Usability Test Report of Goldblatt Systems Clinical Semantic Network (CSN) v 8.0

Goldblatt Systems Clinical Semantic Network, Version 8.0

Dates of Usability Test: July 15 through July 18, 2019

Date of Report:

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1. Executive Summary

A usability test of the Clinical Semantic Network (CSN), Version 8.0 was conducted on July 15, 16, 17 and 18, 2019 in Tucson, Arizona and in Johnstown Pennsylvania by Goldblatt Systems. The purpose of this test was to test and validate the usability of the current user interface and provide evidence of usability in the CSN by End User Usability testing. The CSN product was developed based on ISO 9241-210. The report was prepared following Common Industry Format for Usability Test Reports. ¹ During the usability test, 11 healthcare providers matching the target demographic criteria served as participants and used the EHRUT in simulated, but representative tasks.

This study collected performance data on 12 tasks typically conducted on an EHR:

1. Enter an electronic order for a medication
2. Enter an electronic order for a lab order
3. Enter an electronic order for a Diagnostic Imaging report.
5. Review and edit patient demographics
6. Review and edit the patient problem list.
7. Review and edit the patient medication list.
8. Review and edit the medication allergy list.
9. Enable / Disable a clinical support rule.
10. Write an electronic prescription.
11. Enter information for a Medical Device Implant.
12. Perform clinical information reconciliation from a received CDA.

The above listed tasks were chosen specifically to demonstrate usability on the following criteria:

- 170.314(a)(1) CPOE – medications
- 170.314(a)(2) CPOE - laboratory
- 170.314(a)(3) CPOE – diagnostic imaging
- 170.314(a)(4) Drug-drug, drug-allergy interaction checks
- 170.315(a)(5) Demographics
- 170.315(a)(6) Problem list
- 170.314(a)(7) Medication list
- 170.314(a)(8) Medication allergy list
- 170.314(a)(9) Clinical decision support
- 170.314(a)(14) Implantable device list
- 170.314(b)(2) Clinical information reconciliation and incorporation

http://www.iso.org/iso/catalogue_detail.htm?csnumber=43046
During the approximately 120 minute, one-on-one usability test, each participant was greeted by the administrator and asked to review and sign an informed consent/release form (included in Appendix 2: Informed Consent). Some participants were Beta Client site users, and as such, had prior experience with the main functions of the CSN, such as logging in, choosing a patient, and entering visit documentation. Other participants were Pharmacists, Nurses, and Medical assistants who did not have prior experience with the CSN. Limited training was given to the participants who had no prior experience on patient lookup, and the basics of documentation in the CSN system. Training was given to all the participants for all new functionality in version 8.0 immediately before the testing began for the following tasks: Enabling a clinical decision support rule, interacting with a decision support rule, writing an electronic prescription, adding to and viewing the implantable device list, viewing and accessing/editing the medication list, and the allergy list, and performing clinical information reconciliation. The administrator introduced the test, and instructed participants to complete a series of tasks (given one at a time) using the CSN. During the testing, the Data Loggers timed the test, and recorded user performance data and comments on paper. Participants filled out a satisfaction questionnaire after each test was completed. There was one Data Logger per test participant. Administrators followed a script, but adlibbed questions based on participants’ responses and actions.

The following types of data were collected for each participant:

- Number of tasks successfully completed within the allotted time
- Time to complete the tasks
- Number and types of errors
- Path deviations
- Participant’s verbalizations
- Participant’s satisfaction ratings of the system using the Likert scale

It is important to note that the participant was encouraged to give feedback as they went. That factors into the disparity (the large standard deviations) of the times to complete a task.

