

Guidance for Human Factors Evaluations in the Procurement of Medical Devices, Equipment and Technology

Western Canada Human Factors Collaborative

May 2017





This work is licensed under a [Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International License](https://creativecommons.org/licenses/by-nc-nd/4.0/).

Attribution

Attribution is requested if content from this document is used as a resource or reference in another work that is created. To reference this document, please use the following citation:

Western Canada Human Factors Collaborative. Guidance for human factors evaluations in the procurement of medical devices, equipment and technology. Calgary (AB): Western Canada Human Factors Collaborative; May 2017.

Please contact a co-chair of the Western Canada Human Factors Collaborative for more information (Appendix A).

Acknowledgements

The Western Canada Human Factors Collaborative

The Western Canada Human Factors Collaborative was developed as a subcommittee of the Western Healthcare CEO Forum by request from the Western Canada Quality and Patient Safety Group and the Western Canada Supply Chain Group. The role of the Western Canada Human Factors Collaborative is to share information and expertise with health service delivery organizations in Western Canada about integrating human factors planning, requirements, and evaluation methodologies into procurement processes for medical devices, equipment and technologies.

Contributing Authors

Several members of the Western Canada Human Factors Collaborative contributed to this document:

- Susan Biesbroek, Alberta Health Services
- Katherine Bubric, Alberta Health Services
- Jan Davies, University of Calgary/W21C
- Greg Hallihan, University of Calgary/W21C
- Wrae Hill, Interior Health (now at Vancouver Island Health Authority)
- Jessica Jones, Alberta Health Services
- Jason Laberge, Alberta Health Services
- Shaunna Milloy, Alberta Health Services
- Allison Muniak, Vancouver Coastal Health
- Claire Munro, Alberta Health Services
- Lenore Page, Alberta Health Services
- Amanda Raven, Alberta Health Services
- Emily Rose, Vancouver Coastal Health
- Jonas Shultz, Health Quality Council of Alberta / University of Calgary

Other Reviewers

In addition to the contributions of the Western Canada Human Factors Collaborative members, the following organizations / groups have received presentations and/or reviewed versions of this document:

- Alberta Health Services Contracting Procurement and Supply Management (presentations in 2014 and 2015, document review in 2016)
- British Columbia Clinical and Support Services (presentations in 2014 and 2015, document review in 2016)
- Canadian Patient Safety Institute (document review in 2016)
- HealthPro (presentation in 2014)
- Health Shared Services Saskatchewan (presentation in 2014)
- Manitoba Contracting and Sourcing Group (presentation in 2014)
- Medical Devices Bureau of Health Canada by Kevin Day (document review in 2017)
- Western Canada Quality & Patient Safety Group (presentation in 2015, document review in 2016)
- Western Canada Supply Chain Group (presentation in 2016, document review in 2017)

Thank you to all the individuals who received presentations and reviewed versions of the document.

Foreword

The following provincial representatives from the Western Canada Supply Chain Group have reviewed and endorsed this document:

“Integrating human factors evaluations in appropriate procurement activities are a value added component of the procurement evaluation process. The *Guidance for Human Factors Evaluations in the Procurement of Medical Devices, Equipment and Technology* document outlines the rationale and recommended 5-step approach for integrating human factors evaluations into procurement activities.”

Jitendra Prasad
Chief Program Officer; Contracting, Procurement and Supply Management
Alberta Health Services

“The *Guidance for Human Factors Evaluations in the Procurement of Medical Devices, Equipment and Technology* document provides comprehensive recommendations on how one may integrate human factors evaluations into procurement processes. While it is a relatively new aspect to consider in healthcare supply management, and may entail robust change management to implement, incorporating human factors evaluation in purchasing will enable best value and outcomes in health care.”

Jim Cochran
Acting Vice President; Supply Chain
BC Clinical and Support Services

“Human Factors are an important consideration in the procurement of healthcare supplies and equipment. The *Guidance for Human Factors Evaluations in the Procurement of Medical Devices, Equipment and Technology* document offers a standardized framework to assist healthcare organizations in moving forward with integrating human factors planning, requirements, and evaluation methodologies into their procurement processes. This is extremely valuable as it provides a best practice framework in a quantitative and evidence based approach.”

