Chapter 8. Usability Testing

Section 8.1. Setting the Stage

When a technology or system change is evaluated in isolation, the effect of external factors like the environment of use, interfacing technologies and equipment, and team dynamics of multiple care providers are unknown. Putting that same technology in a simulated environment and in the hands of real end users, however, can reveal what problems or unanticipated consequences to expect when the technology or system change is implemented.

Whereas during a vendor demonstration of a new technology the technology is shown as a stand-alone device and observers must independently consider as many ‘what-ifs’ as they can think of in the moment, to identify how the technology will fit with its environment and work processes, usability testing allows people to think, and work through tasks and any associated difficulties in a systematic way, without the assistance of highly trained product specialists and within a safe environment.

Section 8.2. What is Usability Testing

Usability testing is a human factors method that allows you to evaluate how a technology or process will function in its context of use. It identifies problems related to ease of use, ease of training, and overall effectiveness that in healthcare routinely lead to safety issues.

During usability testing, representative end users interact with the technology or process of interest in a simulated environment. A representative end user is someone who typifies the people who would be interacting with the real system in the field. Depending on the healthcare system being tested, representative end users might be nurses, doctors, pharmacists, technicians, clerks or patients. In addition to the technology or process being evaluated, the environment may include other people and technologies that interact with the technology or process being studied.

Section 8.3. Why Use Usability Testing

No matter how closely biomedical technology professionals, human factors experts, or end users inspect a technology or process, they will never be able to identify all the possible problems and potential use errors that could occur. Often, this is because a device evaluated in isolation only provides a glimpse into the gamut of possible usability issues. It is not until the device is in the hands of the end user, who is carrying out realistic tasks and scenarios in a representative environment, that a truer picture can be seen. Similarly, no matter how many people’s thoughts and opinions are collected about a new technology or system change, it will never be adequate to form the basis of a meaningful decision. This is
because despite our best intentions, we are quite limited in our ability to reconcile our preferences and performance, often preferring products or changes leading to poorer performance (see Performance versus Preference Paradox Section 5.1).

Most, but not all, usability testing of health technology is done in a simulated environment. This is extremely beneficial because it means systems can be evaluated in complex scenarios without immediately affecting patient care or harming patients.

Section 8.4. When to Use Usability Testing

Usability testing should be performed anytime information is needed about how a technology or process will function in its environment of use. Some examples of when it is useful to apply usability testing in hospitals is during the design of a technology, the evaluation of a new technology or process, the modification or customization of a technology or process, as part of a proactive risk assessment, and during an incident investigation.

This chapter will describe a general approach to usability testing for evaluating a single technology or process. Modifications to this approach for comparing multiple products of the same type of technology will be described at the end of this chapter.

Section 8.5. Preparing for a Usability Test

The first task for preparing to conduct a usability test is to get a detailed understanding of the environment of use, the users, and the workflows that are both directly, and indirectly related to the technology or process being studied. For example, if patient monitors are being evaluated, a detailed understanding of the environments, people, and workflows associated with using the monitors will need to be gathered in addition to an understanding of the electronic patient record (EPR) system and the processes related to transforming information from the monitors to the EPR system and retrieving and making use of this information. All of the human factors methods described in this book so far are useful for developing and documenting a detailed understanding of the use environment.

In preparation for running a successful usability test there are several key items that need to be organized in advance:

- Test tasks
- Test scenarios
- Test scripts
- Participant introduction
- Participant training
- Survey design
• Data documentation tools
• Test space setup
• Technology customization
• Pilot testing
• Participant recruitment

Although it may seem daunting to prepare each of these items, they are all important to ensure your usability test runs smoothly, and that you get the most out of the time spent testing. If the preparation of these items has been done well, running the usability test will be relatively straightforward, and the data collected will highlight the level of safety and efficacy that you can expect to see from each system or process evaluated when they are implemented. The remainder of this section will outline how to prepare each of the elements required to run a successful usability test.

Section 8.5.1. Identifying Tasks to Include in a Usability Test

Identifying which tasks to include in a usability test is an important decision. If tasks are omitted that are have the potential to result in safety risks, the test will not reveal the full range of problems that will result from implementing the technology or process change.

In an ideal situation, a task analysis (Chapter 6) will be conducted on the technology or process to identify a comprehensive set of tasks from which to select a subset to include in the usability test. Tasks should be selected that are:

• Primary or routine tasks performed on the device; to identify problems that will occur frequently and ultimately lead to user frustration and poor adoption of the technology or process.
• Safety critical tasks (i.e., tasks that if executed incorrectly will have a direct negative impact on the patient. See single point weakness in Chapter 9.5.6.1); to identify safety issues.
• Tasks that are associated with heuristic violations identified in a heuristic analysis (Chapter 7); to identify safety and usability issues.

Regardless of whether or not a formal task analysis is conducted, the following are helpful for identifying tasks that meet the above listed criteria:

• Observation data,
• Focus groups, interview and survey results,
• Heuristic analysis results
• Past incident data (both from your own organization and other organizations that publish incident data).
Depending on the testing time available for each participant (should not exceed 3 hours), the set of tasks included in the scenarios may need to be trimmed based on the relative priority of each task (e.g., how safety critical the task is, how ubiquitous the task is, or how problematic the task is expected to be based on the results of other human factors methods, such heuristic analysis).

Section 8.5.2. Designing Usability Test Scenarios

A usability test scenario is similar to a scene in a movie script. It is the context or story that provides the motivation for what is about to happen. In the case of usability testing, it is the clinical context that provides the motivation for the participant to conduct a series of tasks. Usability test scenarios are informed by observations, interviews, focus group, and surveys, as well as any task analyses or heuristic analyses that have been completed.

Depending on the number, type and complexity of tasks being tested, more than one scenario may be required in a single usability testing session.

To create your test scenarios, it is helpful to begin by creating a usability summary sheet or outline for each unique user group that will interact with the technology (see Figure 13). The summary sheet should capture the following:

- who the user group is,
- their goals associated with the technology,
- the tasks they would have to perform to achieve each of those goals,
- any supplemental or supportive equipment that would be required, and what environment(s) those tasks are completed in.
Figure 13. Example of a summary sheet for a usability study of electronic smart pumps.

You can then use these outlines to create scenarios that will include the tasks and environments for each type of user (See example in Figure 14). Each scenario should describe the following:

- User group
- Scenario (story)
- Environment setup
- Initial settings (e.g., initial settings have already been programmed prior to starting the scenario)
- Tasks
• Planted errors (optional)

A clinical representative from each user group should help you to develop and then review your scenarios, to ensure they are as realistic as possible.

When testing technologies or proposed system changes it can be extremely valuable to consider whether people are better able to recover from common use errors and failure modes using the new technology or approach. To examine this during a usability test, errors can be planted in the scenarios you create so you can observe whether, and how, participants recover from errors if they are detected in the scenario. Common errors that can be planted are things like wrong patient, an issue with the 5-rights, etc., but the specific errors you choose to plant will depend on what you are testing and why you are testing it.

