

FlagShipMD Safety-Enhanced Design Usability Report

Report based on

NISTIR 7741 Customized Common Industry Format Template for Electronic Health Record Usability Testing

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| | |
|-------------------------|---|
| Product | FlagshipMD Version 7.0 |
| Date of Usability Tests | Tests occurred over multiple encounters between May 2019 - June 2019 |
| Date of Report | June14, 2019 |
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Executive Summary

FlagshipMD conducted usability testing on select features of the FlagshipMD Electronic Health Record (EHR) web application as part of completing the Safety-Enhanced Design requirements outlined in §170.314(g)(3). The purpose of these studies was to test and validate the usability of the current user interfaces and expected functionality of the EHR in order to elicit insights that would be utilized in the design, development, and maintenance of the EHR system. Fifteen health care providers matching the target demographic criteria served as participants and used the EHR in simulated, but representative tasks.

We evaluated ten tasks that were determined based on the required criteria under Safety-Enhanced Design. The following EHR features and processes were tested as part of the tasks of this study:

- §170.315(a)(1) Computerized Provider Order Entry-Medications
- §170.315(a)(4) Drug-drug, drug-allergy interaction checks for CPOE
- §170.315(a)(5) Demographics
- §170.315(a)(6) Problem list
- §170.315(a)(7) Medication list
- §170.315(a)(8) Medication allergy list
- §170.315(a)(9) Clinical decision support (CDS)

During the one hour, one on one usability tests, each participant was greeted by the test administrator, briefed on the testing protocols, and instructed that they could withdraw at any time. The test administrator introduced the test and instructed participants to complete the expected tasks. During the testing, the test administrator timed the tasks and recorded user performance data on paper and electronically. The administrator did not assist participants during the test. Test participants had prior experience with the FlagshipMD; no additional training was provided for the purposes of the usability tests, but all participants had the capability to utilize the FlagshipMD training materials available to all EHR users. FlagshipMD makes a variety of training resources available to all EHR end users, including video instruction, customer support, and written training guides.

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 and types of errors
- Path deviations
- Participant's verbalizations
- Participant's satisfaction ratings of the system

Following the test, all participants completed the System Usability Scale (SUS) Questionnaire. All participant data was de-identified. Following the study each participant was compensated

\$150 for their participation. Table 1: Usability Test Result Summary provides a summary of the findings from the study.

| Criterion | Task Success | Path deviations-Obs | Path deviations-Optimal | Task time (seconds) | Task Time - Observed (Seconds) | Task Time - Optimal (Seconds) | Errors | Task ratings 1-5 1=very easy | Task efficiency 1-5 1=very efficient |
|--|---------------------|----------------------------|--------------------------------|----------------------------|---------------------------------------|--------------------------------------|---------------|-------------------------------------|---|
| 315(a)(1) Computerized Provider Order Entry-Medications | Mean: 90 | 5 | 5 | Mean: 99.6 | Mean: 91 | Mean: 99.6 | Mean: 0 | Mean: 1.22 | Mean: 1.2 |
| | SD: 30 | | | SD: 13 | SD: 11.49 | SD: 13 | SD: 0 | SD: 0.41 | SD: 0.41 |
| 315(a)(4) Drug-drug, drug-allergy interaction checks for CPOE | Mean: 100 | 3 | 3 | Mean: 116.3 | Mean: 109.5 | Mean: 116.3 | Mean: 0 | Mean: 2.2 | Mean: 1.2 |
| | SD: 0 | | | SD: 70.3 | SD: 66.0 | SD: 70.3 | SD: 0 | SD: 1.3 | SD: 0.6 |
| 315(a)(5) Demographics | Mean: 100 | 5 | 5 | Mean: 176.7 | Mean: 171.4 | Mean: 176.7 | Mean: 20 | Mean: 1.6 | Mean: 1.8 |
| | SD: 0 | | | SD: 123.6 | SD: 124 | SD: 123.6 | SD: 40 | SD: 0.6 | SD: 1.09 |
| 315(a)(6) Problem list | Mean: 100 | 5 | 5 | Mean: 176.2 | Mean: 168 | Mean: 176.2 | Mean: 10 | Mean: 1.8 | Mean: 2.3 |
| | SD: 0 | | | SD: 123.5 | SD: 118 | SD: 123.5 | SD: 30 | SD: 0.7 | SD: 1.15 |
| 315(a)(7) Medication list | Mean: 100 | 6 | 6 | Mean: 176.7 | Mean: 168.7 | Mean: 176.7 | Mean: 20 | Mean: 1.7 | Mean: 1.8 |
| | SD: 0 | | | SD: 123.3 | SD: 121.74 | SD: 123.3 | SD: 40 | SD: 0.7 | SD: 1.09 |
| 315(a)(8) Medication allergy list | Mean: 80 | 5 | 5 | Mean: 170 | Mean: 154 | Mean: 170 | Mean: 0 | Mean: 1.25 | Mean: 1.2 |
| | SD: 40 | | | SD: 82.19 | SD: 81 | SD: 82.19 | SD: 0 | SD: 0.43 | SD: 0.45 |
| 315(a)(9) Clinical decision support (CDS) | Mean: 90 | 6 | 6 | Mean: 137 | Mean: 127 | Mean: 137 | Mean: 11 | Mean: 1.85 | Mean: 2.25 |
| | SD: 30 | | | SD: 86 | SD: 81.07 | SD: 86 | SD: 31 | SD: 1.12 | SD: 0.96 |

Introduction

The FlagshipMD EHR tested for these studies was FlagshipMD EHR Version 7.0. FlagshipMD allows clinicians in ambulatory outpatient practices to record and manage patient charts, as well as the ability to order medications, laboratory tests, and radiology tests. It also lets them perform a variety of other clinical and practice-management functions such as maintaining medication lists, recording immunizations, maintaining lists of drug allergies, and scheduling patient appointments.

