

THE DEVICE USABILITY EVALUATION HANDBOOK

An Introductory Resource
for NSW Health Employees



CLINICAL
EXCELLENCE
COMMISSION

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FOREWORD

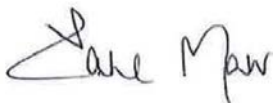
Every staff member in the NSW Health system plays a part in delivering safe care, and the contribution by those individuals involved in medical device procurement and support cannot be understated.

Approximately 2.5 per cent of all patient safety incidents reported in NSW Health identify “Medical device/equipment/property” as the principle incident type. Although this is a small proportion of all incidents in NSW, in 2014 this represented over 4000 incidents ranging from near misses to patient death. In the same year, 68 serious clinical incidents (those requiring a root-cause analysis investigation) identified ‘equipment’ as a “contributing factor” or “issue”.

In 2015, the Clinical Excellence Commission reviewed all clinical incidents reported in the NSW Health Incident Information Management System (IIMS) involving four high-risk device categories (volumetric infusion pumps, syringe drivers, PCA pumps and defibrillators). This review found that more than 80 per cent of the clinical incidents involving these high-risk devices could be attributed to use error. As a consequence, the Clinical Excellence Commission and HealthShare have worked together to strengthen procurement processes for evaluating device and equipment usability.

I am pleased to introduce The Device Usability Evaluation Handbook: An introductory resource for NSW health employees. The handbook is intended to support the work of all individuals involved in the purchase, evaluation, implementation and management of devices and equipment in NSW Health. Its primary purpose is to provide practical advice regarding best-practice methods for assessing the usability of medical devices and equipment. It also provides advice for managing usability risks that are identified post-implementation.

We hope that you enjoy The Device Usability Evaluation Handbook and that it becomes a core resource in your device procurement and management processes.



Carrie Marr
Chief Executive

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1. GLOSSARY

Term	Definition
Consumable	A medical device or product that is not-reusable.
Device	See Medical Device.
Device Trial	Assessing the safety and effectiveness of a device by piloting it in a live site(s).
Heuristic Evaluation	A usability inspection method, whereby evaluators examine a design for compliance with recognised usability principles.
<i>In situ</i> observations	A range of methods for observing how clinicians actually use devices in their local work environment.
Learnability	How easy or difficult it is to learn to effectively use a device.
Medical Device	<p>A medical device is¹:</p> <ul style="list-style-type: none"> a) Any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following: <ul style="list-style-type: none"> i. diagnosis, prevention, monitoring, treatment or alleviation of disease; ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; iii. investigation, replacement or modification of the anatomy or of a physiological process; iv. control of conception; <p>and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or</p> b) An accessory to such an instrument, apparatus, appliance, material or other article.
Shadowing	Observing a professional in their job to gain a better understanding of the role.
Standard	Standards are published documents setting out specifications and procedures designed to ensure that products, services and systems are safe, reliable and consistently perform the way they were intended to.
Usability	The effectiveness, efficiency and satisfaction with which specified users achieve specified goals in particular environments.
Usability Evaluation	Usability evaluation is an umbrella term for a number of methods used to identify impediments to ease-of-use caused by the design or configuration of devices.
Usability Testing	A process for evaluating devices with real users completing realistic work tasks.
Use Error	An act or omission of an act that results in a different medical device response than intended by the manufacturer or expected by the user.

1. Therapeutic Goods Act (1989). Commonwealth of Australia [updated 28 Mar 2012].

2. INTRODUCTION

Usability and safety

The modern healthcare system is supported by a fleet of sophisticated devices and equipment fulfilling a broad range of clinical functions. These technologies are mechanical (beds, syringes), digital (blood glucose monitors), big (integrated digital operating theatres) and small (surgical screws). Many devices are used by highly-trained clinicians, but increasingly devices are used by patients without supervision. Given the complex role of devices and equipment in modern healthcare, it is not particularly surprising that they are implicated in patient safety incidents.

What you may find surprising is that many safety incidents involving devices find no evidence that the device itself was faulty. Indeed, a far greater risk to patients is use error, an “act or omission of an act that results in a different medical device response than intended by the manufacturer or expected by the user”. Indeed, a 2015 review by the CEC of clinical incidents reported in the NSW Health Incident Information Management System (IIMS) involving four high-risk device categories (volumetric infusion pumps, syringe drivers, PCA pumps and defibrillators) found that more than 80% of the clinical incidents could be attributed to use error.¹

It is clear that use error presents a significant risk to patient safety. Fortunately, it is possible to reduce/eliminate use errors by employing a usability evaluation process to identify, assess and mitigate potential patient safety risks associated with the *use* of medical devices. This document outlines a best-practice usability evaluation process.

Just remember - usability is not just a patient safety concern. **Poorly designed devices also pose a risk to workers and visitors.**

What is usability?

Usability is “the effectiveness, efficiency and satisfaction with which specified users achieve specified goals in particular environments.”² Although this definition is relatively short, it describes a number of interrelated issues:

- **“Effectiveness, efficiency and satisfaction”** – usability is the end-result of a number of performance indicators. Many definitions also incorporate the terms ‘*Learnability*’ and ‘*Error tolerance*’.
- **“Specified users”** – usability can depend on the *types* of healthcare workers using the device. User types are commonly differentiated based on job role (i.e. nurses or doctors) and/or experience (i.e. novice or expert), though other characteristics (age, height, technology savviness etc.) may also be appropriate.
- **“Specified goals”** – the usability of a device is also dependent on whether it actually supports the users overall goals. For example, a Ferrari may have great acceleration, but if the driver wants to move their family around then it’s not very practical. Similarly, inserting a central line may be appropriate when administering multiple dose IV medication, but it’s probably too cumbersome (or overkill) for a single dose.
- **“Particular environments”** – the usability of a device can depend on where it’s used. For example, a hospital bed that performs well in one ward may be too large to be easily manoeuvred in the tight corridors of another ward.