Usually, multiple scenarios will have to be developed for a single usability test. The main reasons for this include (1) accounting for different user groups, (2) enhancing realism and reducing participant fatigue when many tasks need to be evaluated, and (3) counterbalancing to minimize learning effects. The first two reasons will be described here. The third reason will be discussed in Section 8.8 Comparative Usability Testing.

(1) Accounting for different user groups

When the technology or process being usability tested impacts multiple user groups, it is important to design scenarios that are specific to each user group, taking into account the goals and resultant tasks from each group's perspective. For example, a nurse and a pharmacist may both interact with a smart pump, but will do so from different perspectives, and with different goals and associated tasks in mind (e.g., programming a pump to deliver medication to a patient versus updating the drug library hard and soft limits for a clinical area). As a result, tailored usability scenarios should be designed so each user group can complete relevant and representative tasks while testing.

(2) Enhancing realism and reducing participant fatigue

When there are many tasks to test, it is strongly recommended that they be distributed across a series of scenarios rather than all being packed into one long clinical story. In many clinical settings, staff must multitask, transitioning between different patients, tasks, and areas within the hospital. Your usability session should be set up in a similar way so participants can transition from patient to patient, completing a task or group of tasks as they go. Although scenario length will vary depending on the types of tasks being completed and how long individual participants need to complete each task, an entire usability session should not typically exceed about 2.5 hours in length and many can be done in much shorter time periods. Breaking this total time down into shorter scenarios
provides participants with a chance to take a quick mental break and recharge before starting with the next set of tasks.
Scenario 1

**User Group:** ICU nurses

**Story:** Two ICU patients being cared for by one nurse are in need of ordered medications. Patient 1 needs an antibiotic administered as a secondary infusion and Patient 2 needs a bolus of IV morphine. While administering the bolus of morphine the nurse is interrupted by a pump that is alarming on the other patient.

**Environment Setup:**

- Mock intensive care environment.
- The participant nurse will be caring for 2 patients.
- Two patient beds set up separated by a curtain.
- Small table next to each bed
- Table and chair in between foot of both beds for nurse charting activities
- Flow sheet and Kardex for each patient on the charting table.
- Patient chart is in the holder at the bottom of each bed
- Patient 1 has an IV pole on the left side of the patient with a triple-channel IV pump attached.
- Patient 2 has an IV pole on both sides of the patient with a triple-channel IV pump connected to each IV pole.
- An actor plays the role of Patient 1
- A mannequin is used for Patient 2
- Patient 1 is connected to a monitor; Patient 2 is not.
- The following medications are running on Patient 1:
  - Normal saline running as a primary infusion at 30mL/hr,
  - Norepinephrine running as a primary infusion at 7 mcg/hr
- The following medications are running on Patient 2:
  - Morphine running as a primary infusion at 5mg/hr.
- Additional medications and supplies required for later in the scenario are on a cart off to the right side of the testing area.
  - 3 saline IV bags
  - Ceftriaxone IV
  - Alcohol wipes
  - Primary IV tubing
  - Secondary IV tubing
  - Multi-port IV tubing connectors
  - IV tubing date labels
  - Medication added stickers
  - 10 mL saline flush syringe (x3)

Figure 14. Scenario for intensive care nurse to support usability testing of an infusion pump (continued on next page)
Initial Settings:

- Patient 1 has two primary infusions:
  1. Normal Saline at 30mL/hr
  2. Norepinephrine at 7 mg/kg/hr.
- The Norepinephrine infusion is almost empty and the volume to be infused is programmed at 2mL so that the pump will alarm during the programming of the morphine bolus on Patient 2.
- Both patients have a 3-lumen central line catheter
- Patient 2 has one primary infusion:
  1. Morphine (1mg/mL) infusing at 0.5 mg/hr
- The monitor is indicating that Patient 1’s Mean Arterial Pressure is 50.
- Mediation orders included in the charts are consistent with the order sets used in our intensive care unit.

Tasks (in order):

Patient 1:

- Set up secondary IV infusion
- Program secondary IV infusion using drug library

Patient 2:

- Program a bolus of IV morphine using the bolus feature of the pump

Planted Errors:

- Morphine is infusing at 0.5 mg/hr but should be 5mg/hr. See if detected when the bolus dose is administered.

(3) Counterbalancing to minimize learning effects

When a usability study is comprised of multiple independent scenarios, the order that the participants complete each of the scenarios should be rotated between participants to reduce learning effects. This is referred to as counterbalancing. For example, if every participant always performs task 2 correctly after they have completed task 1, it is difficult to know whether this is because task 2 is less error prone than task 1, or whether participants learned from task 1 and were able to improve their performance prior to completing task 2.
In addition to counterbalancing the scenarios, the planted errors within the scenarios should also be counterbalanced to minimize learning effects.

Section 8.5.3. Designing Usability Scripts

For each scenario developed, a usability test script is needed. A script contains the dialogue and instructions for the facilitator and actors participating in the scenarios required to guide participants through each scenario. It also includes other prompts and signals in the environment that are needed to initiate tasks for the participants (e.g., technology alarms, changes in patient condition reflected on the monitor, overhead pages).

An excerpt of a usability script for the example in Figure 14 is in Figure 15 below.

[**Nurse Actor**] “Hi ____________, nice to meet you! You must be our float nurse. My name is ____________ and I’m the nurse educator on the ward and am also working at the bedside today because we are so short staffed. What would help me is if you and I could work together to look after my two patients since they are both pretty unstable. They are both new admissions to our unit and they both need medications administered. Since you haven’t worked on this unit before there are a couple of things I’ll show you before I introduce you to our patients. First, here is our medication administration cart where you can find the patient’s chart and medication orders. I’ll need you to be responsible for administering the IV medications, and I will take care of any documentation.”

Alright, are you ready to be introduced to your first patient?”

[**Participant**] “Yes”

[**Nurse Actor**] “Great! Let’s get started. Our first patient is Mrs. Katharine Tuer. She was admitted yesterday after coming to the emergency department having difficulty breathing. She suffers from emphysema and reflux disorder, and since being admitted, we suspect she has also contracted a respiratory infection. She is 88 years old and 54 kg.

She has a maintenance line, but we need to start her ceftriaxone for her suspected respiratory infection. Her patient record, medication order, ceftriaxone, and all the supplies you’ll need are on the cart over there. While you do that, I’m going to go and check on Mrs. Sillian.”

[**Nurse Actor**] While participant is setting up Mrs. Tuer’s infusions, put IV bags and for Mrs. Sillian’s infusion on the table by her bed.

Order: Drug name: Ceftriaxone
Concentration: 1 g/10 mL
Order: 2 g in 100 mL NS, infuse over 2 hours

**Programming:**
- Rate: 50 mL/h
- VTBI: 100 mL
- Duration: 2 hours

**Participant:**
- Read medication order
- Verify the five rights
- Hang ceftriaxone
- Select intermittent (i.e., secondary) infusion
- Enter drug library
- Select ceftriaxone

  Program pump: Rate = 50 mL/h, VTBI = 100 mL
- Connect to the port above pump

**[Nurse Actor]** “Alright, that’s great! Thanks for your help with that. Come on over here and I’ll introduce you to Mrs. Sillian”...