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 post-test questionnaire. Participants were given a $100 gift card for their participation. Various recommended metrics, in accordance with
the examples set forth in the NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records, were used to evaluate the usability of the CSN. Following is a summary of the Performance and rating data collected on the CSN.
<table>
<thead>
<tr>
<th>Measure Task</th>
<th>N</th>
<th>Task Success</th>
<th>Path Deviation</th>
<th>Task Time</th>
<th>Errors</th>
<th>Task Ratings (LIKERT)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>#</td>
<td>Mean (SD)</td>
<td>Deviations (Observed / Optimal)</td>
<td>Mean (SD)</td>
<td>Deviations (Observed / Optimal)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>1 Enter clinical orders for medications.</td>
<td>1</td>
<td>6 (1.29)</td>
<td>6 / 5</td>
<td>43 (34)</td>
<td>43 / 32</td>
<td>0 (0)</td>
</tr>
<tr>
<td>2 Enter clinical orders for lab tests</td>
<td>2</td>
<td>5 (0.30)</td>
<td>5 / 5</td>
<td>60 (25)</td>
<td>60 / 27</td>
<td>0 (0)</td>
</tr>
<tr>
<td>3 Enter clinical orders for Rad/diagnostic images.</td>
<td>3</td>
<td>4 (0)</td>
<td>4 / 4</td>
<td>68 (31)</td>
<td>68 / 19</td>
<td>0 (0)</td>
</tr>
<tr>
<td>4 Observe &amp; document drug-drug, drug-allergy interaction checks</td>
<td>4</td>
<td>6 (0.72)</td>
<td>6 / 5</td>
<td>72 (55)</td>
<td>72 / 44</td>
<td>0 (0)</td>
</tr>
<tr>
<td>5 Patient Demographics</td>
<td>5</td>
<td>2 (0)</td>
<td>2 / 2</td>
<td>12 (7)</td>
<td>12 / 3</td>
<td>0 (0)</td>
</tr>
<tr>
<td>6 Problem List</td>
<td>6</td>
<td>3 (0)</td>
<td>3 / 3</td>
<td>24 (26)</td>
<td>24 / 10</td>
<td>0 (0)</td>
</tr>
<tr>
<td>7 Review / edit the Medication List</td>
<td>7</td>
<td>2 (0.40)</td>
<td>2 / 2</td>
<td>46 (33)</td>
<td>46 / 0</td>
<td>0 (0)</td>
</tr>
<tr>
<td>8 Review / Edit the Medication-Allergy List</td>
<td>8</td>
<td>3 (0.30)</td>
<td>3 / 3</td>
<td>79 (64)</td>
<td>79 / 0</td>
<td>0 (0)</td>
</tr>
<tr>
<td>9 Enable and disable a decision support rule</td>
<td>9</td>
<td>2 (0.67)</td>
<td>2 / 2</td>
<td>32 (16)</td>
<td>32 / 44</td>
<td>0 (0)</td>
</tr>
<tr>
<td>10 Enter information for an implantable device / view the</td>
<td>10</td>
<td>2 (0)</td>
<td>2 / 2</td>
<td>93 (66)</td>
<td>93 / 52</td>
<td>0 (0)</td>
</tr>
<tr>
<td>11 Perform Clinical Information Reconciliation</td>
<td>11</td>
<td>3 (0.65)</td>
<td>3 / 3</td>
<td>81 (75)</td>
<td>81 / 53</td>
<td>0 (0)</td>
</tr>
<tr>
<td>12 Write and send an</td>
<td>12</td>
<td>3 (0.67)</td>
<td>3 / 3</td>
<td>121 (49)</td>
<td>121 / 67</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>
The results from the System Usability Scale scored the subjective satisfaction with the system based on performance with these tasks to be averaged at: 4.25 or satisfied.

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

**Major findings**

Test participants were able to complete all tasks assigned and there were no participants who became 'lost'.

The redesign of the ePrescribe screen was well received, with only one participant voicing the screen seemed “crowded”. When asked to identify any superfluous information on the screen, however, the participant could not find anything that could be removed.

Diagnostic imaging orders were found to be ‘intuitive’ by the test participants with verbalizations of ‘that was easy’ and ‘it’s nice to be able to search all the modalities at once’.

In many scripts, the end user would say, ‘that was easy’ at the end of the script.

- **Areas for improvement**

  - There are several identified workflows in which the test participants instinctively went to the visual alert indicator and clicked on it in an attempt to ‘reconcile’ the alert, and instinctively went to the bottom right corner of a dialog box in order to ‘save’. That presents the opportunity to improve the workflow by reviewing those areas for the UI.

  - Test participants voiced a need to have the ‘number of clicks’ reduced. Some test participants focused on system searches, and gave ideas for reduced clicks.

  - Test participants voiced the preference to stay on the keyboard without transitioning between keyboard and mouse. They wanted the entry of a ‘carriage return’ to begin the action instead of a mouse click. This was especially noted during ‘searching’.

**2. Introduction**

The EHR tested for this study was Goldblatt Systems Clinical Semantic Network (CSN) version 8.0. Designed to present medical information to healthcare providers in ambulatory clinic and physician offices, the EHR consists of a web hosted product where providers may view their patient’s records, document findings, track progress,
and manage tasks. The usability testing attempted to represent realistic exercises and conditions.

The purpose of this study was to test and validate the usability of the current user interface for the 11 tasks listed in the executive summary, and provide evidence of usability in the CSN by an Electronic Health Record Usability Test (EHRUT). To this end, measures of effectiveness, efficiency and user satisfaction, such as Task success, Time on task, and Errors were captured during the usability testing.

3. Method

PARTICIPANTS

A total of eleven participants were tested on the CSN. It was determined that the Clinician Role (which includes Physicians, Nurses and Medical Assistants) would cover all 11 tasks that would be covered in the testing. The Pharmacist was also given a Clinician Role. Participants in the test were 2 Physicians, 1 FNP, 2 LPN’s, 1 RN, 2 Medical Technologists, 2 Medical Assistant, and 1 Pharmacy pHD. Participants were recruited by personnel from the Implementation, Business and Marketing, and Development departments at Goldblatt Systems. Participants were given a $100 gift card. Participants were given a very minimal amount of end user training immediately prior to test participation.

Recruited participants had a mix of backgrounds and demographic characteristics. 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 tied back to individual identities.
Eleven participants (matching the demographics in the section on Participants) were recruited and eleven participated in the usability test. No recruited participant failed to show for the study.

Participants were scheduled for one 2 hour session that was broken down into training time for new functionality that was given directly prior to the test script being performed. Two participants began the study on one day and finished it on a second day.

