Report Based on ISO 13407

Usability Study for Dentrix Enterprise 11.0 CE

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EHR Usability Test Report of Dentrix Enterprise 11.0 CE

Report based on ISO/IEC 25062:2006 Common Industry Format for Usability Test Reports

Dentrix Enterprise Version 11.0 CE

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1. EXECUTIVE SUMMARY

A usability test of Dentrix Enterprise 11.0 CE, dental management system was conducted on 25/02/2019, …

in American Fork, Utah by Henry Schein One. The purpose of this test was to test and validate the usability

of the current user interface, and provide evidence of usability in the EHR Under Test (EHRUT). During the

usability test, ten people with experience working in the dental industry matching the target demographic

criteria served as participants and used the EHRUT in simulated, but representative tasks.

This study collected performance data on 10 tasks typically conducted on an EHR:

- (a.1) CPOE –Meds
  - Record medication via CPOE
  - Change medication via CPOE
  - Display changed CPOE medication order
- (a.2) CPOE – Labs
  - Record Lab order via CPOE
  - Change Lab order via CPOE
  - Display changed CPOE Lab order
- (a.3) CPOE – Diagnostic Imaging
  - Record Imaging order via CPOE
  - Change Imaging order via CPOE
  - Display changed CPOE Imaging order
- (a.5) Demographics
  - Record a patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity, preliminary cause of death (inpatient only), and preliminary date of death (inpatient only)
  - Change the patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity, preliminary cause of death (inpatient only), and preliminary date of death (inpatient only)
  - Display the patient's changed preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity, preliminary cause of death (inpatient only), and preliminary date of death (inpatient only)
- (a.6) Problem List
  - Record a problem to the problem list
  - Change a problem on the problem list
  - Display the active problem list
  - Display the historical problem list
- (a.7) Medication list
  - Record a medication to the medication list
  - Change a medication on the medication list
  - Display the active medication list
  - Display the historical medication list
- (a.8) Medication allergy list
  - Record a medication allergy
  - Change a medication allergy
  - Display the active medication allergy list
  - Display the historical medication allergy list
- (a.9) Clinical Decision support
  - Add a CDS intervention and/or reference resource for each of the required elements
    - Problem list
    - Medication list
    - Medication Allergy List

- At least one Demographic
- Laboratory Test
- Vital Signs
- And a combination of at least 2 of the elements listed above
  - Trigger the CDS interventions/resources added using the applicable data elements from each of the required elements
  - View the intervention/resource information using the Infobutton standard for data elements in the problem list, medication list, and demographics
  - Trigger the CDS interventions/resources based on data elements in the problem list, medication list, and medication allergy list by incorporating patient information from a transition of care/referral summary
  - Access the following attributes for one of the triggered CDS interventions/resources: bibliographic citation, developer, funding source, release/revision date
- (a.14) Implantable Device List
  - Record UDI
  - Change UDI Status
  - Access UDI, device description, identifiers, and attributes
- (b.2) Clinical Information Roconciliation and Incorporation
  - Incorporate a CCDA and conduct a reconciliation of the medications, medication allergies, and problems in the CCDA with the information currently in the patient's record
  - Generate a new CCDA with reconciled data

During the 60-minute usability test, the participants were greeted by

the administrator and were instructed that they could withdraw at any time. Participants did

not have prior experience with the EHR. The administrator gave a training that users would

typically give before the usability study began.

The administrator introduced the test, and instructed participants to complete a series of tasks

(given one at a time) using the EHRUT. A video capture software was used to provide video

capture of the user as the study progressed. As a result, participant screens, head shots and

audio were recorded for subsequent analysis. The administrator read the instructions shown

on the screen before the participant started each task but did not give the participant

assistance in how to complete the task. The following types of data were collected for each

participant:

- Number of tasks successfully completed within the allotted time without assistance
- Time to complete the tasks
- Number of errors
- Participant's verbalizations
- Participant's satisfaction ratings of the system

All participant data was de-identified – no correspondence could be made from the identity of the participant to the data collected. Following the conclusion of the testing, participants were asked to complete a posttest questionnaire and were compensated with a $100 Amazon gift card for their time. In addition to the performance data, the following qualitative observations were made:

- Major findings

> Much of the program is designed with input from those already using the program, and said users have an easier time than those who are new to Dentrix Enterprise. Many of the users who had never seen the program before had a harder time understanding the workflow and layout of many of the modules. Many of the older parts of the program (i.e. the ledger) have lost much of their inherent usability as overall ledger methodologies have changed in the medical realm. These older parts of the program, although still very usable, take longer than desired to learn and use. The newer modules did not have this issue and implements newer UX/UI approaches and were easier to use and more visually appealing to new users.

- Areas for improvement

> The concept of a glabal setting or secrity right is non-existent with new users of this program, which causes some issues in workflow. For example, for one of our users the setting that allowed the creation of new users was unintentionally turned off. The user in this scenario was asked to create a new patient and they constantly searched to no avail. Users should have some indication (either by a greyed out button or something similar) to let them know that the option is there, just not available to them for some reason. This would save time in training new users.

[1]See Tullis, T. & Albert, W. (2008). Measuring the User Experience. Burlington, MA: Morgan Kaufman (p. 149). Broadly interpreted, scores under 60 represent systems with poor usability; scores over 80 would be considered above average.

2. INTRODUCTION

The EHRUT tested for this study was Dentrix Enterprise 11.0 CE dental practice management system. Designed to present medical information to healthcare providers in dental clinics, the EHRUT consists of several modules that each have a purpose in the collecting, storing, and manipulation of health information for dental clinics. The usability testing attempted to represent realistic exercises and conditions.

The user-centered designing standard/process that was followed to create Enterprise 11.0 CE is an organic process, but matches closest to the ISO standard (ISO 13407).

ISO 13407 is a guide to assisting developers of EHRs to create human-centered design processes for interactive systems. This development approach is designed to support discovery early in the development cycle for new needs and needs to change existing functionality through direct dialog with clients, usability testing, beta testing with survey feedback, user groups, and forums. Changes and enhancements are implemented throughout the entire development cycle for any given version to be released.

 The purpose of this study was to test and validate the usability of the current user interface, and provide evidence of usability in the EHR Under Test (EHRUT). To this end, measures of effectiveness, efficiency and user satisfaction, such as time taken per task were captured during the usability testing.

3. METHOD

3.1   PARTICIPANTS

A total of 10 participants were tested on the EHRUT(s). Participants in the test all had several

years of experience working in a dental practice in various positions. Participants were recruited

by David Danielson and Ben Nielson from Henry Schein One and were compensated with a $100

Amazon gift card for their time. Participants were not from the testing or supplier organization.

Participants were given the opportunity to have the same orientation and level of training as the

actual end users would have received. For the test purposes, end-user characteristics were

identified using a demographics questionnaire filled out by the proctor. Recruited participants had

a mix of backgrounds and demographic characteristics. The following is a table of participants by

characteristics, including demographics, professional experience, and user needs for assistive

technology. Participant names were replaced with Participant IDs so that an individual's data

cannot be tied back to individual identities.

Table 1

Part ID	Gender	Age	Background	Professional Experience	Computer Experience	Participant Product Experience	Participant Assistive Technology Needs
1	F	35-40	Dental Assistant	High	High	Medium	No
2	F	30-35	Front Desk Volunteer	None	High	None	No
3	F	20-25	Dental Hygiene Student	Medium	High	None	No
4	F	20-25	Student	None	High	None	No
5	F	40-45	Hygienist	High	High	None	No
6	M	25-30	Dental Marketing / sales	None	High	None	No
7	F	20-25	Student	None	High	None	No
8	F	20-25	Student	None	High	None	No
9	F	35-40	Dental Product Analyst	None	High	None	No
10	M	25-30	Marketing Manager	None	High	None	No

Ten participants were originally recruited; however, one participant was not able to start the tasks due to technical difficulties. This participant's data was disregarded and another participant was found to replace them. Participants were scheduled for an hour session with a brief introduction before the testing began. The screen capture software was used to record participant interactions, answers to questions and each participant's demographic characteristics.

3.2   STUDY DESIGN

Overall, the objective of this test was to uncover areas where the application performed well – that is, effectively, efficiently, and with satisfaction – and areas where the application failed to meet the needs of the participants. The tasks were designed around features that are required for Meaningful Use. The data from this test may serve as a baseline for future tests with an updated version of the same EHR and/or comparison with other EHRs provided the same tasks are used. In short, this testing serves as both a means to record or benchmark current usability, but also to identify areas where improvements must be made.

