tasks are listed in the moderator’s guide in Appendix D.

**Usability Metrics**

According to the NIST Guide to the Process 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 of DocuTAP EMR by measuring participant success rates and errors
2. Efficiency of DocuTAP EMR by measuring average task time and path deviations
3. Satisfaction with DocuTAP EMR by measuring ease of use ratings

**Data Scoring**

The following table (Table 8) details how tasks were scored, errors evaluated, and time data analyzed.
<table>
<thead>
<tr>
<th>Measures</th>
<th>Rationale and Scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Effectiveness:</strong></td>
<td><em>Task Success</em></td>
</tr>
<tr>
<td></td>
<td>A task was counted as a “Success” if the participant was able to achieve the correct outcome, without any assistance, within the time allotted on a per task basis. The total number of successes were calculated for each task and then divided by the total number of times the task was attempted. The results are provided as a percentage. Task times were recorded for successes. Observed task times divided by the optimal time for each task is a measure of optimal efficiency. Optimal task performance time, as benchmarked by expert performance under realistic conditions, was recorded when constructing the tasks. Target task times used for task times in the Moderator's Guide were defined by taking multiple measurements of the optimal performance and multiplying it by 1.5 which allows some time buffer because participants were not trained to expert performance. Therefore, if expert optimal performance on a task was 60 seconds, then allotted task time performance was [ 60 \times 1.5 = 90 ] seconds. This ratio was aggregated across tasks and reported with both mean and variance scores.</td>
</tr>
<tr>
<td><strong>Effectiveness:</strong></td>
<td><em>Task Failures</em></td>
</tr>
<tr>
<td></td>
<td>If the participant abandoned the task, did not reach the correct answer, performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as a “Failure.” The total number of errors was calculated for each task and then divided by the total number of times the task was attempted. Not all deviations were counted as errors. This is the mean number of failed tasks per participant. A count of errors and error types was collected.</td>
</tr>
<tr>
<td><strong>Efficiency:</strong></td>
<td><em>Task Deviations</em></td>
</tr>
<tr>
<td></td>
<td>The participant’s path through the EHR was recorded. Deviations occur if the participant, for instance, went to a wrong screen or clicked on an incorrect menu item. This path was compared with the optimal path. The number of steps in the observed path was divided by the number of optimal steps to provide a ratio of path deviation. Optimal paths were recorded during task development.</td>
</tr>
<tr>
<td><strong>Efficiency:</strong></td>
<td><em>Task Time</em></td>
</tr>
<tr>
<td></td>
<td>Each task was timed from when the administrator said “Begin.” until the participant said, “Done.” If a participant failed to say, “Done,” the time was stopped when the participant stopped performing the task. Only task times for tasks that were successfully completed were included in the average task time analysis. Average task time was completed for each task. Variance measures (standard deviation and standard error) were also calculated.</td>
</tr>
<tr>
<td><strong>Satisfaction:</strong></td>
<td><em>Task Rating</em></td>
</tr>
<tr>
<td></td>
<td>Participants' subjective impression of the ease of use of the EHR was measured by administering both a simple post-task question as well as a post-session questionnaire. After each task, the participant was asked to rate “How would you rate [task] on a scale from 1 (very difficult) to 5 (very easy). These scores were averaged across participants. According to common convention, system that are judged to be easy to use are rated 3.3 or above. To measure participants' confidence in and likeability of the DocuTAP EHR overall, the testing team administered the System Usability Scale (SUS) post-</td>
</tr>
</tbody>
</table>
session questionnaire. See Appendix F for the full questionnaire.

Table 8: Details of How Observed Data Were Scored

The following table (Table 9) details the four-point risk assessment scale utilized.

<table>
<thead>
<tr>
<th>Rating</th>
<th>Risk</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Low</td>
<td>Negligible – little to no impact on patient safety.</td>
</tr>
<tr>
<td>3</td>
<td>Moderate</td>
<td>Tolerable level of risk with patient safety, no more risky than risk experienced in daily life.</td>
</tr>
<tr>
<td>2</td>
<td>High</td>
<td>Undesirable level of risk that potentially creates a dangerous situation that could affect patient safety.</td>
</tr>
<tr>
<td>1</td>
<td>Critical</td>
<td>Intolerable level of risk that creates a dangerous situation that adversely impacts patient safety.</td>
</tr>
</tbody>
</table>

Table 9: Risk Assessment Scale

Results

Data Analysis and Reporting

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

The usability study results for the EHRUT are detailed below (see Table 10). The results should be considered with the objectives and goals outlined in the Study Design section above. The data provides actionable insights that, if corrected, could have a positive impact on user performance.

<table>
<thead>
<tr>
<th>Measure</th>
<th>N</th>
<th>Task Success</th>
<th>Path Deviation</th>
<th>Task Time (in seconds)</th>
<th>Errors</th>
<th>Task Ratings</th>
<th>Risk Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Task</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4 = Low</td>
</tr>
<tr>
<td></td>
<td>#</td>
<td>% of successful attempts</td>
<td>Deviations (Observed / Optimal)</td>
<td>Mean (SD)</td>
<td>Deviations (Observed / Optimal)</td>
<td>Mean</td>
<td>Mean (SD)</td>
</tr>
</tbody>
</table>

Clinical Decision Support

1. Configure & active new alert
   - N: 5
   - % of successful attempts: 20
   - Path Deviation: 1.1
   - Task Time (in seconds): 81.0 (0.0)
   - Errors: 1.5 (0.0)
   - Task Ratings: 3.8 (0.4)
   - Risk Rating: 3

2. Open patient record & view patient alerts for age & problem list; & vitals
   - N: 5
   - % of successful attempts: 100
   - Path Deviation: 1.0
   - Task Time (in seconds): 10.4 (0.5)
   - Errors: 1.0 (0.0)
   - Task Ratings: 5 (0.0)
   - Risk Rating: 4
### Table 10: Provider Summary Data

The results from the System Usability Scale scored the subjective satisfaction with the system based on performance with the tasks performed in the entire session to be 83. Common convention suggests that scores under 60 represent systems with poor usability; scores over 80 would be considered above average. Give the data findings related to effectiveness, efficiency, and satisfaction for the tasks evaluated, it is evident that the majority of the tasks do not require changes. Yet, the alerts creation task could benefit from additional research as well as more in-depth training for users. Participants were efficient or nearly efficient at completing the tasks other than for the alert creation task. Only one participant could complete the task within the time allotted. Errors were made with the alerts creation task and medication reconciliation task.

### Effectiveness

All of the Clinical Decision Support tasks were competed successfully 100% of the time except the task that required participants to create a new alert. The majority of the participants failed to select the new alert button and tried to overwrite the existing alert selected. This caused many to fail the task because they exceeded the time limit. All participants needed assistance with this task. The alert creation task was the only task where participants committed errors.

The majority of the Clinical Information Reconciliation tasks were completed successfully more than 60% of the time. When opening a record to reconcile and reconciling the medication list and the problem list, participants struggled with taking longer than the optimal time. Yet, they could all complete the tasks. An error was made when reconciling the medication list when the

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The table above shows the results for each task, including the number of participants, the percentage of successful completions, and the completion time. The tasks are categorized into three sections: Open med list to view patient alerts based on lab tests/results & medication list; & med allergy, Review diagnostic & therapeutic reference for lab tests/results, and Clinical information reconciliation. The results indicate that the tasks related to medication and allergy lists have lower success rates and longer completion times compared to the diagnostic and therapeutic reference section.
participant cancelled out of the screen instead of completing the prescription matching process.

**Efficiency**

Participants were just as efficient as the optimal task time for all of the Clinical Decision Support tasks except the alert creation task. Many participants made the error of attempting to overwrite and existing alert rather than following the new alert process.

The Clinical Information Reconciliation tasks had varied efficiencies where reconciling the problem and medication allergies list took slightly longer and the reconciling medications was slightly shorter.

**Satisfaction**

Each participant completed the SUS at the end of their session and, on average, the SUS was 83. This score is considered above average. In addition, each of the provider scores were above average ranging from 70 to 95. Previous research utilizing the SUS dictates that the average SUS score is 68.

