Chapter 11. Human Factors Informed Procurement and Implementation Process

Section 11.1. Setting the Stage

Unfortunately, insufficient consideration of human factors in technology design and selection is so pervasive in healthcare that most biomedical technology professionals can easily recall patient safety incidents involving technology use-errors. Incidents involving inadvertent electrosurgical burns [59, 60], electrocution [61, 62], and misconnections between different types of tubing, such as epidural and IV tubing, are all examples of use errors that can be prevented by incorporating human factors principles in the design and selection of medical technology [63-66].

Although a typical procurement process usually results in the selection and implementation of a technology that meets the needs and wants of the hospital organization, it will not inherently lead to a product that satisfies the needs and wants of end users. This is problematic for a number of reasons; not only will the end user be stuck using the technology for a number of years, but patient safety can also be compromised when a technology does not support users in the context of their work. It is not enough to simply select a technology that works according to defined specifications because having a technology that is technically robust does not necessarily translate into a product that will perform well in the actual work environment. A device that is technically robust may actually turn out to be quite weak when it comes to usability, especially if human factors has not been incorporated into the device design, or if the device fits poorly with the intended users and use environments.

By incorporating human factors into a more traditional procurement process, not only does a healthcare organization have the potential to select a product that (1) meets technical specifications, (2) meets clinical requirements, (3) meets budgetary constraints, and (4) comes from a reputable vendor who can provide sustained maintenance and training support over time, but also a product that will fit and support the user, given the context of use. This is important because it is when there are areas of mismatch between a technology and user needs that incidents are more likely to occur.

Fortunately, thanks in part to efforts by the United States Food and Drug Administration (FDA), human factors is increasingly becoming a standard requirement of the medical technology design process, particularly for the design of infusion pumps [67]. A study by Johnson et al. [68] highlighted several common challenges experienced during the procurement of infusion devices, including that: (1) front line users routinely do not contribute to the final purchasing decision, (2) too few products are considered for purchase, (3) there is a lack of systematic feedback from clinical users resulting in a lack of

focus and rigour related to safety issues, (4) assessments are limited to a consideration of technical specifications, (5) cost tends to drive decisions early on in the process, and (6) the final decision is made based on implications of the aforementioned factors rather than a consideration of usability and safety. The human factors informed procurement and implementation process ([HF]PIP) presented in this chapter aims to address many of these challenges to improve upon the traditional procurement process.

By raising the profile of human factors during the procurement process, biomedical technology professionals have the potential to directly impact patient safety, and serve as advocates for end users.

Section 11.2. What is [HF]PIP

The human factors informed procurement and implementation process ([HF]PIP) is a framework that can be followed to support the human factors informed selection of medical technologies in hospital organizations. This framework builds on the traditional procurement process by incorporating human factors methods and standards to help inform a decision, and proactively mitigate residual risk as identified through human factors evaluations. This framework was developed iteratively based on the experience gained during several hospital procurement activities (e.g.,[69]).

Section 11.3. Why Use [HF]PIP

The procurement process is a prime opportunity to make a difference to patient safety by ensuring selected technologies, which usually remain in use for a number of years, fit well with the people who will be using them. Although there has been progress made in recognizing the importance of human factors during device design by manufacturers, standards for when and how to incorporate human factors into medical technologies and information systems are not yet well established or required for all technologies. Further, even when a medical technology has a robust, well-designed user interface, the device itself may not be a good fit for the particular users or use environment. Consequently, it is highly recommended that healthcare organizations incorporate human factors into their own procurement processes using the [HF]PIP framework.

Applying human factors methods during the procurement process not only has the potential to improve patient safety, but can also increase staff satisfaction and acceptance of a new technology, decrease the amount of training required, and reduce financial costs associated with litigation and obsolescence [68-72]. Finally, the human factors methods presented as part of the [HF]PIP can be used to identify mitigating strategies that address areas of residual risk associated with a technology implementation.