During the usability test, participants interacted with multiple fictitious EHR. Each participant used the system in one of two rooms, and was provided with 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
- Time to complete the tasks
- Number of errors
- Participant's verbalizations (comments)
- Participant's satisfaction ratings of the system

Additional information about the various measures can be found in Section 3.9 on Usability Metrics.

3.3   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:

- (a.1) CPOE –Meds
  - Record medication via CPOE
  - Change medication via CPOE
  - Display changed CPOE medication order
- (a.2) CPOE – Labs
  - Record Lab order via CPOE
  - Change Lab order via CPOE
  - Display changed CPOE Lab order
- (a.3) CPOE – Diagnostic Imaging
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    - Medication list
    - Medication Allergy List
    - At least one Demographic
    - Laboratory Test
    - Vital Signs
    - And a combination of at least 2 of the elements listed above
  - Trigger the CDS interventions/resources added using the applicable data elements from each of the required elements
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  - Trigger the CDS interventions/resources based on data elements in the problem list, medication list, and medication allergy list by incorporating patient information from a transition of care/referral summary
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- o Change UDI Status
- o Access UDI, device description, identifiers, and attributes
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  - o Incorporate a CCDA and conduct a reconciliation of the medications, medication allergies, and problems in the CCDA with the information currently in the patient's record
  - o Generate a new CCDA with reconciled data

Tasks were selected based on their frequency of use, criticality of function, and those that may be most troublesome for users. Tasks should always be constructed in light of the study objectives. A full list of the design of the tasks can be found in Appendix 5.1.2.

3.4   PROCEDURES

Upon arrival, participants were greeted, their identity was verified and matched with a name on the participant schedule.

To ensure that the test ran smoothly, a usability administrator participated in each of the tests, along with a technical supervisor. The usability administrators conducting the test. The administrator moderated the session including administering instructions and tasks.

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

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

For each task, the participants were shown a typed task on the computer screen. Task timing began once the administrator finished reading the question. The task time was stopped once the participant indicated they had successfully completed the task.

Scoring is discussed below in Section 3.9.

Participants were thanked for their time and compensated. Participants signed a receipt and acknowledgement form (See Appendix 6) indicating that they had received the compensation.

3.5   TEST LOCATION

The test facility included a waiting area and a quiet testing room with a table and a computer for the participant, which also had Morae to record the needed data and patient interactions. Only the participant and administrator were in the test room, with the occasional appearance from the technical supervisor to make sure the machines were working in each room.

3.6   TEST ENVIRONMENT

The EHRUT would be typically be used in a dental-related healthcare office or facility. In this instance, the testing was conducted at Henry Schein One headquarters. For testing, the computers used were laptops with Windows 10 that were running a virtual machine, which was also running Windows 10. The Dentrix Enterprise program and test database was running in the virtual machine.

 The participants used a wireless mouse and the laptop keyboard when interacting with the EHRUT. The application was set up by the technical supervisor according to the vendor's documentation describing the system set-up and preparation. The application itself was running on a virtual machine with a local test database. 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 (such as control of font size).

3.7   TEST FORMS AND TOOLS

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

1. Informed Consent
2. Participant Task List and Standard Moderator Script/Questions
3. Post-test Questionnaire
4. Incentive Receipt and Acknowledgment Form

Examples of these documents can be found in Appendices 3-6 respectively. The Moderator's Guide was devised so as to be able to capture required data. The participant's interaction with the EHRUT was captured and recorded digitally with screen capture software running on the test machine. A web camera

recorded each participant's facial expressions synced with the screen capture, and verbal comments were

recorded with a microphone. The test sessions were saved to the test laptops where analysts could

observe the test session later.

3.8 PARTICIPANT INSTRUCTIONS

The administrator welcomed the participants and explained the study in a manner as follows:

> *Thank you for participating in this study. Your input is veryimportant. Our session today will last about 1 hour. During that time you will use an instance of an electronic health record. I will ask you to complete a few tasks using this system and answer some questions. Please try to complete the tasks on your own following the instructions very closely. Please note that we are not testing you we are testing the system, therefore if you have difficulty all this means is that something needs to be improved in the system. I will be here in case you need specific help, but I am not able to instruct you or provide help in how to use the application. Overall, we are interested in how easy (or how difficult) this system is to use, what in it would be useful to you, and how we could improve it. I did not have any involvement in its creation, so please be honest with your opinions. All of the information that you provide will be kept confidential and your name will not be associated with your comments at any time. Should you feel it necessary you are able to withdraw at any time during the testing.*

Following the procedural instructions, participants were shown the EHR and as their first task, were given

time to explore the system and make comments.

Participants were then given ten tasks to complete. Tasks are listed in the moderator's guide in Appendix 4.

3.9 USABILITY METRICS

According to the NIST Guide to the Processes Approach for Improving the Usability of Electronic Health

Records, EHRs should support a process that provides a high level of usability for all users. The goal is for

users to interact with the system effectively, efficiently, and with an acceptable level of satisfaction. To this

end, metrics for effectiveness, efficiency and user satisfaction were captured during the usability testing.

The goals of the test were to assess:

1. Effectiveness of Dentrix Enterprise by measuring participant success rates
   and errors

2. Efficiency of Dentrix Enterprise by measuring the average task time and path
   deviations

3. Satisfaction with Dentrix Enterprise by measuring ease of use ratings

3.10   DATA SCORING

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

Measures	Rationale and Scoring
Effectiveness: Task Success	A task was counted as a "Success" if the participant was able to achieve the correct outcome, without assistance, within the time allotted on a per task basis. The total number of successes were calculated for each task and then divided by the total number of times that task was attempted. The results are provided as a percentage. 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, is recorded when constructing tasks. Target task times used for task times in the Moderator's Guide must be operationally defined by taking multiple measures of optimal performance and multiplying by some factor [e.g., 1.25] that allows some time buffer because the participants are presumably not trained to expert performance. Thus, if expert, optimal performance on a task was 20 seconds then allotted task time performance was 148 seconds (multiplier of 7.25). This ratio should be aggregated across tasks and reported with mean and variance scores.
Effectiveness: Task Failures	If the participant abandoned the task, did not reach the correct answer or performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as an "Failures." No task times were taken for errors of this sort. The total number of errors was calculated for each task and then divided by the total number of times that task was attempted. Not all deviations would be counted as errors.[11] This should also be expressed as the mean number of failed tasks per participant. On a qualitative level, an enumeration of errors and error types should be collected.
Efficiency: Task Deviations	The participant's path (i.e., steps) through the application was recorded. Deviations occur if the participant, for example, went to a wrong screen, clicked on an incorrect menu item, followed an incorrect link, or interacted incorrectly with an on-screen control. This path was compared to the optimal path. The number of steps in the observed path is divided by the number of optimal steps to provide a ratio of path deviation.
	It is strongly recommended that task deviations be reported. Optimal paths (i.e., procedural steps) should be recorded when constructing tasks.

Efficiency: Task Time	Each task was timed from when the participant pressed the "Start Task" button until the participant pressed "End Task." If he or she failed to press "End Task," 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 per task was calculated for each task. Variance measures (standard deviation and standard error) were also calculated.
Satisfaction: Task Rating	Participant's subjective impression of the ease of use of the application 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 "Overall, this task was:" on a scale of 1 (Very Easy) to 5 (Very Difficult). These data are averaged across participants. Common convention is that average ratings for systems judged easy to use should be 3.3 or above. To measure participants' confidence in and likeability of the Dentrix Enterprise overall, the testing team administered the System Usability Scale (SUS) post-test questionnaire. Questions included, "I think I would like to use this system frequently," "I thought the system was easy to use," and "I would imagine that most people would learn to use this system very quickly." See full System Usability Score questionnaire in Appendix 5.

Table 2. Details of how observed data were scored.

4. RESULTS

4.1   DATA ANALYSIS AND REPORTING

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above. A couple of issues with the testing details affected the actual usage of the participant. These issues directly influenced the task time and ultimately influenced the task ratings. It was not possible to quantify the exact impact the issues had on the related tasks, so the data shown in table 2 does not include any adjustments due to the two following issues:

1. One of the usability laptops experienced hardware failure (blue screen) multiple times during one of the participant's test. It is suspected that the systems RAM is failing and the errors were not caused by Dentrix Enterprise or the virtual machine that the software was running in because the other machine functioned properly with the same virtual machine.