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Figure 15. Excerpt of usability script for usability test comparing two infusion pumps

Section 8.5.4. Designing Data Documentation Tools

Documenting is one of the most important tasks during a usability test. You want to capture as much data as you can in real time during the testing because reviewing video footage to extract your data is extremely time consuming. The finalized usability scenarios will be used as the basis for any data documentation tools you create. There is no official method for documenting usability test data, but generally, a computerized spreadsheet format is recommended with the tasks and metrics listed for each scenario in the usability test. For each task it is useful to capture whether they successfully completed the task (e.g., pass/fail) and to write free form notes about any difficulties or comments they made that are relevant to usability. Pass/fail criteria should be established in advance. One of the pass/fail criteria should be task time (e.g., if a participant takes more than 5 minutes to complete this task they fail the task since this will result in an unacceptable consequence to the patient) or number of requests for assistance before they could complete the task. If the tasks are done in an order that was not expected, this should also be documented in the notes.

When using a computer, the ability to add a time stamp of when each task is performed (or when difficulties were experienced) can be very useful, especially for
determining the order of tasks, and how long various tasks took participants to complete. Some spreadsheet computer programs provide keyboard shortcuts that allow you to capture a time stamp in a spreadsheet cell. Depending on the number of participants and the purpose of your usability test, you may want to have a single data documentation sheet per participant, or you may want to have a single spreadsheet for all participants.

An example of a data documentation spreadsheet can be found in Table 5.

Section 8.5.5. Setting up the Testing Space

The physical location chosen for usability testing will depend on the resources you have available. Usability tests are often run in (1) simulation labs, (2) unoccupied clinical environments, (3) an empty office, room, or hallway. If you do not have access to a simulation lab, almost any environment can be turned into an appropriate usability testing space. A usability study can most certainly be executed successfully without having access to a formal simulation lab.

Section 8.5.5.1 Simulation Lab

If you have access to a simulation lab, this is an excellent option for running your usability sessions. Generally, a true simulation lab has both a testing room and an observation room. The testing room is where the usability test session takes place. The technology, or system change being tested, is placed in the testing room along with any props, equipment, etc. The participant and any actors remain in the testing room to complete the usability test. The observation room is where the facilitator sits to observe and document what goes on during the usability test. Some facilities have audio and video recording equipment in the observation room, and a one-way glass or mirror separating the testing room from the observation room. This physical barrier between the facilitator and participant means that unintentional distraction can be minimized, keeping the participant focused on the tasks at hand.

Section 8.5.5.2 Unoccupied Clinical Environment

If you have access to an unoccupied clinical environment that matches the type of environment being simulated, this is also an excellent option for a usability test. An example would be an unoccupied patient room/bed area. Ensure you have permission to use the space, as well as any supplies for the session. Set up the technology, or system change to be tested, along with any other equipment and supplies in the unoccupied clinical environment. In terms of documenting your observations during the session, it is unlikely that this kind of space will have a physical barrier, so as you document during the test session, be sure to be as quiet as possible. Whenever possible, set up a video camera to record each session. Ideally, use a tripod or stabilizing surface to allow you to take notes during the session or have someone else look after the video recording while you observe and take notes.
Section 8.5.5.3 Empty Office, Room, or Hallway

If you do not have access to a simulation lab or an unoccupied clinical environment, any room where patient care is not being provided can be set up to help you collect valuable data through usability testing. If you can, borrow equipment like hospital beds, physiological monitors, infusion pumps, supplies, etc. to make the environment look as realistic as possible.

Section 8.5.6. Recording the Session

If you are able to video and audio record each usability test session, it can be a valuable resource to support the analysis of your usability test data and to help communicate your findings to others. During a usability test scenario, things tend to happen quickly, and it can be difficult to capture and absorb everything as it happens in real time, even if you have a good data documentation tool. Knowing you have the ability to go back to a video recording to review or confirm something you saw can provide some peace of mind. However, as noted in Section 8.6.3, it is still important to capture as much detail about the session as possible in real time using your data documentation tool, because relying on video footage as the sole data collection medium will significantly increase the time required for analysis. Video recordings should be used as a backup to real-time observations and documentation only.

Consider using multiple video and audio recorders to capture the usability test from different angles because it may be difficult to capture both the larger picture and more detailed tasks like pump programming from a single camera. Having someone in charge of filming the session can improve the quality of video and audio footage, as they can move, pan, and zoom the video cameras as required. Using tripods for each camera can support the flexibility of camera placement. Advanced, or fancy recording equipment is not required to capture a usability test on film. A standard video camera, or even a cell phone camera, can often suffice.

A pilot usability test (Section 8.6.12) will help you determine the best camera placement for optimal video and audio. Prior to running each usability test session, ensure you have the permission to video and audio record the session from the participant.

Section 8.5.6.1 Other Set-up Considerations

Some additional items you may want to consider preparing for your usability test space include:

- A designated space for participants to store their belongings (e.g., phones, bags, drinks)

- A separate area for participant training if training and usability sessions will be happening for different participants at the same time
Pens, paper, and a calculator for participants if there are any calculations or surveys included in your usability test.

Table 5. Data documentation spreadsheet for capturing usability testing data in real-time.

<table>
<thead>
<tr>
<th>Scenario 2</th>
<th>Time</th>
<th>Pass / Fail</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Read medication record</td>
<td>8:38:07</td>
<td>P</td>
<td></td>
</tr>
<tr>
<td>Verify five rights of medication administration</td>
<td>8:40:02</td>
<td>F</td>
<td>Did not notice wrong patient name on wristband</td>
</tr>
<tr>
<td>Hang 0.9% NS</td>
<td>8:40:15</td>
<td>P</td>
<td></td>
</tr>
<tr>
<td>Connect tubing to bag</td>
<td>8:40:13</td>
<td>P</td>
<td></td>
</tr>
<tr>
<td>Connect infusion to patient</td>
<td>8:40:17</td>
<td>P</td>
<td></td>
</tr>
<tr>
<td>Enter drug library</td>
<td>8:40:21</td>
<td>P</td>
<td></td>
</tr>
<tr>
<td>Select 0.9% NS</td>
<td>8:40:31</td>
<td>P</td>
<td></td>
</tr>
<tr>
<td>Enter volume to be infused (VTBI)</td>
<td>8:40:37</td>
<td>P</td>
<td></td>
</tr>
<tr>
<td>Enter rate</td>
<td>8:40:44</td>
<td>P</td>
<td></td>
</tr>
<tr>
<td>Enter duration</td>
<td></td>
<td></td>
<td>Did not enter</td>
</tr>
<tr>
<td>Start infusion</td>
<td>8:40:37</td>
<td>P</td>
<td></td>
</tr>
<tr>
<td>Open clamp</td>
<td>8:40:39</td>
<td>P</td>
<td></td>
</tr>
<tr>
<td>Read medication record</td>
<td>8:40:52</td>
<td>P</td>
<td></td>
</tr>
<tr>
<td>Verify five rights of medication administration</td>
<td>8:41:10</td>
<td>P</td>
<td>Caught wrong name on patient wristband for this infusion</td>
</tr>
<tr>
<td><strong>ERROR: Wrong Patient</strong></td>
<td>8:41:25</td>
<td>P</td>
<td>Double checked NS order and programming parameters</td>
</tr>
<tr>
<td>Hang furosemide</td>
<td>8:41:32</td>
<td>P</td>
<td></td>
</tr>
<tr>
<td>Connect tubing to bag</td>
<td>8:41:27</td>
<td>P</td>
<td></td>
</tr>
<tr>
<td>Connect infusion to patient</td>
<td>8:41:45</td>
<td>P</td>
<td></td>
</tr>
<tr>
<td>Enter drug library</td>
<td>8:41:56</td>
<td>P</td>
<td></td>
</tr>
<tr>
<td>Select furosemide from drug library</td>
<td>8:43:11</td>
<td>P</td>
<td>Had trouble finding furosemide in drug library</td>
</tr>
<tr>
<td>Enter volume to be infused</td>
<td>8:43:16</td>
<td>P</td>
<td></td>
</tr>
<tr>
<td>Enter rate</td>
<td>8:43:20</td>
<td>P</td>
<td></td>
</tr>
<tr>
<td>Enter duration</td>
<td></td>
<td></td>
<td>Did not enter</td>
</tr>
<tr>
<td>Start infusion</td>
<td>8:43:24</td>
<td>P</td>
<td>Forgot to open clamp</td>
</tr>
</tbody>
</table>