All of the tasks, in general, were rated as being easy to complete (5.0 where 5 = very easy) excluding the alert creation task. This task was rated as being moderately easy at 3.8 with a variance of 0.4.

**Major Findings**

When evaluating the effectiveness, efficiency, and satisfaction of the tasks, it is evident that the majority of the task areas do not need much for changes. However, the alert creation task should be reviewed and could benefit from clarification. Considerations on how to create a new alert versus edit an existing alert should be made. It was easy for participants to attempt to overwrite an existing alert and realize their mistake later in the process. At that point they have to start over with the new alert.

It is a positive finding that the tasks rated higher on the risk rating scale, reconciling medication and medication allergy lists, were all completed successfully. The only task failure was due to taking longer than the optimal task time.

Participants were efficient or nearly efficient at completing the tasks other than for the alert creation task. Only one participant could complete the task within the time allotted.

Errors were made while completing the alerts creation task and the medication reconciliation task. Most participants attempted to overwrite and existing alert rather than creating a new one. In the medication reconciliation task, a participant cancelled out of matching up prescriptions rather than completing the step.

Overall, participants were happy with both features. Some participants did have negative comments about alert creation even though they liked the idea of having clinic-wide notifications. Many were excited about the reconciliation process and ecstatic that they could do this electronically rather than attempt to review scanned or faxed documents.
Areas for Improvement

Additional research and considerations should be made around the alert creation process. More in-depth training and understanding by users would be also helpful. Further research into how many clinics utilize the alerts feature and how often they create alerts could provide guidance on how to best make the changes to make it easier and faster for users to complete the task. One other item for consideration is for the system to recognize a brand name and automatically include the generics when creating an alert, however, further research into feasibility and safety of this needs to be completed. Participants also mentioned they would appreciate the ability to access the alerts creation screen from both the Practice Management and Electronic Medical Record applications.
Chapter 3: Medical Assistant Study

Executive Summary

A remote usability study of the DocuTAP software, version 4.1, was conducted via remote sessions between October 2013 and November 2013 by DocuTAP’s User-Centered Design (UCD) Team. The purpose of this study was to test and validate the usability of the current user interface (UI) and provide evidence of usability in the EHR Under Test (EHRUT). During the usability study, five medical assistants matching the target demographic criteria served as participants and used the EHRUT in simulated, but representative tasks.

The study collected performance data on several tasks. The tasks include:

- Medication List (314.a.6)
  - Record patient active medication list
  - Access and change patient active medication list
- Medication Allergy List (314.a.7)
  - Record patient active medication allergy list
  - Access and change patient active medication allergy list

During the 45 minute one-on-one remote usability session, each participant was greeted by the moderator. An informed consent document (included in Appendix B) was reviewed and participants were informed that they could withdraw at any time. All participants had prior experience with the EHRUT. The moderator introduced the study and instructed participants to complete a series of tasks, given one at a time, using the EHRUT. During the testing session, the moderator timed the test and recorded user performance data on paper and electronically. The moderator did not give the participants assistance in how to complete the tasks. Participant screens and audio were recorded for subsequent analysis.

The following types of data were collected for each participant:

- Number of tasks successfully completed within the allotted time without assistance
- Ease in which task was completed (e.g., easily completed, completed with difficulty)
- Time on task
- Perceived difficulty of task on 5-point Likert scale
- Number and types of errors
- Path deviations
- Participant’s comments
- Participant’s satisfaction ratings of the system (i.e., System Usability Scale (SUS) ratings)

All participant data was de-identified – no correspondence could be made from the identity of the participant to the collected data. Following the conclusion of the testing, participants were asked to complete a post-test questionnaire and were compensated with an American Express gift card for their time. Various recommended metrics, in accordance with the examples set forth in the NIST Guide to the Process Approach for Improving Usability of Electronic Health Records, were used to evaluate the usability of the EHRUT. Following is a summary of the performance and rating data collected on the EHRUT.
Safety-Enhanced Design Summative Usability Testing Report

<table>
<thead>
<tr>
<th>Success</th>
<th>Deviation</th>
<th>Ratings</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>#</td>
<td>% of successful attempts</td>
<td>Deviations (Observed / Optimal)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Medication List</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Record med list</td>
<td>5</td>
<td>100</td>
<td>1.0</td>
</tr>
<tr>
<td>2. Access &amp; change med list</td>
<td>5</td>
<td>83</td>
<td>1.1</td>
</tr>
<tr>
<td>Medication Allergy List</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Record med allergy list</td>
<td>5</td>
<td>40</td>
<td>1.0</td>
</tr>
<tr>
<td>2. Access &amp; change med allergy list</td>
<td>5</td>
<td>60</td>
<td>1.1</td>
</tr>
</tbody>
</table>

Table 11: Medical Assistant Summary Data

The results from the System Usability Scale scored the subjective satisfaction with the system based on performance with the tasks performed in the entire session to be: 88. Common convention suggests that scores under 60 represent systems with poor usability; scores over 80 would be considered above average.

**Major Findings**

In addition to the performance data, the following qualitative observations were made:

After evaluating the effectiveness, efficiency, and satisfaction with the medication list tasks, it is apparent that there is not much need for changes or further research. Some self-reported nice-to-have features from the participants could create more user satisfaction with the software. However, it is apparent that there is a need for further research and adjustment to recording medication allergies. Further investigation on how to reduce task time would be beneficial and increase user satisfaction.

Participants were effective in completing the medication list tasks and only one participant made the minor error of adding a step when completing the accessing and changing a medication list. They were also extremely satisfied with the features and functionality of this portion of the software. They appreciated having the search functionality and the ease of moving medications from active to inactive lists.

Participants could complete both medication allergy list tasks, but not as effectively or efficiently as they could. There were longer task times and errors associated with the recording patient medication allergy task. Given this, participants were still satisfied with the software and rated the tasks as being very easy to complete.
Areas for improvement

For the medication list tasks, the only area for improvement is based on participant feedback from the study. Participants stated that it would be nice to be able to put in a type of drug and report that a patient is taking it, but that the patient can’t remember which medication they are taking. For example, a patient may know that she’s taking a birth control pill, but doesn’t remember the exact medication.

The biggest area for improvement related to the medication allergy list tasks is around recording medication allergies and the amount of time it takes to record. Participants like the speed with which they can record medications to the medication list and expect the same for recording medication allergies.

Participants commented that at their clinic it can take a long time for the medication allergy list to generate. When selecting the Drugs option, they will click it again thinking that they may not have selected it which then delays the list from being displayed even longer. The other feature that patients would like to see is an easier way to edit/add reactions to an allergy once they leave the screen and come back to it. For instance, they may record that the patient is allergic to penicillin, leave the screen to record a blood pressure and then come back to the allergy screen to record the reaction to penicillin. Participants would like to be able to select the allergy from the list and have the reactions appear in the selection window below instead of the current process.

Introduction

The EHRUT tested for this study was DocuTAP version 4.1. Designed to present medical information to the healthcare providers in Urgent Care Clinics, the EHRUT consists of an EMR where clinic staff can document and review an entire visit from start-to-finish. The usability study attempted to represent realistic exercises and conditions.

The purpose of this study was to test and validate the usability of the current UI, and provide evidence of usability in the EHRUT. Measures of effectiveness, efficiency, and user satisfaction (e.g., time on task, number of steps to complete task) were captured during the sessions.

Method

Participants

A total of five participants were tested on the EHRUT. Participants in the studies were medical assistants. Participants were recruited by DocuTAP’s UCD Team and were compensated with American Express gift cards for their time. All were existing users of the DocuTAP software. In addition, participants had no direct connection to the development of the EHRUT nor were participants employees of DocuTAP.

Recruited participants had a mix of backgrounds and demographic characteristics conforming to standard research methods and principles. The following is a table of participants by characteristics, including demographics, professional experience, and computing experience. Participant names were replaced with Participant IDs so that an individual’s data cannot be linked back to the individual identities.
Six participants were recruited and 5 participated in the usability study. One participant was on the waitlist to participate if someone failed to participate.