From the biomedical technology professional's perspective, using the HFPIP framework during the procurement process will be helpful for:

- Selecting a technology that; satisfies technical specifications and clinical requirements, meets budgetary constraints, comes from a reputable vendor, and meets user needs given the context of use
- Proactively developing mitigating strategies to address residual risk before the technology is implemented

Section 11.4. When to Use HFPIP

The HFPIP framework should be used whenever a healthcare organization is planning to procure a technology that meets one or more of the following criteria:

- The technology is considered to be high risk
- The technology is considered to be high use (i.e., is used frequently by one or more clinical areas)
- The technology has a history of safety issues (either internal, or external to the organization)
- The technology will require a large capital investment
- The technology is pervasive across the organization (either used in many areas or times for different applications)
- The technology is inherently complicated

In any of these instances, the healthcare organization can greatly benefit from using the HFPIP framework to incorporate human factors methods as part of the procurement process.

Section 11.5. In Preparation for HFPIP

In preparation for an HFPIP, the biomedical technology professional should understand why a procurement process is being undertaken by the healthcare institution (e.g., to replace an existing device, to fulfill a need that is not currently being addressed), and what type of device is being considered (e.g., infusion pump, physiological monitor).

Section 11.6. Completing an HFPIP

The HFPIP framework is outlined in Figure 34. Each step will be outlined and described in this section.

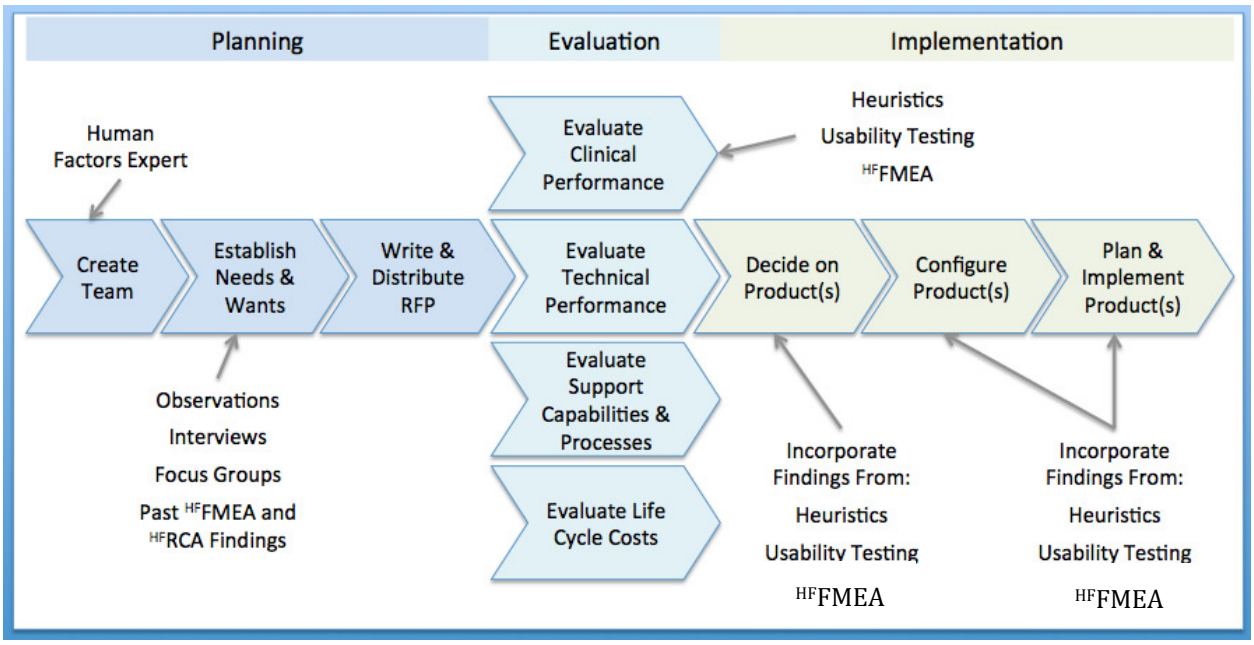

Figure 34. The Human Factors Procurement and Implementation Process (HFPIP)

The ability for each organization to follow the HFPIP will vary depending on jurisdiction-specific rules and regulations related to procurement. Some jurisdictions, because of very rigid criteria for engaging with vendors, will not support the inclusion of human factors inquiry and methods in the decision making process. It is recommended that as much human factors evaluation as possible be included where ever possible throughout the process so that even if the results of the human factors evaluations are not used in the decision making process they can be used to support implementation and training efforts.