Audrey Mulla
Director; Contracting Services
Winnipeg Regional Health Authority

“The *Guidance for Human Factors Evaluations in the Procurement of Medical Devices, Equipment and Technology* document is very helpful in laying out a concise process that will guide areas that already have a Human Factors program and those that are just establishing a program for procurement activities. It is simple, clear-cut, and a great roadmap to utilize.”

Val Klassen
Director; Supply Chain
3sHealth

Table of Contents

Acknowledgements	2
Foreword.....	3
Introduction	5
What is human factors?	5
What is procurement?	5
Why is human factors relevant to procurement activities?	5
Why human factors evaluations in the procurement of medical devices, equipment and technology?.....	6
Integrating Human Factors Evaluations into Procurement Activities	8
Step 1: Identify if a human factors evaluation should be included	8
Step 2: Determine which human factors evaluation method(s) is appropriate given the specific procurement context	9
Step 3: Incorporate human factors requirements and evaluation information into procurement activity documentation	11
Step 4: Conduct the human factors evaluation(s)	14
Step 5: Share human factors evaluation results and provide recommendations to the procurement committee	20
Challenges When Integrating Human Factors Evaluations in Procurement.....	21
Conclusions	22
Appendices	25
Appendix A – Members of the Western Canada Human Factors Collaborative	25
Appendix B – Highest Priority Devices for Human Factors Evaluation in Procurement	26
Appendix C – Human Factors in Procurement Checklist	27
Appendix D – Additional Optional Human Factors Questions.....	28

Introduction

What is human factors?

Human factors is defined as a “body of information about human abilities, human limitations, and other human characteristics that are relevant to design”.¹ In simple terms, human factors is the study of how to design ‘anything’ for human use. The aim of human factors is to ensure usability, that is ‘ease of use’.² With respect to the design of a medical device, equipment or technology, human factors embodies a range of evaluation methods to assess usability.³

What is procurement?

Procurement is the process of buying something from an external source. The fundamental question answered in the procurement process is ‘what is the best medical device, equipment or technology to buy?’ Procurement processes for medical devices, equipment and technologies may include Request for Proposal (RFP), Request for Information (RFI), Request for Quote (RFQ), Request for Pre-Qualification (RFPQ), and sole sourcing, and other procurement activities such as clinical trials. Throughout this document the term procurement activity will be used to represent any one of RFP, RFI, RFQ, RFPQ, sole sourcing or clinical trial. The procurement process is administratively led and managed by a procurement lead and typically includes an evaluation committee who makes recommendations based on the identified procurement scope.

Why is human factors relevant to procurement activities?

Despite the best selection, training, experience, competence and intentions, *all* users of poorly designed medical devices, equipment and technologies will at least operate inefficiently and, at worst, make errors that can contribute to harm or death.^{4,5} Such errors have been documented as contributing factors to adverse events and patient safety incidents in healthcare by numerous investigative bodies, including the Institute for Safe Medication Practices Canada⁶, the US Food and Drug Administration (FDA)⁴, US Joint Commission, European Commission⁷ and the Health Quality Council of Alberta.⁸

Traditional procurement processes thoroughly evaluate the utility of the device (i.e., can the device perform the required functions) and the financial feasibility (i.e., pricing options and competitive bids). Figure 1 shows that a third criterion to consider in procuring medical devices, equipment and technologies is usability.^{9,10} Therefore, in addition to verifying that the device can do what we need it to do (i.e., utility), we should evaluate characteristics of the device that relate to its potential to reduce use errors as well as effectiveness, efficiency, and user satisfaction (i.e., usability). Furthermore, we should try to determine areas of concern with the device that may need to be either further vetted or focused on during implementation, so as to decrease the probability of patients and personnel suffering harm, and damage to equipment and/or working environment (i.e., risk mitigation). When usability is not given equal emphasis with utility and financial feasibility in procurement decisions, there can be an increased probability of patients suffering harm or close calls.¹⁰