Participants were scheduled for 45-minute sessions with at least 30 minutes between each session for debrief by the administrator, and to reset the systems to proper test conditions. A spreadsheet was used to track the participant recruitment and schedule.

**Study Design**

Overall, the objective of the study was to uncover areas where the application performed well (i.e., effectively, efficiently, and with satisfaction) and areas where the application failed to meet the needs of the participants. The data from this study may serve as a baseline for future studies with an updated version of the same EHR and/or comparison with other EHRs provided the same tasks are used. In short, this study serves as both a means to record or benchmark current usability, but to also identify areas where improvements must be made.

During the usability study, participants interacted with the EHR. Each participant used the same system in his or her remote clinic location, and was provided the same instructions. The system was evaluated 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
- Ease in which task was completed (e.g., easily completed, completed with difficulty)
- Time on task
- Perceived difficulty of task on 5-point Likert scale
- Number and types of errors
- Path deviations
- Participant’s comments
- Participant’s satisfaction ratings of the system (i.e., System Usability Scale (SUS) ratings)

Additional information about the various measures can be found in the section for Usability Metrics below.
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:

Medication List
1. Record patient active med list
2. Access and change patient active med list

Medication Allergy List
1. Record patient active medication allergy list
2. Access and change patient active medication allergy list

Tasks were selected based on their frequency of use, criticality of function, and those that may be most troublesome for users.

Procedure
Upon arrival, participants were greeted and their identity verified with the participant schedule. Participants were then assigned a random participant ID. Each participant reviewed and verbally consented to the consent form (see Appendix B). The verbal consent was recorded and witnessed by the test team.

To ensure the session ran smoothly, an experienced usability administrator facilitated the study. The usability administrator has seven years of experience and a master’s degree in Human Factors Psychology.

The administrator moderated the session including providing instructions and tasks. The administrator also monitored task times, obtained post-task rating data, and took notes on participant comments. The sessions were recorded to review and compute additional findings (e.g., task success, path deviations, etc.).

Participants were instructed to perform the tasks (see specific instructions below):

- As they normally would and as quickly as possible
- Without assistance; administrator could provide clarification, but not instruction

For each task, the task was visually presented to the participants on their screen. Task timing began once the administrator finished reading the question. The task time stopped once the participant indicated they had successfully completed the task. Scoring is discussed in the Usability Metrics section below.

Following the session, the administrator gave the participant the post-test questionnaire (i.e., System Usability Scale, see Appendix F), requested their mailing address to send compensation, and thanked them for their time and participation.

Participants’ demographic information, task success rate, time on task, errors, deviations, verbal responses, and post-test questionnaire were recorded.
Test Location
The test facility consisted of the administrator’s computer workstation and the participants’ personal workstations at home or clinic, as the study was completed remotely. Only the administrator and the participant were connected to the remote session.

Test Environment
The EHRUT would be typically used in an urgent care clinic. In this instance, testing was conducted either in participants’ homes or clinics. For testing, the moderator and participant connected via GoToMeeting software. The participants used a mouse and keyboard to interact with the EHRUT.

The EMR was set up by the test team according to new installation documentation. The application itself was running in a Citrix environment using a test database on a LAN connection. Technically, the system performance (i.e., response time) was representative to what actual users would experience in a field implementation. Additionally, participants were instructed not to change any of the default system settings.

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

1. Informed Consent Form
3. System Usability Scale (SUS)

Examples of these documents can be found in Appendices Appendix B, Appendix E, and Appendix F, respectively. The Moderator’s Guide was devised so as to be able to capture required data.

The participant’s interaction with the EHRUT and verbal comments were recorded digitally with GoToMeeting software running on the moderator’s test machine.

Participant Instructions
The administrator read the following instructions to each of the participants (full moderator’s guide is available in Appendix E):

Thank you for helping us with this study. Our session today will last approximately 45 minutes. We are conducting research around recording patient medications and patient medication allergies. I will ask you to perform a few tasks. I want you to use the software like you normally would and then I will ask you some specific questions around your experience today.

When designing software, there are always so many ideas about how it should look and work. Today, you are going to help us review allergy and medication lists. I want you to work through the tasks like you normally would and try to complete them as quickly as possible without rushing. I will not be able to assist you with the tasks, but I can provide you more clarification if you need it. At the end of each task, I will ask you some questions about what you completed. Please feel free to share any thoughts or feelings you have about the features of the software – positive or negative. All of the feedback
you share is important and very helpful to me. I did not have any involvement in the creation, so please be honest with your opinions.

I want to emphasize that we are not evaluating you, we are evaluating the software. We will record the session. All recordings will be kept strictly confidential. We may use footage to share with our developers and/or management the experience you have to help highlight both positive findings and areas for improvement. It also helps so that I don’t have to take as many notes during this session.

Following the procedural instructions, participants were asked a few pre-study questions for demographic information (e.g., age, degree, experience with EHRs and computers). Once this was complete, the administrator gave the following instructions:

For each task, I will read the description and say “Begin.” At that point, please start the task and say, “Done,” once you believe you have successfully completed the task. I want you to complete the task like you normally would and as quickly as possible. Please refrain from proving your thoughts and comments until you complete the task. I will ask your impressions about the task once you are done.

Participants were then given four tasks to complete. Tasks are listed in the moderator’s guide in Appendix E.

**Usability Metrics**

According to the NIST Guide to the Process 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 of DocuTAP EMR by measuring participant success rates and errors
2. Efficiency of DocuTAP EMR by measuring average task time and path deviations
3. Satisfaction with DocuTAP EMR by measuring ease of use ratings

**Data Scoring**

The following table (Table 13) details how tasks were scored, errors evaluated, and time data analyzed.

<table>
<thead>
<tr>
<th>Measures</th>
<th>Rationale and Scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Effectiveness:</strong></td>
<td>A task was counted as a &quot;Success&quot; if the participant was able to achieve the correct outcome, without any assistance, within the time allotted on a per task basis. The total number of successes were calculated for each task and then divided by the total number of times the task was attempted. The results are provided as a percentage. Task times were recorded for successes. Observed task times divided by the optimal time for each task is a measure of optimal efficiency. Optimal task performance time, as benchmarked by expert performance under realistic conditions, was recorded when constructing the tasks. Target task times used for task times in the Moderator’s Guide were defined by.</td>
</tr>
<tr>
<td>Task Success</td>
<td></td>
</tr>
</tbody>
</table>
Taking multiple measurements of the optimal performance and multiplying it by 1.5 which allows some time buffer because participants were not trained to expert performance. Therefore, if expert optimal performance on a task was 60 seconds, then allotted task time performance was \([60 \times 1.5 = 90]\) seconds. This ratio was aggregated across tasks and reported with both mean and variance scores.

**Effectiveness:**

**Task Failures**
If the participant abandoned the task, did not reach the correct answer, performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as a “Failure.” The total number of errors was calculated for each task and then divided by the total number of times the task was attempted. Not all deviations were counted as errors. This is the mean number of failed tasks per participant. A count of errors and error types was collected.

**Efficiency:**

**Task Deviations**
The participant’s path through the EHR was recorded. Deviations occur if the participant, for instance, went to a wrong screen or clicked on an incorrect menu item. This path was compared with the optimal path. The number of steps in the observed path was divided by the number of optimal steps to provide a ratio of path deviation. Optimal paths were recorded during task development.

**Efficiency:**

**Task Time**
Each task was timed from when the administrator said “Begin,” until the participant said, “Done.” If a participant failed to say, “Done,” the time was stopped when the participant stopped performing the task. Only task times for tasks that were successfully completed were included in the average task time analysis. Average time task was completed for each task. Variance measures (standard deviation and standard error) were also calculated.

**Satisfaction:**

**Task Rating**
Participants’ subjective impression of the ease of use of the EHR was measured by administering both a simple post-task question as well as a post-session questionnaire. After each task, the participant was asked to rate “How would you rate [task] on a scale from 1 (very difficult) to 5 (very easy).” These scores were averaged across participants.