The purpose of this study was to meet the Safety-Enhanced design requirements for 2014 ONC EHR certification and to collect data for our ongoing usability program. Overall, we measured effectiveness, efficiency, and user satisfaction.

User-Centered Design Process

The FlagshipMD product development process is based on a Design First strategy. Instead of traditional requirements-based development, we leverage a user centered design process, rapidly iterating to an ideal state which is then used to anchor requirements and development discussions. FlagshipMD utilizes a user-centered design process based on the principles of the ISO 9241- 210 standards, including utilizing many of the cited methods for gathering feedback from our user community and evaluating the usability of our product.

User-centered design is core to the FlagshipMD business. We use a goal-directed methodology for bringing new products and features to market that is broken down into specialized phases:

- **Research** – We utilize ethnographic and quantitative research methods to understand our users, their behaviors, and the needs of their practices.
- **Model** – Using the results of our research, coupled with proven design patterns and principles, we develop personas and ideal experience scenarios as the cornerstones of our designs.
- **Frame** – By building a flexible, robust design framework we can support the existing needs of our customers and accommodate new situations and technological updates in a seamless manner.
- **Refine** – FlagshipMD’s design team works closely with our developers and program managers as they scope and prepare for development. As part of this process, we provide the development team with detailed visual designs including all states for each component.
- **Test** – Testing occurs throughout the design and development process, as well as after a piece of functionality is released. The testing process also involves actively seeking feedback and guidance from users and subject matter experts to help improve what is

built. FlagshipMD instruments all of our interactions so we can monitor and evaluate the performance of our product.

- Feedback – We are always listening and responding to our users. One mechanism for gathering feedback is through our user forums. As topics are posted, which may represent future product designs or features, in addition to current features, users can up-vote the things that they agree with or vote down things they think are idiosyncratic or not useful. We evaluate this feedback on a regular basis and it is a core contributor to our feature prioritization strategy.

Method

FlagshipMD is in the process of completely redesigning the user interface of the EHR to create a consistent HTML-based application. We've started releasing new features built with this design, and will accelerate implementation in 2014. As a result, many of the EHR features that were designed and developed as part of the requirements for ONC EHR certification were built using HTML. The usability tests conducted as part of this study were conducted on an EHR system that included a combination of the FlagshipMD Flex-based application and the HTML-based application.

Participants

A total of 10 healthcare providers matching the target demographic criteria (below) participated in this usability study. Participants in the test were physician users of FlagshipMD's EHR system and were compensated \$150 for their participation. In addition, test participants had no direct connection to the development of the FlagshipMD EHR and are not connected to any FlagshipMD, Inc. employees or contractors. Test participants had the opportunity to utilize all of the available EHR training materials that are available to all FlagshipMD EHR end users, including video tutorials, customer support, and written guidelines.

Target Demographic Data

1. FlagshipMD EHR users for at least one year.
2. Have not participated in a focus group or usability test in the last 3 months.
3. Does not, nor does anyone in their home, work in marketing research, usability research, or web design.
4. Does not, nor does anyone in their home, have a commercial or research interest in an electronic health record software or consulting company.

Participant Demographic Data

| Participant ID | Specialty | Role | Years in Healthcare | Time using FlagshipMD | Assistive Tech Needs |
|-----------------------|---------------------------------|-------------|----------------------------|------------------------------|-----------------------------|
| 01 | Geriatrics | Admin Staff | 30 | 3 years | None |
| 02 | Internal Medicine and Neurology | Physician | 43 | 2 years | None |
| 03 | Gynecology | Physician | 25 | 2 years | None |
| 04 | Dermatologist | Physician | 10 | 2 years | None |
| 05 | Endocrinology and Metabolism | Physician | 22 | 8 months | None |
| 06 | Weight Loss, Clinical Research | Physician | 12 | 3 years, 6 months | None |
| 07 | Functional Psychiatrist | Physician | 15 | 18 months | None |
| 08 | Naturopathic Medicine | Physician | 6 | 18 months | None |
| 09 | General Practice | Physician | 6 | 2 years | None |
| 10 | Family Practice | Physician | 28 | 14 months | None |

Study Design

Overall, the objective of this test was to evaluate the features required for Safety-Enhanced Design M2 certification. For each feature we sought to identify areas where the application performed well, as well as areas where it fell short of customer needs and our company's user experience goals. The data from this test will serve as a baseline for future evaluations.

Usability Metrics

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
- Task ratings: Ease and efficiency
- Time to complete the tasks
- Number and types of errors
- Path deviations
- Ease of use rating
- Efficiency rating
- Participant's verbalizations (comments)
- Participant's satisfaction ratings of the system

Tasks

We constructed the following representative tasks to exercise the EHR functionality for each feature specified by the ONC. The individual tasks that each participant completed during the usability test are listed in italics below each larger EHR feature. For each of the specific usability tests that occurred, the test administrator provided sample test data for each participant to use when completing the tasks as listed, for example, specific medications to enter into the patient chart. For the purposes of this report, that test data has been omitted.

For the purposes of testing the EHR functions for both 170.314(a)(1) - Computerized Provider Order Entry (Laboratory orders) and 170.314(a)(8) - Clinical Decision Support, FlagshipMD's EHR system has identical work flows for both laboratory and imaging orders as well as for accessing/displaying all categories of clinical decisions support interventions. The tasks that a provider would complete to order, access, and change an imaging order are exactly the same, not just similar, as the tasks that a provider would complete to order, access, and change a laboratory order. In addition, FlagshipMD treats all categories of clinical decision support interventions (specifically problem list interventions, medication list interventions, medication allergy list interventions, demographics related interventions, lab tests/results interventions, and vital sign interventions) in the same, not just similar, method.