Section 11.6.1. Planning

Section 11.6.1.1 Create Team

The first step when conducting an HFPIP is to assemble a multidisciplinary team that represents all stakeholders who are affected by the procurement decision. Consider including the following team members:

- Biomedical technology professionals
- A representative from purchasing
- A human factors representative. This could be a trained human factors expert (either internal or external to the organization), or a biomedical technology professional willing to lead human factors evaluations based on the methods outlined in this handbook.
- Front line staff
- Educators and clinical leaders

- A representative from information technology and information systems. For technologies considered to be an information system, or technologies that interface with an information system.
- A representative from facilities planning. For technologies that require, are influenced by, or part of a project involving changes to the facility (e.g., building a new unit).
- A representative from central stores for technologies that require storage in a central location or access to stored disposables.
- A representative from central processing for technologies that require sterilization or that have special cleaning requirements.
- Cleaning staff for technologies that will have to be cleaned by janitorial staff.
- Someone from legal, risk management and/or a patient safety representative. To provide historical knowledge about past incidents and insight to the potential impact of adverse events related to the technology being evaluated.
- A hospital executive or another senior leader to provide a broad, organizational perspective, facilitate access to required resources, and to help achieve buy-in related to change management, implementation processes, policy changes, and training requirements.

Section 11.6.1.2 Establish Needs and Wants

The next step when conducting an HFPIP is to establish the requirements that a device must fulfill if it is to be considered by the organization. This is one of the most important steps of the procurement process, as it provides the basis for ensuring the selected device will meet the technical, clinical, and usability requirements of the organization and end-users after implementation. In an HFPIP, establishing these requirements relies heavily on the use of several human factors methods including observations (Chapter 4), interviews, surveys and focus groups (Chapter 5), task analysis (Chapter 6) and any previous HFFMEA (Chapter 9) and/or HFRCA (Chapter 10) findings.

The needs and wants of each user group who will interact with the device, not only on the front lines but also during servicing, cleaning, and storage over the entire technology life cycle will need to be established. To do this, each type of end user will first have to be defined. An end user can be considered any category of user who is likely to interact with the technology over the course of the entire technology life cycle. It is extremely important that every distinct user group be included, otherwise the needs and wants of that user group will not be incorporated into the procurement process.

Once each type of end user has been defined, the needs and wants of each of those groups will have to be established. To assess user requirements, the following questions should be answered:

- What tasks must the technology support?
- If a similar technology is already in use at the healthcare organization, then
    - What specific features, settings, reports, and other customizable elements are currently being used?
    - What features are unused, and why?
    - What would users like the technology to do that is not currently possible?
    - Are there any past incidents or near misses from the healthcare organization that can be reviewed?
- Are there any incidents related to the technology that can be found in public incident reporting databases (e.g., FDA MAUDE)
- Are there any issues related to the technology that have been reported by safety organizations (e.g., ECRI Institute, ISMP), standards organizations (e.g., AAMI), or regulators (e.g., FDA)? An excellent example of reported issues related to infusion pumps can be found on the FDA's website.

To determine the tasks a technology must support, conducting observations (Chapter 4) is highly recommended. Those tasks can then be documented using Task Analysis (Chapter 6). Determining what specific features are used and unused on a similar technology, and whether there are other things users would like a similar technology to do, can be collected through a combination of observations (Chapter 4), and interviews, focus groups and surveys (Chapter 5). As noted in Chapter 4, observational data is complementary to data gathered using other qualitative data collection techniques, and so observations should be done whenever interviews, focus groups, or surveys have also been conducted.

To gather the remaining information about user requirements, a search of internal and public incident reporting databases, and information from safety organizations, standards organizations and regulators related to the technology being procured, should be reviewed.

Once the user needs and wants have been established, they will be translated into functional requirements for the Request for Proposal (RFP), and used later to help support the implementation phase.

Section 11.6.1.3 Write and Distribute RFP

In addition to standard RFP elements such as legal terms, contractual agreements, evaluation criteria, and technical product requirements, three additional features augment an RFP for an HFPIP:

1. Functional requirements (i.e., what the technology must be able to do) based on established user needs and wants

2. A request for information about how the technology complies with human factors standards
3. An outline of the human factors evaluation process the technology will undergo

Functional requirements based on established user needs and wants

Establishing user requirements is outlined in Section 11.6.1.2. Once established, the user requirements should be translated into functional requirements in the RFP. For example, users of an infusion pump may express a need to be able to set up the pump and not start it immediately, without the pump alarming because it is inactive. The RFP could specify this as a functional requirement by saying "The pump must provide a means of delaying the start of an infusion, without alarming".