This handbook describes a number of methods for evaluating the usability of a device whilst accounting for differences between users, goals and environments.

Why consider device usability?

There are a number of benefits associated with selecting devices with good usability:

- ✓ Reduced clinical risk;
- ✓ Fewer use errors, which decreases the likelihood of worker injury and/or patient safety incidents;
- ✓ Improved patient care outcomes;
- ✓ Greater job satisfaction for users with a decrease in frustration associated with poor device usability;
- ✓ Better job performance through gains in efficiency and effectiveness of treatments;
- ✓ Decreased service calls due to the selection of devices that are easier to use;
- ✓ Easy to learn devices have lower training costs;
- ✓ The device is more likely to be used.

Ultimately, however, you should consider usability because poor usability can result in the death or injury of patients and staff.

What this handbook will do

- Help you to decide if device usability evaluation is needed;
- Describe how usability can be assessed as one component of the broader device evaluation process;
- Give you a description of a number of basic device usability evaluation methods;
- Provide tips and tricks for you to use when conducting usability evaluations;
- Identify several common implementation (and post-implementation) issues. This includes how you can manage usability problems identified after the purchase of equipment.

What this handbook won't do

- The handbook does not replace pre-existing routine device evaluation activities completed by Biomedical Engineers, Work, Health and Safety, Manual Handling and Infection Control personnel. These personnel must be contacted to discuss testing the device for safety and function before it goes to clinicians for evaluation (where appropriate).
- This handbook is not a substitution for your own clinical judgement and expertise. Instead, the handbook is designed to help you identify hazards caused by poor usability.
- This handbook does not describe every usability evaluation method. It should be treated as an introductory book of highlights.
- This handbook is not a guideline, standard or checklist by which all usability evaluations should be conducted. Rather, it illustrates best practice principles for usability testing.
- The methods outlined in this handbook are not an alternative to current end-user consultation processes. At best, the handbook may help you determine how best to engage with those end-users.

Who should use this handbook?

This handbook has been written primarily for individuals involved in the purchase, evaluation, implementation and management of devices and equipment in NSW Health. This includes, but is not limited to, procurement contract managers, clinical product managers and purchasers, biomedical engineers, work health and safety officers, and clinical reference group members. However, this handbook is an introductory resource and, consequently, can be utilised by any clinician interested in learning more about device usability.

References

1. Clinical Excellence Commission (CEC), Medical device single supply contracts: a quality and safety perspective. Sydney: CEC.
2. International Organization for Standardization. Ergonomics of Human-system Interaction: Part 210: Human-centred Design for Interactive Systems. ISO; 2010.

3. USABILITY EVALUATION

What is 'usability evaluation'?

Usability evaluation is an umbrella term for a number of methods used to identify impediments to ease-of-use caused by the design or configuration of devices. Most usability evaluation methods are based on the principle that it is better to meet the needs, limitations and expectations of the users rather than expecting the user to adapt to the device. Even a well-trained, experienced and conscientious user can experience a use error (or hindrance) when a device is poorly designed.

Which usability evaluation methods are included in this handbook?

The following usability evaluation methods are included in this handbook:

- *In situ* observations – Observing users in real-life environments to confirm how the device is actually used and to identify specific environment, process and design issues that impact safe use.
- Heuristic Evaluations – Using a set of design principles to evaluate usability.
- Usability Testing – A method of evaluating devices in which real users are asked to complete typical work activities that involve the use of the device. Observers take notes of any usability problems encountered.
- Device trials – Pilot testing a device prior to implementation.

You do not need to employ all of these methods for every usability evaluation. You will need to use your judgment and experience to determine which methods will deliver the most benefit proportional to the potential risks associated with each device category. However, it should be noted that a basic usability evaluation would at least include a structured heuristic (desktop) evaluation process. A *comprehensive usability evaluation* would typically involve all of these methods. A broad guide for when a comprehensive usability evaluation is likely to be beneficial is outlined below.

Do you need to do a usability evaluation?

Due to the large number of devices and consumables on the market, it isn't practical (or even necessary) to perform a usability evaluation before every purchasing decision. Therefore, the first question you'll want to ask yourself is whether the procurement process for a device is likely to benefit from a formal Usability Evaluation. To help you, here are some criteria developed by the Western Canada Human Factors Collaborative (WCHFC):

You *could* do a usability evaluation if:

- The device has a visual display
- The device has alarms to alert the user to problems

A *usability* evaluation is recommended if:

- The user needs to program information into the device
- Patients are required to interact with the device

A *comprehensive usability* evaluation is recommended if:

- The device infuses fluids, blood, medications and/or nutrients into patients*
- The device is used to maintain life support measures or for the monitoring of patients*

* You are strongly advised to contact a Human Factors Specialist for guidance if evaluating these types of devices.

4. IN SITU OBSERVATIONS

What is an *in situ* observation and what is it used for?