FlagshipMD assessed the risk level for all tasks that were created for each of the required EHR features. These tasks were evaluated based on the potential risk for adverse events to the patient and assigned a risk category of high, moderate, or low risk. For example, tasks that included entering in or modifying data that is used to feed EHR alerts or notifications were

determined to be of high risk, while accessing in-product resources or ordering tests that do not contribute to in-product notifications were determined to be low. Tasks that were determined to be of high risk were prioritized in terms of not only evaluation during the usability tests but also in prioritizing product changes related to those tasks. The risk category for each individual task, as well as an overall risk level for the EHR feature, can be found in the table below.

| Task | Risk Category |
|---|----------------------|
| 170.315(a)(1) Computerized provider order entry – medication | High |
| <i>1. Enter a medication order for a patient from the medication (Rx) list.</i> | <i>High</i> |
| <i>2. Access and change a medication order</i> | <i>High</i> |
| 170.315(a)(4) Drug-drug, drug-allergy interaction check for CPOE | High |
| <i>1. Enter a medication order for a patient.</i> | <i>High</i> |
| <i>2. Update the alert settings so that, for all users, only severe alerts are displayed for both drug-drug alerts and drug-allergy alerts.</i> | <i>High</i> |
| 170.315(a)(5) Demographics | |
| 170.315(a)(6) Problem List | |
| 170.315(a)(7) Medication list | High |
| <i>1. Add a medication to the patient’s Rx List</i> | <i>High</i> |
| <i>2. Change the prescription</i> | <i>High</i> |
| <i>3. View the medication order</i> | <i>High</i> |
| 170.315(a)(8) Medication allergy list | High |
| <i>1. Add a medication allergy to the patient’s allergy list</i> | <i>High</i> |
| <i>2. Access and change a medication allergy</i> | <i>High</i> |
| 170.315(a)(9) Clinical decision support (CDS) | Moderate |
| <i>1. Access clinical decision support interventions in the patient chart</i> | <i>Moderate</i> |
| <i>2. Identify diagnostic and therapeutic reference information</i> | <i>Low</i> |
| <i>3. Configure clinical decision support interventions</i> | <i>Moderate</i> |

Procedures

To prepare for each session, the test administrator oriented the test observers who would assist with data logging as needed. In addition, the testing lab was set up to ensure that all data would be captured and the remote access to the test participant was successful, secure, and stable. This included connecting the computer to the shared display so that the administrator and the data loggers could view the action, connecting the shared video and audio that would allow access to viewing and hearing the information from the test participant, and ensuring that the test participant had the correct access information prior to the session. Once the session time began and the test participant joined the session remotely, the test administrator verified the identity of the participant prior to beginning the tasks.

The test administrator moderated the session, including providing instructions to the test participants and reading through the task list prior to beginning the session. The administrator also monitored task times, obtained post-task rating data, and took notes that would assist with evaluating the session at the conclusion of the test. Following the session, the administrator gave each participant the post-test System Usability Scale Questionnaire (Appendix 3) and compensated them for their time via an electronic payment system.

Test Location

The usability tests conducted as a part of this study were conducted remotely from a lab at FlagshipMD's headquarters in Jacksonville, Florida using a controlled testing environment with representative but fictitious patient records. The remote tests were conducted using guidelines found at www.usability.gov, including utilizing stable and reliable screen share technology and independent and reliable teleconferencing systems. Since FlagshipMD is a completely web-based EHR system, the EHR users who comprised our test participant group were comfortable with accessing the system using their computers and as a result, the remote testing provided an opportunity to observe the tests in a realistic scenario. Additional information on the test environment can be found below.

Test Environment

To ensure a realistic environment, participants were asked to interact with the system using their own computers and the networks they normally use to access the EHR system. Participants were given access to the remote screen share session and teleconference dial-in information. The test administrator and other assistants were able to view the test participant's computer screen and hear the participant's comments via these mechanisms to ensure that data was captured in real time during the course of the test.

Test Forms and Tools

During the usability test, various documents and instruments were used, including a Moderator's Guide (Appendix 2) and a post-test questionnaire (Appendix 3). The Moderator's Guide was devised so as to be able to capture required data and to follow along with the tasks that each participant was asked to complete during the test. Following each task we asked participants to the ease of use and efficiency, and to explain their rationale, as described in the Moderator's Guide. At the conclusion of the session, participants were also asked to complete a post-test questionnaire, which was based on the standard System Usability Scale.

Participant Instructions

In order to accurately capture the participant's background, we asked the participant to provide the following demographic and experiential information required for the study prior to scheduling the testing session: specialty, role in their medical practices, years in healthcare, time using the FlagshipMD EHR, and any assistive technical needs they may have, if applicable.

At the beginning of each testing session, the test administrator asked each participant about their expectations during the test, managing them as needed. We also used this time to explain the goals for the session, emphasizing the participant's role, urging them to comment without concern for our feelings. The test administrator also reviewed the agenda for the session with the participant prior to beginning the tasks.

In describing the task scenarios, the test administrator explained that the participant was going to be asked to complete a series of tasks:

- As quickly and efficiently as possible,
- Without help from the administrator, and
- Without discussion, but that the participant could comment as they felt necessary.

The participant was then asked to sign into the EHR testing system and complete each task, while the test administrator recorded their time to completion, errors, and deviations from the optimal path. Any comments that the participant shared during the tasks were also recorded.

After each task the participant was asked to rate the ease of use for the task and the task efficient on a

Likert scale from 1 to 5 where 1 represented "very easy" and "very efficient" respectively, and 5 represented "very difficult" and "very inefficient," respectively. At the conclusion of the complete usability test, the participants were also asked to complete the SUS questionnaire (reflecting on all tasks).