Request for information about how the technology complies with human factors standards

Documentation that illustrates how a technology design and features comply with the relevant sections of the human factors standard *ANSI/AAMI HE75: 2009 Human factors engineering – Design of medical devices[73]* should be requested from each vendor. Since this standard is quite detailed and fairly lengthy, all relevant sections of the standard for the technology being considered should be specified as part of the RFP. As an alternative to specifying this information, vendors could be asked to outline how the *ANSI/AAMI HE75* standard was used to design the technology in question.

There are other medical technology human factors standards; some of them are more pertinent to specific types of technology. Table 23 provides a list of compiled medical device human factors standards that was presented at the 2012 Human Factors and Ergonomics Society Healthcare Symposium [74].

Table 23. Medical device human factors standards

Standard	Title	Purpose
ANSI/AAMI HE75: 2009	*Human factors engineering – Design of medical devices*	Provide a single, comprehensive document for human factors guidance related to the design of medical devices.
IEC 60601-1:2005 ANSI/AAMI ES60601-1:2011, 3rd ed.	*General safety & essential performance standard for medical electrical equipment*	Introduction to standard with subparts for a variety of electrical medical devices.

IEC 60601-1-8: 2006	*Collateral to IEC 60601-1:2005 on general requirements, tests and guidance for* ***alarm systems***	Recommends visual and auditory alarm design parameters, e.g. color, frequency and cadence.
IEC TR 60878:2003	***Graphical symbols*** *for electrical equipment in medical practice*	Collects existing symbols applicable to medical devices and presents them in 15 medical device categories
ISO 15223-1:2012 ISO 15223-2:2010	*Medical devices –* ***Symbols*** *to be used with medical device labels, labeling and information to be supplied*	Part 1– Identifies requirements for symbols used in medical device labelling that convey information on the safe and effective use of medical devices Part 2 – Symbol development, selection and validation
ISO 14971:2007	*Medical devices -- Application of* ***risk management*** *to medical devices*	The definitive standard on principles of risk management, e.g. FTA, FMEA to medical devices
IEC 60601-1-11: 2011	*- Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the* ***home healthcare environment***	Describes particular requirements for home healthcare medical devices
ISO 80369 – 1:2010	***Small-bore connectors*** *for liquids and gases in healthcare applications - Part 1: General Requirements Parts 2 to 7 for particular devices*	Describes standard connectors that are usable and impossible to misconnect across medical device categories
IECEE – TRF's	*TRF – Test Report Forms*	Used by Notified Bodies in EU and elsewhere to gauge compliance with IEC/ISO standards

The purpose of requesting and collecting this information is two-fold: First, it provides an indication of whether the technology is likely to be robust in terms of the user interface design. Second, it acts as a signal to vendors that human factors is an important

consideration when making procurement decisions, and thus, needs to be addressed by vendors during product development.

Outline of human factors evaluation processes the technology will undergo

A description of the human factors evaluations that will be conducted during the evaluation phase of the procurement process should be included as part of the HFPIP RFP. Examples of human factors evaluations that might be applied include a heuristic analysis (Chapter 7), and/or usability testing (Chapter 8). For usability testing, it is important that vendors understand they will not be present during these evaluations, but that they may be expected to provide the following:

- A specified number of devices and disposables
- Customization of the product settings to support the evaluation
- Training for the biomedical technology professional, or human factors specialist

Most procurement processes will require that the RFP specify detailed evaluation criteria. This will include specifying the metrics associated with the human factors evaluations. This is challenging because human factors testing results are primarily qualitative. One way to address this is to assign points to, or weight, each stage of the evaluation process and include the human factors evaluation as one of the stages (for example: cost = 30%, ability to meet specifications 30%, human factors/clinical evaluation 40%). To determine the number of points that each product receives for the human factors/clinical evaluation, the evaluation points should be allocated to categories that correspond to various aspects of the evaluation, for example:

- Usability issues: comparison or critical, severe and moderate issues
- Task efficiency: comparison of time to complete frequent and time critical tasks
- Post-test questionnaires: comparison of direct user feedback and preferences of each pump

Hazard scores, similar to those developed for a HFFMEA, should be developed to assign quantitative values to the identified usability issues.