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 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 only the Goldblatt System CSN. Each participant 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:

- All tasks were completed, the time to take the test did vary with the person taking the test.
- Time to complete the tasks
- Number and types of errors
• Path deviations
• Participant’s verbalizations (comments)
• Participant’s satisfaction ratings of the system

Additional information about the various measures can be found in the Usability Metrics Section of this document.

TASKS

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

1. Find the patient in the Patient Management screen. Review and edit patient demographics.
2. Enter an electronic order for a medication, a lab order, and a Diagnostic Imaging report.
4. Review and edit the patient problem list.
5. Review and edit the patient medication list.
6. Review and edit the medication allergy list.
7. Modify interventions and reference resources on a decision support rule.
8. Interact with a decision support rule.
9. Write an electronic prescription.
10. Enter information for a Medical Device Implant.
11. Perform clinical information reconciliation from a received CDA.

Tasks were selected based on their frequency of use, criticality of function, and those that may be troublesome for users. Tasks were constructed in light of the study objectives.

PROCEDURES

Upon arrival, participants were greeted. Participants were then assigned a participant ID. Each participant reviewed and signed an informed consent and release form (See Appendix 2). Non-Disclosure Agreements are included in the Beta Agreement between Goldblatt Systems and our Beta Usability Participants, so Goldblatt systems did not require an additional Non-Disclosure form to be signed.

Goldblatt systems provided a $100 gift card to usability participants.

A representative from the test team witnessed the participant’s signature on the Informed Consent Form.
To ensure that the test ran smoothly, a test administrator and a data logger for each participant present participated in this test. The test administrator conducting the test was an experienced usability practitioner with over 25 years of healthcare computer experience. Assisting staff members were college graduates with 3 or more years of clinical experience, and/or healthcare computer experience.

The administrator/data logger moderated the session including administering instructions and tasks. The administrator also monitored task times, obtained post-task rating data, and took notes on participant comments. The Data Loggers monitored task success, path deviations, number and type of errors, and comments. The test Administrator and Data loggers served as functionality experts, and instructed the participants on the new functionality.

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

- As they would expect to perform them in their office.
- Using a think aloud technique.
- Encouraged to verbalize when they were 'lost' and what was confusing to them.

The Administrator and Data Loggers were allowed to give guidance and clarification on tasks, as well as instructions on use.

For each task, the participants were told the goal of the task, and were walked through the task. Task timing began once the Trainer finished reading each main step. The task time was stopped once the participant indicated they had completed the task. Scoring is discussed below in the Data Scoring Section of this document.

Following each section completion, the administrator gave the participant the post-six question questionnaire (see Appendix 4). At the end of the session the participants were thanked for their participation.

TEST LOCATION

The test facility included a quiet testing room with a table, and a computer for the participant. Testing was performed at the Goldblatt Offices in Tucson Arizona, and also at the Goldblatt Offices in Johnstown Pennsylvania. Only the participant(s), the Trainer, and administrator/data logger were in the test room. To ensure that the environment was comfortable for users, noise levels were kept to a minimum with the ambient temperature within a normal range.

Two participants were tested in their office during a non-patient day. The testing area included a desk, and a computer for the participant. The participant, the system trainer, the test administrator, / data logger were present.
TEST ENVIRONMENT

The Goldblatt Systems CSN would be typically used in a healthcare office or healthcare facility. In this instance, the testing was conducted in the Goldblatt Systems Office, 5151 E. Broadway Blvd, Suite 1000, Tucson, AZ; At the Molecular DX, 620 7th St, Windber, PA 15963 and at a Physician’s office in Tucson AZ. The computers used were:

1. A Microsoft Surface connected to a secondary monitor running Windows 10.
2. A Microsoft Surface laptop.

The participants used wireless mouse and wireless full size keyboard when interacting with the system that was connected to a secondary monitor and a wireless mouse when connected to the Microsoft Surface laptop.

The secondary monitor used for testing was a Dell 22 inch color monitor, 2160 X 1440 Resolution. In the test that was performed in the physician’s office, a Microsoft Surface running windows 10 was used. The application was set up by CSN employees according to the vendor’s documentation describing the system set-up and preparation. The application itself was running on Windows 10.0 connecting to a test database via a wide area network (WAN) using a secure network connection. Technically, the system performance (i.e., response time) was representative to what actual users would experience in a field implementation.

TEST FORM AND TOOLS

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

1. Informed Consent
2. Moderator’s Guide
3. Testing Scripts (Task scripts)
4. Post-test Questionnaire
5. Participant Demographic form
6. Timers

Examples of these documents can be found in Appendices 1-5 respectively.

PARTICIPANT INSTRUCTIONS

The moderator greeted the participants and read the following instructions:

Moderator’s Guide
**Orientation (5 minutes)**

Thank you for participating in this study. Our session today will last about 90 minutes. During that time you will take a look at version 8.0 of our CSN.

Restrooms are located outside the main door, immediately on the right-hand side. In the event of an evacuation, the stairs are accessible immediately outside the door on the right-hand side. The meeting place for our company in the case of an evacuation is in the northeast side of the parking lot, directly behind the building.

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) it is for you to complete the tasks, what additional information in the screen would be useful to you, how the response time of the system here compares to your response time, and your ideas for improvement.