Usability Metrics

The information below provides information on how each of the tasks were scored, how the errors evaluated, and how the time-on-task data was analyzed.

| Measure | Scoring |
|--|---|
| Effectiveness: Task Success | We recorded a task as a success if the participant was able to achieve the correct outcome without assistance. To calculate the total number of successes we divided number of tasks attempted by the number of participants. The results are reported as a percentage. We recorded task times for successes only. |
| Effectiveness: Task Failures | If the participant abandoned the task, did not reach the correct result, performed it incorrectly, or gave up, we recorded the task as a failure. We did not record task times for failures in this report. |
| Efficiency: Task Deviations | We recorded the participant's path (i.e., steps) through the application. Deviations included, for example, navigating to the wrong screen, choosing an incorrect menu item, or interacting incorrectly with an on-screen control. We compared this path to the optimal path. |
| Efficiency: Task Time | We timed each task from the moment the administrator said "Begin" until the participant said, "Done." If the participant failed to say "Done," we stopped the time when the participant stopped performing the task. Only times for tasks that were successfully completed were included in the average task time analysis. Average time per task was calculated for each task. |
| Satisfaction: Task Rating | After each task, we asked the participant to rate the task ease of use on a scale of 1 to 5, where 1 was Very Easy and 5 was Very Difficult. We averaged the ratings across participants. We also asked participants to rate task efficiency on a scale of 1 to 5, where 1 was Very Efficient and 5 was Very Inefficient. In addition, we asked participants to complete the SUS, administered using a web-based survey distribution tool, at the conclusion of the test. |

Results

Data Analysis and Reporting

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above. There were several participants that did not follow the test instructions closely and therefore the results for those participants do not reflect the ideally conducted usability test. Test participants who did not follow the task instructions have their results excluded from this report.

There were other testing sessions that had individual failed tasks as a result of non-test participant errors, including software environment issues. In cases where the task failure was not the fault of the participant, we did not ask the participant to re-complete the task in order to respect the allotted time scheduled for that particular test participant. In some cases, participants didn't follow the protocol to the letter, e.g., they commented extensively during the task, inflating the task time and resulting in less efficiency in completing the tasks. One participant declined to complete a task all together.

314.a.1 CPOE: Record a Medication Order

| Us er | Task succes s | Path deviati ons - Obs | Path deviati ons - Optimal | Task time (seconds) | Task Time - Observed (Seconds) | Task Time - Optimal (Seconds) | Error s | Task ratings 1-5 1 = very easy | Task efficien cy 1-5 1 = very efficient |
|-------|---------------|------------------------|----------------------------|---------------------|--------------------------------|-------------------------------|---------|--------------------------------|---|
| 1 | Y | 5 | 5 | 100 | 90 | 100 | 0 | 1 | 1 |
| 2 | Y | 5 | 5 | 110 | 100 | 110 | 0 | 1 | 1 |
| 3 | Y | 5 | 5 | 120 | 100 | 120 | 0 | 2 | 2 |
| 4 | Y | 5 | 5 | 80 | 75 | 80 | 0 | 1 | 1 |
| 5 | Y | 5 | 5 | 101 | 90 | 101 | 0 | 1 | 2 |
| 6 | Y | 5 | 5 | 120 | 115 | 120 | 0 | 1 | 1 |
| 7 | Y | 5 | 5 | 90 | 85 | 90 | 0 | 2 | 1 |
| 8 | N | | | | | | | | |
| 9 | Y | 5 | 5 | 98 | 80 | 98 | 0 | 1 | 1 |
| 10 | Y | 5 | 5 | 92 | 85 | 92 | 0 | 1 | 1 |
| | Mean: 0.9 | 5 | 5 | Mean: 99.6 | Mean:91 | Mean: 99.6 | Mean: 0 | Mean: 1.22 | Mean: 1.2 |
| | SD: 0.3 | | | SD: 13 | SD: 11.49 | SD: 13 | SD: 0 | SD: 0.41 | SD: 0.41 |

315.a.1 CPOE: Access and Change a Medication Order

| Us er | Task succe ss | Path devia tions - Obs | Path devia tions - Opti mal | Task time (second s) | Task Time - Observ ed (Secon ds) | Task Time - Optimal(Seconds) | Errors | Task ratings 1-5 1 = very easy | Task efficienc y 1-5 1 = very efficient |
|-------|---------------|------------------------|-----------------------------|----------------------|----------------------------------|-------------------------------|------------|--------------------------------|---|
| 1 | N | | | | | | | | |
| 2 | Y | 5 | 5 | 170 | 160 | 170 | 0 | 1 | 1 |
| 3 | Y | 5 | 5 | 120 | 100 | 120 | 0 | 1 | 3 |
| 4 | Y | 5 | 5 | 95 | 85 | 95 | 0 | 1 | 1 |
| 5 | Y | 5 | 5 | 68 | 55 | 68 | 0 | 1 | 1 |
| 6 | Y | 5 | 5 | 170 | 158 | 170 | 0 | 1 | 3 |
| 7 | Y | 5 | 5 | 210 | 203 | 210 | 0 | 2 | 4 |
| 8 | Y | 5 | 5 | 100 | 90 | 100 | 0 | 3 | 2 |
| 9 | Y | 5 | 5 | 90 | 80 | 90 | 0 | 1 | 1 |
| 10 | Y | 5 | 5 | 120 | 95 | 120 | 1 | 1 | 3 |
| | Mean: 0.9 | 5 | 5 | Mean: 127 | Mean:114 | Mean: 127 | Mean: 0.11 | Mean: 1.33 | Mean: 2.1 |
| | SD: 0.3 | | | SD: 43 | SD: 45.44 | SD: 43 | SD: 0.31 | SD: 0.66 | SD: 1.09 |