Section 8.5.7. Customizing the Technology

If a specific technology is being tested (as opposed to a process) you will want to ensure all settings have been customized to the needs of the scenarios and to match the ideal settings for the intended facility or unit where the technology will be used. If new technology is being evaluated you will have to work with clinical experts and other stakeholders to determine what settings are the most appropriate for each clinical unit of interest. If it is not possible to determine all the proper settings and values prior to usability testing, you may want to consider using the factory settings to get a realistic picture. Alternately, changing the settings so they are either very sensitive (to trigger alarms and subsequent troubleshooting), or so they are not sensitive at all (to mask potential problems) can provide a glimpse into the worst-case scenarios.
Section 8.5.8. Creating a Participant Introduction

Making participants feel comfortable during a usability test is just as important, if not more so, than the design of the usability test scenarios themselves. If participants feel comfortable during a usability test, they are more likely to complete the test and to take the time to provide meaningful feedback. They are also more likely to volunteer as a participant for a future usability test.

The way in which a usability test is introduced to a participant can go a long way in making a participant feel at ease. To support a proper and welcoming introduction for participants, it is highly recommended the biomedical technology professional take the time to prepare a script, which should cover:

- An introduction to the person running the session
- An introduction to the project and/or goals of usability testing
- An overview of the usability testing process and purpose
- An estimate of how long the session is expected to take
- An explanation that the participant can take breaks or stop the usability test completely at any time without experiencing any negative consequences
- An explanation that it is the technology, and not the participant, being tested
- An explanation that the data collected will be treated as strictly confidential (Appendix A), and that results will not be shared with the participants' supervisor or others

A sample introduction text is shown in Figure 16, based on the usability scenarios and script in Figure 15.

A key item to include in the introduction of a usability test is the request to ask participants to think out loud while they are working. This is referred to as the think aloud protocol. When participants think aloud, it provides the biomedical technology professional or facilitator with insight as to why a participant did something in a particular way. This information helps you to determine whether a technology or system design matches a participant's mental model, and whether errors or near misses during testing are due to design issues, or a lack of knowledge and understanding.
General Introduction

“Hi Mary, it’s nice to meet you. I’m John, and I’m a clinical engineer here at the hospital. Thank you for coming in to participate in this usability test of smart infusion pumps. Before we get started I’ll give you some background information about why you’re here and then I’ll walk you through what we’re going to do as part of the session. Feel free to stop me at any time to ask questions along the way.

Our hospital will be purchasing new smart infusion pumps, but before we make a decision about which model to buy, we want to test what is available to make sure the one we choose supports you in doing your work safely, efficiently and effectively. Unfortunately, there is no perfect smart pump, and so we’ll be usability testing three different options today to help identify which one will work the best for our hospital and what changes to other elements of the system may be required to support its safest possible use.

Usability testing is a method we use to test technologies with real users like you. We observe as you use the technology to see whether there are design or usability issues that cause you trouble. When we can identify those design and usability issues early on, we can either decide to purchase another pump, or come up with mitigating strategies to try to prevent those issues from happening in the hospital.

I really want to stress that the purpose of usability testing is not to evaluate your skills or performance, and will not affect your position at the hospital in any way. If you experience any problems while using the pumps, it is not a reflection of your skills, but rather, an indication to me that the technology is not meeting your needs. You are our expert, and we are here to learn from you. If you have difficulty using a pump it points to a technology design or usability issue that is also likely to be experienced by your colleagues.

Do you have any questions so far?”

Explanation of the Informed Consent Process

“The first thing I’ll ask you to do is to sign a consent form. The consent form explains that your participation in this usability study is completely voluntary, and that you are free to stop participating at any time with no impact to you, or your employment here at the hospital. Also, everything that happens during the usability test session will be kept confidential, with all data, including any feedback or comments you share with us, never being linked back to your real name. Now, I’ll give you some time to read through and sign the consent form, but if you have any questions, please feel free to ask me as you go.”

Explanation of the Usability Testing Process

“Thanks for completing the consent form. Now I’ll give you an overview of how this usability test has been set up. We will be testing two different smart infusion pumps today, and for each of those pumps, we’ll go through four main steps. First I’ll provide you with training on the pump, then I’ll ask you to fill out a survey about your experience and training related to smart
pumps, thirdly you'll be guided through a series of clinical scenarios with the pump, and finally, I'll ask you to complete a survey to share your thoughts and any comments about the smart pump. Then we'll repeat those four steps again for the second smart infusion pump.

After you've completed the training and the first survey, I'll introduce you to our confederate (actor) nurse who will be here in the room with you to help guide you through each scenario. If you have any questions, you can ask her. You may find though, that if you ask her a question she'll respond by asking you what you would normally do in your own unit or what you think should be done. This is not to be patronizing, it is because we are genuinely interested in learning what you would do if you were confronted with that same question or challenge in reality.

Finally, as you work through the clinical scenarios, if you can think out loud in terms of what you are doing, this can be extremely insightful for us. So, for example, if you were verifying a medication label, you might say “Ok, I see the medication label says Mr. Smith, February 20, 1954, so now I’m checking the patient’s wristband, and I see this is Mr. Smith and his birthday is February 20, 1954. That matches, so I can go ahead and set up his infusion.”

Do you have any questions?”

**Figure 16. Introductory script for usability test comparing two infusion pumps**

**Section 8.5.9. Designing Training**

Participants should receive training prior to carrying out a usability test to ensure all participants have the same baseline level of knowledge and understanding of the technology, or the system change, before the test begins. An exception to this is when you are usability testing a device where the end users are expected to use the device without any training (e.g., an automatic external defibrillator). In these cases training should not be provided to ensure the user experience is representative of the conditions post implementation of the device or process.