2. It was discovered during the training that the CCDA file that was supplied on the training laptop to be imported during the training, was corrupt and prevented the ability to view the CCDA

incorporation screen. Time did not permit to allow participants to see a proper training on the reconciliation so only verbal training was given. The CCDA files on the usability testing laptops were valid files, but it was apparent that the lack of training affected the ability of the participants to complete the task in optimal time.

4.2   DISCUSSION OF THE FINDINGS

This usability study was performed to test the UX/UI design of new features required my new meaningful use requirements. Participants who have never viewed the program before were given tasks to perform and their feedback was used to determine if the new requirements were up to the highest standard of usability. At least one participant failed each of the tasks, other were failed due to poor setup, and others were consistently successful. It was found that the tasks that failed more than others were found in older parts of the program, which need to be updated in some respects to match new workflow methodologies. Many of the failed tasks were not due to problems in the workflow per se, but were instead due to time constraints that were given to the participants. Most of the tasks had a five-minute time limit, which was sufficient for most users.

4.2.1   EFFECTIVENESS

Each participant was given an hour to perform all of the tasks, and this was found to be not nearly enough time to complete the full list of tasks. The tasks were tested beforehand for effectiveness, but those testing had at least some experience with the modules used, which could have skewed the time that was expected to be needed. Most of the tasks were relatively simple for new users, while others required knowledge that would normally be given in a training (such as global settings). For example, some patients had trouble creating new patients for the A.5 test due to unintended global settings circumstances. There was no way to know these in the moment though for the participant. Due to this test, a change could be made where a message appears letting users know that an action they would like to perform is locked due to settings under manager control.

It was found during testing that one or two tasks were too vague for the participant. Proctors were attempting to create tasks that did not specifically tell the participant what to do, but also gave them enough information to complete the tasks. This balance was seemingly found with most of the tasks, others were analyzed for

problems, which were recorded for future alterations. An example of this is not letting the patient know that the previous task completed was directly connected to the next task. This caused some confusion as some participants left the open module to "start fresh" for each task, when the task was written as if the module in question was already opened.

4.2.2 EFFICIENCY

Each task was given 5 minutes to complete, and while this was more than enough time for many of the tasks, this was not enough for others. Specifically test a.9 would have been hard to finish in 5 minutes for even those familiar to the program. The first few participants who did this test went well over time to complete the task, however deviations do not account for this, as those are low. There was also some confusion with participants where the previous participant's work was not redacted. For example, the participants were required to set up a medical alert for a patient, which pops up a window showing that alert, and one of the participants had this alert appear before they even made it. Many of the tasks could be improved for greater efficiency in future tests, while a more in-depth pre-training could be effective for new participants to understand the basic sections of the program to get them started quicker.

4.2.3 SATISFACTION

The apparent satisfaction of the participants was sufficient for the modules and tests. The few deviation from this were mostly due to problems in the test description or problems in the setup. Some participants mentioned that some parts of the product looked slightly dated, but usability was not affected by this perception. Issue details are described in previous sections.

4.2.4 MAJOR FINDINGS

There are many workflows in the program that are slightly longer than is needed, and due to the nature of dental software, there are many options on each screen which can be overwhelming to new users. Many updates to older modules of the application have shown to be much more user friendly and these findings should be used in the rewriting of other modules in the future. These older parts of the program, although still very usable, take longer than desired to learn and use. The newer modules implement newer UX/UI approaches, are easier to use, and more visually appealing to new users. We can use what we have learned

in the newer model and apply them to the shortcomings of modules some users found complex. Tasks that were failed were mostly not due to a participant giving up, but was rather due to time constraints that were given to the participants. Many of the parts of the software need not be overhauled, but rather redesigned to be more streamlined and efficient. Giving users an experience that is easier to follow (maybe with the use of dashboards or navigation maps) would allow users to more easily notice the complexities of enterprise level dental software.

4.2.5   AREAS FOR IMPROVEMENT

Much of the program was designed with input from those already using the program, and said users have an easier time than those who are breand new to Dentrix Enterprise. Many of th users who had never nees the program before had a harder time understanding the workflow and layout of many of the modules. Many of the older parts of the program (i.e the ledger) have lost much of their inherint usability as overall ledger methadlogies have changed in the medical realm. These older parts of the program, although still very usable, take longer than desired to learn and use. The newer modules did not have this issue and have been created with newer UX/UI approaches. They were eaier to use and more visually appealing to new users. An update to older modules would allow for a greater ease-of-use, modeling them after newer, more appealing modules.

The goal of the UX design is to keep required training minimal for all modules of the application. Many backend functions (such as accounting principles and global (manager) settings) are not currently easily apparent to new users. This could easily be changed with use of warnings or extra tooltips in more unclear sections of the program. Some modules could make use of more descriptive names to allow users to know exactly how the module is used. For example, the "Messenger" module is easy to understand, while the "Medical Alerts" module was not implicitly apparent on functionality from just its name and the main page when opening the module.

4.2.6   RISK ANALYSIS

Many of the participants had to have medical alerts explained to them, which could be a risk for offices. If a clinic worker knows of a problem, allergy, or medication that a patient has, but cannot find where to enter that into the application, then they may give up and forget to address it later. This could cause a patient to come in and a doctor not knowing that have some dangerous allergy. A name change or a more descriptive module home screen could fix this. Some of the participants did open up the help files where a better description of the module is found.

We have many modules that are apparently simple to use (such as demographics) however, some workflows (such as implantable devices) are not as intuitive. Because this is an enterprise level software, there is a lot that the program needs to do. Below is a list of all of the tasks according to risk before testing was performed.

Task	Risk
(a.8) Medication allergy list	High
(a.7) Medication list	High
(b.2) Clinical Information Roconciliation and Incorporation	High
(a.6) Problem List	Med
(a.9) Clinical Decision support	Med
(a.14) Implantable Device List	Med
(a.1) CPOE –Meds	Low
(a.2) CPOE – Labs	Low
(a.3) CPOE – Diagnostic Imaging	Low
(a.5) Demographics	Low

A.8 and a.7 are the highest risk to patients as mistakes in these modules could have more detrimental effects than if a mistake were to be made on a task such as a.5 (demographics). B.2 is ranked as such due to the bulk of this module dealing with various types of information about a patient. Dentists deal with many types of medication during and after procedures, and needs to know the risks with certain patients. Usability testing will focus on results of these tasks much closer to determine potential failings in the software. A.6 has similar yet less extensive repercussions for mistakes and has a lower associated risk as such.

Below is a list of all of the tested tasks with their associated risk after testing was performed.

Task	Risk
(b.2) Clinical Information Roconciliation and Incorporation	High
(a.14) Implantable Device List	High
(a.8) Medication allergy list	High
(a.7) Medication list	Med
(a.6) Problem List	Med
(a.9) Clinical Decision support	Med
(a.1) CPOE –Meds	Low
(a.2) CPOE – Labs	Low
(a.3) CPOE – Diagnostic Imaging	Low
(a.5) Demographics	Low

The risk stayed the same as considered risk before testing was performed except for task a.14, b.2, and a.7. A.14 and b.2 are marked as the highest due to the lack of sufficient testing during the user testing process. No participant was able to finish a.14 due to the complicated nature of the task combined with the lack of time provided in the usability-testing environment while b.2 only had one articipant succeed the task for similar reasons. A.14 was the last task on the list, and participants upon reaching this task were over the allotted one hour given to complete all testing. Due to this fact, participants were given insufficient time to complete each of these tasks. While all of a.14 should have been given around 20 minutes to complete under the circumstances, participants were instead given 5 to 10 minutes, which was shown to be insufficient for grounds to completion. A.7 dropped in potential risk as the module was shown to much easier than expected for participants to use. 90% of participants were able to finish these tasks with minimal deviations as compared to other tasks. A.8 and is marked as high due to the extensive amount of time it took the participants to understand and use this part of the software. The test results show that in a fast-paced environment of a dental office one would have a probable chance to miss critical information regarding the patient's health. For example, 50% of the participants were not able to complete task 8.1 of filling out an allergy in the allotted time. This could cause problems in the real world where not marking a patient's allergy to a certain medication could be extremely dangerous to the patient's health. The same issues are associated with a.6 and a.9 but to a smaller extent. A.9 has a success rate of 30% in the allotted time; however, the consequences of failing this task in a real world situation are much lower than that of the higher level risk items. The last four on the list are low due to their effect on patients, but also due to their more easily usable features. Some of the features may have taken the patients a considerable amount of time; however, that was due to workflow, not confusion. The workflows were relatively straightforward and understandable for the bulk of the participants.