Once the RFP has been written and distributed, and proposals have been received by the healthcare organization, those technologies that meet the requirements set out in the RFP should be identified and short-listed.

Section 11.6.2. Evaluation

The HFPIP framework augments a typical technology evaluation for procurement by including human factors methods to evaluate the clinical performance of the technology. These human factors methods include heuristic analysis (Chapter 7), usability testing (Chapter 8) and HFFMEA (Chapter 9).

Section 11.6.2.1 Heuristic analysis

When applied during a procurement process, a heuristic analysis (Chapter 7) should be conducted before usability testing or HFFMEA because it can be done quickly and does not require participation from people outside of the procurement team. Also, the results of a heuristic analysis can occasionally provide enough evidence to support the elimination of one or more products because it may highlight that the product does not meet the functional requirements or usability criteria outlined in the RFP. Note that this outcome is rare because the violations identified in the heuristic analysis must clearly demonstrate violations of functional requirements outlined in the RFP.

Ideally the human factors specialist, and two to four other team members who are trained in conducting heuristic analyses, should review each technology. It is preferable to have at least one evaluator who is a double expert – someone who is both a subject matter expert (i.e., user) and trained in conducting heuristic analyses. Each person conducting a heuristic analysis should do so in isolation from one another so as not to bias the findings, unless the human factors specialists are not familiar with the technology or context of use. In this case, the human factors specialist should pair up with a subject matter expert to do the analysis.

Once each evaluator has completed the heuristic analysis, and documented their findings, the human factors specialist should compile the results, and summarize them for the entire procurement team. The summary should include detailed descriptions of the potential impact to staff and/or patient safety for each of the heuristic violations. The purpose of sharing the results of the heuristic analysis is to alert the team to potential issues and consequences of each issue stemming from a heuristic violation. The team may want to rate each heuristic violation using a severity scale. Any issues that have potential impacts to patient safety should be highlighted so tasks associated with these issues can be included in the usability testing scenarios, which are needed because heuristic violations do not always result in usability issues when used in the context. Usability testing, however, is aimed at identifying issues in context.

Section 11.6.2.2 Usability Testing

When applied during a procurement process, usability testing (Chapter 8) should be conducted after a heuristic analysis. Usability test scenarios should incorporate any learnings from the heuristic analysis so any potential issues stemming from violations can be tested in practice. Usability testing is recommended in addition to a heuristic analysis

because it tends to be a much more comprehensive evaluation that allows for the consideration of user performance in the context of the use environment. When issues are identified through a heuristic analysis, the manifestation of these issues, their impact on patient safety, and their root causes may only become apparent when the technology is put into a representative environment with real end users.

When usability testing is done to support procurement, participants should be asked to think aloud (Section 8.5.8) so those collecting data can more easily get to the root causes of any issues that arise.

Usability testing as part of an HFPIP will provide the procurement team with an understanding of the usability issues associated with a particular technology, a comparison of usability issues across the devices being considered, videos highlighting how device issues led to use errors and reactions of users as they interacted with the technology, and a training script (as well as knowledge about potential areas of improvement for the training script) that can be used as a basis for training users during implementation.

Section 11.6.2.3 HFFMEA

When applied during a procurement process, HFFMEA (Chapter 9) should be conducted following usability testing, if resources permit. The results of the heuristic analysis and usability testing provide a fairly comprehensive understanding of the failure modes associated with each product. An HFFMEA can provide insight to the residual risk likely to be associated with a technology after any mitigating strategies intended to fix the issues identified proactively have been implemented.

Section 11.6.2.4 In-Use Trials

In some cases, a healthcare organization may opt to include an in-use trial as part of the procurement process. An in use trial is a hands-on assessment period where the technology is used on patients in a clinical setting. In this way, the ability of a technology to meet user needs can be determined. If an in-use trial is conducted, additional observations can be conducted during that process. Further, interviews, focus groups, and surveys can also be completed to gather users' perceptions of the technology.