We have 9 areas that we will be testing today. They are:

1. Computerized provider order entry - medications 170.315(a)(1)
   a. Laboratory 170.315(a)(2)
   b. Diagnostic imaging 170.315(a)(3)
2. Drug-drug and Drug-Allergy Interaction Checks for CPOE 170.315(a)(4)
3. Demographics 170.315(a)(5)
4. Problem List 170.315(a)(6)
5. Medication List 170.315(a)(7) and Medication Allergy List 170.315(a)(8)
6. Clinical Decision Support 170.315(a)(9)
7. Implantable Device List 170.315(a)(10)
8. Clinical information reconciliation and incorporation 170.315(b)(2)
9. Electronic prescribing 170.315(b)(3)

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. Please ‘think out loud’ so that we may log your observations and help us identify when you ‘get lost’.

Please be honest with your opinions. Do not feel that you have to ‘like’ the system, the purpose of this testing is to identify where there are problems in the display, information shown, or workflow, so your honest opinion is what we are looking for.

The product you will be using today is our next version, CSN version 8.0.

All of the information that you provide will be kept confidential and your name will not be associated with your comments at any time.
Explanation of scripts and materials:

You will be asked to fill out a short form that will cover your education and career, this is required for the testing. All information will be kept confidential.

We will be going through 1 testing scenario at a time. I will walk you through the script, and then you will be asked to follow the script and perform the tasks. The Data logger will be timing your tasks – please don’t rush, try to imagine you are doing this for real and use that same tempo. Once each test scenario has been completed, we ask that you complete a ‘Usability Questionnaire’ of 6 questions. We will then proceed to the next testing scenario.

Walk through 1st script to explain how each script should be used and what the ‘Data Logger’ will be doing.

Do you have any questions or concerns?

Participants were then given a total of eleven test scripts to complete, one at a time. The tasks are listed in the moderator’s guide in Appendix 3 of this document.

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 the CSN by measuring participant success rates and errors.
2. Efficiency of the CSN by measuring the average task time and path deviations.
3. Satisfaction with the CSN by measuring ease of use ratings from the questionnaire.

DATA SCORING

The following table (Table 1) details how tasks were scored, errors evaluated, and the time data analyzed.
<table>
<thead>
<tr>
<th>Measures</th>
<th>Rationale and Scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Effectiveness:</strong> Task Success</td>
<td>A task was counted as a “Success” if the participant was able to achieve the correct outcome 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.</td>
</tr>
<tr>
<td><strong>Errors</strong> Task Errors</td>
<td>An error was counted when a participant entered incorrect data and continued to the end of the task without correcting the data.</td>
</tr>
<tr>
<td><strong>Efficiency:</strong> Path Deviations</td>
<td>The participant’s path (i.e., steps) through the application was observed. 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.</td>
</tr>
<tr>
<td><strong>Efficiency:</strong> Task Time</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. Optimal task performance time for the Goldblatt CSN was calculated by using the mean time for an expert user. The mean</td>
</tr>
<tr>
<td><strong>Effectiveness:</strong> Task Failures</td>
<td>If the participant abandoned the task, the task was counted as a “Failure.” No task times were taken for failures</td>
</tr>
<tr>
<td><strong>Satisfaction:</strong> Task Rating</td>
<td>Participant’s subjective impression of the ease of use of the application was measured by administering a post-session questionnaire. These data are averaged across participants. Averaged ratings above 3.3 are judged easy. To measure participants’ confidence in and likeability of the CSN 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 “The tasks reflect my workflow well”. See full System Usability Score questionnaire in Appendix 5.</td>
</tr>
</tbody>
</table>
4. Results

DATA ANALYSIS AND REPORTING

The results of the usability test were calculated according to the methods and definitions specified in the Usability Metrics section above. Based on the results of the usability ranking system, the CSN is considered satisfactory in usability.

Tasks were ranked by Risk in order that comments and deviations could be assessed according to Risk. Task success, Path deviation, task failures, and task ratings were assigned by the definitions given in the Data Scoring table above.

The results from the SUS (System Usability Scale) scored the subjective satisfaction with the system based on performance with these tasks to be: 4.33 or Satisfactory.

<table>
<thead>
<tr>
<th>Measure Task</th>
<th>N</th>
<th>Task Success</th>
<th>Path Deviation</th>
<th>Task Time</th>
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</tbody>
</table>
DISCUSSION OF THE FINDINGS

The Goldblatt CSN was determined to be effective and efficient with an above average satisfaction rating of 4.33 overall (Mean). Areas of improvement were identified and will be considered for inclusion as new releases of the product are planned.

EFFECTIVENESS

Effectiveness was rated using the data gathered for Task Success and Task failures. A task was counted as a “Success” if the participant was able to achieve the correct outcome 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 for the Goldblatt CSN was calculated by using the mean time for an expert user. The mean time was calculated by timing the task of a trained CSN employee and determining the mean time to complete the task.

The Goldblatt CSN was determined to be effective.
EFFICIENCY

Efficiency was measured in absolute terms by the length of time required to complete a task. It was compared to the mean time to complete a task as performed by a trained CSN employee. The mean time was calculated by timing the task of a trained CSN employee and determining the mean time to complete the task.