28-Feb-19

5. APPENDICES

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

1. Participant Demographics

2. Non-Disclosure Agreement (NDA) and Informed Consent Form

3. Participant Task List and Standard Moderator Script/Questions

4. Incentive receipt

It is important to note that these Appendices are **examples** only. They are not intended to be used exactly as rendered below.

For example, the intended users of the system will determine sampling requirements which drive screener questions. Likewise, the goals of the study will determine the exact tasks and data to be recorded; this will create the tasks and data collection plan in the moderator's guide.

See some of the previously cited references for examples of these documents.

5.1 Appendix 2: PARTICIPANT DEMOGRAPHICS

Part ID	Gender	Age	Background	Professional Experience	Computer Experience	Participant Product Experience	Participant Assistive Technology Needs

5.1.2 Appendix 2.1: TASK DESIGN

Required User Tasks for (g.3) SED Testing:

(a.1) CPOE –Meds

Given steps

- Record medication via CPOE
- Change medication via CPOE
- Display changed CPOE medication order

Preconditions

- Access Prescription Setup
- Setup following list of prescriptions:
  - Ceftriaxone 250 MG/ML; twice daily; RxNorm code: 563973; NDC product code: 55154-6962-5
  - Ceftriaxone 500 MG/ML twice daily; RxNorm: 1665004; sample NDC product code: 25021-105-10
  - Tylenol 500 MG; one tablet by mouth as needed for 10 days; RxNorm code: 209459; NDC product code: 50580-451-03

- Darbepoetin Alfa 0.5 MG/ML; once a week; injection; RxNorm: 576586; NDC product code: 55513-025-04
- Amoxicillin 500 MG; one capsule by mouth every 12 hours; RxNorm code: 308191; NDC product code: 35356-985-21

Task List

Record CPOE Medication Orders

- Login into Enterprise under central clinic
- Select any patient e.g. Prescription Test
- Add prescriptions for selected patient as follows:
    - Ceftriaxone 250 MG/ML; twice daily; RxNorm code: 563973; NDC product code: 55154-6962-5
    - Tylenol 500 MG; one tablet by mouth as needed for 10 days; RxNorm code: 209459; NDC product code: 50580-451-03
    - Darbepoetin Alfa 0.5 MG/ML; once a week; injection; RxNorm: 576586; NDC product code: 55513-025-04
    - Amoxicillin 500 MG; one capsule by mouth every 12 hours; RxNorm code: 308191; NDC product code: 35356-985-21

Change CPOE Medication Orders

- Access prescription settings
- Edit an existing prescription and change the following, medication orders (changes underlined)
    - Ceftriaxone <u>500 MG/ML</u> twice daily; RxNorm: <u>1665004</u>; sample NDC product code: <u>25021-105-10</u>
    - Tylenol 500 MG; <u>one tablet twice daily for 3 days</u>; RxNorm code: 209459; NDC product code: 50580-451-03
    - Amoxicillin 500 MG; one capsule by mouth <u>every 6 hours</u>; RxNorm code: 308191; NDC product code: 35356-985-21
- Update the patient prescription list by inactivating invalid prescription.
- Add following prescriptions to patient and update the list as follows:
    - Ceftriaxone 500 MG/ML twice daily; RxNorm code: 1665004; sample NDC product code: 25021-105-10
    - Tylenol 500mg one tablet twice daily for 3 days; RxNorm code: 209459; sample NDC product code: 50580-451-03
    - Darbepoetin Alfa 0.5 MG/ML once a week; injection; RxNorm: 576586; sample NDC product code: 55513-025-04
    - Amoxicillin 500 MG one capsule by mouth every 6 hours; RxNorm code: 308191; sample NDC product code: 35356-985-21

Access CPOE Medication Orders:

- From either chart, appointment book, family file, ledger or treatment planner, with a patient selected, access prescriptions
- From the list of patient prescriptions, view inactive prescriptions

(a.2) CPOE – Labs

Given Steps

- Record Lab order via CPOE

- Change Lab order via CPOE
- Display changed CPOE Lab order

Task List

Record Lab order via CPOE

- Login to Dentrix using the 'Central' Clinic
- Add a laboratory order for a patient
- Select any patient e.g. Prescription Test
- Enter the LOINC code# 2085-9 of the laboratory order "Cholesterol in HDL in serum or plasma"
- Select any future date as the scheduled test date

Change Lab order via CPOE

- Change status of the "Cholesterol in HDL in serum or plasma" (LOINC code# 2085-9) to "Canceled"
- Add the laboratory order "Cholesterol in LDL in serum or plasma by direct assay" (LOINC code: 18262-6) for the patient
- Select any future date as the scheduled test date

Display changed CPOE Lab order

- Review the orders section for the patient to confirm that the correct changes were made.

(a.3) CPOE – Diagnostic Imaging

Given Steps

- Record Imaging order via CPOE
- Change Imaging order via CPOE
- Display changed CPOE Imaging order

Task List

Record imaging order via CPOE

- Login to Dentrix using the 'Central' Clinic
- Add Imaging order for a patient
- Select any patient e.g. Prescription Test
- Open 'Dentrix Chart' module for the selected patient
- Enter Radiology procedure code# D0277 in text area under the Complete button
- Click on the 'Complete' button

Change Imaging order via CPOE

- Open the 'Edit or Delete Procedure' window
- Change the Radiology procedure code# to D0330

Display changed CPOE Diagnostic Imaging order

- Review the grid below the chart for the patient to confirm that the correct changes were made.

(a.5) Demographics

Given Steps

- Record a patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity, preliminary cause of death (inpatient only), and preliminary date of death (inpatient only)

- Change the patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity, preliminary cause of death (inpatient only), and preliminary date of death (inpatient only)
- Display the patient's changed preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity, preliminary cause of death (inpatient only), and preliminary date of death (inpatient only)

Preconditions

- Access *Dentrix Office Manager > Maintenance > Practice Setup > Definitions:*
- *Language Category:*
  - 'French' Language with ISO639-1 Code: fr is added
  - 'Spanish' Language with ISO639-1 Code: es is added
- *Definitions > Race:*
  - 'Haitian' Race with CDC Race code 2071-9 is added
  - 'Dominican' Race with CDC Race code 2069-3 is added
- *Definitions > Ethnicity:*
  - 'Not Hispanic or Latino' Ethnicity with CDC Ethnicity code 2186-5 is added
  - 'Dominican' Ethnicity with CDC Ethnicity code 2184-0 is added
- *Definitions > Sexual Orientation:*
  - 'Straight or heterosexual' Sexual Orientation with SnomedCode 20430005 is added
  - 'Bisexual' Sexual Orientation with SnomedCode 42035005 is added
- *Definitions > Gender Identity:*
  - 'Identifies as Male' Gender Identity with SnomedCode 446151000124109 is added
  - 'Male-to-Female (MTF)/Transgender Female/Trans Woman' Gender Identity with SnomedCode 407376001 is added

Task List

Record a patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity

- Login to Dentrix using the 'Central' Clinic
- Create new patient with Demographics information:
  - Enter value into Last and First Name fields (e.g. Demographics/Test)
  - Add Patient's Primary Provider and EDI PI
  - And Address (e.g. Ivy St, Denver, CO, 80203, United States of America)
  - Date of Birth : 8/31/1938
  - Sex : Male
  - Preferred Language : French (ISO639-1 Code: fr)
  - Race: Haitian (CDC: 2071-9). OMB standard Black or African American (CDC: 2054-5)
  - Ethnicity : Not Hispanic or Latino (CDC: 2186-5)
  - Sexual Orientation : Straight or heterosexual (SNOMED: 20430005)
  - Gender Identity : Identifies as Male (SNOMED: 446151000124109)

Change the patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity

- Change Demographics information for a patient.
- Select the same patient > Fill following data for the patient:
  - Date of Birth : 3/15/1982
  - Sex : Female

- o Preferred Language : Spanish (ISO639-1 Code: es)
- o Race: Dominican (CDC: 2069-3). OMB standard: Black or African American (CDC: 2054-5)
- o Ethnicity: Dominican (CDC: 2184-0). OMB standard: Hispanic or Latino (CDC: 2135-2)
- o Sexual Orientation : Bisexual (SNOMED: 42035005)
- o Gender Identity : Male-to-Female (MTF)/Transgender Female/Trans Woman (SNOMED: 407376001)
- Click 'OK' button to save the changed demographic information

Display the patient's changed preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity

- Select the same patient > Open 'Patient Information' screen
- Review the 'Patient Information' screen for the patient to confirm that the correct changes were made.