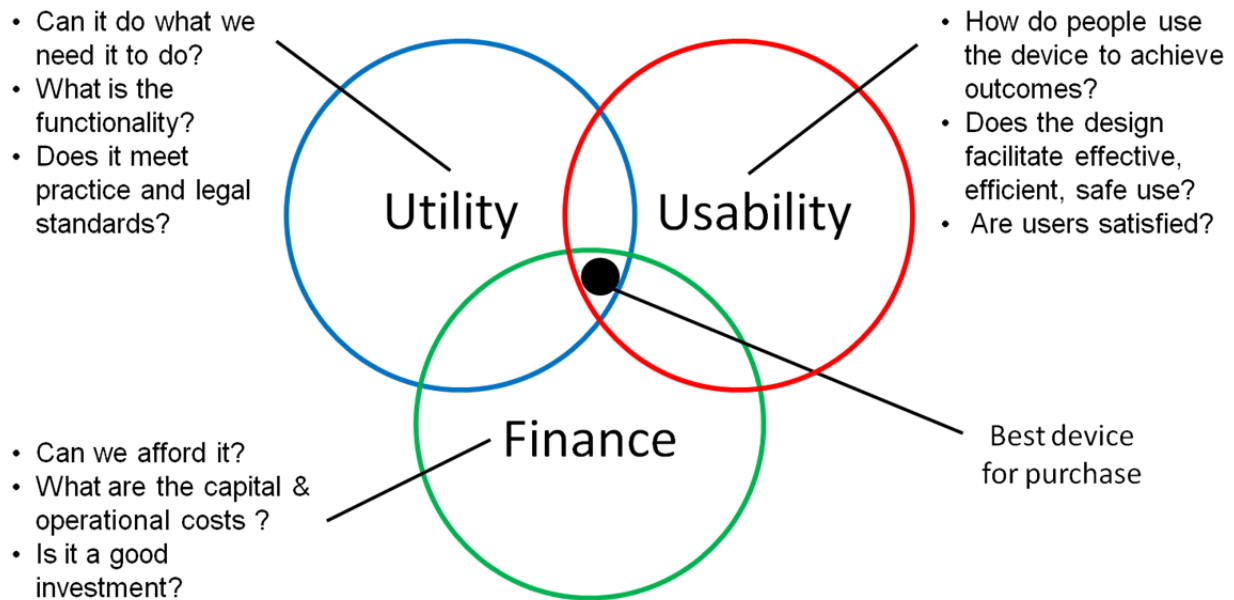


Figure 1. Traditional utility and finance criteria for procurement decisions with usability as an equally important criterion.

Why human factors evaluations in the procurement of medical devices, equipment and technology?

Human factors encompasses a range of processes that are applicable in the design and evaluation of health systems.^{11,12} Indeed, the evaluation of medical device, equipment and technology usability, as part of a procurement activity, is a core component of the application of human factors in healthcare. The ability to evaluate usability before wide-spread implementation of a device, equipment or technology enables Human Factors Specialists to proactively identify and mitigate causes of inefficiency, frustration and human error.

The application of human factors to a healthcare procurement activity provides scientifically validated evaluation methods that can generate empirical evidence to quantify and qualify the usability of medical devices, equipment and technologies. The goal is to purchase safe and easy-to-use devices. When human factors evaluations are incorporated into procurement activities, procurement committees are better informed, so that chosen devices, equipment and technologies are more usable, more effective, and safer for patients and end-users.

The safety and performance benefits of incorporating human factors evaluations into procurement activities include:^{9,10,13,14}

- Improved user performance, fewer use errors and high user satisfaction from purchasing medical devices, equipment and technologies with better usability.
- Fewer implementation problems by creating opportunities to address concerns or problems identified through human factors evaluations prior to the implementation of medical devices, equipment or technologies.
- Increased organizational performance through the identification of improvement opportunities (e.g., changes in practice, training requirements, accessibility) to support local use.
- Improving end-user readiness for any applicable changes in practice by allowing users to test drive devices, equipment and technologies in actual working environments.

- Cost savings through lower training related costs, less frequent trouble shooting calls, and fewer adverse events and patient safety incidents.
- Increasing end-user engagement by having them participate in human factors evaluations and taking their opinions, characteristics, and workflow into consideration as part of the purchasing process.
- Informing procurement committees so they are equipped to choose medical devices, equipment or technologies based on usability in addition to utility and financial considerations.