Training should be delivered to participants in a realistic manner, meaning that the length, format, and depth of content presented during usability test training should match what would be provided by the vendor during the implementation process. Training content should cover all the tasks that will be evaluated during the usability test session, and should be consistent across participants to ensure each subject has the same level of baseline knowledge. Ideally, participants should be trained 48 hours or more before the testing to allow for some natural training decay to occur [36], although this is often difficult to schedule.

Although training is meant to be comparable to vendor training, a vendor should not provide it. This is because a vendor may not provide all the required information consistently across all participants and may not provide training specific to the tasks of the usability test. Ideally, when developing training materials for a usability test, the biomedical technology professional, or usability test facilitator, would receive training from
the vendor, and then develop a training program for the usability testing that is comparable in length and breadth and includes all the content necessary to carry out the tasks of the usability test. If participants are already quite familiar with the specific technology or system change being tested (e.g., it is already in use on their unit), training may not be required at all.

Section 8.5.10. Designing Pre- and Post-Usability Test Surveys

As a part of most usability tests you will want to design and carry out surveys both before and after the usability test itself. The purpose of these surveys is to collect information about (1) how representative your participants are with respect to the actual population of users, and (2) their perceptions of the technology or system change being tested.

Section 8.5.10.1 Pre-Usability Test Survey

The pre-usability test survey (Figure 17) is usually divided into two parts to collect information about: demographics (e.g., age, number of years of experience, clinical area of expertise, past training on similar devices); and the level of background knowledge relating to the technology or system change being tested.

Demographic information is helpful for getting a sense of whether your group of participants is representative of the larger population of users. If your test group of participants is not demographically representative of the larger population, you may not observe the full range, or frequency of issues that could be expected in the general population of users during usability testing.

Gathering information about the level of background knowledge is also helpful in understanding the baseline understanding of participants related to the technology or system change being tested, especially if your test group of participants is representative of the general population. Conducting this survey prior to the training session, and then observing as participants complete each scenario after the training session can help to establish the effectiveness of the training. If several participants do not gain the knowledge required to complete the test scenarios through the training session, it can either point to a need to revise training content and delivery, or to design issues with the technology being tested.
<table>
<thead>
<tr>
<th>Demographics</th>
<th>Knowledge and Experience</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. What best describes your role in the hospital?</strong></td>
<td><strong>1. Do you know what a smart pump is?</strong></td>
</tr>
<tr>
<td>- Registered nurse, full-time</td>
<td>- Yes</td>
</tr>
<tr>
<td>- Registered nurse, part-time</td>
<td>- No</td>
</tr>
<tr>
<td>- Other: __________</td>
<td></td>
</tr>
<tr>
<td><strong>2. What is your age?</strong></td>
<td><strong>2. Have you ever used a smart pump before?</strong></td>
</tr>
<tr>
<td>- 18-29 years old</td>
<td>- Yes</td>
</tr>
<tr>
<td>- 30-39 years old</td>
<td>- No</td>
</tr>
<tr>
<td>- 40-49 years old</td>
<td>- Not sure</td>
</tr>
<tr>
<td>- 50-64 years old</td>
<td></td>
</tr>
<tr>
<td>- 65 years old and over</td>
<td></td>
</tr>
<tr>
<td><strong>3. How long have you been a registered nurse?</strong></td>
<td><strong>3. What is a smart pump hard limit?</strong></td>
</tr>
<tr>
<td>- Less than a year</td>
<td>- A hardware feature meant to restrict programming parameters</td>
</tr>
<tr>
<td>- 1 to 4 years</td>
<td>that fall outside of a safe window</td>
</tr>
<tr>
<td>- 5 to 9 years</td>
<td>- A hardware feature meant to verify whether users want to</td>
</tr>
<tr>
<td>- 10 to 20 years</td>
<td>program the pump using the parameters they have chosen</td>
</tr>
<tr>
<td>- More than 20 years</td>
<td>- A software feature meant to restrict programming parameters</td>
</tr>
<tr>
<td></td>
<td>that fall outside of a safe window</td>
</tr>
<tr>
<td></td>
<td>- A software feature meant to verify whether users want to</td>
</tr>
<tr>
<td></td>
<td>program the pump using the parameters they have chosen</td>
</tr>
<tr>
<td></td>
<td>- Not sure</td>
</tr>
<tr>
<td><strong>4. Which unit(s) do you typically work in (check all that apply):</strong></td>
<td><strong>4. Have you ever received training about how to use a smart pump?</strong></td>
</tr>
<tr>
<td>- Outpatient</td>
<td>- Yes</td>
</tr>
<tr>
<td>- ER</td>
<td>- No</td>
</tr>
<tr>
<td>- OR</td>
<td>- Not sure</td>
</tr>
<tr>
<td>- NICU</td>
<td></td>
</tr>
<tr>
<td>- PICU</td>
<td></td>
</tr>
<tr>
<td>- SICU</td>
<td></td>
</tr>
<tr>
<td>- PACU</td>
<td></td>
</tr>
<tr>
<td>- Other: __________</td>
<td></td>
</tr>
<tr>
<td><strong>5. How long have you been working in your current clinical area?</strong></td>
<td><strong>5. In general, what is your preferred method to learn about how to use a new medical device?</strong> (rank options from 1 to 6, with 1 being most preferred, and 6 being least preferred)</td>
</tr>
<tr>
<td>- Less than a year</td>
<td>- Read about the device</td>
</tr>
<tr>
<td>- 1 to 4 years</td>
<td>- Attend a hands on demonstration</td>
</tr>
<tr>
<td>- 5 to 9 years</td>
<td>- Attend a lecture or seminar</td>
</tr>
<tr>
<td>- 10 to 20 years</td>
<td>- Have access to the device to practice on your own and ask</td>
</tr>
<tr>
<td>- More than 20 years</td>
<td>questions as needed</td>
</tr>
<tr>
<td></td>
<td>- Work side by side with an expert colleague</td>
</tr>
<tr>
<td></td>
<td>- Watch a training video</td>
</tr>
</tbody>
</table>

Figure 17. Sample demographics and knowledge and experience questions as part of a pre-usability test survey
Section 8.5.10.2 Post-Usability Test Survey

The post-usability test survey (Figure 18) is conducted to collect participant perceptions and feedback about the technology or system change being tested. This type of data is helpful in understanding participant’s opinions, confidence level, and safety and workflow concerns while using the device or interacting with the system change. Although this information is valuable, remember that participants’ perceptions and preferences of a technology are influenced by many factors and should never trump actual user performance data gathered through usability testing (see Section 5.1 Performance versus Preference Paradox). When participants are confident about their abilities to use a technology, but did not perform well in reality, it often points to a poor technology design.

Section 8.5.11. Recruiting Participants

Usability test participants are an integral part of any usability test. Participants should be representative of the range of intended end users of the new technology or system change being tested in terms of demographics, knowledge and experience, and clinical area of expertise. When a range of representative end-users are included as part of the usability testing process (e.g., doctors, nurses, and pharmacists), the data generated will be more encompassing, representative, and beneficial to the evaluation process, as different issues may be uncovered by different types of end users.