According to common convention, system that are judged to be easy to use are rated 3.3 or above.

To measure participants’ confidence in and likeability of the DocuTAP EHR overall, the testing team administered the System Usability Scale (SUS) post-session questionnaire. See Appendix F for the full questionnaire.

| Table 13: Details of How Observed Data Were Scored |

The following table (Table 14) details the four-point risk assessment scale utilized.

<table>
<thead>
<tr>
<th>Rating</th>
<th>Risk</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Low</td>
<td>Negligible – little to no impact on patient safety.</td>
</tr>
<tr>
<td>3</td>
<td>Moderate</td>
<td>Tolerable level of risk with patient safety, no more risky than risk experienced in daily life.</td>
</tr>
<tr>
<td>2</td>
<td>High</td>
<td>Undesirable level of risk that potentially creates a dangerous situation that could affect patient safety.</td>
</tr>
<tr>
<td>1</td>
<td>Critical</td>
<td>Intolerable level of risk that creates a dangerous situation that adversely impacts patient safety.</td>
</tr>
</tbody>
</table>

| Table 14: Risk Assessment Scale |
Results

Data Analysis and Reporting

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

The usability study results for the EHRUT are detailed below (see Table 15). The results should be considered with the objectives and goals outlined in the Study Design section above. The data provides actionable insights that, if corrected, could have a positive impact on user performance.

<table>
<thead>
<tr>
<th>Task</th>
<th>Measure</th>
<th>N</th>
<th>Task Success</th>
<th>Path Deviation</th>
<th>Task Time</th>
<th>Errors</th>
<th>Task Ratings</th>
<th>Risk Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>% of successful attempts</td>
<td>Deviations (Observed / Optimal)</td>
<td>Mean (SD)</td>
<td>Deviations (Observed / Optimal)</td>
<td>Mean</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Deviations (Observed / Optimal)</td>
<td>Mean (SD)</td>
<td>Deviations (Observed / Optimal)</td>
<td>Mean</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>1.</td>
<td>Record med list</td>
<td>5</td>
<td>100</td>
<td>1.0</td>
<td>34.8 (18.3)</td>
<td>0.7 (0.3)</td>
<td>0.0</td>
<td>5.0 (0.0)</td>
</tr>
<tr>
<td>2.</td>
<td>Access &amp; change med list</td>
<td>5</td>
<td>83</td>
<td>1.1</td>
<td>7.6 (1.4)</td>
<td>1.3 (0.2)</td>
<td>0.2</td>
<td>5.0 (0.0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Task</th>
<th>Measure</th>
<th>N</th>
<th>Task Success</th>
<th>Path Deviation</th>
<th>Task Time</th>
<th>Errors</th>
<th>Task Ratings</th>
<th>Risk Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>% of successful attempts</td>
<td>Deviations (Observed / Optimal)</td>
<td>Mean (SD)</td>
<td>Deviations (Observed / Optimal)</td>
<td>Mean</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Deviations (Observed / Optimal)</td>
<td>Mean (SD)</td>
<td>Deviations (Observed / Optimal)</td>
<td>Mean</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>1.</td>
<td>Record med allergy list</td>
<td>5</td>
<td>40</td>
<td>1.0</td>
<td>17.5 (0.5)</td>
<td>1.5 (0.0)</td>
<td>1.0</td>
<td>4.8 (0.4)</td>
</tr>
<tr>
<td>2.</td>
<td>Access &amp; change med allergy list</td>
<td>5</td>
<td>60</td>
<td>1.1</td>
<td>8.7 (1.7)</td>
<td>1.1 (0.2)</td>
<td>0.2</td>
<td>5.0 (0.0)</td>
</tr>
</tbody>
</table>

Table 15: Medical Assistant Study Summary Data

The results of the SUS scored the subjective satisfaction with the system based on performance with these tasks to be: 88. Common convention suggests that scores under 60 represent systems with poor usability; scores over 80 would be considered above average. Provided the data findings related to effectiveness, efficiency, and satisfaction for the MA tasks, it is evident that the medication allergy list tasks portion of the software could be improved. Improving how medication allergies are entered and edited, and additional nice-to-have features for the medication list would enhance efficiency and user satisfaction.

Effectiveness

The only medical assistant task that was completed successfully 100% of the time, within the time allotted, was recording a medication list. Accessing and changing a medication list was completed 83% of the time, as one of the participants attempted the task twice. She wanted to redo it to meet her expectations and clinic workflow. Recording was completed successfully 40% and accessing and changing was completed successfully 60% of the time.
Participants completed both medication list tasks with minimal task deviations. A single error was made during the task where participants accessed and changed a medication list. The participant added an unnecessary step to completing the task.

Participants completed the recording medication allergy task in a variety of methods that involved attempting to search for medication allergies on the allergies screen just like they would search for medications on the medication list screen. Three of five participants used the add field to do a search not realizing that it does not function as a search field. Participants' expectations were that they could search, just like they do on the medication list screen. This was one of the most common errors made by participants. This error also considerably increased the amount of time it took for participants to complete the task.

The next most common error was not fully documenting the allergy. Participants would remember to record the allergy and the reaction, but did not record when it occurred (i.e., as a child). This is a minor error compared to the searching, as the most important information about the allergy was recorded, the drug and reaction.

**Efficiency**

Participants were less efficient than the optimal task time for all but one task. They were more efficient for recording a medication list, but less efficient for recording a medication allergy list, accessing and changing a medication list, and accessing and changing a medication allergy list.

Recording a medication list had a task time that varied from 20 to 70 seconds. The amount of information recorded in the medication list is dependent upon the clinic workflow and requirements, as some clinics require that both the medication and dosage be recorded. Others only require the medication.

The task times for recording to the medication allergy list were 1.5 times longer than the optimal task time. The longer task times were typically due to the participants attempting to search for the medication using an add field. The task times for this task, including task failures, varied from 17 to 46 seconds.

**Satisfaction**

Each participant completed the SUS at the end of their session and, on average, the SUS was 88. This score is considered above average. In addition, each of the MA scores were above average ranging from 77.5 to 100. Previous research utilizing the SUS dictates that the average SUS score is 68.

All of the MA tasks were rated as being very easy to complete. Participants commented that it is easy to document patient information. They find the medication list search to be very useful and helps decrease the amount of time needed to enter data. This is especially true when patients have long medication lists. They also appreciate the ease in which medications can be moved from the active to the inactive list. The participant comments included wanting the creating a medication allergy task to be easier and allow them to search more effectively. Yet, participants did appreciate the ease with being able to access and modify the medication allergy list.
Major Findings

After evaluating the effectiveness, efficiency, and satisfaction with the medication list tasks, it is apparent that there is not much need for changes or further research. Some self-reported nice-to-have features from the participants could create more user satisfaction with the software. However, it is apparent that there is a need for further research and adjustment to recording medication allergies. Further investigation on how to reduce task time would be beneficial and increase user satisfaction.

Participants were effective in completing the medication list tasks and only one participant made the minor error of adding a step when completing the accessing and changing a medication list. They were also extremely satisfied with the features and functionality of this portion of the software. They appreciated having the search functionality and the ease of moving medications from active to inactive lists.

Participants could complete both medication allergy list tasks, but not as effectively or efficiently as they could. There were longer task times and errors associated with the recording patient medication allergy task. Given this, participants were still satisfied with the software and rated the tasks as being very easy to complete.

Areas for Improvement

For the medication list tasks, the only area for improvement is based on participant feedback from the study. Participants stated that it would be nice to be able to put in a type of drug and report that a patient is taking it, but that the patient can’t remember which medication they are taking. For example, a patient may know that she’s taking a birth control pill, but doesn’t remember the exact medication.

The biggest area for improvement related to the medication allergy list tasks is around recording medication allergies and the amount of time it takes to record. Participants like the speed with which they can record medications to the medication list and expect the same for recording medication allergies.