(a.6) Problem List

Given Steps

- Record a problem to the problem list
- Change a problem on the problem list
- Display the active problem list
- Display the historical problem list

Preconditions

- Set up the list of problems under *Dentrix Office Manager > Maintenance > Practice Setup > Definitions>Problems:*
  - o Essential Hypertension (disorder); SNOMED code: 59621000
  - o Diabetes Mellitus Type 2 (disorder); SNOMED code: 44054006
  - o Acquired Hypothyroidism (disorder): SNOMED code: 111566002
  - o Chronic Rejection of Renal Transplant (disorder); SNOMED code: 236578006
  - o Severe Hypothyroidism (disorder) SNOMED code: 83986005

Task List

Record a problem to the problem list

- Login to Dentrix using the 'Central' Clinic
- Add a new Problem to the problem list
- Select any patient e.g. Prescription Test
- Enter the problems as follows:
  - o Essential Hypertension (disorder); SNOMED code: 59621000
  - o Diabetes Mellitus Type 2 (disorder); SNOMED code: 44054006
  - o Acquired Hypothyroidism (disorder): SNOMED code: 111566002
  - o Chronic Rejection of Renal Transplant (disorder); SNOMED code: 236578006

Change a problem on the problem list

- RESOLVE Diabetes Mellitus Type 2 (disorder) SNOMED code: 44054006
  - o Inactivate with 'Resolved' reason
- Edit Acquired Hypothyroidism (disorder): SNOMED code: 111566002
  - o Change selected problem to Severe Hypothyroidism (disorder) SNOMED code: 83986005

Display the active problem list

- Review the active problem list for the patient:
  - Essential Hypertension (disorder); SNOMED code: 59621000
  - Severe Hypothyroidism (disorder); SNOMED code: 83986005
  - Chronic Rejection of Renal Transplant (disorder); SNOMED code: 236578006

Display the historical problem list

- Access Medical Alerts History to review historical records:
  - ADDED: Essential Hypertension (disorder); SNOMED code: 59621000
  - RESOLVED Diabetes Mellitus Type 2 (disorder) SNOMED code: 44054006
  - MODIFIED Severe Hypothyroidism (disorder) SNOMED code: 83986005
  - ADDED: Chronic Rejection of Renal Transplant (disorder); SNOMED code: 236578006

(a.7) Medication list

Given Steps

- Record a medication to the medication list
- Change a medication on the medication list
- Display the active medication list
- Display the historical medication list

Preconditions

- Set up the list of Medications under *Dentrix Office Manager > Maintenance > Practice Setup > Definitions>Medications:*
  - Ceftriaxone 250 MG/ML twice daily; RxNorm: 563973
  - Ceftriaxone 500 MG/ML twice daily; RxNorm code: 1665004
  - Tylenol 500 MG one tablet by mouth as needed for 10 days; RxNorm: 209459;
  - Darbepoetin Alfa 0.5 MG/ML once a week; injection; RxNorm: 576586;
  - Amoxicillin 500 MG one capsule by mouth every 12 hours; RxNorm: 308191;
  - Lisinopril 20 MG; three tablets once daily for 30 days; 100 count; 1 refill; RxNorm: 316153;

Task List

Record a medication to the medication list

- Login to Dentrix using the 'Central' Clinic
- Select any patient e.g. Prescription Test
- Add a medication for a patient
- Enter the medications as follows:
  - Ceftriaxone 250 MG/ML twice daily; RxNorm: 563973
  - Tylenol 500 MG one tablet by mouth as needed for 10 days; RxNorm: 209459;
  - Darbepoetin Alfa 0.5 MG/ML once a week; injection; RxNorm: 576586;
  - Amoxicillin 500 MG one capsule by mouth every 12 hours; RxNorm: 308191;
  - Lisinopril 20 MG; three tablets once daily for 30 days; 100 count; 1 refill; RxNorm: 316153;

Change a medication on the medication list

- DISCONTINUE Lisinopril 20 MG; RxNorm: 316153 medication;
- Instead of Ceftriaxone 250 MG/ML; RxNorm code: 563973 medication, add Ceftriaxone 500 MG/ML; RxNorm code: 1665004 medication
- Select Tylenol 500 MG, RxNorm: 209459 and change the 'Sig' from 'one tablet by mouth as needed for 10 days' to 'one tablet twice daily for 3 days';

Display the active medication list

- Access the "Medical Alerts" window for selected patient
- Review the active medication list in the "Medications / Prescriptions" section:
  - Ceftriaxone 500 MG/ML twice daily; RxNorm: 1665004
  - Tylenol 500 MG one tablet twice daily for 3 days; RxNorm: 209459;
  - Darbepoetin Alfa 0.5 MG/ML once a week; injection; RxNorm: 576586;
  - Amoxicillin 500 MG one capsule by mouth every 12 hours; RxNorm: 308191;

Display the historical medication list

- Access Medical Alerts History to review historical records:
  - INACTIVATED - Lisinopri1 20 MG; RxNorm Code: 316153
  - MODIFIED - Ceftriaxone 500 MG/ML twice daily; RxNorm code: 563973;
  - ADDED - Darbepoetin Alfa 0.5 MG/ML once a week; injection; RxNorm: 576586;
  - MODIFIED - Tylenol 500mg one tablet twice daily for 3 days; RxNorm code: 209459;
  - ADDED - Amoxicillin 500 MG one capsule by mouth

(a.8) Medication allergy list

Given Steps

- Record a medication allergy
- Change a medication allergy
- Display the active medication allergy list
- Display the historical medication allergy list

Preconditions

- Set up the list of Allergies under *Dentrix Office Manager > Maintenance > Practice Setup > Definitions>Allergies:*
  - Sulfasalazine; RxNorm code: 9524
  - Penicillin V; RxNorm code: 7984
  - Carbamazepine; RxNorm code: 2002
  - Penicillin G; RxNorm code: 7980
  - Codeine; RxNorm code: 2670
- Set up the list of reaction under *Definition > Allergy Reaction:*
  - Wheezing
  - Dizziness
  - Skin rash

Task List

Record a medication allergy

- Login to Dentrix using the 'Central' Clinic
- Select any Patient e.g. Prescription Test
- **Add Allergies** for selected Patient
- Enter the allergies as follows:
  - Sulfasalazine; RxNorm code: 9524; Reaction: Wheezing
  - Penicillin V; RxNorm code: 7984; Reaction: Dizziness
  - Carbamazepine; RxNorm code: 2002; Reaction: Skin rash

Change a medication allergy

- INACTIVATE Sulfasalazine; RxNorm code: 9524; Reaction: Wheezing

- Instead of Penicillin V; RxNorm code: 7984; Reaction: Dizziness add Penicillin G; RxNorm code: 7980 Reaction: Dizziness
- Instead of Carbamazepine; RxNorm code: 2002; Reaction: Skin rash add Codeine; RxNorm code: 2670 Reaction: Skin rash

Display the active medication allergy list

- Access the "Medical Alerts" window for selected patient
- Review the active medication allergy list in the "Allergies":
  - Penicillin G; RxNorm code: 7980 Reaction: Dizziness
  - Codeine; RxNorm code: 2670 Reaction: Skin rash

Display the historical medication allergy list

- Access Medical Alerts History to review historical records:
  - INACTIVATED - Sulfasalazine; RxNorm code: 9524; Reaction: Wheezing
  - MODIFIED - Penicillin G; RxNorm code: 7980 Reaction: Dizziness
  - MODIFIED - Codeine; RxNorm code: 2670 Reaction: Skin rash

(a.9) Clinic Decision Support

Given steps

- Add a CDS intervention and/or reference resource for each of the required elements:
  - Problem List
  - Medication List
  - Medication Allergy List
  - At least one Demographic
  - Laboratory Test
  - Vital Signs
  - And a combination of at least 2 of the elements listed above

- Trigger the CDS interventions/resources added using the applicable data elements from each of the required elements.
- View the intervention/resource information using the Info button standard for data elements in the problem list, medication list, and demographics.
- Trigger the CDS interventions/resources based on data elements in the problem list, medication list, and medication allergy list by incorporating patient information from a transition of care/referral summary.
- Access the following attributes for one of the triggered CDS interventions/resources: bibliographic citation, developer, funding source, release/revision date.