Based on the observations of the task time and deviation data, the Goldblatt CSN was determined to efficient. It is important to note that the standard deviations found in the test were attributed to the users ‘thinking out loud’ and discussing the screen with the data loggers.

SATISFACTION

Based on the task ratings and the SUS (System Usability Scale Questionnaire) data, the Goldblatt CSN was determined to give above average satisfaction with an overall average rating of 4.33.

MAJOR FINDINGS

Test participants were able to complete all tasks assigned and there were no participants who became ‘lost’ and gave up on a task.

The redesign of the ePrescribe screen was well received, with only one participant voicing the screen seemed ‘crowded’. When asked to identify any superfluous information on the screen, however, the participant could not find anything that could be removed.

Diagnostic imaging orders were found to be ‘intuitive’ by the test participants with verbalizations of ‘that was easy’ and ‘it’s nice to be able to search all the modalities at once’.

In many scripts, the end user would say, ‘that was easy’ at the end of the script.

AREAS FOR IMPROVEMENT

Areas for improvement are:

- There are several identified workflows in which the test participants instinctively went to the visual alert indicator and clicked on it in an attempt to ‘reconcile’ the alert, and instinctively went to the bottom right corner of a dialog box in order to ‘save’. That presents the opportunity to improve the workflow by reviewing those areas for the UI.

- Test participants voiced a need to have the ‘number of clicks’ reduced. Some test participants focused on system searches, and gave ideas for reduced clicks.

- Test participants voiced the preference to stay on the keyboard without transitioning between keyboard and mouse. They wanted the entry of a ‘carriage return’ to begin the action instead of a mouse click. This was especially noted during ‘searching’.
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. Informed Consent Form
3. Moderator’s Guide
4. System Usability Scale Questionnaire
5. Test Scripts
Appendix 1: Participant Demographics

The following form was filled out by each study participant.

Gender: __________

Occupation: ____________________

Years of Clinical Experience: __________

Years of Computer Experience at healthcare facilities: ________________

Years of experience on the Goldblatt System CSN: ________________
Appendix 2: Informed Consent

INFORMED CONSENT FOR BETA USABILITY TESTING

Goldblatt Systems
5151 E. Broadway Blvd, Suite 1000
Tucson, AZ  85711
520-382-5999

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

I understand that the information is for research purposes only and that my name will not be used for any purpose other than research.

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 Goldblatt Systems and Goldblatt System’s clients. I understand and agree that data confidentiality is assured, because only de-identified data – i.e., identification numbers not names – will be used in analysis and reporting of the results.

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

Please check one of the following:

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

Signature:                                                                                    Date:
Appendix 3: Moderator’s Guide

Orientation (5 minutes)

Thank you for participating in this study. Our session today will last about 90 minutes. During that time you will take a look at version 8.0 of our CSN.

Restrooms are located outside the main door, immediately on the right hand side. In the event of an evacuation, the stairs are accessible immediately outside the door on the right hand side. The meeting place for our company in the case of an evacuation is in the northeast side of the parking lot, directly behind the building.

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) it is for you to complete the tasks, what additional information in the screen would be useful to you, how the response time of the system here compares to your response time, and your ideas for improvement.

We have 9 areas that we will be testing today. They are:

1. Computerized provider order entry - medications 170.315(a)(1)
   a. Laboratory 170.315(a)(2)
   b. Diagnostic imaging 170.315(a)(3)
2. Drug-drug and Drug-Allergy Interaction Checks for CPOE 170.315(a)(4)
3. Demographics 170.315(a)(5)
4. Problem List 170.315(a)(6)
5. Medication List 170.315(a)(7) and Medication Allergy List 170.315(a)(8)
6. Clinical Decision Support 170.315(a)(9)
7. Implantable Device List 170.315(a)(10)
8. Clinical information reconciliation and incorporation 170.315(b)(2)
9. Electronic prescribing 170.315(b)(3)

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. Please ‘think out loud’ so that we may log your observations and help us identify when you ‘get lost’.

Please be honest with your opinions. Do not feel that you have to ‘like’ the system, the purpose of this testing is to identify where there are problems in the display, information shown, or workflow, so your honest opinion is what we are looking for.
The product you will be using today is our next version, CSN version 8.0.

All of the information that you provide will be kept confidential and your name will not be associated with your comments at any time.

**Explanation of scripts and materials:**

You will be asked to fill out a short form that will cover your education and career, this is required for the testing. All information will be kept confidential.

We will be going through 1 testing scenario at a time. I will walk you through the script, and then you will be asked to follow the script and perform the tasks. The Data logger will be timing your tasks – please don’t rush, try to imagine you are doing this for real and use that same tempo. Once each test scenario has been completed, we ask that you complete a ‘Usability Questionnaire’ of 6 questions. We will then proceed to the next testing scenario.

Walk through 1st script to explain how each script should be used and what the ‘Data Logger’ will be doing.