Participants commented that at their clinic it can take a long time for the medication allergy list to generate. When selecting the Drugs option, they will click it again thinking that they may not have selected it which then delays the list from being displayed even longer. The other feature that patients would like to see is an easier way to edit/add reactions to an allergy once they leave the screen and come back to it. For instance, they may record that the patient is allergic to penicillin, leave the screen to record a blood pressure and then come back to the allergy screen to record the reaction to penicillin. Participants would like to be able to select the allergy from the list and have the reactions appear in the selection window below instead of the current process.
Appendices
The following appendices include supplemental data for this usability study report. Following is a list of the appendices provided:

A. Participant Demographics
B. Informed Consent Form
C. Moderator's Guide – Provider Study A
D. Moderator's Guide – Provider Study B
E. Moderator's Guide – MA/Nurse Study
F. System Usability Scale Questionnaire
Appendix A: Participant Demographics

Following is a breakdown of the participants.

### Providers – Study A

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<thead>
<tr>
<th>Gender</th>
<th>Count</th>
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</thead>
<tbody>
<tr>
<td>Male</td>
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<tr>
<td>Female</td>
<td>2</td>
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<tr>
<td><strong>Total (participants)</strong></td>
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<table>
<thead>
<tr>
<th>Age</th>
<th>Count</th>
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<tr>
<td>NP</td>
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<td><strong>Total (participants)</strong></td>
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<table>
<thead>
<tr>
<th>Length of Time in Role</th>
<th>Count</th>
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<tbody>
<tr>
<td>0-1 year</td>
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<tr>
<td>2-3 years</td>
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</tr>
<tr>
<td>3-4 years</td>
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</tr>
<tr>
<td>4-5 years</td>
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</tr>
<tr>
<td>5+ years</td>
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<td><strong>Total (participants)</strong></td>
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### Providers – Study B

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<td><strong>Total (participants)</strong></td>
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<th>Occupation/Role</th>
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<td>MD</td>
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<td>PA</td>
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<tr>
<td>NP</td>
<td>2</td>
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<tr>
<td><strong>Total (participants)</strong></td>
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<table>
<thead>
<tr>
<th>Length of Time in Role</th>
<th>Count</th>
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<tr>
<td>0-1 year</td>
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<td>3-4 years</td>
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<td>4-5 years</td>
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</tr>
<tr>
<td>5+ years</td>
<td>1</td>
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<tr>
<td><strong>Total (participants)</strong></td>
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</table>

<table>
<thead>
<tr>
<th>Years of Experience with EHRs</th>
<th>Count</th>
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<tbody>
<tr>
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<td>5</td>
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<td><strong>Total (participants)</strong></td>
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<table>
<thead>
<tr>
<th># of EHRs Experienced</th>
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<tr>
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<td>MAs/Nurses</td>
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<td>---------------</td>
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<tr>
<td><strong>Gender</strong></td>
<td><strong>Count</strong></td>
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<tr>
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<table>
<thead>
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<table>
<thead>
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<th><strong>Occupation/Role</strong></th>
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<tbody>
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<td>Rad Tech/MA</td>
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<td><strong>Total (participants)</strong></td>
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<table>
<thead>
<tr>
<th><strong>Length of Time in Role</strong></th>
<th><strong>Count</strong></th>
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<tbody>
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<tr>
<td>2-3 years</td>
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<td>3-4 years</td>
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<tr>
<td>4-5 years</td>
<td>2</td>
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<tr>
<td>5+ years</td>
<td>1</td>
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<tr>
<td><strong>Total (participants)</strong></td>
<td><strong>5</strong></td>
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<table>
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<tr>
<th><strong>Years of Experience with EHRs</strong></th>
<th><strong>Count</strong></th>
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<tbody>
<tr>
<td>0-1 year</td>
<td>1</td>
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<tr>
<td>2-3 years</td>
<td>1</td>
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<tr>
<td>3-4 years</td>
<td>0</td>
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<tr>
<td>4-5 years</td>
<td>2</td>
</tr>
<tr>
<td>5+ years</td>
<td>1</td>
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<tr>
<td><strong>Total (participants)</strong></td>
<td><strong>5</strong></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th><strong># of EHRs Experienced</strong></th>
<th><strong>Count</strong></th>
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<tbody>
<tr>
<td>1-2</td>
<td>5</td>
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<tr>
<td><strong>Total (participants)</strong></td>
<td><strong>5</strong></td>
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</table>
Appendix B: Informed Consent Form

DocuTAP 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 software and give your feedback. The study will last about 60 minutes. At the conclusion of the test, you will be compensated for your time.

Agreement

I understand and agree that as a voluntary participant in the present study conducted by DocuTAP 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 DocuTAP.

I understand and consent to the use and release of the videotape by DocuTAP.

I understand that the information and videotape is for research purposes, evaluation, demonstration, and/or training only and that my name and image will not be used for any other purpose. I understand that by signing this form I hereby give my consent to DocuTAP, to other such persons as DocuTAP may designate, to use my voice, verbal statements, and video for purposes of research, evaluation, demonstration, and/or training.

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 DocuTAP. I understand and agree that data confidentiality is assured, because only deidentified 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.

Printed Name: __________________________________________

Signature: __________________________________________

Date: ___________________
Appendix C: Moderator’s Guide – Provider Study A

Pre-study Questions

1. Male or Female
2. Which of the following best describes your age?
   a. 18-24
   b. 25-34
   c. 35-44
   d. 45-54
   e. 55-64
   f. 65-74
   g. 75 and older
3. What is your current position and title?
4. How long have you held this position?
5. Which of the following best describes your highest level of education?
   a. Graduate School
      i. NP
      ii. PA
      iii. DO
      iv. MD
6. How many years have you used an electronic health record (EHR)?
7. How many EHRs do you have experience with?
8. Are you using a computer or tablet for today’s session?

Tasks

Task 1: Adjust drug-drug interaction checking

Open PM to provide access to Drug Modifications screen.

You would like to create a drug-drug interaction warning for all providers for Coumadin so that it warns for all interactions.

Observations/Notes/Comments:

How would you rate being able to adjust a drug-drug interaction checking?

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<th>5</th>
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</thead>
<tbody>
<tr>
<td>Very easy</td>
<td>Neutral</td>
<td>Very hard</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Why did you rate the task as being easy/neural/hard?

Success: □ Easily Completed
□ Completed with difficulty or help – see comments section below
□ Not Completed

Comments:

Task Time (seconds):
Optimal Path

☐ Correct
☐ Minor Deviations/Cycles – see comments section below
☐ Major Deviations – see comments section below

Comments:

Task 2: Order a rapid strep test

Open EMR to patient encounter note.

Johnathan Swift has come in today complaining of sinus pressure, sinus drainage, and a sore throat. He has also been exposed to strep in the past 10 days. After your examination, you’ve decided that he should be tested for strep. Do what you need to do to order a rapid strep test.

Observations/Notes/Comments:

How would you rate being able to order a rapid strep test?

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<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very easy</td>
<td>Neutral</td>
<td>Very hard</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Why did you rate the task as being easy/neutral/hard?

Success:  ☐ Easily Completed
☐ Completed with difficulty or help – see comments section below
☐ Not Completed

Comments:

Task Time (seconds):

Optimal Path

☐ Correct
☐ Minor Deviations/Cycles – see comments section below
☐ Major Deviations – see comments section below

Comments:

Task 3: Order head x-ray of sinuses

You have also decided that you would like to have an x-ray of Johnathan’s sinuses. Do what you need to do to order the x-rays.

Observations/Notes/Comments:

How would you rate being able to order the x-rays?

<table>
<thead>
<tr>
<th>1</th>
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<th>3</th>
<th>4</th>
<th>5</th>
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<tbody>
<tr>
<td>Very easy</td>
<td>Neutral</td>
<td>Very hard</td>
<td></td>
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</table>
Safety-Enhanced Design Summative Usability Testing Report

Why did you rate the task as being easy/neutral/hard?
Success:  □ Easily Completed
□ Completed with difficulty or help – see comments section below
□ Not Completed
Comments:

Task Time (seconds):
Optimal Path:
□ Correct
□ Minor Deviations/Cycles – see comments section below
□ Major Deviations – see comments section below
Comments:

Task 4: Prescribe medication – view drug-allergy interaction

Johnathan’s rapid strep test came back negative. You’ve determined that he has a sinus infection. You would like to prescribe him 500 mg of augmentin twice a day for 10 days.