In situ observation refers to a range of methods for observing how clinicians actually use devices in their local work environment. *In situ* observation is also an effective method of identifying the types of clinicians who will use the device, what the device will be used for, if there are any variations between individuals in the operation of the device and challenges of using the device in the real world. More advanced information that can be collected includes the steps that users follow in order to complete tasks, how quickly and effectively users complete tasks, and how often users make errors when using devices.

A common strategy for conducting *in situ* observations is *shadowing*. This involves following an individual around on a typical work day to observe and record their activities, particularly key interactions/difficulties with clinical devices. Alternatively, one could follow the device instead, noting who uses the device, when, and for what purpose. Both methods can be complemented by asking the users to “*think aloud*” while completing their work tasks. This will help to reveal their thought processes when using the device. Obviously, asking the user to think aloud can be intrusive, and could potentially disrupt the users natural work routine. For this reason, you can instead video record the use of the device. The user can then be asked to review the footage and provide a running commentary of their thought processes at the time of use.

When should you do an *in situ* observation?

In situ observations can be used to help identify the functional and technical specifications of devices for requests for proposals (RFPs). Typically, this is used to enhance other stakeholder engagement processes like workshops and expert panels, by helping to identify those ‘in-the-moment’ requirements that can be difficult to recall later. As an example, imagine a syringe driver with a two metre power cord. For a nursing unit with relatively small rooms and a lot of spare power sockets, this device may be acceptable. However, for units with larger work spaces, it is probable the utility of the devices would increase if they came with a longer power cord. This example shows that the ‘usability’ of a device can depend on who is using the device, where and when. It’s also the sort of mundane problem that is often forgotten during workshops and focus groups.

Tips for *in situ* observations

- Remember that users are likely to be on their best behaviour when being observed. It can help to tell them that you’re not there to evaluate them, but to learn about how the device is *actually* used.
- *In situ* observations work best with other techniques used to gather requirements for devices, such as interviews and questionnaires.
- If you don’t understand why something was done a certain way, don’t be afraid to ask for clarification. However, try to avoid making assumptions when asking clarifying questions. Instead, ask open ended questions to uncover the reasons for users’ behaviour.
- Users of the device can often be decomposed into specific ‘types’ of users. Most commonly, this is based on work role. If more than one type of user (i.e. nurses or doctors) interacts with the device, you should try to observe at least one user from each type. It’s also advisable to recruit users with different levels of experience in their roles.

5. HEURISTIC EVALUATION

What is a Heuristic Evaluation and what is it used for?

Heuristic Evaluation is a usability inspection method whereby experienced practitioners examine and interact with a device to determine if the design complies with established usability principles (heuristics). A set of heuristics for medical devices is provided on the following pages.

Because Heuristic evaluation can be done away from where the device is used clinically, **it can be readily incorporated into pre-existing desktop evaluation processes.**

When should you do a Heuristic Evaluation?

Heuristic Evaluation provides a useful *initial* evaluation of usability because it is particularly effective at identifying common or known usability problems. It is also relatively efficient compared to other usability evaluation methods which typically require time and the participation of end users.

Jakob Nielsen, the creator of the Heuristic Evaluation process, has reported that a single evaluator can uncover approximately 35% of usability problems using heuristics. By recruiting 3 – 5 evaluators you should be able to identify 60–75% of a device's usability issues.

How to conduct a Heuristic Evaluation?

Typically three to five individuals familiar with the heuristic evaluation methodology will independently evaluate the device, with each creating a list of device design features that violate the heuristic evaluation principles. A set of heuristics for medical devices, adapted from those published by Zhang and colleagues in 2003¹, is provided on the following pages. The evaluators should identify **which** heuristic is violated for **each** of the design features and **how** the heuristic is violated. If desired, the evaluators can also generate a severity rating for each of the problems identified, which will help with their prioritisation - you can use a simple scale ranging from 1 to 5.

The problems identified by each of the evaluators can then be combined into a master list. If necessary, the evaluators can meet to negotiate agreement about the severity of each of the problems they found.

Summary of steps in a Heuristic evaluation:

1. Identify 3-5 individuals who are familiar with the heuristic evaluation methodology
2. Have the evaluators perform their reviews **independently**
3. Ensure the evaluators identify design characteristics that violate usability heuristics
4. Remind the evaluators to document how the heuristics are violated and give a severity rating
5. Collate the individual reviews into a master document
6. Arrange for the evaluators to meet to negotiate the severity of each issue (Optional)
7. Use the results of the heuristic evaluation to compare devices.