The information in this guidance document is based on previous human factors work conducted in Alberta and British Columbia by members of the Western Canada Human Factors Collaborative (a subgroup of the Western Canada Healthcare CEO Forum). The audience for this document is the Human Factors Specialists responsible for implementing human factors evaluations within procurement activities. The intention of this guidance document is to establish recommended best practice amongst the member provinces of the Western Canada Healthcare CEO Forum for integrating human factors evaluations into any procurement activity. The human factors evaluation approach described in this document does not replace the evaluations that are administratively led and managed by procurement leads and completed by procurement evaluation committees. When appropriate it is best to consider the human factors evaluations described in this document as an embedded component of the procurement evaluation process. This document includes recommendations for human factors evaluations of high priority medical devices, equipment, and technologies to help determine when a human factors evaluation may be appropriate.

This document may also be used by healthcare organizations that are interested in introducing human factors evaluations as part of their procurement activities. The document includes a section that describes some of the challenges that organizations may experience when integrating human factors in to procurement activities and provides guidance on strategies to overcome those challenges. Interested organizations may also wish to contact member(s) of the Western Canada Human Factors Collaborative for guidance (Appendix A).

Integrating Human Factors Evaluations into Procurement Activities

There are five major steps when integrating human factors evaluations into procurement activities:

- Step 1: Identify if a human factors evaluation should be included
- Step 2: Determine which human factors evaluation method(s) is appropriate given the specific procurement context
- Step 3: Incorporate human factors requirements and evaluation information into procurement activity documentation
- Step 4: Conduct the human factors evaluation(s)
- Step 5: Share human factors evaluation results and provide recommendations to the procurement committee

Step 1: Identify if a human factors evaluation should be included

Due to constraints such as the availability of Human Factors Specialists, time, and multiple procurement efforts occurring simultaneously, choices must be made as to which procurement activities could include a human factors evaluation. This determination should occur during the activity planning phase in order to integrate the human factors evaluation with the rest of the procurement evaluation and decision making process. Early planning also allows procurement leads to make the intent to do human factors evaluation(s) clear to vendors via the procurement activity documentation, as described in Step 3. Lastly, an early determination to do a human factors evaluation allows procurement leads to develop a schedule that accounts for any extra evaluation time that may be required.

Prioritizing medical devices, equipment or technologies can aid in determining whether a human factors evaluation(s) should be included in a procurement activity. The **first step** in prioritization is to identify categories or groups of medical devices, equipment and technologies that would be high priority for including human factors evaluation(s) in their procurement process as there are known usability and patient safety related hazards. For example, one could suggest that all infusion pump devices, such as general purpose infusion pumps, patient-controlled analgesia devices, and epidural pumps require human factors evaluations in procurement decisions. The Western Canada Human Factors Collaborative has compiled a list of device, equipment and technology categories that are highest priority for human factors evaluation(s) (Appendix B). The list is based on past human factors evaluation experience, known incidents of adverse events in Canada and elsewhere, and is cross-referenced with the published literature (e.g., FDA, ECRI, ISMP). Note that the list is comprehensive, but not exhaustive, and reflects recommendations from the Western Canada Human Factors Collaborative.

If the medical device, equipment or technology that is the focus of a procurement activity is not included in Appendix B, then the **second step** is to identify if the specific device, equipment, or technology carries more risk of contributing to patient harm based on specific criteria. Appendix C includes a series of questions about the specific medical device, equipment or technology. The answers to these questions can help procurement leads identify whether or not a human factors evaluation(s) should be incorporated into the procurement activity.

Outcome: Decision whether to include a human factors evaluation(s) in a procurement activity

Step 2: Determine which human factors evaluation method(s) is appropriate given the specific procurement context

Once it has been determined that a human factors evaluation will be part of a procurement activity, it is essential to determine which evaluation method(s) should be used.