315.a.4 Drug-drug, drug-allergy interactions checks

| Us er | Task succe ss | Path devia tions - Obs | Path devia tions - Opti mal | Task time (second s) | Task Time - Observ ed (Secon ds) | Task Time - Optimal(Seconds) | Errors | Task ratings 1-5 1 = very easy | Task efficienc y 1-5 1 = very efficient |
|-------|---------------|------------------------|-----------------------------|----------------------|----------------------------------|-------------------------------|---------|--------------------------------|---|
| 1 | Y | 3 | 3 | 47 | 45 | 47 | 0 | 2 | 1 |
| 2 | Y | 3 | 3 | 59 | 55 | 59 | 0 | 1 | 1 |
| 3 | Y | 3 | 3 | 90 | 86 | 90 | 0 | 1 | 1 |
| 4 | Y | 3 | 3 | 60 | 54 | 60 | 0 | 1 | 1 |
| 5 | Y | 3 | 3 | 288 | 270 | 288 | 0 | 3 | 3 |
| 6 | Y | 3 | 3 | 184 | 170 | 184 | 0 | 1 | 1 |
| 7 | Y | 3 | 3 | 75 | 70 | 75 | 0 | 2 | 1 |
| 8 | Y | 3 | 3 | 120 | 115 | 120 | 0 | 5 | 1 |
| 9 | Y | 3 | 3 | 150 | 145 | 150 | 0 | 2 | 1 |
| 10 | y | 3 | 3 | 90 | 85 | 90 | 0 | 4 | 1 |
| | Mean: 1 | 3 | 3 | Mean: 116.3 | Mean: 109.5 | Mean: 116.3 | Mean: 0 | Mean: 2.2 | Mean: 1.2 |
| | SD: 0 | | | SD: 70.3 | SD: 66.0 | SD: 70.3 | SD: 0 | SD: 1.3 | SD: 0.6 |

315.a.4 Drug-drug, drug-allergy interactions checks- Configuration

| Us er | Tas k suc ces s | Path deviat ions - Obs | Path deviat ions - Optimal | Task time (seconds) | Task Time - Observed (Seconds) | Task Time - Optimal(Seconds) | Errors | Task ratings 1-5 1 = very easy | Task efficiency 1-5 1 = very efficient |
|-------|-----------------|------------------------|----------------------------|---------------------|--------------------------------|------------------------------|---------|--------------------------------|--|
| 1 | N | | | | | | | | |
| 2 | Y | 4 | 4 | 25 | 23 | 25 | 0 | 1 | 1 |
| 3 | N | | | | | | | | |
| 4 | Y | 4 | 4 | 70 | 65 | 70 | 0 | 1 | 1 |
| 5 | N | | | | | | | | |
| 6 | Y | 4 | 4 | 40 | 35 | 40 | 0 | 1 | 1 |
| 7 | Y | 4 | 4 | 35 | 32 | 35 | 0 | 1 | 1 |
| 8 | Y | 4 | 4 | 100 | 97 | 100 | 0 | 1 | 1 |
| 9 | y | 4 | 4 | 70 | 60 | 70 | 0 | 1 | 1 |
| 10 | y | 4 | 4 | 90 | 85 | 90 | 0 | 1 | 1 |
| | Mean: 0.7 | 4 | 4 | Mean: 61.42 | Mean: 57 | Mean: 61.42 | Mean: 0 | Mean: 1 | Mean: 1 |
| | SD: 0.45 | | | SD: 26.5 | SD: 26 | SD: 26.5 | SD: 0 | SD: 0 | SD: 0 |

315.a.5 Demographics List

| Us er | Task success | Path deviat ions - Obs | Path deviation s - Optimal | Task time (seconds) | Task Time - Observed (Seconds) | Task Time - Optimal(Seconds) | Errors | Task ratings 1-5 1 = very easy | Task efficiency 1-5 1 = very efficient |
|-------|--------------|------------------------|----------------------------|---------------------|--------------------------------|------------------------------|-----------|--------------------------------|--|
| 1 | Y | 5 | 5 | 135 | 130 | 135 | 0 | 2 | Not rated |
| 2 | Y | 5 | 5 | 77 | 70 | 77 | 0 | 1 | 1 |
| 3 | Y | 5 | 5 | 495 | 490 | 495 | 1 | 1 | 3 |
| 4 | Y | 5 | 5 | 90 | 85 | 90 | 0 | 1 | 1 |
| 5 | Y | 5 | 5 | 300 | 295 | 300 | 0 | 3 | 4 |
| 6 | Y | 5 | 5 | 205 | 200 | 205 | 0 | 2 | 3 |
| 7 | Y | 5 | 5 | 95 | 90 | 95 | 0 | 2 | 2 |
| 8 | Y | 5 | 5 | 100 | 95 | 100 | 0 | 1 | 1 |
| 9 | Y | 5 | 5 | 150 | 145 | 150 | 0 | 2 | 1 |
| 10 | Y | 5 | 5 | 120 | 114 | 120 | 1 | 1 | 1 |
| | Mean: 1 | 5 | 5 | Mean: 176.7 | Mean: 171.4 | Mean: 176.7 | Mean: 0.2 | Mean: 1.6 | Mean: 1.8 |
| | SD: 0 | | | SD: 123.6 | SD: 124 | SD: 123.6 | SD: 0.4 | SD: 0.6 | SD: 1.09 |