Usability heuristics to evaluate the usability of medical devices¹

Criteria	Definition	Questions to ask
Consistency and standards	Product words, situations, actions should be consistent so that it is obvious to the user what they mean.	<ul style="list-style-type: none"> How consistent is the sequence of actions for similar/different tasks? How consistent are the colours used, layout, and position of elements, font, capitalisation and terminology/language used? Does the product adhere to official standards and conventions for design?
Visibility of system state	Users should be informed about the status/mode of the device through appropriate feedback and display of information.	<ul style="list-style-type: none"> How easy is it to tell what is happening? Is it possible to infer what can be done in each device state? Is there appropriate feedback?
Match	The design of the device should match the conceptual model the users have about the system.	<ul style="list-style-type: none"> Does the design of the device match the way the user conceptualises task completion (i.e. sequence, labels, icons, etc.)? Does the device communicate the real world implications of initiating any of its functions?
Minimalist	Any extraneous information is a distraction and a slow-down.	<ul style="list-style-type: none"> What extraneous information is included? Is this functionality actually useful at point-of-care? Is the use of the device efficient?
Minimise memory load	Users should not be required to memorise a lot of information to carry out tasks.	<ul style="list-style-type: none"> Does the device guide the user through the task (i.e. recognition rather than recall)? Does the device use concrete examples for entering information (i.e. DD/MM/YYYY)
Informative feedback	Users should be given prompt and informative feedback from the product.	<ul style="list-style-type: none"> Does the product give prompt and informative feedback about the user's actions? Is the feedback concrete and specific? Is the system sufficiently responsive?
Flexibility and efficiency	Different users have different ways of learning. It is sometimes desirable to include things like shortcuts for advanced users.	<ul style="list-style-type: none"> Are shortcuts available for advanced users? Is it possible to for users to save pre-sets?
Good error messages	The product should provide error messages informative enough so that users can understand what the error is, learn from this error and recover from the error.	<ul style="list-style-type: none"> Are error messages specific? Does the error message provide instructions to help the user recover from the error? Are error messages in plain language?
Prevent errors	Interfaces that help stop users from making errors in the first place are highly desirable.	<ul style="list-style-type: none"> Is the device designed in a way that stops users making common errors? Does the device incorporate design features that decrease the likelihood of a slip or lapse occurring.
Clear closure	Every task has a clear beginning and end. Users should be notified when a task is completed.	<ul style="list-style-type: none"> When a task is completed, is the user clearly notified?
Reversible actions	Users should be able to recover from errors with reversible actions.	<ul style="list-style-type: none"> Does the product allow users to 'undo' or 'go back' when they've made an error?

User language	Information should be written and/or spoken in a form that users understand.	<ul style="list-style-type: none"> Does the device use the same phrases, acronyms, and units of measurement used by users every day?
Users in control	Do not give users the impression that they are controlled by the device. Users are the initiators of actions.	<ul style="list-style-type: none"> Does the product give users a sense that they are in control of the device/product? Are users 'surprised' by device actions? Are users the initiators of actions?
Easy to clean	The design should make it easy for users to thoroughly clean the device	<ul style="list-style-type: none"> Are provided cleaning instructions appropriate? Is it easy for users to thoroughly clean the device (i.e. no dirt traps, accessible surfaces, non-shedding materials, water resistant surfaces etc.)? Are routine cleaning tasks easy to complete (i.e. flushing lines, etc.)?
Help and documentation	Context sensitive help is highly desirable.	<ul style="list-style-type: none"> Is help accessible to the user when it's needed? Does the product provide help related to the task at hand? Is there a search option?

Further resources

1. Adapted with permission from: Zhang J, Johnson TR, Patel VL, Paige DL, Kubose T. Using usability heuristics to evaluate patient safety of medical devices. *Journal of biomedical informatics*. 2003 Apr 30;36(1):23-30.
2. Gagnon R, Laberge J, Lamsdale A, Histon J, Hudson C, Davies J, Caird J. A user-centered evaluation of three intravenous infusion pumps. In *Proceedings of the Human Factors and Ergonomics Society Annual Meeting 2004 Sep 1* (Vol. 48, No. 15, pp. 1773-1777). SAGE Publications.

6. USABILITY TESTING

What is 'usability testing' and what is it used for?

Usability testing is a process for evaluating devices with real users completing realistic work tasks. Typically, this involves asking users to work through a scenario that requires them to interact with the device. Those interactions are observed to help identify any usability problems with the design of the device.

The advantages of completing usability testing are significant. For instance, usability testing:

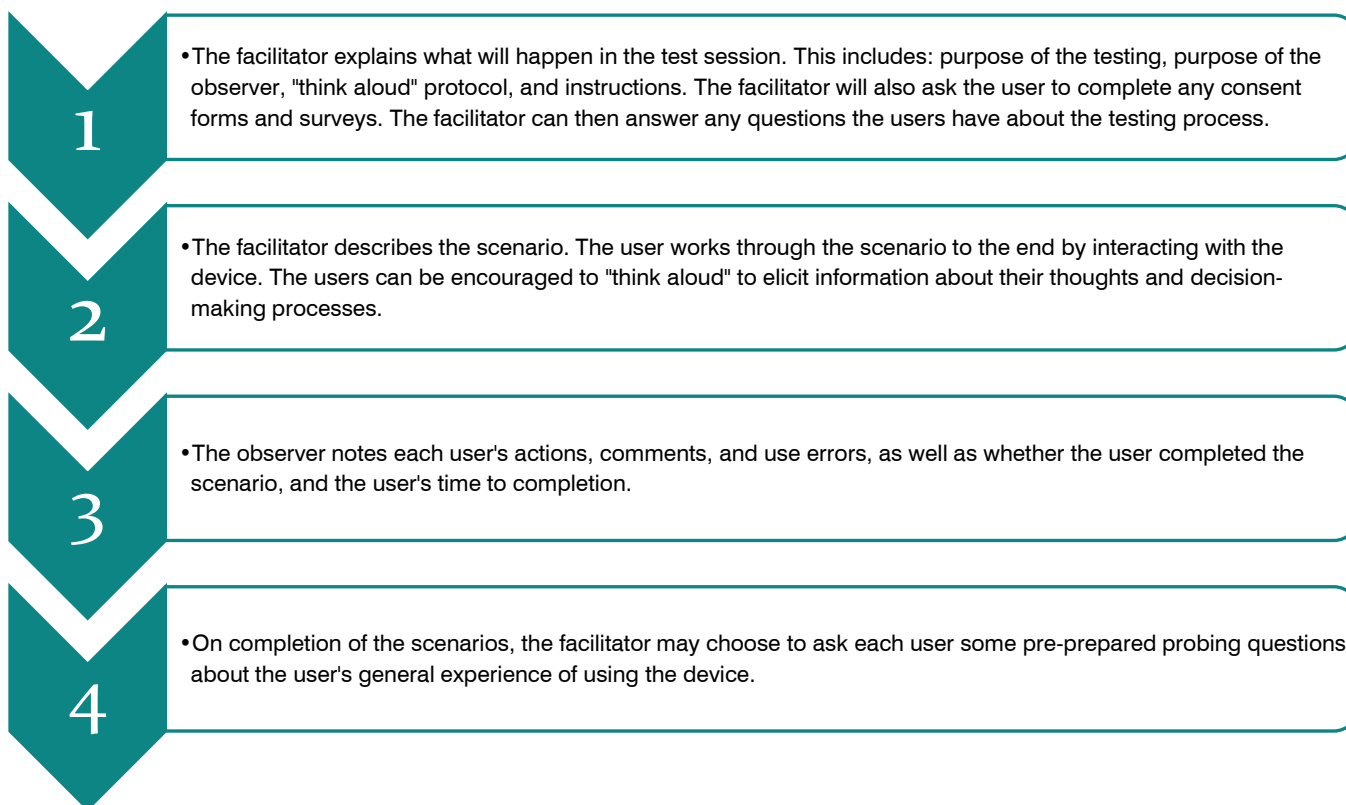
- Helps you to observe rare (but important) events where the device might be used;
- Allows you to test devices without placing real patients at risk of potentially being harmed;
- Can identify more than 90% of usability issues (Nielsen, 2012); and
- Can require as few as six participants (assuming they represent actual users of the device).

How to conduct a usability test

Before you can carry out a usability test, you'll need to develop some clinical scenarios. This should be done with the assistance of one or more subject-matter experts (e.g. experienced clinicians). The scenarios can be based on actual events or cases with which the users are familiar. You could also base scenarios on events you encountered while conducting *in situ* observations.

Once you've developed the scenarios, you'll need to identify and recruit representative users. As you'll only be testing a small number of users, targeted recruitment is appropriate. Generally, you should try to recruit a novice, intermediate and expert clinician for each type of user (according to work role) who interacts with the device. For instance, because nurses are the most common users of infusion pumps, usability testing would require recruiting a novice, intermediate and senior nurse.

The following diagram describes the major components of a usability test session.



General principles of usability testing

By following these six core principles you will be able to generate the most valuable information from usability testing.

1. Use scenarios, not discrete tasks

The scenarios used for usability testing should be based on situations that the user could encounter in a real clinical setting. The scenario must be detailed enough to be realistic, but should avoid hinting at how the device should be used. For example, to perform usability testing of an infusion pump, it is preferable to provide the medication order as it would be received in the user's local setting, rather than providing that information in the sequence in which it would be entered into the pump. Scenarios designed in this way allow you to see what the user would do in real life without intervention or help. It is also preferable for the scenario to require the user to use the device from start to finish, rather than as a series of discrete tasks.

2. Remember the facilitator is there to run the session, not instruct the user

The facilitator's role is to provide guidance about the testing process and to build rapport with the users to help them feel comfortable with the testing process. The facilitator is not there to answer users' questions about the device. If a user asks for assistance, then you can respond with something like "Because we are interested in how you use the device without having someone there to help you, we'd encourage you to see if you can figure it out alone." Of course, the user may become profoundly stuck. As a general rule you can help users if they've asked for assistance with the same problem three times.

3. Consider using the "think aloud" protocol

The "think aloud" protocol involves encouraging users to describe what they are doing as they are completing the scenario. This technique is ideal for gaining an understanding of users' goals, strategies and decision-making processes when they are trying to work out how to use the device. This technique can help reveal when a user has misunderstood how to correctly use a device or is confused about what mode the device is in during testing.

A limitation of the "think aloud" protocol is that completion times are no longer a valid measure. Additionally, some users may find it extremely difficult to talk while doing. Consequently, an alternative method is to record the user completing the scenario and then ask them to immediately review the footage and provide commentary. This is strongly recommended when the device is intended to be used in time critical situations (i.e. defibrillators).

4. Have an observer

Normally the facilitator will have his or her hands full running the session. As a consequence, you might find it useful to have the assistance of a trained observer to note down the user's actions, comments and body language. Because some people can become nervous when asked to perform a task while being watched, the observer should try to be a fly on the wall. Better yet, many simulation centres have one way mirrors so the observer doesn't even need to be in the same room. As an alternative to having an observer, you can record the session and take notes yourself later.

5. Comparative usability testing

Because usability testing requires more effort than other evaluation methods, it probably isn't worthwhile usability testing for every device in a product category. For this reason, we recommend performing *comparative* usability testing with a shortlist of two or three preferred devices that meet the requirement specifications. The devices in a comparative usability test should be evaluated using the same scenarios and preferably with the same observers/facilitators. It should also be noted that objective usability data (number of errors, task completion, time to completion, etc.) is most useful when making direct comparisons between devices.

6. Treat all identified issues as probable

Because usability testing typically only involves a small number of participants and trials, it is generally advisable to treat all identified errors and design impediments to ease of use as being likely to occur in real-world settings.