Depending on whether in-use trials take place before or after usability testing, they can either confirm what was found during usability testing, or help inform the scenarios that will be used for later testing. To get the highest quality information from in-use trials, try to minimize the amount of interacting and problem-solving the vendors do with the technology while it is in use in favour of the users doing it unassisted, so long as the product is being used safely. Too much involvement from vendors can mask design flaws in the technology that affect its usability. Also, when users have difficulty using a technology prior to implementation it provides a valuable opportunity to experience and observe

issues and challenges related to the device in the context of use. This also helps users to identify, for themselves, the need for training on the device during implementation.

Section 11.6.2.5 Providing Vendor Feedback

The healthcare organization may want to consider sharing some results from the human factors evaluations with vendors to provide important feedback. However, this should be done with caution as confidentiality requirements and hospital policies will have to be maintained. Never share reports across different vendors.

Section 11.6.3. Implementation

The fit between a technology, users, and the use environment is critical to ensuring users accept, and routinely and effectively use a technology once it has been implemented [75-81]. The Technology Acceptance Model, a model that describes how users come to accept and use a technology, [82, 83] explains that for users to develop a behavioural intention to use a technology, which is a reliable predictor of actual use, they must have a positive attitude towards that technology. This positive attitude is formed based on the perceived usefulness and ease of use of the technology to the user.

Applying human factors methods throughout the HFPIP process will help to ensure there is an appropriate fit between the technology and the work system, and will result in the selection of a technology that is user centered. However, even after applying human factors methods during the planning and evaluation processes, there are still a number of tasks required during the implementation phase to support an easy transition for users. These tasks include deciding on the product, configuring the product, and planning and implementing the product.

Section 11.6.3.1 Decide on Product(s)

Once the technology evaluations have been completed, a decision about the final product selection must be made. To make this decision several factors will have to be weighed by the procurement team. Key to the HFPIP framework is the incorporation of findings from the human factors evaluation methods that were carried out as part of the procurement process (i.e., heuristic analysis, usability testing, and HFFMEA). The procurement team may find it helpful to summarize the human factors issues found as part of the HFPIP either in categories across the technologies considered, and/or using an HFFMEA-style scoring matrix to assess potential usability issues based on their relative risk.

If a prospective risk assessment such as HFFMEA has been completed for the technology being procured, any potential mitigating strategies likely to address issues associated with the technology should also be incorporated in the decision making process. For further detail see Chapter 9 HFFMEA, and Section 3.5 Hierarchy of Effectiveness.

Section 11.6.3.2 Configure Product(s)

As will have been identified during the evaluation phase of the HFPIP, the technology being evaluated may have standard features that can be modified or turned on/off by the healthcare organization. How these settings are configured can have serious implications for safety and usability, and thus, any decisions should be made with careful consideration and consultation with each user group. For example, if deciding how to configure alarm settings, consider the potential for either missed alarms (false negatives), or false alarms (false positives). The alarm settings chosen should ensure that alarms are generated only when staff need to be alerted to a situation that could pose a risk to a patient's effective care. Findings from the human factors evaluations (i.e., heuristics, usability testing, HFFMEA) should also be used to help support choosing appropriate customization settings.

Section 11.6.3.3 Plan and Implement Products

Making Changes to the Work System

As part of the planning required prior to implementation, it may be necessary to make changes to the work system in order to support the integration of the new technology into that system. These changes might relate to things like policies, staff workflow, information technology systems, or forms and checklists, for example. The human factors evaluations conducted as part of the HFPIP will provide insight into which changes are necessary given the context of the particular technology and implementation project.

Training and Education

Also as part of the planning process prior to implementation, it will be necessary to train staff to use the new technology. The reader may recall from Section 3.5, Hierarchy of Effectiveness, that *Education and Training* is the least effective type of mitigating strategy along the hierarchy. This is true when training is meant to teach users to overcome a poorly designed product. In contrast, when users are being introduced to a technology for the first time, it will be necessary to provide some level of training to familiarize users with technology interfaces and how to use the technology to achieve clinical goals. In the case of the HFPIP, since several human factors methods will have been used to evaluate the technology, any significant design issues will already be known to the procurement team, and mitigating strategies can then be planned that target higher levels of the Hierarchy of Effectiveness.