Members of the Western Human Factors Collaborative have been conducting human factors evaluations of medical devices, equipment and technologies for over 10 years. Almost 10,000 hours of effort have been allocated to complete more than 65 procurement related human factors evaluations. Human Factors Specialists working in Alberta and British Columbia have used Heuristic Evaluation, Usability Walkthroughs, Task Analysis, Field Studies and Usability Testing as their primary evaluation tools. Interviews, Focus Groups, Site Visits, and Expert Reviews have also been used, although less frequently. The four human factors evaluation methods recommended for use by Human Factors Specialists in procurement activities include:

1. Usability walkthrough = an informal usability inspection method that involves end-users exploring and interacting with a medical device, equipment or technology and commenting on their experiences.¹⁵
 - *Evaluation question: Do users identify usability problems during exploratory use?*
2. Heuristic evaluation = a usability inspection method that involves human factors experts assessing the design of a medical device, equipment or technology against established usability principles.¹⁶
 - *Evaluation question: Does the design of the device, equipment or technology violate any established usability principles or heuristics?*
3. Usability testing = systematic observation of a representative sample of end-users completing realistic task scenarios with a medical device, equipment or technology.¹⁷
 - *Evaluation question: What usability problems can be identified when users act out or simulate realistic task scenarios?*
4. Field study = observation and/or feedback from end-users who use a medical device, equipment or technology for a period of time in actual clinical practice.¹⁸
 - *Evaluation question: Do factors such as the actual working environment and real clinical practice affect usability?*

These methods are described in more detail in Step 4.

Table 1 gives the characteristics of four recommended evaluation methods to help support decisions about integrating human factors evaluations into procurement activities. The characteristics are based on the expertise and lessons learned by members of the Western Canada Human Factors Collaborative. When determining an appropriate human factors evaluation method(s), consideration should be given to other procurement evaluation plans being administratively led and managed by the procurement lead, and completed by the committee members.

Table 1. Characteristics of Four Recommended Evaluation Methods to Help Support Decisions about Integrating Human Factors Evaluations into Procurement Activities

Method	Time Required	Sensitivity	Objectivity	Realism	Involves End-users	Uses Task Scenarios	Control
Usability Walkthrough	1+ weeks	Low to Medium	Low	Low to Medium	Yes	Maybe	Low to Medium
Heuristic Evaluation	2+ weeks	Low to Medium	Low	Low	No	Maybe	Low to Medium
Usability Testing	4+ weeks	Medium to High	Medium to High	Medium	Yes	Yes	Medium to High
Field Study	2+ weeks	Medium	Low to Medium	High	Yes	No	Low

- Time Required = an estimate inclusive of planning, execution and generation of results and recommendations. Time estimates are based on the experiences of Western Human Factors Collaborative members and may vary.
- Sensitivity = likelihood that using the method will result in the identification of all usability problems taking into account all other characteristics
- Objectivity = extent to which opinion, subjectivity and bias is minimized through the systematic collection and analysis of empirical data and direct measures of usability
- Realism = how well the evaluation method approximates operational situations
- Involves End-users = whether a sample of representative end-users is required for the evaluation
- Uses Task Scenarios = whether the evaluation is guided by representative task scenarios
- Control = how well a method controls for unknown variables or factors that influence the evaluation results

Outcome: Determination of human factors evaluation methodology and appropriate timelines for planning purposes

Step 3: Incorporate human factors requirements and evaluation information into procurement activity documentation

This step involves determining the human factors related requirements and questions that may be asked of vendors and incorporating human factors evaluation information into the procurement activity documentation (e.g., an RFP or RFI). Human Factors Specialists should collaborate with procurement leads and committee members to ensure human factors questions and evaluation information is appropriately reflected in procurement activity documentation. The following information may be useful to include in procurement activity documentation:

- **Human factors requirements** that require written responses from vendors.
- **Evaluation description** explaining the human factors methodology that will be used and any support required from vendors.
- **Information sharing** that would allow the results of human factors evaluations to be shared with others
- **Evaluation weighting** describing how results from human factors evaluation(s) will affect procurement decisions.

Human Factors Requirements

In order to align with the overall procurement process, human factors requirements and questions can be broken into three types: (1) general information requirements, (2) essential or mandatory requirements, and (3) detailed device requirements. The inclusion of human factors requirements in procurement activity documentation (e.g., an RFP or RFI) is necessary to elicit information from vendors about how their medical device, equipment or technology complies with human factors standards and other criteria. Gathering information from vendors provides the entire procurement committee with context and helps inform any subsequent human factors evaluation(s).