315.a.6 Problem List

| Us er | Task succe ss | Path deviati ons - Obs | Path deviati ons - Optimal | Task time (seconds) | Task Time - Observed (Seconds) | Task Time - Optimal(Seconds) | Errors | Task ratings 1-5 1 = very easy | Task efficiency 1-5 1 = very efficient |
|-------|---------------|------------------------|----------------------------|---------------------|--------------------------------|------------------------------|-----------|--------------------------------|--|
| 1 | Y | 5 | 5 | 135 | 130 | 135 | 0 | 2 | Not rated |
| 2 | Y | 5 | 5 | 77 | 70 | 77 | 0 | 1 | 1 |
| 3 | Y | 5 | 5 | 495 | 467 | 495 | 1 | 1 | 3 |
| 4 | Y | 5 | 5 | 90 | 87 | 90 | 0 | 1 | 1 |
| 5 | Y | 5 | 5 | 300 | 297 | 300 | 0 | 3 | 4 |
| 6 | Y | 5 | 5 | 205 | 195 | 205 | 0 | 2 | 3 |
| 7 | Y | 5 | 5 | 95 | 90 | 95 | 0 | 2 | 2 |
| 8 | Y | 5 | 5 | 110 | 103 | 110 | 0 | 1 | 2 |
| 9 | Y | 5 | 5 | 120 | 115 | 120 | 0 | 2 | 1 |
| 10 | y | 5 | 5 | 135 | 125 | 135 | 0 | 3 | 4 |
| | Mean: 1 | 5 | 5 | Mean: 176.2 | Mean: 168 | Mean: 176.2 | Mean: 0.1 | Mean: 1.8 | Mean: 2.3 |
| | SD: 0 | | | SD: 123.5 | SD: 118 | SD: 123.5 | SD: 0.3 | SD: 0.7 | SD: 1.15 |

315.a.7 Medication List

| Us er | Task succe ss | Path deviati ons - Obs | Path deviati ons - Optimal | Task time (seconds) | Task Time - Observed (Seconds) | Task Time - Optimal(Seconds) | Errors | Task ratings 1-5 1 = very easy | Task efficiency 1-5 1 = very efficient |
|-------|---------------|------------------------|----------------------------|---------------------|--------------------------------|------------------------------|-----------|--------------------------------|--|
| 1 | Y | 6 | 6 | 135 | 132 | 135 | 0 | 2 | Not rated |
| 2 | Y | 6 | 6 | 77 | 73 | 77 | 0 | 1 | 1 |
| 3 | Y | 6 | 6 | 495 | 480 | 495 | 0 | 1 | 3 |
| 4 | Y | 6 | 6 | 90 | 85 | 90 | 0 | 1 | 1 |
| 5 | Y | 6 | 6 | 300 | 295 | 300 | 0 | 3 | 4 |
| 6 | Y | 6 | 6 | 205 | 202 | 205 | 0 | 2 | 3 |
| 7 | Y | 6 | 6 | 95 | 90 | 95 | 0 | 2 | 2 |
| 8 | Y | 6 | 6 | 120 | 110 | 120 | 1 | 3 | 1 |
| 9 | Y | 6 | 6 | 110 | 100 | 110 | 0 | 1 | 1 |
| 10 | y | 6 | 6 | 140 | 120 | 140 | 1 | 1 | 1 |
| | Mean: 1 | 6 | 6 | Mean: 176.7 | Mean: 168.7 | Mean: 176.7 | Mean: 0.2 | Mean: 1.7 | Mean: 1.8 |
| | SD: 0 | | | SD: 123.3 | SD: 121.74 | SD: 123.3 | SD: 0.4 | SD: 0.7 | SD: 1.09 |

315.a.8 Medication Allergy List

| U se r | Task succe ss | Path deviati ons - Obs | Path deviati ons - Optima l | Task time (secon ds) | Task Time - Observ ed (Secon ds) | Task Time - Optima l(Secon ds) | Errors | Task ratings 1-5 1 = very easy | Task efficiency 1-5 1 = very efficient |
|--------------|---------------------|---------------------------------|---|-------------------------------|---|--|---------|---|--|
| 1 | Y | 5 | 5 | 150 | 130 | 150 | 0 | 2 | 1 |
| 2 | Y | 5 | 5 | 305 | 290 | 305 | 0 | 1 | 2 |
| 3 | Y | 5 | 5 | 300 | 280 | 300 | 0 | 2 | Not rated |
| 4 | Y | 5 | 5 | 90 | 70 | 90 | 0 | 1 | 1 |
| 5 | N | | | | | | | | |
| 6 | N | | | | | | | | |
| 7 | Y | 5 | 5 | 88 | 78 | 88 | 0 | 1 | 1 |
| 8 | Y | 5 | 5 | 100 | 90 | 100 | 0 | 1 | 1 |
| 9 | Y | 5 | 5 | 150 | 135 | 150 | 0 | 1 | 2 |
| 10 | Y | 5 | 5 | 180 | 155 | 180 | 0 | 1 | 1 |
| | Mean: 0.8 | 5 | 5 | Mean: 170 | Mean: 154 | Mean: 170 | Mean: 0 | Mean: 1.25 | Mean: 1.2 |
| | SD: 0.4 | | | SD: 82.19 | SD: 81 | SD: 82.19 | SD: 0 | SD: 0.43 | SD: 0.45 |

315.a.9 Clinical Decision Support – Interventions

| U se r | Task succe ss | Path deviati ons - Obs | Path deviati ons - Optima l | Task time (secon ds) | Task Time - Observ ed (Secon ds) | Task Time - Optima l(Secon ds) | Errors | Task ratings 1-5 1 = very easy | Task efficiency 1-5 1 = very efficient |
|--------------|---------------------|---------------------------------|---|-------------------------------|---|--|---------------|---|--|
| 1 | N | | | | | | | | |
| 2 | Y | 6 | 6 | 116 | 110 | 116 | 0 | 3 | 3 |
| 3 | Y | 6 | 6 | 69 | 60 | 69 | 0 | 2 | 2 |
| 4 | Y | 6 | 6 | 192 | 180 | 192 | 0 | NOT RATED | NOT RATED |
| 5 | Y | 6 | 6 | 97 | 88 | 97 | 0 | 1 | 1 |
| 6 | Y | 6 | 6 | 304 | 287 | 304 | 0 | 4 | 4 |
| 7 | Y | 6 | 6 | 54 | 48 | 54 | 0 | NOT RATED | 2 |
| 8 | Y | 6 | 6 | 252 | 230 | 252 | 1 | 1 | 3 |
| 9 | Y | 6 | 6 | 54 | 49 | 54 | 0 | 1 | 2 |
| 10 | Y | 6 | 6 | 100 | 88 | 100 | 0 | 1 | 1 |
| | Mean: 0.9 | 6 | 6 | Mean: 137 | Mean: 127 | Mean: 137 | Mean: 0.11 | Mean: 1.85 | Mean: 2.25 |
| | SD: 0.3 | | | SD: 86 | SD: 81.07 | SD: 86 | SD: 0.31 | SD: 1.12 | SD: 0.96 |