Do you have any questions or concerns?
Appendix 4: System Usability Scale Questionnaire

The following questionnaire was filled out following the completion of each test script for:

1. Computerized Provider order entry (CPOE)
2. Medication list and Drug-Drug Drug-Allergy Interaction checking
3. Electronic Prescribing
4. Clinical information reconciliation
5. Clinical Decision Support Rules firing
6. Clinical Decision Support Configuration
7. Implantable Device List
8. Medication Allergy List
9. Medication List

1. I found the system unnecessarily complex.
   | Strongly Disagree | Strongly Agree |
   | 1 | 2 | 3 | 4 | 5 |

2. I thought the system was easy to use.
   | 1 | 2 | 3 | 4 | 5 |

3. I found the various functions in this system were well integrated.
   | 1 | 2 | 3 | 4 | 5 |

4. I found the system cumbersome to use.
   | 1 | 2 | 3 | 4 | 5 |

5. The tasks reflect my workflow well.
   | 1 | 2 | 3 | 4 | 5 |

6. I found the display of information pleasing.
   | 1 | 2 | 3 | 4 | 5 |
Goal: The goal of this script is to identify issues and failures encountered by the end user when placing an order for medications, laboratory or diagnostic imaging.

This script meets the requirement for testing for:

1. §170.315(a)(1)(i) Computerized provider order entry – Medications - Enable a user to record, change, and access medication orders.
2. §170.315(a)(2)(i) Computerized provider order entry – laboratory – Enable a user to record, change, and access laboratory orders.
3. §170.315(a)(3)(i) Computerized provider order entry – diagnostic imaging – Enable a user to record, change, and access diagnostic imaging orders.

SCRIPT:

SCENARIO 1: MEDICATION ORDERS [§170.315(a)(1) Computerized provider order entry – medications

You are provider Hawkeye Pierce. You have seen (Use patient 1) in the clinic and you are updating the patient chart.

1. Search for your patient _____________________
   a. Stop
2. You are going to enter a computerized order for medications.
3. You are going to chart against the problem of ‘General symptoms’.
   a. Place an order for ‘quinapril [Accupril] 10 mg tablet.
   b. The reason for the medication is ICD-10 code I10 Essential (primary) hyprtension.
4. This ends the testing scenario.
SCENARIO 2: LABORATORY ORDERS  §170.315(a)(2) Computerized provider order entry – laboratory

1. Continue with your same patient and choose the 'orders' tab to place a laboratory order.
2. You are going to enter a computerized order for a Lipid Profile LIPD.
3. You are going to chart against the problem of E88.89 Other specified metabolic disorders
4. You are going to use the Requisition Named LMS
5. Place an order for ‘Lipid Panel’
6. Choose to exit the patient chart.
7. This ends the testing scenario.

SCENARIO 3  CPOE Diagnostic imaging

1. Continue with the same patient.
2. You are going to enter a computerized order for a ‘FFD mammogram Breast Screening’.
3. You are going to use the Radiology Ancillary named, “Radiology”.
4. Accept the order.
5. This ends the testing scenario.
Goal: The goal of this script is to identify issues and failures encountered by the end user when performing Drug-Drug, and Drug-allergy interaction checks on the Goldblatt System CSN.

This script meets the requirement for testing for:

1. §170.314(a)(2) Drug-drug, drug-allergy interaction checks
2. §170.314(a)(6)(c) Problem list

SCRIPT:

You are provider Hawkeye Pierce. You have seen patient, (Use Patient 1) in the clinic and you are updating the chart. The patient has come in for follow up for the problem, ‘Congestive heart failure, unspecified’

Drug-Drug Alert:

You are going to order medications and view the Drug-Drug, Drug Allergy screening messages.

1. Search for your patient (Patient 1) __________________
2. Place an order for the medication, "Digoxin 125mcg Tab" to be taken as, “1 tablet by oral route once daily” as a new medication. 30 tablets, no refills. (Patient 1 is taking Potassium and there is a drug-drug interaction between Potassium and Digoxin.)
3. Enter the number of refills as “12”, and allow substitutions.
4. View the patient’s problem list. Choose to change the status of one of the problems.
5. The reason for the prescription is ICD-10 I50.33 Acute on chronic diastolic (congestive) heart failure. Select to document against that problem. You may have to search for the ICD-10 code.
6. Choose to view the Clinical Screening alerts
7. Choose all alerts and reconcile them with the Action ‘Patient Assessment’ and the Result ‘Not Specified’.
8. Close the alerts screen and place the order.
9. This ends the Drug-drug alert testing scenario.

Drug-Allergy Alerts:

1. Search for and select a different patient (Patient 3) ___________________
2. Note the patient’s allergy list, the patient has an allergy to caffeine.
3. You are going to order the medication ‘Fiorinal’ for the problem, ‘Classical migraine’.
4. Order a quantity of 30 tablets of “Fiorinal capsule 50-325-40mg, 1 capsule by oral route every 4 hours as needed” with 0 refills for Alley, allowing substitutions.
5. View the patient’s problem list. Note the lists of problems. Choose to remove one of the problems.
6. Note the Major and Minor Drug-Allergy Screening Message that is displayed. (Patients taking Fiorinal should not be allergic to caffeine.)
7. Enter a an ‘Action Taken’ as ‘No Intervention Given’, and a reason of ‘Not Specified’ for giving the medication even though a warning is given.
8. Continue the task to completion, and exit the patient chart.
9. This ends the testing scenario.
Goal: The goal of this script is to identify issues and failures encountered by the end user when viewing and updating the Medication List on the Goldblatt System CSN.