Training is an opportunity to positively shape users' attitudes about the usefulness of a technology, and so it is important to structure a training program to ensure staff get an appropriate amount of information at the right level of detail to support their work activities. Content presented during training should cover not only the 'knobology' (e.g., what button to press to start an infusion pump), but also the underlying principles governing how the technology works, or why a process must be done in a certain way (e.g.,

the fluid dynamics behind having to flush a medication line with enough normal saline to deliver the medication to the patient). When users are taught by rote without any real understanding of the underlying principles of operation, they will be more vulnerable to errors.

To develop training content, consider using updated training scripts from usability testing. Another approach would be to start with the task analysis to ensure training materials address, and are specific to, each task for each type of user. Be prepared to iteratively test and revise the training design prior to rolling it out for implementation. Depending on the context of the procurement exercise, it may be desirable to assess the competence of new users with a hands-on exercise to demonstrate their ability to perform each required task.

Allow adequate time for users to gain hands-on experience during training. Consider setting up a simulation, similar to a low fidelity usability test, so users can get a better sense of how to use the technology while still in a safe environment (i.e., before it is connected to a patient). This will provide users with added confidence and is likely to help them retain the information learned.

Implementation

How and when a technology is actually implemented will depend not only on the technology that was procured, but also on internal decisions made by the healthcare organization and HFPIP team. Once the technology has been implemented, it is important that staff feel supported, as the transition to a new technology can be quite stressful. To help ensure staff feel supported, consider having highly trained clinical champions, or biomedical technology professionals, who are readily available on each affected unit who can act as a primary resource for staff during the transition.

Transitional and Ongoing Support

As with any new skill, learning to use a new technology can be associated with a steep learning curve, and can lead to frustration and anxiety on the part of the user. In healthcare, this anxiety is often amplified because most technologies have the potential to harm patients and/or staff when used incorrectly. Ensure staff have the option to get ongoing practice and specialized training on the technology if they are not comfortable using it after the planned training session. Regular competency testing may be desirable depending on the context of the technology implementation, where users would be asked to demonstrate the common uses of the technology as taught.

Section 11.7. What to do with HFPIP Findings

Once the HFPIP has been completed and the technology implemented, a report should be created that summarizes HFPIP process. This type of report can provide helpful context and organizational memory about the procurement process that was followed and a rationale for the decisions made.

Section 11.8. Limitations of HFPIP

Although HFPIP can improve patient safety and provide insight during procurement to aid in the selection of a technology that meets technical, user, and organizational needs, there are a number of limitations that should be taken into account.

Section 11.8.1. The Resources Required

Procuring a new technology is a resource intensive undertaking, and incorporating human factors methods into the process as outlined in the HFPIP framework can require even more resources. Organizations committed to improving patient safety, and keen to realize the other gains that can come from incorporating human factors, will need to provide the biomedical technology professional with dedicated time to complete these activities.

Section 11.8.2. HFPIP May Not be Feasible for Every Medical Device

Due to the resources required, it will not be feasible to undergo the HFPIP process for every technology being procured. To help determine whether HFPIP should be used, refer to Section 11.4 When to Use HFPIP.

Section 11.8.3. Implementation is Rarely, if Ever Seamless

Even when the HFPIP framework is used, and human factors methods are incorporated throughout the procurement process it is unlikely that the implementation of a new technology will be seamless. Depending on the technology being procured, there will be an enormous amount of complexity to manage, and it is inevitable there will be lessons learned along the way. Whenever possible, try to stagger the "go live" implementation of a technology so that only one unit makes the transition at a time. That way, any lessons learned can be incorporated for future unit implementations.

Section 11.8.4. Even the Best-Designed Technology Will Fail From Time to Time

Even the best-designed technology will still fail from time to time. For this reason, it is important that a contingency plan be put into place so that users know what to do. Ensure the healthcare organization has a reporting mechanism in place so potential issues from across the organization can be compiled and interpreted. Users should understand the technology well enough to be able to improvise a response (either with the technology or with a biomedical technology professional) in a way that is safe and clinically appropriate.

Section 11.9. Additional Resources

Human factors medical device standards

- ANSI/AAMI HE75, 2009 Edition - Human factors engineering— Design of medical devices. Available at: http://www.aami.org/publications/standards/he75.html

Resources

- FDA 2014 Examples of Reported Infusion Pump Problems. Available at: http://www.fda.gov/medicaldevices/productsandmedicalprocedures/generalhospitaldevicesandsupplies/infusionpumps/ucm202496.htm#3