Preconditions

- Set up the list of Allergies under *Dentrix Office Manager > Maintenance > Practice Setup > Definitions>Allergies:*
  - Codein; RxNorm code: 2670
- Set up the list of reaction under *Definition > Allergy Reaction:*
  - Shortness of Breath (Unknown)
- Set up the list of Problems under *Definition > Problems:*
  - Problem: Pneumonia with SNOMED code '233604007';
  - Endometriosis (disorder) (SNOMED 129103003),
- Set up the list of Medications under *Definition > Medications:*

- o 200 ACTUAT Albuterol 0.09 MG/ACTUAT Dry Powder Inhaler; RxNorm code: 1649560;
  - o Norethindrone (RxNorm 7514),
- *<Provider1> should have enabled 'Global Alerts, Add/Edit/Delete' and 'Global Alerts, Enable/Disable' security rights*
- *<Patient1, Patient1 > is created with next medical alerts in the 'Medical Alerts' feature:*
  - o Problem: Pneumonia with SNOMED code '233604007'; Status: Active;
  - o Medication: 200 ACTUAT Albuterol 0.09 MG/ACTUAT Dry Powder Inhaler; RxNorm code: 1649560; Dosage: Qty: 2; every 12 hours at institution specified times; Route: Respiratory (inhalation); Status: Inactive (Resolved);
- *<Patient2, Patient2> is created with next medical alerts in the 'Medical Alerts' feature:*
  - o Problem: Pneumonia with SNOMED code '233604007'; Status: Active;
- *<Patient 3, Patient 3> is created with next medical alerts in the 'Medical Alerts' feature:*
  - o Medication: 200 ACTUAT Albuterol 0.09 MG/ACTUAT Dry Powder Inhaler; RxNorm code: 1649560; Dosage: Qty: 2; every 12 hours at institution specified times; Route: Respiratory (inhalation); Status: Inactive (Resolved);
- *<Patient 4, Patient 4> is created with next medical alerts in the 'Medical Alerts' feature:*
  - o Allergy: Codein; Severity: Moderate; Allergen Type: Drug allergy; Reactions: Shortness of Breath (Unknown); RxNorm code: 2670; Status: Active;
- *<Patient 5, Patient 5> is created with a Vital Sign in the 'Patient Health Assessment' feature with Systolic equal to 120.*
- *The <Patient6, Patient 6> is created with next demographics: a female 48 years old.*
- *<Patient 7, Patient 7> is created with a Laboratory Test with selected 'Proteine [Mass/volume] in Urine by Test strip' test name and test result 'Is equal to' 10*
- *<Patient 8, Patient 8> is a female 40 years old with created medical alerts in the 'Medical Alerts' feature:*
  - o Problem: Endometriosis (disorder) (SNOMED 129103003), Status: Active;
  - o Medication: Norethindrone (RxNorm 7514), Status: Active
- *<Patient 9, Patient 9> is created and has no PAM data.*

Task list

Add a CDS intervention and/or reference resource for:

- Problem List:

  - o Login to the Enterprise under Central clinic
  - o Maintenance | Practice Setup | Global Alerts Setup… | Click 'New Global Alert' button
  - o Fill in 'Alert Name' (e.g. Test CDS - Problem), 'Alert Text' (e.g. Test Clinical Decision Support - Problem)
  - o Select areas where this alert will be displayed (e.g. 'Family File')
  - o Select types of users who will be able to see alert in the 'User types that will see this alert' section (primary providers, secondary providers, and staff)
  - o Go to 'Patient Filters' tab | Click 'Select' button in the 'Problems' section | Add 'Pneumonia'(SNOMED code: 233604007) problem to the Problem list
  - o Click 'Finish' | Verify that new Global Alert record with CDS intervention and reference for Problem list is displayed in the 'Global Alerts Setup' grid

- Medication List:

  - Maintenance | Practice Setup | Global Alerts Setup… | Click 'New Global Alert' button
  - Fill in 'Alert Name' (e.g. Test CDS - Medication), 'Alert Text' (e.g. Test Clinical Decision Support - Medication)
  - Select areas where this alert will be displayed (e.g. 'Family File')
  - Select types of users who will be able to see alert in the 'User types that will see this alert' section (primary providers, secondary providers, and staff)
  - Go to 'Patient Filters' tab | Click 'Select' button in the 'Medications' section | Add '200 ACTUAT Albuterol 0.09 MG/ACTUAT Dry Powder Inhaler' (RxNorm code: 1649560) medication to the Medications list
  - Click 'Finish' | Verify that new Global Alert record with CDS intervention and reference for Medication list is displayed in the 'Global Alerts Setup' grid

- Medication Allergy List:

  - Maintenance | Practice Setup | Global Alerts Setup… | Click 'New Global Alert' button
  - Fill in 'Alert Name' (e.g. Test CDS – Allergy), 'Alert Text' (e.g. Test Clinical Decision Support – Allergy)
  - Select areas where this alert will be displayed (e.g. 'Family File')
  - Select types of users who will be able to see alert in the 'User types that will see this alert' section (primary providers, secondary providers, and staff)
  - Go to 'Patient Filters' tab | Click 'Select' button in the 'Allergies' section | Add 'Codein' (RxNorm code: 2670) record to the Allergies list
  - Click 'Finish' | Verify that new Global Alert record with CDS intervention and reference for Allergy list is displayed in the 'Global Alerts Setup' grid

- Demographic

  - Maintenance | Practice Setup | Global Alerts Setup… | Click 'New Global Alert' button
  - Fill in 'Alert Name' (e.g. Test CDS – Demographics), 'Alert Text' (e.g. Test Clinical Decision Support – Demographics)
  - Select areas where this alert will be displayed (e.g. 'Family File')
  - Select types of users who will be able to see alert in the 'User types that will see this alert' section (primary providers, secondary providers, and staff)
  - Go to 'Patient Filters' tab | Click 'Add' button in the 'Patient Information' section | Add 'Female' gender and patient age from '12' to '75' records to the Patient Information list
  - Click 'Finish' | Verify that new Global Alert record with CDS intervention and reference for Demographic list is displayed in the 'Global Alerts Setup' grid

- Laboratory Test

  - Maintenance | Practice Setup | Global Alerts Setup… | Click 'New Global Alert' button
  - Fill in 'Alert Name' (e.g. Test CDS – Lab Test), 'Alert Text' (e.g. Test Clinical Decision Support – Lab Test)
  - Select areas where this alert will be displayed (e.g. 'Family File')

- Select types of users who will be able to see alert in the 'User types that will see this alert' section (primary providers, secondary providers, and staff)
- Go to 'Patient Filters' tab | Click 'Add' button in the 'Lab Tests Results' section | Select 'Proteine [Mass/volume] in Urine by Test strip' test name and test result 'Is equal to' 10 within '1 month' | Click 'Ok' button.
- Click 'Finish' | Verify that new Global Alert record with CDS intervention and reference for Lab Results list is displayed in the 'Global Alerts Setup' grid

- Vital Signs

  - Maintenance | Practice Setup | Global Alerts Setup… | Click 'New Global Alert' button
  - Fill in 'Alert Name' (e.g. Test CDS – Vital Signs), 'Alert Text' (e.g. Test Clinical Decision Support – Vital Signs)
  - Select areas where this alert will be displayed (e.g. 'Family File')
  - Select types of users who will be able to see alert in the 'User types that will see this alert' section (primary providers, secondary providers, and staff)
  - Go to 'Patient Filters' tab | Click 'Add' button in the 'Patient Health Assessment' section |Select a 'Systolic' with '120' value which 'Is equal to' within '1 month' | Click 'Ok' button.
  - Click 'Finish' | Verify that new Global Alert record with CDS intervention and reference for Vital Signs list is displayed in the 'Global Alerts Setup' grid
- Combination:

  - Maintenance | Practice Setup | Global Alerts Setup… | Click 'New Global Alert' button
  - Fill in 'Alert Name' (e.g. Test CDS – Combination), 'Alert Text' (e.g. Test Clinical Decision Support – Combination)
  - Select areas where this alert will be displayed (e.g. 'Patient Chart')
  - Select types of users who will be able to see alert in the 'User types that will see this alert' section (primary providers, secondary providers, and staff)
  - Go to 'Patient Filters' tab | Click 'Select' button in the 'Problems' section | Add 'Pneumonia'(SNOMED code: 233604007) problem to the Problem list
  - Click 'Select' button in the 'Medications' section | Add '200 ACTUAT Albuterol 0.09 MG/ACTUAT Dry Powder Inhaler' (RxNorm code: 1649560) medication to the Medications list
  - Click 'Finish' | Verify that new Global Alert record with CDS intervention and reference for Combination list is displayed in the 'Global Alerts Setup' grid

Trigger the CDS interventions/resources added using the applicable data elements from each of the required elements:

Combination:

- Login to the Enterprise under 'Central' clinic or <Provider1> Log ID: DEF_PROV Pass: Qwerty1!
- Open 'Family File' module and select <Patient1, Patient1>
- Go to the 'Patient Chart' module with selected <Patient1, Patient1>
- Verify that 1 global alert appeared for a combination of 2 required elements on the screen for <Patient1> with next title: 'Test CDS – Combination'

Problem List:

- Login to the Enterprise under 'Central' clinic or <Provider1> Log ID: DEF_PROV Pass: Qwerty1!
- Open 'Family File' module and select <Patient2, Patient2>
- Verify that 1 global alert appeared for <Patient2, Patient2> with next title: 'Test CDS – Problems'

Medication List:

- Login to the Enterprise under 'Central' clinic or <Provider1> Log ID: DEF_PROV Pass: Qwerty1!
- Open 'Family File' module and select <Patient3, Patient3>
- Verify that 1 global alert appeared for <Patient3, Patient3> with next title: 'Test CDS – Medication'

Medication Allergy List:

- Login to the Enterprise under 'Central' clinic or <Provider1> Log ID: DEF_PROV Pass: Qwerty1!
- Open 'Family File' module and select <Patient4, Patient4>
- Verify that 1 global alert appeared for <Patient4, Patient4> with next title: 'Test CDS – Allergy'

Vital Signs

- Login to the Enterprise under 'Central' clinic or <Provider1> Log ID: DEF_PROV Pass: Qwerty1!
- Open 'Family File' module and select <Patient5, Patient5>
- Verify that 1 global alert appeared for <Patient5, Patient5> with next title: 'Test CDS – Vital Signs'

Demographic:

- Login to the Enterprise under 'Central' clinic or <Provider1> Log ID: DEF_PROV Pass: Qwerty1!
- Open 'Family File' module and select <Patient6, Patient6>
- Verify that 1 global alert appeared for <Patient6, Patient6> with next title: 'Test CDS – Demographic'

Laboratory Test

- Login to the Enterprise under 'Central' clinic or <Provider1> Log ID: DEF_PROV Pass: Qwerty1!
- Open 'Family File' module and select <Patient7, Patient7>
- Verify that 1 global alert appeared for <Patient7, Patient7> with next title: 'Test CDS – Lab Test'

View the intervention/resource information using the Info button standard for data elements in the problem list, medication list, and demographics:

- Maintenance | Practice Setup | Global Alerts Setup… | Click 'New Global Alert' button
- Fill in 'Alert Name' (e.g. Test CDS - Info button), 'Alert Text' (e.g. Test Clinical Decision Support – Info button)
- Select areas where this alert will be displayed (e.g. 'Ledger')
- Select types of users who will be able to see alert in the 'User types that will see this alert' section
- Check 'Show on Alert' check box | Fill in next fields:
    - Bibliographic Citation: 'Test CDS';
    - Developer/Author: 'Test Provider';
    - Funding Source Of Technical Information: 'Test';
    - Release Date: [01/01/2018];
    - Revision Date: [01/01/2019];
        - Specify referential resources regarding the alert (Problems, Medications) in the 'Diagnostic and Therapeutic reference Resources' section:
    - Endometriosis (disorder) (SNOMED 129103003);

- Norethindrone (RxNorm 7514);
- Relaxation of pelvic floor (SNOMED 444599008);
  - Go to 'Patient Filters' tab | For 'Problem List' section, click 'Select' in Problems group box to select the problems that you want to check for:
- Endometriosis (disorder) (SNOMED 129103003);
- Relaxation of pelvic floor (SNOMED 444599008);
- Back pain (SNOMED 419258005);
  - For 'Medication List' filter, click 'Select' in Medication group box to select the medications that you want to check for e.g. Norethindrone (RxNorm 7514)
  - For 'Demographic' filter, click 'Select' in Patient Information group box to select the demographics that you want to check for e.g. Female, Age from 12 to 75;
  - Click 'Finish'
  - Go to the 'Family File' and select <Patient8> | Click on the 'Ledger' button | Verify that alert for <Patient8> is occurred with educational links.
  - Click on Educational URL e.g. Endometriosis (disorder) and Relaxation of pelvic floor. The web browser opens with the page of the "MedlinePlus" web-site which contain the information regarding the Problem. Verify that info is Gender specific.

Trigger the CDS interventions/resources based on data elements in the problem list, medication list, and medication allergy list by incorporating patient information from a transition of care/referral summary:

Task List:

- Login to the Enterprise under 'Central' clinic or <Provider1> Log ID: DEF_PROV Pass: Qwerty1!
- Click 'Maintenance' | 'Practice Setup' | 'Global Alerts Setup'
- Click 'New Global Alert' button
- Fill in 'Alert Name' (e.g. Test CDS - Patient Information Incorporating), 'Alert Text' (e.g. Test Clinical Decision Support – Patient Information Incorporating)
- Select 'C-CDA/eRx Reconciliation' area where this alert will be displayed.
- Select types of users who will be able to see alert in the 'User types that will see this alert' section
- Go to 'Patient Filters' tab
- For Problem List filter, click 'Select' button in the 'Problems' section | Add e.g. 'Pneumonia' (SNOMED 233604007)
- For Medication List filter, click 'Select' button in the 'Medications' section | Add e.g. 200 ACTUAT Albuterol 0.09 MG/ACTUAT Dry Powder Inhaler (RxNorm 1649560)
- For Medication Allergy list filter, click 'Select' button in the 'Allergies' section | Add e.g. Codeine (RxNorm 2670) | Click 'Finish'
- Open 'Family File' module | Select <Patient9, Patient 9> | Open 'Patient Health Exchange' feature
- On the 'Import/Received' tab click 'Browse' button and select "170.315_b2_ciri__r11_sample1_recon_v10' file with Problem – Pneumonia (SNOMED 233604007, Medication - 200 ACTUAT Albuterol 0.09 MG/ACTUAT Dry Powder Inhaler (RxNorm 1649560) and Allergy - Codeine (RxNorm 2670), location C:\Users\kwagner\Desktop\170.315_b2_ciri__r11_sample1_recon_v10.xml
- Click 'Import' button | The imported patient file appears in the History list box.

- Select the imported patient file and click on the 'Update Patient Info' button
- Set 'Add to Patient' action on all tabs in the 'Comparison' window | Click 'Finish' button.
- Click 'Yes' button on the notification | Close 'Summary of the Clinical Information Reconciliation' window.
- Verify that the Global Alert message for a <Patient9, Patient9> is displayed.