315.a.9 Clinical Decision Support – Configuration

| Us er | Task succe ss | Path deviati ons - Obs | Path deviati ons - Optima l | Task time (secon ds) | Task Time - Observ ed (Seco nds) | Task Time - Optima l(Seco nds) | Errors | Task ratings 1-5 1 = very easy | Task efficiency 1-5 1 = very efficient |
|----------|---------------------|---------------------------------|---|-------------------------------|---|--|---------------|---|--|
| 1 | Y | 5 | 5 | 87 | 75 | 87 | 0 | 1 | 1 |
| 2 | Y | 5 | 5 | 88 | 79 | 88 | 0 | 1 | 1 |
| 3 | Y | 5 | 5 | 90 | 81 | 90 | 0 | 1 | 2 |
| 4 | Y | 5 | 5 | 110 | 100 | 110 | 0 | 1 | 1 |
| 5 | N | | | | | | | | |
| 6 | N | | | | | | | | |
| 7 | Y | 5 | 5 | 105 | 95 | 105 | 1 | 3 | 4 |
| 8 | Y | 5 | 5 | 85 | 78 | 85 | 0 | 1 | 1 |
| 9 | Y | 5 | 5 | 116 | 106 | 116 | 0 | 2 | 2 |
| 10 | Y | 5 | 5 | 105 | 98 | 105 | 0 | 1 | 1 |
| | Mean: 0.8 | 5 | 5 | Mean: 98.25 | Mean: 89 | Mean: 98.25 | Mean: 0.12 | Mean: 1.37 | Mean: 1.6 |
| | SD: 0.4 | | | SD: 11.28 | SD: 11.22 | SD: 11.28 | SD: 0.33 | SD: 0.69 | SD: 0.99 |

The results from the System Usability Scale (SUS) scored the subjective satisfaction of the system based on performance with these tasks had a mean value of 69, with a standard deviation of 29. To generate this score, we asked users to complete the SUS questionnaire, and scored their ratings according to the SUS scoring system.

Discussion of the Findings

The test result tables provide insight into the success of each of the tasks by analyzing the number of path deviations, task time, number of errors, task ratings, and the task efficiency rating. While there were some errors logged for many of the tasks, these errors would not be categorized as resulting in adverse consequences and the occurrence would likely decline over time with more familiarity with the product. Test participants were observed and errors were evaluated with patient safety in mind – where reported errors or comments from the test participants were categorized as design or product changes that could reduce safety concerns, the user research team took note of this and shared it with the product development and design teams as appropriate.



FlagshipMD will address all product changes that would improve reported errors prior to releasing the feature to production. Reported errors or concerns that can be improved via additional user training will be addressed by the Customer Support and Education teams.

Effectiveness

In most cases, participants completed the tasks effectively as evidenced by their task completion rates. Error rates were low, though there were some path deviations. There was a key distinction in the task effectiveness rates between EHR features that have been in the product for a short amount of time versus product features that are relatively new. For example, the laboratory computerized provider order entry feature has only been available in the FlagshipMD EHR since mid-2013, while the drug-drug and drug-allergy interaction checks have been available since mid-2011. Not unexpectedly, the task rating for lab ordering tasks are much lower than the task ratings for drug-drug and drug-allergy interaction alerts.

Efficiency

Based on the results of this usability study, efficiency is an area where FlagshipMD can improve the user experience. Efficiency is a key design criterion in our new, HTML based framework because navigation is minimized and primary users will be able to use the keyboard to increase efficiency of use. The efficiency ratings outlined in the results tables above were impacted by many of the users commenting throughout the course of the study, even though they were asked to complete the tasks as efficiently as possible and that comments would be gathered at the conclusion of the test. While the impact of the continued conversation was taken into account across all tasks, there was also overall conclusions drawn that task efficiency can improve over time since users rated EHR features that have been available for a longer period time as more efficient than tasks that utilized EHR features that are relatively new.

Satisfaction

Overall, users expressed satisfaction with many of the EHR features tested during this study. Based on comments from the participants following the studies, it was clear that the level of satisfaction with the FlagshipMD EHR was commensurate with their overall satisfaction with using electronic health records in general. For example, the primary source of dissatisfaction was a lower level of efficiency when using the EHR; however, this efficiency level was compared to completing tasks using paper records. Test participants were very satisfied with the ability to complete tasks such as electronic prescribing and medication, laboratory, and imaging ordering in the EHR, and they also expressed high satisfaction in the way the EHR displays and allows configuration of drug-drug and drug-allergy interactions and other types of clinical decisions support interventions.

Major Findings and Areas for Improvement

FlagshipMD was able to gather a lot of very good information from the usability studies that we completed as part of the Safety-Enhanced Design requirement for 2015 ONC EHR



certification. Our major findings included determining that the FlagshipMD EHR has a very high ease of use, while confirming our known limitations related to usability in the current HTML Version used.

FlagshipMD is actively moving towards to upgrade the latest HTML standards and components. In the meantime, an area for improvement would be to develop education materials that clearly outline the benefits of using the recommended software standards for internet connectivity and web browsing so that EHR users are able to understand the issues at the onset of joining FlagshipMD.