Section 8.5.11.1 Eligibility

To ensure participants are representative of the intended test population(s), a list of eligibility criteria should be established to help with the recruiting process. Eligibility criteria should define the desired characteristics of your participants, such as the number of years of experience they have, or their professional credentials. Exclusion criteria can also be outlined as part of your definition of eligibility. People interested in participating who do not meet the eligibility criteria should not be included in the actual usability test, however, they could be included as a pilot usability test participant (Section 8.5.12), or as a participant in a different, upcoming usability test.

Section 8.5.11.2 Staff Participation and Reimbursement

Staff participation in a usability test is usually set up in one of two ways, either staff participate in the test during work hours with their position being backfilled during the time of the testing, or staff participate in the test after work hours and are compensated for their time. Ideally, when a healthcare organization is planning to implement the new technology or system change being tested, a participant’s position should be backfilled so they can take part in testing during work hours. However, if this is not possible, participants should be compensated for their time outside of work hours. Consider using gift cards as a means of compensating participants if the institution is not able to backfill positions during work hours.
<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Using this smart infusion pump was intuitive:</td>
<td>- Strongly agree</td>
</tr>
<tr>
<td></td>
<td>- Agree</td>
</tr>
<tr>
<td></td>
<td>- Undecided</td>
</tr>
<tr>
<td></td>
<td>- Disagree</td>
</tr>
<tr>
<td></td>
<td>- Strongly disagree</td>
</tr>
<tr>
<td>Additional comments:</td>
<td></td>
</tr>
<tr>
<td>2. I have concerns about using this smart infusion pump in my nursing</td>
<td>- Strongly agree</td>
</tr>
<tr>
<td>environment:</td>
<td>- Agree</td>
</tr>
<tr>
<td></td>
<td>- Undecided</td>
</tr>
<tr>
<td></td>
<td>- Disagree</td>
</tr>
<tr>
<td></td>
<td>- Strongly disagree</td>
</tr>
<tr>
<td>Additional comments:</td>
<td></td>
</tr>
<tr>
<td>3. This smart infusion pump will make my job easier as a nurse:</td>
<td>- Strongly agree</td>
</tr>
<tr>
<td></td>
<td>- Agree</td>
</tr>
<tr>
<td></td>
<td>- Undecided</td>
</tr>
<tr>
<td></td>
<td>- Disagree</td>
</tr>
<tr>
<td></td>
<td>- Strongly disagree</td>
</tr>
<tr>
<td>Additional comments:</td>
<td></td>
</tr>
<tr>
<td>4. Using this smart infusion pump will change how I think about pump</td>
<td>- Strongly agree</td>
</tr>
<tr>
<td>programming:</td>
<td>- Agree</td>
</tr>
<tr>
<td></td>
<td>- Undecided</td>
</tr>
<tr>
<td></td>
<td>- Disagree</td>
</tr>
<tr>
<td></td>
<td>- Strongly disagree</td>
</tr>
<tr>
<td>Additional comments:</td>
<td></td>
</tr>
<tr>
<td>5. Using this infusion pump in my unit will help to improve patient</td>
<td>- Strongly agree</td>
</tr>
<tr>
<td>safety:</td>
<td>- Agree</td>
</tr>
<tr>
<td></td>
<td>- Undecided</td>
</tr>
<tr>
<td></td>
<td>- Disagree</td>
</tr>
<tr>
<td></td>
<td>- Strongly disagree</td>
</tr>
<tr>
<td>Additional comments:</td>
<td></td>
</tr>
<tr>
<td>6. I found the set up tasks during the scenario to be difficult to</td>
<td>- Strongly agree</td>
</tr>
<tr>
<td>complete:</td>
<td>- Agree</td>
</tr>
<tr>
<td></td>
<td>- Undecided</td>
</tr>
<tr>
<td></td>
<td>- Disagree</td>
</tr>
<tr>
<td></td>
<td>- Strongly disagree</td>
</tr>
<tr>
<td>Additional comments:</td>
<td></td>
</tr>
<tr>
<td>7. I am confident I completed all the tasks correctly during the</td>
<td>- Strongly agree</td>
</tr>
<tr>
<td>scenario:</td>
<td>- Agree</td>
</tr>
<tr>
<td></td>
<td>- Undecided</td>
</tr>
<tr>
<td></td>
<td>- Disagree</td>
</tr>
<tr>
<td></td>
<td>- Strongly disagree</td>
</tr>
<tr>
<td>Additional comments:</td>
<td></td>
</tr>
<tr>
<td>8. The training I received was comprehensive enough to allow me to</td>
<td>- Strongly agree</td>
</tr>
<tr>
<td>complete all of the scenarios:</td>
<td>- Agree</td>
</tr>
<tr>
<td></td>
<td>- Undecided</td>
</tr>
<tr>
<td></td>
<td>- Disagree</td>
</tr>
<tr>
<td></td>
<td>- Strongly disagree</td>
</tr>
<tr>
<td>Additional comments:</td>
<td></td>
</tr>
</tbody>
</table>
Section 8.5.11.3 Recruitment Strategies

To start recruiting, it is recommended you reach out to (1) the clinical experts who provided feedback on your clinical scenarios, and (2) the leaders of the units where the technology or system change will be implemented. Involving these staff members will not only help to ensure your participants are representative, it will make it easier to recruit participants since they can help to facilitate the process of backfilling positions and can encourage the participation of their staff (e.g., send an email to all staff on the unit, communicate the importance of the usability testing during staff meetings).

To initiate contact with potential participants, the biomedical technology professional can attend staff meetings, put up recruitment posters, and ask clinical experts and leaders to share information about the study opportunity with colleagues. The most effective recruitment strategy tends to be presenting information about the study to potential participants in person during regular staff meetings. If this approach is used, be prepared to summarize and answer questions about the usability test during the meeting. A poster that summarizes the usability test, and includes your contact information (Figure 19), should be brought to the meeting so it can be posted in the unit for those who are not ready to decide about their participation on the spot.

Alternatively, if participants' positions are being backfilled, you could ask the clinical manager of the unit to decide which staff members to send to participate in usability testing. However, while this approach makes recruitment easier from the perspective of the biomedical technology professional, it is less likely to result in the recruitment of participants who are fully engaged and ready to cooperate, and will not typically be a satisfactory approach to pass most research ethics boards.

Section 8.5.11.4 Number of Participants to Recruit

For a traditional usability test, aim to recruit between 5 and 15 representative users for each clinical area of expertise. The more participants included in testing, the more likely the majority of usability and design issues will be identified, and the more comprehensive your understanding of the issues will be.

At the time of publication, the FDA requires that 15 representative end users participate in usability testing to validate a new medical device design prior to receiving FDA approval. Although fifteen users per clinical area of expertise would be ideal for a usability test, it may not be possible to include this many participants in testing led by hospital facilities, depending on the number of people available to participate.