Further resources

1. Nielsen Norman Group. Nielsen Norman Group [Internet]. How Many Test Users in a Usability Study; 2012 June 4 [cited 2016 April 13]. Available from: <https://www.nngroup.com/articles/how-many-test-users/>
2. National Center for Human Factors in Healthcare. Med Device Online [Internet]. An Introduction to Human Factors Engineering for Medical Device Development; 2014 July 24 [cited 2016 April 13]. Available from: <http://www.meddeviceonline.com/doc/an-introduction-to-human-factors-engineering-for-medical-device-development-0001>
3. Israelski EW. Testing and Evaluation. Handbook of Human Factors in Medical Device Design. 2010 Dec 13:201 .
4. Lamsdale A, Chisholm S, Gagnon R, Davies J, Caird J. A usability evaluation of an infusion pump by nurses using a patient simulator. In Proceedings of the human factors and ergonomics society annual meeting 2005 Sep 1 (Vol. 49, No. 11, pp. 1024-1028). SAGE Publications.

7. DEVICE TRIALS

What is a device trial and what is it used for?

A device trial assesses the safety and effectiveness of a device by piloting it in a live site(s). Because the device is being used to treat real patients, device trials should be performed after other usability evaluation methods have been completed. After all, we don't want to expose patients to unnecessary risk. In NSW Health, device trials are often the final check of a device before it is approved by a local products committee for wider use.

Tips for doing a device trial

1. Choose the best location

The location of the device trial may influence the way the user interacts with the device. Local context can affect which features of the device are used and which are not. If the site chosen is not representative of those in other facilities, it might not be possible to generalise the findings of the device trial.

2. Check site representativeness

As a component of choosing the best location, you should ensure the users at your site are generally representative of users in other facilities. For example, you could find that some wards are staffed by workers who possess unusually high computer literacy – these users are more likely to prefer a touch interface than workers with less exposure to various electronic devices.

3. Consider shadowing/observation

Shadowing and observation are an important component of device trials as it can provide you with direct evidence of how users actually use devices, rather than how they say they use them. Shadowing involves following one user for a specified period of time and noting what tasks he or she completes, how the user interacts with the device and which usability issues they encounter.

Shadowing may also involve the observation of specific events with multiple users present. This is a good idea when the device is used in a team context. For example, patient bedside monitors are typically used by a number of different users before, during and after a rapid response. Typically the device is setup by the local nurse, who may also enter critical thresholds and alarms. By comparison, doctors typically only glance at the device and do so from a distance (often the bed end). This indicates that these job roles have unique requirements – nurses want a straightforward, easy to configure device, whereas doctors want to be able to see all of the relevant information from a distance.

4. Choose and collect key performance indicators

One of the main advantages of a device trial is that it allows you to collect specific and useful indicators of real-world performance. You'll want to make sure you identify both objective and subjective key performance indicators (KPIs). Objective KPIs refer to fact-based measurable outcomes, e.g., total use, duration of use, logged errors/changes. Subjective KPIs include things that are opinion-based, such as verbal statements and survey responses.

5. Ensure the device is being used

Just because a device is placed on the ward, doesn't mean it's being used. The lack of negative feedback may mean it was tucked away in a corner where it couldn't do any harm.

8. QUANTIFYING IDENTIFIED USABILITY ISSUES

Regardless of which usability evaluation methods you choose to employ, you'll inevitably collect a large amount of information about each device. Occasionally you'll encounter a usability issue so serious that you'll be able to eliminate the device from consideration almost immediately. More often, you'll require some method of analysis by which to quantify the information gathered in order to provide a basis for comparison between devices.

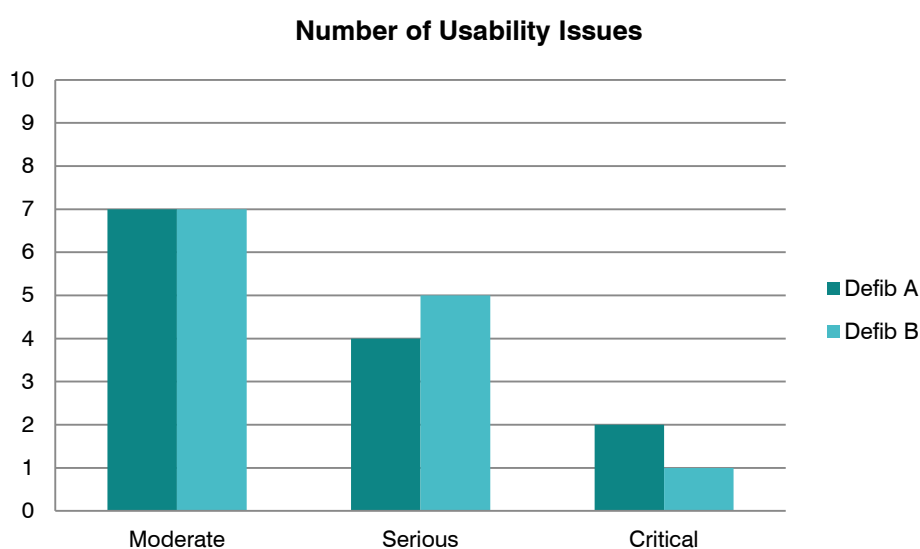
Analysis

One of the key outputs of usability evaluation is the identification of specific design problems that either impede efficient use or facilitate use error. Typically, this will be a simple list of issues. Obviously, it's not really possible to do a quantifiable comparison of information in this format. For this reason, we recommend doing a **severity** analysis of each of the issues identified during the evaluation. Canada's Healthcare Human Factors decompose severity using the following criteria¹:

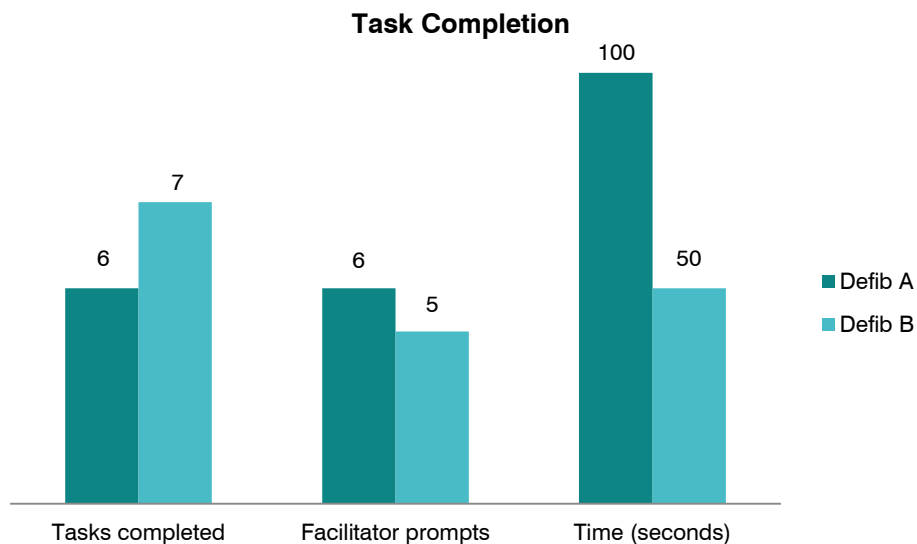
Critical	Issues that could have direct patient safety implications and/or prevent users from completing tasks
Serious	Issues that could have a potential indirect patient safety impact and/or could result in considerable user frustration and inefficiencies
Moderate	Issues that affect general usability and/or the user's overall impression of the system

The reason we recommend focusing on the *severity* of the usability issues identified rather than *risk* is because usability evaluation is based on a small sampling methodology. If the issue presents when trialling the device with only six users, it's fair to assume it will probably recur when the device is used by two-hundred. For this reason, **issues identified through usability testing should be treated as 'probable'** - we assume that all observed use errors will recur in the real world without intervention.

Once you've performed a severity analysis of each of the device design issues, you can then do a simple count of the number of critical, serious and moderate issues identified for each device. The following table provides a comparison of two defibrillator units.



In addition to the design issues identified, you've likely obtained a number of quantitative metrics like time to completion, number of errors, task completion, user satisfaction ratings, etc. Sometimes this information is critically important to the usability of the device – all things being equal, users are generally going to prefer the device that takes half the time to do the same task. Therefore, it's often prudent to include this data alongside the severity analysis results:



Additional considerations

Heuristic evaluation results are not as valid as other methods

Typically the source of the identified issues doesn't play into the severity analysis directly. However, in general, results obtained during usability testing and device trials (especially those observed directly) are treated as being **more valid** than those identified during a heuristic evaluation. In those instances where the heuristic evaluation and the usability testing results are contradictory, most of the time you should assume that the results of the usability testing are correct.

Pre-define which metrics are the best indicators of device usability

Although you'll generally want to focus on the number of critical and serious issues encountered for each device, there are exceptions. For example, the time to task completion is critical for devices like defibrillators, where a minor delay can result in the preventable death of a patient. As a consequence, you need to consider the function and purpose of the device and **pre-define** which metrics are the best indicators of the effectiveness of the device.

Overall weighting of usability evaluation results in procurement decisions

The NSW Health does not, at present, recommend a specific *weighting* for the results of usability evaluation on the final procurement decision. However, some healthcare providers give usability evaluation as much as a 30% weighting on the final procurement decision for high-risk devices.

Further resources

1. Taneva S, Chagpar A, Cafazzo J. Choosing the Right Product: Using Human Factors in Procurement Decision Support in a Hospital Setting. Poster session presented at: 2014 International Symposium on Human Factors and Ergonomics in Health Care: Leading the Way; 2014 March 16-19; Chicago, Illinois.
2. International Organization for Standardization. ISO 14971: medical devices-application of risk management to medical devices. ISO; 2000.

9. IMPLEMENTATION – THINGS TO CONSIDER

Selecting the right device is only half the battle – the implementation can be just as important as the testing, selection and purchase. The following section provides a few lessons learned by experienced Clinical Product Managers, Biomedical Engineers, and Human Factors Specialists.