Appendix 1: Recruiting Screener

We're conducting a usability study with FlagshipMD users in which you'll be asked to complete a series of tasks in FlagshipMD. We're testing how well the system works for you, not how well you use the system. After the scenarios, you will have time to discuss your ideas for improving the product.

We'll conduct the sessions remotely, via phone and screen share. You will log into a special test account. You won't use your own account, and none of your personal or patient information will be displayed.

After the session you'll receive a \$150 gift.

Are you interested in participating? [If so] may I ask you a few questions?

How long have you been using FlagshipMD? [If less than a year, Terminate.]

Have you participated in a focus group or usability test in the past xx months? [If yes, Terminate]

Do you, or does anyone in your home, work in marketing research, usability research, web design

[...etc.]? [If yes, Terminate]

Do you, or does anyone in your home, have a commercial or research interest in an electronic health record software or consulting company? [If yes, Terminate]

Session times

Monday through Friday

Sessions will begin at 8:00am, 10:00am, 12:00pm, 2:00pm, 4:00pm, or 6:00pm Pacific Time.

Appendix 2: Moderator's Guide

Session Introduction

To kick off the session with the participant:

- Ask the participant about their expectations, managing them as needed
- Explain our goals for the session, emphasizing the participant's role
- Urge them to comment without concern for our feelings (because the study team didn't design or build the product)
- Review the agenda

Participant Background

Ask the participant to provide the following demographic and experiential information required for the study:

- Specialty
- Role
- Years in healthcare
- Time using FlagshipMD
- Assistive Tech needs

Sign In

- Sign into FlagshipMD
- Please assume your name is Jessie Gordon

Practice ID

1. Administrator Account
 - Practice ID: *Redacted*
 - User Name: *Redacted*
 - Password: *Redacted*
2. Non-Administrator Account
 - Practice ID: *Redacted*
 - User Name: *Redacted*
 - Password: *Redacted*

Scenario 1: Order a Medication

User instructions: *Enter a medication order for a patient from the medication (Rx) list.*

Task outcome:

Completion:

Time on task:

Ease rating:

Efficiency

rating:

Scenario 2: CPOE: Access and Change a Medication Order

User Instructions: *Enter a new prescription for the same medication, but this time dispense a different amount.*

Task outcome:

Completion:

Time on task:

Ease rating:

Efficiency rating:

Scenario 3: Enter a Lab Order

User Instructions: *Enter a draft lab order.*

Task outcome:

Completion:

Time on task:

Ease rating:

Efficiency rating:

Scenario 4: Access and Change a Lab Order

User Instructions: *Open the lab order you just created, add a diagnosis, and submit the order.*

Task outcome:

Completion:

Time on task:

Ease rating:

Efficiency

rating:

Scenario 5: Drug-Drug, Drug-Allergy Interaction Checks – Ordering a Medication

User instructions: *Enter a medication order for a patient.*

Task outcome:

Completion:

Time on task:

Ease rating:

Efficiency

rating:

Scenario 6: Drug-Drug and Drug-Allergy Interaction Checks – Change Alert Settings

User Instructions: *Update the alert settings so that, for all users, only severe alerts are displayed for both drug-drug alerts and drug-allergy alerts.*

Task outcome:

Completion:

Time on task:

Ease rating:

Efficiency

rating:

Scenario 7: Medication List

User Instructions: *Add two medications to the patient's medication list; update a medication from the medication list; view a medication*

Task outcome:

Completion:

Time on task:

Ease rating:

Efficiency

rating:

Scenario 8: Medication Allergy List

User Instructions: *Record a patient's medication allergy; access the patient's medication allergy list; access the patient's medication allergy history.*

Task outcome:

Completion:

Time on task:

Ease rating:

Efficiency

rating:

Scenario 9: Clinical Decision Support

User Instructions: *Finalize a patient encounter to view the clinical decision support interventions.*

Task outcome:

Completion:

Time on task:

Ease rating:

Efficiency

rating:

Scenario 10: Configure Clinical Decision Support Settings

User Instructions: *Change your Clinical Decision Support settings so that allergy notifications will not be displayed to you.*

Task outcome:

Completion:

Time on task:

Ease rating:

Efficiency

rating:

Appendix 3: System Usability Scale

| | | Strongly disagree | | | Strongly Agree |
|----|---|--------------------------|--------------------------|--------------------------|--------------------------|
| 1 | I think that I would like to use this system frequently | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | 1 | 2 | 3 | 4 5 |
| 2 | I found the system unnecessarily complex | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | 1 | 2 | 3 | 4 5 |
| 3 | I thought the system was easy to use | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | 1 | 2 | 3 | 4 5 |
| 4 | I think that I would need the support of a technical person to be able to use this system | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | 1 | 2 | 3 | 4 5 |
| 5 | I found the various functions in this system were well integrated | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | 1 | 2 | 3 | 4 5 |
| 6 | I thought there was too much inconsistency in this system | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | 1 | 2 | 3 | 4 5 |
| 7 | I would imagine that most people would learn to use this system very quickly | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | 1 | 2 | 3 | 4 5 |
| 8 | I found the system very cumbersome to use | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | 1 | 2 | 3 | 4 5 |
| 9 | I felt very confident using the system | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | 1 | 2 | 3 | 4 5 |
| 10 | I needed to learn a lot of things before I could get going with this system | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | 1 | 2 | 3 | 4 5 |

Source: <http://www.usabilitynet.org/trump/documents/Suschapt.doc>



Appendix 4: Incentive Receipt and Acknowledgement form

I hereby acknowledge receipt of \$_____ for my participation in a research study run by FlagshipMd LLC.

Printed Name:

Address:

Signature:

Date:



Appendix 5: FlagshipMD Usability Study Participant Instructions