Stop provider after drug-allergy interaction alert appears and they go to move from that alert.

Observations/Notes/Comments:
How would you rate being able to view a drug-allergy interaction?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very easy</td>
<td>Neutral</td>
<td>Very hard</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Why did you rate the task as being easy/neutral/hard?

What do you think of the drug-allergy interaction warnings?
Success:  □ Easily Completed
□ Completed with difficulty or help – see comments section below
□ Not Completed
Comments:

Task Time (seconds):
Optimal Path:
□ Correct
□ Minor Deviations/Cycles – see comments section below
□ Major Deviations – see comments section below
Comments:
Task 5: Create prescription

Go to Plan screen.

Since your patient is allergic to penicillin and is unable to take augmentin, you’ve decided to prescribe azithromycin. You would like him to take 500 mg per day for 5 days.

Stop before sending prescription.

Observations/Notes/Comments:

How would you rate being able to create a prescription?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very easy</td>
<td>Neutral</td>
<td>Very hard</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Why did you rate the task as being easy/neutral/hard?

Success:  □ Easily Completed
          □ Completed with difficulty or help – see comments section below
          □ Not Completed

Comments:

Task Time (seconds):

Optimal Path:

□ Correct
□ Minor Deviations/Cycles – see comments section below
□ Major Deviations – see comments section below

Comments:

Task 6: Prescribe Motrin and view drug-drug interaction alert

To help reduce your patient’s fever, you want him/her to take two 200 mg caplets of Motrin every 4 hours. Please set up that prescription.

Stop provider after drug-allergy interaction alert appears.

Observations/Notes/Comments:

How would you rate being able to view a drug-drug interaction alert?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very easy</td>
<td>Neutral</td>
<td>Very hard</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Why did you rate the task as being easy/neutral/hard?

What do you think of the drug-drug interaction alert?

Success:  □ Easily Completed
          □ Completed with difficulty or help – see comments section below
Task 7: Preview prescription & e-prescribe

Go to Plan screen.

The prescription for your patient is ready to be sent to the pharmacy. Do what you need to do to send the prescription.

Observations/Notes/Comments:

How would you rate being able to review a prescription?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
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<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very easy</td>
<td>Neutral</td>
<td>Very hard</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Why did you rate the task as being easy/neutral/hard?

How would you rate being able to send a prescription to the pharmacy?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
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<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very easy</td>
<td>Neutral</td>
<td>Very hard</td>
<td></td>
<td></td>
</tr>
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</table>

Why did you rate the task as being easy/neutral/hard?

Success:  □ Easily Completed
          □ Completed with difficulty or help – see comments section below
          □ Not Completed

Comments:

Task Time (seconds):

Optimal Path:

□ Correct
□ Minor Deviations/Cycles – see comments section below
□ Major Deviations – see comments section below

Comments:
Task 8: View and change lab order for HCG

Open EMR to chart room and select patient

Chelsey Patient is ready to be seen and is here for a follow-up HCG lab. Please review the labs ordered for her.

Wait for provider to obtain information.

You notice that the lab test order is for HCG Qualitative, but you really want HCG Quant. Do what you need to do to get the lab test changed.

Observations/Notes/Comments:

How would you rate being able to review a lab order?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
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<tbody>
<tr>
<td>Very easy</td>
<td>Neutral</td>
<td>Very hard</td>
<td></td>
<td></td>
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</tbody>
</table>

Why did you rate the task as being easy/neutral/hard?

How would you rate being able to change a lab order?

<table>
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<tr>
<th>1</th>
<th>2</th>
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<th>4</th>
<th>5</th>
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</thead>
<tbody>
<tr>
<td>Very easy</td>
<td>Neutral</td>
<td>Very hard</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Why did you rate the task as being easy/neutral/hard?

Success:  □ Easily Completed

□ Completed with difficulty or help – see comments section below

□ Not Completed

Comments:

Task Time (seconds):

Optimal Path:

□ Correct

□ Minor Deviations/Cycles – see comments section below

□ Major Deviations – see comments section below

Comments:

Task 9: View and change x-ray

While your patient is in to have her lab work done, she needs to have a wrist x-ray of the left wrist completed to be sure the break is healing correctly. Please review the x-ray orders

Wait for provider to obtain information.

You notice that the x-rays are for the right wrist, but they need to be for the left wrist. Do what you need to do to adjust the x-rays order.
Safety-Enhanced Design Summative Usability Testing Report

Observations/Notes/Comments:

How would you rate being able to review an x-ray order?

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<tr>
<th>1</th>
<th>2</th>
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<tbody>
<tr>
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<td>Neutral</td>
<td>Very hard</td>
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</table>

Why did you rate the task as being easy/neutral/hard?

How would you rate being able to change an x-ray order?

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<tbody>
<tr>
<td>Very easy</td>
<td>Neutral</td>
<td>Very hard</td>
<td></td>
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</table>

Why did you rate the task as being easy/neutral/hard?

Success: □ Easily Completed
□ Completed with difficulty or help – see comments section below
□ Not Completed

Comments:

Task Time (seconds):

Optimal Path:

□ Correct
□ Minor Deviations/Cycles – see comments section below
□ Major Deviations – see comments section below

Comments:

Task 10: Change prescription

Since it is apparent that Chelsey is pregnant, you recommend that she taper her current Prozac dosage. She currently has a prescription set up for 20 mg, but needs one for 10 mg. She will take 1 per day for 30 days. Please update her prescription.

Observations/Notes/Comments:

How would you rate being able to change a prescription?

<table>
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<tr>
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<th>5</th>
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</thead>
<tbody>
<tr>
<td>Very easy</td>
<td>Neutral</td>
<td>Very hard</td>
<td></td>
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</table>

Why did you rate the task as being easy/neutral/hard?

Success: □ Easily Completed
□ Completed with difficulty or help – see comments section below
□ Not Completed

Comments:
Task Time (seconds):
Optimal Path:

☐ Correct
☐ Minor Deviations/Cycles – see comments section below
☐ Major Deviations – see comments section below

Comments:

**Follow-Up Questions**

1. What is your overall impression of the software?
2. What three things did you like best?
3. What three things did you like least?
4. Were there any features that you were surprised to see today?
5. Are there any features you expected to encounter today, but did not see? Do you feel like there's anything missing?
6. Were there aspects of the software that are useful to you? Were there any that frustrated you?
7. If you could change one thing about your experience today, what would it be?
8. Overall, how satisfied are you with the software? Why?

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<tbody>
<tr>
<td></td>
<td>I hate it and wish I could use something else.</td>
<td>I will use it but I don’t love it or hate it.</td>
<td>I love it and would tell other people to use it.</td>
<td></td>
<td></td>
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</tbody>
</table>

*Administer SUS.*
Appendix D: Moderator’s Guide – Provider Study B

Pre-study Questions

1. Male or Female
2. Which of the following best describes your age?
   a. 18-24
   b. 25-34
   c. 35-44
   d. 45-54
   e. 55-64
   f. 65-74
   g. 75 and older
3. What is your current position and title?
4. How long have you held this position?
5. Which of the following best describes your highest level of education?
   a. Graduate School
      i. NP
      ii. PA
      iii. DO
      iv. MD
6. How many years have you used an electronic health record (EHR)?
7. How many EHRs do you have experience with?
8. Are you using a computer or tablet for today’s session?

Tasks

Task 1: Create a new alert to notify providers to order a Protime lab test for patients who have an active Coumadin prescription.

Open PM to provide access to alerts editor.

Observations/Notes/Comments:

How would you rate being able to create a new alert?

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<tr>
<td>1</td>
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<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Very easy</td>
<td>Neutral</td>
<td>Very hard</td>
<td></td>
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</tr>
</tbody>
</table>

Why did you rate the task as being easy/neutral/hard?