Access the following attributes for one of the triggered CDS interventions/resources: bibliographic citation, developer, funding source, release/revision date

- Login to the Enterprise
- Open 'Family File' module
- Select <Patient8, Patient 8> and go to the 'Ledger' module
- Verify that the global alert with bibliographic citation, developer, funding source, release/revision date is displayed on the screen

(a.14) Implantable Device List

Given Steps

- Record UDI
- Change UDI Status
- Access UDI, device description, identifiers, and attributes

Task List

Record UDI

- Login to Dentrix using the 'Central' Clinic
- Add Implantable Device for a patient
- Select any patient > Open 'Medical Alerts' screen > Click on 'New Medical Alert(s)' button > Click on 'Implantable Device'
- Add following list of implantable devices:
    - Enter UDI in 'GS1 Issuing Agency' format: '(01)10884521062856(11)141231(17)150707(10)A213B1(21)1234' into the 'UDI' search field in the 'Implantable Device Selection' window > Click 'Search' button > Click 'OK'
    - Enter UDI in 'Health Industry Business Communications Council (HIBCC)' format: '+B066000325011NS1/$$420020216LOT123456789012345/SXYZ456789012345678/16D20 130202C1' into the 'UDI' search field on the 'Implantable Device Selection' window > Click 'Search' button > Click 'OK'
    - Enter UDI in 'International Council for Commonality in Blood Banking Automation (ICCBBA)' format: '=/W4146EB0010T0475=,000025=A99971312345600=>014032=}013032&,1000000000000 XYZ123' into the 'UDI' search field on the 'Implantable Device Selection' window > Click 'Search' button > Click 'OK'

Change UDI Status

- Select Implantable device > Click on 'View/Edit Alert' button
- Click on 'Inactivate' button > Select the reason for inactivation e.g. 'Resolved' > Click 'OK' > Click 'OK'
- Access UDI, device description, identifiers, and attributes

- Select Implantable device > Click on 'View/Edit Alert' button > Review the screen with 'Active' Implantable Device to confirm that all required data is displayed
- Click on 'View Active and Inactive Alerts' button > Select the 'Inactive' Implantable Device > Click on 'View/Edit Alert' button > Review the screen to confirm that all required data is displayed

Access UDI, device description, identifiers, and attributes

- Select Implantable device > Click on 'View/Edit Alert' button > Review the screen with 'Active' Implantable Device to confirm that all required data is displayed
- Click on 'View Active and Inactive Alerts' button > Select the 'Inactive' Implantable Device > Click on 'View/Edit Alert' button > Review the screen to confirm that all required data is displayed

(b.2) Clinical Information Reconciliation and Incorporation
Given steps:
- Incorporate a CCDA and conduct reconciliation of the medications, medication allergies, and problems in the CCDA with the information currently in the patient's record.
- Generate a new CCDA with reconciled data.

Preconditions:
- Set up the list of Allergies under *Dentrix Office Manager > Maintenance > Practice Setup > Definitions>Allergies:*
  - Codein; RxNorm code: 2670
- Set up the list of reaction under *Definition > Allergy Reaction:*
  - Shortness of Breath (Unknown)
- Set up Problem under *Definition > Problems:*
  - Problem: Pneumonia with SNOMED code '233604007';
- Set up Medication under *Definition > Medications:*
  - Medication: 200 ACTUAT Albuterol 0.09 MG/ACTUAT Dry Powder Inhaler; RxNorm code: 1649560;
- <Patient1> has next 'Problem', 'Medication', 'Allergy' added in the 'Medical Alert' feature:
  - Problem: Pneumonia with SNOMED code '233604007'; Status: Active;
  - Medication: 200 ACTUAT Albuterol 0.09 MG/ACTUAT Dry Powder Inhaler; RxNorm code: 1649560; Dosage: Qty: 2; every 12 hours at institution specified times; Route: Respiratory (inhalation); Status: Inactive (Resolved);
  - Allergy: Codein; Severity: Moderate; Allergen Type: Drug allergy; Reactions: Shortness of Breath (Unknown); RxNorm code: 2670; Status: Active.
- <Provider1> should have enabled 'Patient Health Exchange, Disable Encryption' and 'Patient Health Exchange, Open' security rights.
- <Related Refferal 1> is created

Task list:
Incorporate a CCDA and conduct reconciliation of the medications, medication allergies, and problems in the CCDA with the information currently in the patient's record:
- Login into Enterprise as <Provider1> Log ID: DEF_PROV Pass: Qwerty1!
- under central clinic;
- Open 'Family File' module and select <Reconciliation Patient>;
- Open 'Patient Health Exchange' feature on the 'Import/Received' tab;
- Click 'Browse' button and select XML Data File, e.g. '170.315_b2_ciri__r11_sample1_recon_v10' from Desktop

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- Click 'Import' button and Update Patient info
- Set 'Add to Patient' action in the 'Data from Document' section in opened 'Comparison' dialog on all tabs and click 'Finish' button

Generate a new CCDA with reconciled data:
- Open 'Patient Health Exchange' feature for < Reconciliation Patient > and go to the 'Export' tab
- Click 'Browse' button to select the space for CCDA export
- Select 'Transition of Care Summary – For Referral (TC)' radio button
- Click '>>' button and add <Referral 1> in the 'Referred To' section
- Select 'v2.1' option in the 'C-CDA version' dropdown
- Check 'Disable Export Encryption' checkbox and click 'Export' button

Note: If the 'Disable Export Encryption' checkbox is unchecked then the provider should specify a password for encrypting the file after clicking 'Export' button.

5.2 Appendix 3: NON-DISCLOSURE AGREEMENT AND INFORMED CONSENT FORM

These are sample forms. The non-disclosure agreement is discretionary. Other examples may be found at www.usability.gov.

Non-Disclosure Agreement

THIS AGREEMENT is entered into as of [ENTER DATE] between ____ ("the Participant") and the testing organization Henry Schein One located at 1220 South 630 East Suite 100, American Fork, UT 84003.

The Participant acknowledges his or her voluntary participation in today's usability study may bring the Participant into possession of Confidential Information. The term "Confidential Information" means all technical and commercial information of a proprietary or confidential nature which is disclosed by Henry Schein One, or otherwise acquired by the Participant, in the course of today's study.

By way of illustration, but not limitation, Confidential Information includes trade secrets, processes, formulae, data, know-how, products, designs, drawings, computer aided design files and other computer files, computer software, ideas, improvements, inventions, training methods and materials, marketing techniques, plans, strategies, budgets, financial information, or forecasts.

Any information the Participant acquires relating to this product during this study is confidential and proprietary to Henry Schein One and is being disclosed solely for the purposes of the Participant's participation in today's usability study. By signing this form the Participant acknowledges that s/he will receive monetary compensation for feedback and will not disclose this confidential information obtained today to anyone else or any other organizations.

Date: _____

Participant's printed name:

Signature:

Informed Consent

Henry Schein One would like to thank you for participating in this study. The purpose of this study is to evaluate an electronic health records system. If you decide to participate, you will be asked to perform several tasks using the prototype and give your feedback. The study will last about 60 minutes. 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 Henry Schein One I am free to withdraw consent or discontinue participation at any time. I understand and agree to participate in the study conducted and videotaped by the Henry Schein One.

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

28-Feb-19

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 with outside of Henry Schein One and Henry Schein One client. I understand and agree that data confidentiality is assured, because only de- identified data – i.e., identification numbers not names – will be used in analysis and reporting of the results.

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

Please check one of the following:

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

Signature: _____

 Date: _____

5.3 Appendix 4: PARTICIPANT TASK LIST AND STANDARD MODERATOR SCRIPT/QUESTIONS

All tasks were entered into the Morae usability testing software and all data was recorded and stored in that software. Below is a script that both moderators read as a standard and it includes a list of tasks that the participants were asked to perform.

Orientation_____

Thank you for participating in this study. Our session today will last 20 to 30 minutes. During

that time you will take a look at an electronic health record system.

I will ask you to complete a few tasks using this system and answer some questions. We are interested in how easy (or how difficult) this system is to use, what in it would be useful to you, and how we could improve it. You will be asked to complete these tasks on your own trying to do them as quickly as possible with the fewest possible errors or deviations. Do not do anything more than asked. If you get lost or have difficulty I cannot answer help you with anything to do with the system itself. Please save your detailed comments until the end of a task or the end of the session as a whole when we can discuss freely.

I did not have any involvement in its creation, so please be honest with your opinions.

The product you will be using today is an alpha version of Dentrix Enterprise 8.0 CE/MCE. Some of the data may not make sense as it is placeholder data.

We are recording the audio and screenshots of our session today. All of the information that you provide will be kept confidential and your name will not be associated with your comments at any time.

Do you have any questions or concerns?

5.4 Appendix 6: INCENTIVE RECEIPT AND ACKNOWLEDGMENT FORM

Acknowledgement of Receipt

I hereby acknowledge receipt of a gift card in the amount of $100 for my participation in a research study run by Henry Schein One.

Printed Name: _____

Address: _____

_____

Signature: _____   Date: _____

Usability Researcher: _____

Signature of Usability Researcher: _____

Date: _____

Witness: _____

Witness Signature: _____

Date: _____