When recruiting, it is common for participants to express interest, and then be unable to participate in the actual testing. If possible, plan to recruit an extra participant to cover a participant who is unable to attend at the last minute. This way, you will be prepared for a last minute cancellation, and even if everyone is able to attend, the extra
subject will serve to strengthen the usability test by adding one more participant to the test population.

Figure 19. Example of a poster summarizing the usability test to be used for recruitment

Section 8.5.12. Conducting a Pilot Usability Test

Prior to usability testing, it is highly recommended that a practice, or pilot usability test, session be run either with your first participant, or ideally, with a colleague who is willing to pretend to be a participant. A pilot usability test session will serve to highlight any preparatory items that are either missing, or require modification, before the actual usability test sessions begin. Data collected from this pilot session should not be included as part of your actual usability test data, and you should allow enough time between the pilot session and the start of usability testing to incorporate any changes.
Completing a pilot usability test session allows you to ensure the environment, participant introduction, consent process, surveys, training, and usability test scenarios are prepared and that your presentation of each part and transition from one to the next flows smoothly. Running a pilot usability test session provides you with an opportunity to practice recording the session, using your data collection tool in real time, and, for a high-fidelity test, to communicate with the testing room facilitator.

Section 8.5.13. Usability Test Checklist Prior to Running the First Session

As outlined in this section, there are a number of items that must be prepared prior to conducting a usability test to ensure your test runs smoothly and that you get the most out of the time spent testing. The following checklist (Figure 20) outlines the items that should be ready in advance of usability testing.

☐ Recruitment information and poster
☐ Introductory script
☐ Consent form
☐ Pre-usability test survey
☐ Training content
☐ Usability scripts
☐ Data documentation tools and laptop
☐ Test space
☐ Technology or system change being tested
☐ Supplies and equipment (e.g., infusion pump, tubing sets, IV bags, hospital bed, simulated patient, patient monitor, ventilator, sharps bin, hospital table, hand sanitizer, garbage bin)
☐ Video/audio recording equipment and tripods
☐ Post-usability test survey

Figure 20. Summary checklist for required items in advance of usability testing

Section 8.6. Completing a Usability Test

The actual completion of a usability test tends to be fairly straightforward, as long as all the preparatory work has been done comprehensively, in advance of testing.

Section 8.6.1. Overview of the Usability Test Session

Each usability test session should be completed by a single participant at a time, and every participant should go through the steps outlined in Figure 21 below. A unique internal participant number should be assigned to each participant for inclusion on all information relating to the participant’s session, including data documentation sheets and video recordings. Participants do not need to know or be made aware of their unique
internal participant numbers. These internal codes are simply meant to help you delineate between various participant sessions while maintaining confidentiality.

Upon arrival, the participant should be welcomed, with the facilitator delivering the introductory script and going through the informed consent process with them. After the consent form has been signed, the participant should complete the pre-usability test survey, the training session, the usability session, the post-usability test survey, and an informal debrief session. If multiple technologies or system changes are being tested, this process is then repeated by every participant.

![Usability Test Session Diagram](figure21)

**Figure 21. Overview of usability testing process**

**Section 8.6.2. Required Resources for Running A Usability Test Session**

In order to get the most out of each session, it is highly recommended that in addition to the participant, a minimum of at least three people be present to help run each usability test session. A suggestion as to how to divide responsibilities during the usability test session is included in **Figure 22**. Expecting a single person to facilitate the session, document observations in real time, and manage the cameras is *not* feasible. If only one person is available to run the usability test then it is best to set one or more cameras up in such as way that they will capture as much detail as possible without needing to be moved or zoomed and the facilitator should document observations in as much detail as they can during the session.
Depending on the complexity of the usability test scenarios and script, it may be necessary to have more than one actor present to help facilitate the test scenarios. Depending on the purpose and context of your usability test, it may also be necessary to have more than one person collecting data.

If resources restrict the number of staff available to help run a usability test, attention should be paid to facilitating the session, and capturing as much information as possible in real time on the data documentation tool. Video cameras can still be set up, but will likely have to remain stationary during the usability test.

**Section 8.6.3. Data Collection During Usability Test Scenarios**

Depending on the environment in which usability testing takes place, the participant, and the person responsible for data collection, may either be in the same room or a different room from one another, as the usability scenarios are completed. When the participant and data collector are in the same room, the data collector should strike a balance between being close enough to the participant to see what is happening, and keeping enough distance so the participant does not feel added pressure as a result of the observer being too close. See Chapter 4 and Section 4.5.1 for more information on How to Conduct Observations, and the Hawthorne Effect, respectively. When the participant and data collector are in different rooms, as is common in a formal usability lab, the proximity of the data collector to the participant is of much less concern.

After the participant has completed all the scenarios and the post-usability test survey, an informal debrief session can be conducted with the participant to solicit any feedback that goes beyond the scope of the surveys. This is a good time to ask participants...
specific questions about their session. For example if you saw them do something surprising, or if they made an error and you are not sure what happened. When asking questions of the participant, ensure you do so in a way that does not make them feel uncomfortable if they performed a task incorrectly. Try to avoid telling them they made an error, and instead, ask open-ended questions about how they approached the task to get an understanding of the factors that contributed to the error. Also, ensure that any questions you ask of the participant are not leading in nature. See Chapter 5, for more information about interviewing without introducing unintentional bias.

Section 8.7. What to do with Usability Test Findings

Usability testing generates a large volume of data in several different formats including data documentation spreadsheets, usability session video files, pre- and post-usability test surveys, and notes from informal debrief sessions. The number of participants taking part in testing amplifies the volume of data generated. As a result, it is normal for the analysis of usability test data to feel overwhelming at first.

Section 8.7.1. User Performance Data

A good place to start is to consider the primary purpose of usability testing, which is to evaluate how well representative end users interact with a technology, or a change to a system. Thus, analyzing user performance should be a primary focus of any usability test.

Section 8.7.1.1 Analysis of Use Errors

To analyze user performance, the data documentation spreadsheets tend to be the most helpful source of data. Data documentation spreadsheets should be compiled across participants and a determination of which tasks were “passed” and which were “failed” should be made. When participants have difficulty completing a task step correctly, this is a cue that further investigation should be focused in this area. From a human factors perspective “fails”, or use errors in a usability test are like an “X marks the spot”, indicating where you should start digging to uncover the factors that contributed to the error occurring in the first place. Often these contributing factors can be determined either based on your observations, or from the informal debrief session conducted after the scenario.

It is important to note that instances where a task was failed, or an error occurred, are described in terms of the system rather than the user. For example, if the user successfully scanned a drug barcode several times before manually entering the drug and dose information into the infusion pump, the error would be described as ‘the pump does not provide adequate feedback to the user when the barcode is scanned’. Adopting a human factors perspective means embracing the philosophy that humans do not intend to cause harm and are already working as hard as they can to manage complex healthcare environments. As a result, error mitigation strategies need to be focused on the system rather than the user to have a positive effect. When digging to uncover the factors that
contributed to an error, the question you should continuously ask is ‘what features of the system are contributing to this error?’