Success: □ Easily Completed
        □ Completed with difficulty or help – see comments section below
        □ Not Completed

Comments:

Task Time (seconds):

Optimal Path:
Task 2: Charley Patient has come in today with a sore throat. Let’s open his chart. Review any alerts that are shown. (Alerts are generated and populated based on age and problem list; and vitals.)

Open EMR to chart room.

Observations/Notes/Comments:

How would you rate being able to review the alerts?

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<td>1</td>
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<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Very easy</td>
<td>Neutral</td>
<td>Very hard</td>
<td></td>
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</tr>
</tbody>
</table>

Why did you rate the task as being easy/neutral/hard?

Success: □ Easily Completed

□ Completed with difficulty or help – see comments section below

□ Not Completed

Comments:

Task Time (seconds):

Optimal Path:

□ Correct

□ Minor Deviations/Cycles – see comments section below

□ Major Deviations – see comments section below

Comments:

Task 3: You notice that Charley has an electronic record that has been send to your clinic. Let’s reconcile the information with the information recorded in his current record. We want to review the record with the date of April 16, 2014.

a. Reconcile active med list
b. Reconcile active problem list
c. Reconcile active med allergy list

Observations/Notes/Comments:

How would you rate being able to reconcile a patient’s record?

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<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
Safety-Enhanced Design Summative Usability Testing Report

Why did you rate the task as being easy/neutral/hard?
What do you think of the reconcile feature?
Success: □ Easily Completed
□ Completed with difficulty or help – see comments section below
□ Not Completed
Comments:
Task Time (seconds):
Optimal Path:
□ Correct
□ Minor Deviations/Cycles – see comments section below
□ Major Deviations – see comments section below
Comments:

Task 4: Let's review Charley's medication list. (Alerts generated based on lab tests/results and medication list; and med allergy.)

a. Review diagnostic and therapeutic reference related to lab test/results.
Observations/Notes/Comments:

How would you rate being able to review the alert and review the reference for the protime lab?

<table>
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<tr>
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</thead>
<tbody>
<tr>
<td>Very easy</td>
<td>Neutral</td>
<td>Very hard</td>
<td></td>
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</tbody>
</table>

Why did you rate the task as being easy/neutral/hard?
Success: □ Easily Completed
□ Completed with difficulty or help – see comments section below
□ Not Completed
Comments:
Task Time (seconds):
Optimal Path:
□ Correct
□ Minor Deviations/Cycles – see comments section below
□ Major Deviations – see comments section below
Comments:

Follow-Up Questions

1. What is your overall impression of the software?
2. What three things did you like best?
   1.
   2.
   3.
3. What three things did you like least?
   1.
   2.
   3.
4. Were there any features that you were surprised to see today?
5. Are there any features you expected to encounter today, but did not see? Do you feel like there’s anything missing?
6. Were there aspects of the software that are useful to you? Were there any that frustrated you?
7. If you could change one thing about your experience today, what would it be?
8. Overall, how satisfied are you with the software? Why?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>I hate it and wish I could use something else.</td>
<td>I will use it but I don’t love it or hate it.</td>
<td>I love it and would tell other people at my clinic to use it.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Administer SUS.
Appendix E: Moderator’s Guide – MA Study

Pre-study Questions

1. Male or Female
2. Which of the following best describes your age?
   a. 18-24
   b. 25-34
   c. 35-44
   d. 45-54
   e. 55-64
   f. 65-74
   g. 75 and older
3. What is your current position and title?
4. How long have you held this position?
5. Which of the following best describes your highest level of education?
   c. High School
   d. Some College
   e. Associate Degree
      a. MA
      b. Rad Tech
      c. LPN
      d. RN
   f. Bachelor’s Degree
      a. BSN
6. How many years have you used an electronic health record (EHR)?
7. How many EHRs do you have experience with?
8. Are you using a computer or tablet for today’s session?

Tasks

Task 1: Create med allergy list

Open EMR to Henrik’s vitals screen.

You just completed taking your patient’s vitals. You’ve asked if he has any medication allergies and he said he’s allergic to penicillin. The reaction happened when he was a child and his body went into shock.

Observations/Notes/Comments:

How would you rate being able to add a medication allergy?

```
1 2 3 4 5
Very easy Neutral Very hard
```

Why did you rate the task as being easy/neutral/hard?

Success: □ Easily Completed
Safety-Enhanced Design Summative Usability Testing Report

____

☑ Completed with difficulty or help – see comments section below
☑ Not Completed

Comments:

Task Time (seconds):

Optimal Path:

☑ Correct
☑ Minor Deviations/Cycles – see comments section below
☑ Major Deviations – see comments section below

Comments:

Task 2: Create current med list

Now that you have allergies recorded, you ask Henrik if he is taking any medications. He says that he is currently taking a daily multivitamin and zyrtec D for allergies.

Observations/Notes/Comments:

How would you rate being able to record the patient's current medications?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very easy</td>
<td>Neutral</td>
<td>Very hard</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Why did you rate the task as being easy/neutral/hard?

What is standard protocol for your clinic, do you just enter the medication or do you also try to gather dosage information?

Success: ☑ Easily Completed

☑ Completed with difficulty or help – see comments section below
☑ Not Completed

Comments:

Task Time (seconds):

Optimal Path:

☑ Correct
☑ Minor Deviations/Cycles – see comments section below
☑ Major Deviations – see comments section below

Comments:

Task 3: Edit Allergy List

Open EMR to Manny's vitals screen – patient 2.

Manny reports that he is not actually allergic to sulfa antibiotics. Remove the allergy from his list.
Safety-Enhanced Design Summative Usability Testing Report

Observations/Notes/Comments:

How would you rate being able to set a med allergy to inactive?

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
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<td>Very hard</td>
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□ Not Completed

Comments:

Task Time (seconds):

Optimal Path:

□ Correct
□ Minor Deviations/Cycles – see comments section below
□ Major Deviations – see comments section below

Comments:

**Task 4: Edit Medication List**

Your patient is no longer taking Prilosec. Remove the medication from the active med list.

Observations/Notes/Comments:

How would you rate being able to set a medication as inactive?

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Very easy</td>
<td>Neutral</td>
<td>Very hard</td>
<td></td>
<td></td>
</tr>
</tbody>
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Why did you rate the task as being easy/neutral/hard?

Success: □ Easily Completed
□ Completed with difficulty or help – see comments section below
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Task Time (seconds):

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Comments:

Follow-Up Questions

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Administer SUS.
Appendix F: System Usability Scale (SUS)¹

1. I think that I would like to use this system frequently.

<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 2 3 4 5</td>
<td></td>
</tr>
</tbody>
</table>

2. I found the system unnecessarily complex.

   |                      |
   | 1 2 3 4 5           |

3. I thought the system was easy to use.

   |                      |
   | 1 2 3 4 5           |

4. I think I would need the support of a technical person to be able to use the system.

   |                      |
   | 1 2 3 4 5           |

5. I found the various functions in this system were well integrated.

   |                      |
   | 1 2 3 4 5           |

6. I thought there was too much inconsistency in this system.

   |                      |
   | 1 2 3 4 5           |

7. I would imagine that most people would learn to use this system very quickly.

   |                      |
   | 1 2 3 4 5           |

8. I found the system very cumbersome to use.

   |                      |
   | 1 2 3 4 5           |

9. I felt very confident using the system.

   |                      |
   | 1 2 3 4 5           |

10. I needed to learn a lot of things before I could get going with this system.

    |                      |
    | 1 2 3 4 5           |

---

Signature of Report Veracity & Authenticity

On 29 April 2014, we attest to the veracity and authenticity of the safety-enhanced design summative usability testing report using the NISTIR 7742 template on DocuTAP software version 5.1.

Printed Name of DocuTAP representative: Eric McDonald

Date: 4/29/14

Signature:
Quality Management System

Measure: 170.314(g)(4) Quality Management System

DocuTAP has developed and adheres to its own Quality Management System (QMS). The development team uses two different development methods: Agile and Waterfall.