This script meets the requirement for testing for:

§170.314(a)(6) Medication list

SCRIPT:

You are provider Hawkeye Pierce. You have seen referred patient, and he has told you that he is currently taking Erythromycin 250 mg every 6 hours. You are updating his chart with that information.

1. Select your patient, Patient 3
2. Choose the Medication Management tab and document ‘Erythromycin 250mg tablet’ as a patient presented medication.
3. Choose to ‘Save’ patient presented medication and close the dialog box.
4. Now choose to review all current medications. (Review Med Button)
5. This ends the testing scenario.
Goal: The goal of this script is to identify issues and failures encountered by the end user when viewing and updating the Medication Allergy List on the Goldblatt System CSN.

This script meets the requirement for testing for:

§170.314(a)(7) Medication Allergy list

SCRIPT:

You are provider Hawkeye Pierce. You have seen your patient (Patient 3) and he has told you that he has an allergy to ‘Codeine’ and Ampicillin. You are going to review his allergy list and add the ‘History of Codeine allergy’ and the History of Ampicillin allergy.

1. Select your patient, (Patient 3)
2. Choose to document a visit.
3. Choose the PFSH tab and click on the ‘Allergies’ blue arrow to open it.
4. Search for the ‘History of Codeine Allergy’.
5. Choose to indicate a history of codeine allergy, with the allergic reaction of ‘hives’.
6. Now document the ampicillin allergy with an allergic reaction of ‘Diarrhea.’
7. Choose to view the Allergy list from the top menu.
8. Exit out of the Visit Documentation screen.
9. This ends the testing scenario.
Goal: The goal of this script is to identify issues and failures encountered by the end user when performing e-Prescribing on the Goldblatt System CSN.

This script meets the requirement for testing for:

§170.315 (b)(3) Electronic Prescribing

SCRIPT:

You are provider Hawkeye Pierce. You have seen patient, (Use Patient Three)

1. Search for your patient.
2. Access the medications tab and choose to search for azithromycin [Zithromax] 500 mg tablet
3. Select to give a 3 days supply of ‘Azithromycin 500 mg Tab once daily, by oral route for 3 days’.
4. Enter the number of refills as “0”.
5. Indicate that substitutions are permissible.
6. Search for the pharmacy “CA Pharmacy store 10.6 [Take off the ‘Patient and clinic zip codes’ checkmark to find the California Pharmacy.
7. The patient is complaining of infection, and you will use ICD-10 code A49 Bacterial infection of unspecified site as the reason for the prescription.
8. Confirm the prescription.
9. This ends the testing scenario.
Goal: The goal of this script is to identify issues and failures encountered by the end user when performing clinical information reconciliation on the Goldblatt System CSN.

This script meets the requirement for testing for:

1. §170.315 (b)(2) Clinical Information Reconciliation and Incorporation

SCRIPT:

You are provider Hawkeye Pierce. You have seen (Use Patient 2) the clinic. You have received a care document from another clinic and want to review and reconcile that document in Mary’s electronic record.

1. Search and select for your patient.
2. Select to view Documents tab.
3. Select to integrate the CDA document in the list.
4. Integrate the document into the ‘EHR’
5. Choose to integrate all medications, all Allergies, all Problems, and commit the document.
6. Choose to exit the patient chart.
7. This ends the testing scenario.
**Goal:** The goal of this script is to identify issues and failures encountered by the end user when interacting with a Clinical Decision Support rule.

This script meets the requirement for testing for:

§170.315(a) (9) Clinical decision support

**SCRIPT:**

1. **PROBLEM CDS Rule: Use Patient 1**

The Problem List rule triggers the presentation of the PHQ-9 Depression Questionnaire when a problem of Depression is present on the patient’s problem list

1. You are provider Hawkeye Pierce. You have seen patient,(Use Patient One) a 63 year old male, in the clinic and you are updating his chart.
2. Search for your patient.
3. You are going to **document a visit** for your patient.
4. Go into the documentation tab, choose the ‘Exam’ tab, and then choose the ‘ROS’ tab. Navigate in the tree to PSYCHOLOGICAL’ and open the tree by choosing the blue arrow in front of PSYCHOLOGICAL. Scroll down, and open the blue arrow in front of ‘Depression Symptoms, and document a red box for ‘Depressed mood’ [F-2318075], and ‘Loss of interest’ [F-2318076].
5. Now go into the diagnosis tab and make ‘Depressive disorder, not elsewhere classified’ [DS-65252] a clinical diagnosis.
6. An alert has been triggered. View the ‘Pending Alert’ and note that the diagnosis has triggered an alert for ‘PHQ-9 should be performed when diag is Depression’.
7. This ends the test for CDS PROBLEM Rule.

2. **MEDICATION LIST CDS RULE TEST: Use Patient 1**
The Medication List rule tests for the scenario where a patient should be on a specific medication for a given diagnosis and the medication is not on the patient's medication list.

**SCRIPT:**

1. Continue the documentation for your patient.
2. Search for the Diagnosis of ‘Atrial Fibrillation’ DS-64376 and choose that diagnosis.
3. Notice that an alert has been triggered due to the fact that there is no anti-coagulant on the patient’s med list, and Atrial Fibrillation has been diagnosed. Choose to view and over-ride the alert.
4. This ends the Medication List CDS rule test.