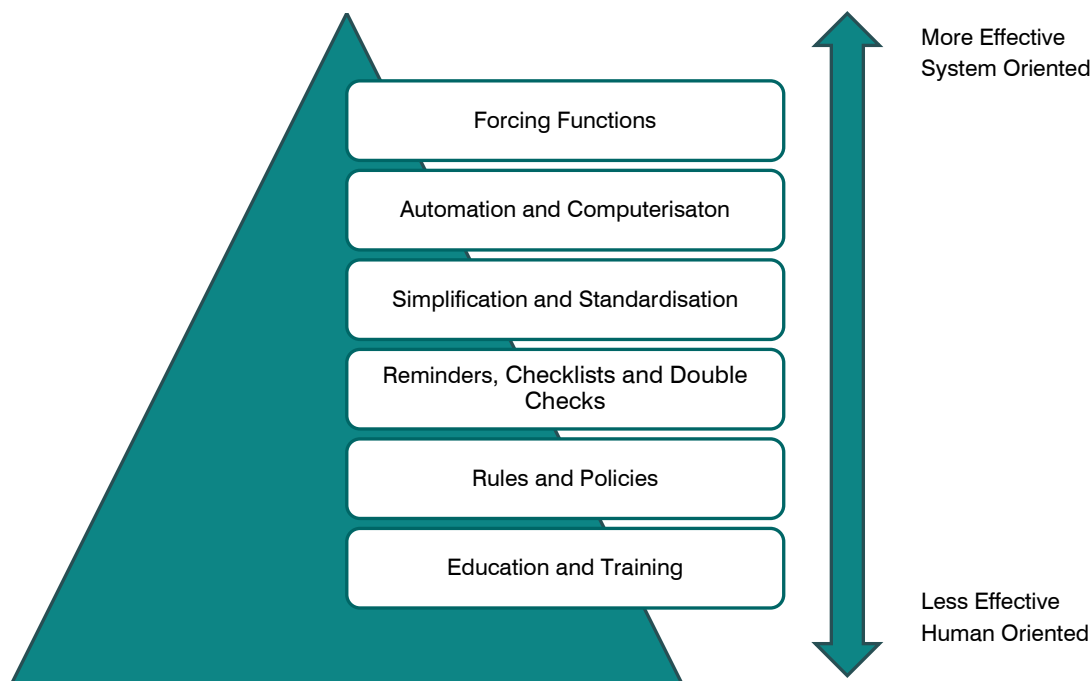
1. Think about configuration

The ability to configure a device to suit the local context is often desirable. However, it should be noted that the 'local' configuration of the device can result in use errors. MedStar has a great video called “[Annie's Story](#)”, which tells the story of how the configuration of an alert in a blood glucose monitor prompted a well-meaning nurse to administer glucose to a patient with critically low blood-sugar. As it turned out, the warning was written for local pathologists – it was never anticipated that nurses might encounter the warning.

2. Remember that training and protocols cannot (reliably) overcome usability problems

Vendors often propose training or changes in procedures or protocols to manage usability problems. Unfortunately, these are 'weak interventions' for dealing with design issues because they assume that with the right training or punishments *we can stop people from making errors*. This is not the case - error is a normal, everyday occurrence. Therefore, the best (or strongest) interventions are those that recognise human beings are fallible and implement *design* changes that either reduce the likelihood of *use errors* occurring or catch use errors before they result in significant harm.

To help you determine if an intervention is likely to resolve usability issues, you should consider the Hierarchy of Effectiveness published by the Institute for Safe Medication Practices (ISMP) in 1999:



Note that the strongest interventions (forcing functions) are those that make the right way to use the device the only way possible.

3. Don't forget that education is still important

Even well-designed medical devices can have inherently complex functions. As a consequence, training is often required. Sometimes a vendor will be able to supply a training program. One thing for you to consider, in addition to any training supplied by a vendor, is whether or not the users have any incorrect assumptions about the device based on their previous experience with older devices. For example, although Guedel airway sizes are usually indicated through the use of different colours, there is actually no standardised colour scheme *between* manufacturers. As a consequence, if you change supplier, you'll need to ensure that users know that the colour coding of sizes is different.

4. Implement post-purchase monitoring

There are several reasons why post-purchase monitoring is critical. First, although heuristic evaluations and usability testing can reveal more than 90% of usability issues, some problems will not be detected. Second, certain sites may have unique difficulties in implementing a device into pre-existing clinical processes. Third, the context of use can change – medications, procedures and protocols change all the time in healthcare. Finally, despite our best intentions, it sometimes turns out that device trial sites are not as representative as thought – this could mean that additional problems will come to light once the device has been implemented. Those problems will then have to be dealt with to ensure that patients and staff do not come to harm.

Here are a few post-purchase monitoring strategies you can employ:

- **Staff satisfaction surveys** – in addition to questions about their general satisfaction with the device, be sure to ask if they've identified any potential safety/usability issues.
- **Review reports from the Health Quality Reporting System (HQRS) and the NSW Health's Incident Management System** – although technically all incidents involving medical devices should be reported in both systems, in practice this is not always the case.
- **On-site observations and shadowing** – the use and application of devices can sometimes change overtime. Making informal, periodic visits to wards and checking how devices are being used can provide information for future device tender specifications.

Further resources

1. Cohen MR, Schneider P, Niemi K. Effective approaches to standardization and implementation of smart pump technology. ISMP Newsletter. 2007.
2. MedStar Health. Annie's Story: How A System's Approach Can Change Safety Culture [Internet]. Available from: <https://www.youtube.com/watch?v=zeldVu-3DpM>

NOTES

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Western Canada Human Factors Collaborative

The Western Canada Human Factors Collaborative was developed as a subcommittee of the Western Healthcare CEO Forum. It is comprised of Human Factors (HF) experts to develop a consensus based approach outlining how to embed HF into the procurement process. The purpose of the Western Canada Human Factors Collaborative is to help ensure that human factors evaluations during procurement leads to the purchase of devices with better designs and usability resulting in better user performance and safety, fewer errors, and reduced risk of adverse patient outcomes.