The Agile process was applied to all capabilities for which DocuTAP is seeking certification in 2014, except for those listed here. The Waterfall QMS was used for the following capabilities:

- 170.314(a)(1)(2) Image results
- 170.314(a)(15) Patient-specific education resources
- 170.314(d)(4) Amendments

Quality Management System - Agile

DocuTAP’s Agile approach to software development uses primarily Scrum with a mixture of Kanban and Extreme Programming (XP) practices.

Releasable Software Every Sprint

Each sprint results in releasable code. The team works a portion of the product backlog in the form of user stories. User stories are created after thorough research to understand customer, compliance, and technical requirements. To be accepted as complete, user stories must meet a Definition of Done (DoD).

Testing/Development

<table>
<thead>
<tr>
<th>Testing/Development</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit Testing</td>
<td>Unit tests express the internal behaviors of the software and are part of the regression test suite.</td>
</tr>
<tr>
<td>Acceptance Testing</td>
<td>User stories provide high level descriptions of the external behavior and business rules of the software. Each user story has at least one acceptance test that elaborates the description provided by the user story.</td>
</tr>
<tr>
<td>Test Driven Development (TDD)</td>
<td>TDD results in low level code based unit tests. TDDs are checked into the code repository and become part of the regression test suite.</td>
</tr>
<tr>
<td>Behavior Driven Development (BDD)</td>
<td>BDD results in user-facing acceptance tests. BDD is performed for user stories that have a user facing element and are checked into the code repository.</td>
</tr>
<tr>
<td>Regression Testing</td>
<td>TDD and BDD tests are automated as part of the regression test suite. There is a separate, overarching regression test suite that is executed once daily encompassing testing features from the entire development organization in a single build.</td>
</tr>
<tr>
<td>Exploratory Testing</td>
<td>Exploratory testing uses manual, unscripted testing efforts to identify new types of problems with the software.</td>
</tr>
<tr>
<td>Performance Testing</td>
<td>Performance testing uses a variety of load testing scenarios to run against the software build.</td>
</tr>
<tr>
<td>Integration Testing</td>
<td>The week before Beta, Quality Assurance (QA) Analysts take another pass through the software changes to ensure there is no unexpected impact from the planned changes.</td>
</tr>
</tbody>
</table>

Code Review

A peer code review is performed on each user story to verify that it follows agreed coding standards, conforms to design guidelines and is easily understood by developers other than the original developer.

Product Reviews/Status Meetings

Work completed during a sprint is formally reviewed during Sprint Review. The Product Owner (PO) presents the changes to interested stakeholders providing an opportunity for the stakeholders to provide feedback. To reduce risk, the Agile team holds daily meetings to monitor project progress and expose roadblocks.
Quality Management System - Waterfall

DocuTAP’s Waterfall approach to software development also incorporates aspects of Kanban. Software specifications are created after thorough research to understand customer, compliance, and technical requirements.

Development
For new feature requests and complex bug fixes, the Developer documents their software development approach. The Developer solicits feedback on software changes through a peer review to ensure that code meets the coding standards, conforms to design guidelines, and is documented for maintenance.

Testing

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exploratory/Planned</td>
<td>QA Analysts use manual, unscripted testing efforts to identify software issues.</td>
</tr>
<tr>
<td>Regression Testing</td>
<td>A Regression Tester ensures the changes do not adversely affect the software. Results of these tests are shared with the team and provide advance warning of potential issues with the code. After QA Analyst testing and signs off, a final regression test is performed to ensure there are no issues.</td>
</tr>
<tr>
<td>Performance Testing</td>
<td>A Load Tester performs a variety of performance tests on the software build.</td>
</tr>
<tr>
<td>Integration Testing</td>
<td>The week before Beta, QA Analysts take another pass through the software changes to ensure there is no unexpected impact from the planned changes.</td>
</tr>
</tbody>
</table>
170.314.d.7 - Encryption of Data at Rest

DocuTAP utilizes the third party software Citrix XenApp, version 6.5, for seamless application publishing. Through the seamless application session all Electronic Health Record data is only a remote screen representation and no data is actually being stored on the end-user devices.
DocuTAP attests to the validity of the information below to satisfy the documentation requirements for testing and certification of the ONC 2014 Edition criteria: 170.314(d)2 - Auditable Events and Tamper-Resistance.

As required by measure 170.314.d.2, DocuTAP is providing documentation to describe how the Electronic Health Record (EHR) satisfies the measure’s requirements.

1. **170.314.d.2-1 – Default Setting**
   a. In the DocuTAP EHR, auditing is stored in the database and utilizes the Progress OpenEdge database’s built-in auditing functionality. This auditing is on by default and cannot be turned off or manipulated by users. The auditing system is a core part of the DocuTAP application and must be active for the application to function properly.
   
b. The DocuTAP application does not store patient health information on any end user device. As such, there is no data to encrypt and no need to store the encryption status of such data. All data resides centrally on the database and terminal servers and is delivered to end users via a thin client.
   
c. DocuTAP EHR allows deletion of some electronic health information. This is based on user permissions and is recorded in the audit log.

2. **170.314.d.2-2 – Permit Audit Log, Audit Log Status and Encryption Status Disabling**
   a. DocuTAP does not allow the disabling of audit logs, audit log status, or encryption status. The Progress OpenEdge auditing system does audit the disabling of logs if they were disabled at the database level by the DocuTAP database administrator. DocuTAP does not have client side data to encrypt, so there is no need to audit encryption status. Data resides on database and terminal servers and not on any client devices. The DocuTAP application is accessed via a thin client.

3. **170.314.d.2-4 – Protect Audit Log; 170.314.d.2-5 – Detection of Audit Log Alteration**
   a. DocuTAP audit records are stored as part of the database using the Progress OpenEdge auditing system. Audit records are not stored in text files, but are records stored in the database. In addition, audit records are part of the system tables and have special security around them and are not manipulated directly. End users do not have any ability to change, modify, or delete auditing records. Users only have the ability to view data in the auditing tables via auditing viewers developed by DocuTAP. Access to maintain the auditing system is
only given to a database administration user that is controlled by DocuTAP and not by the end user.

b. DocuTAP utilizes the Progress OpenEdge core auditing functionality which allows a message digest or MAC (Message Authentication Code) to be attached to each record to ensure it is not modified. This is not enabled by default in the DocuTAP application as users are unable to modify auditing data directly. The auditing records cannot be modified even in the event of an unforeseen break into the system. Updates are never permitted to the auditing tables by any user. In the event that auditing data would need to be archived to disk, a data integrity check is in place that ensures that data is not modified while it’s at rest. The archive integrity check uses a MAC to ensure data is not modified while it is outside of the auditing tables.

c. Supporting documentation on Progress OpenEdge auditing security is located in their Core Business Services – Security and Auditing Document.

d. Audit logging events are recorded for the following actions on electronic health information: addition, deletion, changes, queries, print, and copy.

**Audit Security for Database Clients, Tools, and Utilities**

In order for database clients to access the audit tables, the clients must be audit-aware. Being audit-aware means that the client understands audit schema and can distinguish an audit-related table from an application or built-in database table.

When a database client recognizes an audit table, the client uses separate access control tables designed specifically for auditing.

From the audit privileges, the client determines whether the user (the application) has the ability to perform **read**, **create**, or **delete** operations on the audit tables. **update** is never allowed on any audit data table; **update** is allowed only on those tables that contain audit configuration and policy information.

The Progress OpenEdge database utilities protect the audit tables by:

- Allowing only the audit data archiver to copy, move, or delete audit data
- Recording each archive, copy, backup, recover, roll forward, dump, and load event into the audit tables
- Recording all changes in auditing configuration or administrator roles
- Using a MAC when dumping audit and policy tables to preserve data integrity
- Confirming the message digest of an audit data dump before loading it into a database

The database utilities also contribute to the data integrity of the audit information. When the database utility recognizes that the task it is to perform requires permissions to access audit tables, the utility performs a series of actions to determine whether the user has the required audit permissions.
I hereby attest that all above statements are true, as an authorized signing authority on behalf of DocuTAP.

[Signature]

Chief Executive Officer, DocuTAP

4/28/14

Date