Once use errors have been identified, the impact of each error needs to be assessed. This task requires input from clinicians or representative end users who understand the implications of the errors performed during usability testing. Each error should be rated using a pre-defined rating scale so that a determination of the most serious errors relative to one another can be made. A rating scale and definitions of your choice may be used, to further tailor the analysis, but one such example is included in Table 6. When a use error could result in multiple different outcomes of varying severity, the worst-case scenario should be chosen as a conservative estimate for relative rating purposes. If there are differing opinions on the severity rating of an error across team members, they should be discussed until a consensus is reached.

Table 6. Example of a severity rating scale for use errors uncovered during usability testing

<table>
<thead>
<tr>
<th>Severity</th>
<th>Rating</th>
<th>Description</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Minor</td>
<td>Patient unlikely to be harmed</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Moderate</td>
<td>Patient could be temporarily harmed</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Severe</td>
<td>Patient could be permanently harmed</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Critical</td>
<td>Patient could die</td>
<td></td>
</tr>
</tbody>
</table>

The next step is to consider how those use errors might be mitigated by the healthcare organization. This exercise should be done in collaboration with clinical experts and other representatives from the organization such as information technology specialists, risk managers, medication safety specialists, etc. Identifying proposed mitigating strategies is an extremely important exercise, especially if usability testing was done in the context of procurement. Unfortunately, there is no perfect technology, so it is likely the organization will have to accept a set of design issues that have the potential to lead to certain use errors. Having a sense of the mitigating strategies likely to address the set of design issues in advance is extremely helpful to decision makers who will benefit from being able to see the bigger picture implications when deciding on one technology over another.
Mitigating strategies that eliminate the possibility for an error occurring by forcing users to perform safely will be the most effective. However, it is important that these strategies are appropriate and users feel they are supportive or they will develop workarounds over time. Examples of these types of solutions include product customizations that limit certain features or options within the system, standardizing processes or systems, and automating tasks. Training is not typically considered an effective strategy for mitigating errors unless the error is caused by a lack of technical knowledge about the fundamental principles of the system. A framework for assessing the effectiveness of various types of mitigating strategies is presented in Section 3.5 The Hierarchy of Effectiveness.

When analyzing the tasks that participants had difficulty with, it is more important to identify the presence of a use error than it is to determine the frequency of that use error. This is especially true when the use error could lead to serious patient harm. Regardless of whether just a single participant made an error that could lead to serious patient harm, the error is still worth addressing because even one incident of patient harm is one too many.

Section 8.7.1.2 Analysis of Time for Task Completion

In addition to identifying use errors, another measure that can be helpful in quantifying user performance is the length of time required to complete various task steps. Again, the data documentation spreadsheets are helpful because the time stamps entered as participants complete each step of a process can be used as a basis for calculating how long various tasks took participants. In this way, technologies or system changes can be compared based on the average length of time required by participants to complete tasks in each case.

Section 8.7.1.3 Analysis of Knowledge and Experience

Responses from survey questions that aim to highlight participants’ knowledge and experience relating to a technology or system change can be used to provide context when interpreting user performance data. When participants are less knowledgeable or experienced with a technology or system change as evidenced by survey responses, it can point to the need for training and education programs for end users.

Section 8.7.2. User Preference Data

Further to user performance, user preferences can also be assessed based on the surveys and informal debrief data. Survey responses relating to user preferences should be compiled across participants so aggregate results can be shared. Descriptive statistics may be used to analyze survey results. As outlined in Section 5.1 Performance versus Preference Paradox, user preference data is beneficial in providing context, but should not be used in isolation of user performance data.
Section 8.7.3. Communicating Findings to Others

Since the volume of data generated by a usability test tends to be vast, it is important for the biomedical technology professional to distil and present key findings so they are understandable to a variety of audiences.

A summary report can be helpful for communicating usability test findings in a consistent way to others across the organization. A report of this nature should be fairly high level, with detailed information included in appendices as required. Including any descriptive statistics that show things like the number of issues having the potential to result in either severe or critical patient outcomes for each technology or system change, can be helpful for quantifying your usability findings for an audience interested in this type of comparison. Incorporating information about the processes considered, methods used, scenarios tested, and issues identified is also highly recommended. A report is an excellent way to share proposed mitigating strategies to use errors identified through testing. Since there is no perfect technology, it is likely the organization will have to live with a variety of design issues that have the potential to lead to certain use errors. Thinking through how those use errors would be addressed for the technologies being considered can help decision makers conceptualize which technology is associated with the lowest risk given the available resources within the organization.

In addition to writing a report, preparing a video highlight reel showing multiple participants making the same use errors can make a strong impression when communicating results with others. If a video reel is prepared, ensure there is no identifying information shown of participants (e.g., blur faces, blur any distinguishing features). A use error highlight reel is effective for showing what the issue is, how it manifests across multiple participants and scenarios, and drives home the fact that the issue is truly a systems issue, as opposed to an issue with a specific person, since multiple people experienced the same issue.

In short, tailoring how usability findings are communicated and presented to different stakeholders can go a long way in optimizing the efforts invested in a usability test. When communicated effectively, everyone from the healthcare organization administration to the front lines can realize the benefit of usability testing.

Section 8.8. Comparative Usability Testing

Usability testing is an effective method for comparing multiple products of the same type of technology (e.g., during the procurement of medical technology). The process for conducting comparative usability testing is similar to the usability testing process described in this chapter, with a few exceptions and considerations that will be described in this section.
Section 8.8.1. Introduction Script

When you introduce the participant to the session, let them know the number of products they will be evaluating. When introducing each of the products, ensure all products are referred to objectively even if there is one product you personally think is superior to the others. Similarly, when testing multiple solutions, or system changes, do not provide information to the participant about who developed various solutions, or which solution or change you think will be best.

Section 8.8.2. Scenario Design

In a comparative usability test, each participant will evaluate all the products in a single session. To accommodate this, the length of each scenario will need to reflect the total time available for the testing session (i.e., no longer than 2.5 hours). Also, since the participants will repeat each scenario on each product, equivalent but different scenarios will need to be created for each product to minimize learning effects. A different but equivalent scenario is a scenario that requires the same tasks and has the same features (e.g., interruptions, planted errors), but has a different story or context. For example, one scenario for evaluating infusion pumps is that a patient’s blood pressure is dropping and so the participant needs to titrate the medication that controls blood pressure. A different but equivalent scenario could be that a patient is complaining of increased pain and so the participant needs to titrate the pain medication.

Section 8.8.3. Counterbalancing

In a comparative usability test the order that each participant tests each product must also be counterbalanced to minimize learning effects. That is, an equal proportion of your participants should use each device first, second, third, etc.

Section 8.8.4. Training

In a comparative usability test, the training for each product should be delivered immediately prior to testing that product. Providing training on all the products at once (prior to starting the testing) will bias the results toward the training that was given last. Additionally, if training on all the products is done several days in advance, it is less likely to be retained than if training on one device is given in advance, which is the common approach during the implementation process.

Section 8.8.5. Post-Test Questionnaire

In a comparative usability test, post-test questionnaires should be administered immediately after each product is tested. After all the testing is complete, a final post-test questionnaire should be administered to get a summary of the participant’s thoughts across all the products.