3. **MEDICATION ALLERGY LIST CDS RULE TEST:**

The Medication Allergy Rule tests for the scenario where a patient has an allergy to Penicillin documented on their Medication Allergy List and an order for a Penicillin is being entered.

**SCRIPT:**

1. Continue with your same patient.
2. View the patient’s Allergy List from the Patient Dashboard. (Has no allergies)
3. Go into documentation, in the PFSH tab. Open the Past medical history tab, and choose H/O penicillin allergy. Document that the patient coughs.
4. Choose to enter an order for Penicillin G.
5. Notice a Clinical Screening Major warning is given.
6. This ends the Medication Allergy List CDS rule test.

4. **DEMOGRAPHICS CDS RULE TEST (Use patient 1)**

The Demographics CDS rule tests for the scenario where a patient’s race puts them at a higher risk for developing a serious side effect. This rule is for the race of African Americans taking an ACE Inhibitor is at a higher risk of developing angioedema.

**SCRIPT:**
1. Your patient is an African American.
2. Choose to enter an order for the Medication, ‘Accupril’. You want to order a 5 mcg tab, to take 1 tablet by oral route 2 times per day, with 30 refills.
3. Note that an alert has been triggered.
4. This ends the Demographics CDS rule test.

5. **LABORATORY TESTS AND VALUES / RESULTS CDS RULE TEST:** (Combo as well)

This scenario tests for the Lab value rule, and the combination rule. (1) It uses a lab value (Creatinine >1.0 within 30 days of the visit being documented) , a medication list value (ACE inhibitor), a diagnosis (Hypertension), and a patient demographic (Age >60 years) in the rule. In this rule, a patient with a diagnosis of ‘hypertension’, who is >60 years old, taking an ACE inhibitor, and has a creatinine value of >1.0 (within 30 days prior to the documentation of the visit), is at risk for a life threatening arrhythmia if the serum potassium is elevated as well. The alert will display the conditions, and suggest to have the Serum Potassium checked.

**SCRIPT:**

1. Continue to use the same patient. (Patient 1)
2. Choose to document the visit.
3. Note the alert, “Patient with evidence of impaired renal function (Creatinine >1.0) who is receiving ACE inhibitor for hypertension is at risk for life threatening arrhythmia if serum K is elevated. Check Serum K immediately.”
4. This ends the Lab/Combination alert test.

6. **VITAL SIGNS RULE TEST:**

The vital signs rules uses vital signs to trigger an alert. This test uses the calculated BMI (calculated from the height and weight entered) to display an alert when the BMI puts the patient in the category of ‘overweight’.

**SCRIPT:**

1. You are still using the same patient (Patient1)
2. Choose to enter 'vital signs' on your patient.
3. Enter a blood pressure of 138/80; Height of 68 inches; Weight of 285 pounds.
4. Note that an alert, ‘Vital signs BMI is out of healthy range’ has been triggered.
5. This ends the Vital signs rule test.
Goal: The goal of this script is to identify issues and failures encountered by the end user when configuring Clinical Decision Support rules. This script meets the requirement for testing for:

4. §170.314(a)(8) Clinical decision support.

(i) Evidence-based decision support interventions. Enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the following data:

(A) Problem list; [PHQ-9 should be performed when diag is Depression.]

(B) Medication list; [The patient has a diagnosis of Atrial Fibrillation and does not have an anticoagulant on their medication list.]

(C) Medication allergy list; [Allergy Rule: Allergies to PEN, use Cephalosporin with caution.]

(D) Demographics; [African Americans taking ACE inhibitors are at an increased risk of developing angioedema.]

(E) Laboratory tests and values/results; [A1c is abnormally high. Refer the patient to a nutritionist and repeat the A1c in 6 months.]

(F) Vital Signs [BMI is out of range. Recommend creating a follow up visit with patient to monitor weight.]

Combo: [Estimated GFR, Creatinine, ACE Inhib, and hypertension alerts to check serum K level]

SCRIPT:

In this scenario, you will be enabling interventions (CDS rules).

1. Log in with Username gsadmin and Password gsadmin
2. Under the left hand menu, GS ADMINS ONLY Choose to edit Clinical Rules.
3. Disable the following 2 rules:
   a. A1c is abnormally high. Refer the patient to a nutritionist and repeat the A1c in 6 months.
   b. African Americans taking ACE inhibitors are at an increased risk of developing angioedema.
4. This ends the test.
Goal: The goal of this script is to identify issues and failures encountered by the end user when recording an implantable device.

This script meets the requirement for testing for:

§ 170.315(a)(14) Implantable Device List

SCRIPT:

You are provider Hawkeye Pierce. You have seen patient, [Use Patient 3] and your patient has given you his implantable device ID card and you are entering the information into the CSN.

1. Select your patient, (Patient 3)
2. Choose to add an Implantable Device.
3. Enter External Clinic (search for ‘Gold’ and choose Goldblatt clinic)
4. Enter the procedure (Search for Cardiac pacemaker)
5. Implanted by Dr. Jones
6. Implanted on 1/14/2019
7. Implantable Device ID: 01006431690072221716012821BLC00461H