General information requirements are questions that are not scored as part of the procurement activity; however, they are important to show how human factors processes were integrated into the design of the device, equipment or technology. Vendor responses to these information requirements can inform the human factors evaluation(s). The recommended minimum information requirements include:

1. Evidence that shows compliance with standards. Evidence could include vendor usability test reports and risk analyses. Standards may include:
 - ANSI/AAMI HE75:2009/(R)2013 (Human Factors Engineering – Design of Medical Devices).¹⁹
 - ISO's IEC 62366: 2007 (Medical Devices – Application of Usability Engineering To Medical Devices).³
2. Description of the extent to which techniques and principles of human factors were incorporated into this device.
3. References to published human factors evaluations if available.
4. Identification of known use errors associated with the device. The term use error refers to undesirable or unexpected events resulting from users interacting with a device.¹⁹

Additional optional information requirements questions can be found in Appendix D.

Essential or mandatory requirements include questions that require ‘yes’ or ‘no’ answers and that the vendor must comply with to move forward in the procurement selection process. Essential or mandatory requirements are usually developed jointly by Human Factors Specialists and other Subject Matter Experts (SME) and/or procurement committee members. The requirements typically relate to important design features that have been deemed critical to ensuring patient safety and/or usability. An example of an essential requirement is ‘Does the infusion pump contain Drug Error Reduction Software (DERS), including a drug library?’

Detailed requirements are questions that are defined for a particular procurement activity (e.g., an RFP or RFI) and may be scored based on criteria set out by the procurement committee. Similar to essential or mandatory requirements, detailed requirements may be defined by Human Factors Specialists and/or SMEs and/or procurement committee members. Detailed requirements do not require compliance by vendors in order to participate in the procurement selection process. An example of a detailed requirement would be ‘Does the device come in different colors to help distinguish different uses?’

The vendor’s written responses to any of these requirements can often be verified (and in some cases scored) by subsequent human factors evaluations. Verifying vendor’s responses can be an important component of due diligence by the procurement committee.

Human Factors Evaluation Description

A high-level description of the human factors evaluation should be provided to the vendor *via* the procurement activity documentation (e.g., an RFP or RFI). Including the human factors evaluation description is important because a level of commitment and participation from vendor(s) is usually required. At minimum, it is recommended that vendors be made aware that they need to provide access to their medical device, equipment or technology for a human factors evaluation. The following additional information could be included in the procurement activity documentation:

- Quantities required for evaluation, including all other supplementary equipment to operate a device. For example IV tubing, IV bags, and clamps would be necessary to operate infusion devices.
- Configuration required for evaluation. This could include uploading of drug libraries, configuration of alarms and other settings, and any other device configurations that could affect usability.
- Training to be provided to the Human Factors Specialist, clinical lead, or users as required. Note that on-site field studies should include regular in servicing and on-going support from vendors.
- Support requirements if a device requires maintenance or trouble shooting during the evaluation period.

Human Factors Specialists should work with procurement leads to determine the specific language and evaluation detail required for the procurement activity documentation.

Information Sharing

The procurement activity documentation (e.g., an RFP or RFI) may also include language that allows the results of human factors evaluations (findings and recommendations) to be shared with other health authorities. Sharing human factors evaluation information allows other human factors experts, procurement committees and Western Canadian provinces to learn from each other and use their collective knowledge and expertise, with the ultimate goal of improving patient safety. If procurement activity documentation does not include appropriate language, sharing would not be permitted.

Evaluation Weighting

Procurement activity documentation may include a description of how results and recommendations from human factors evaluation(s) will be weighed in procurement decisions. There are many different approaches, including assigning a percentage of a device’s score to human factors evaluation results, consideration of human factors recommendations by evaluation committee members, consensus decision making by committee members and hybrid approaches.

The following principles may be used when determining the weighting for human factors evaluations in procurement decisions:

- Sufficient weighting should be assigned, or processes put in place, to ensure human factors evaluations can influence procurement decisions.

- Higher weightings should be assigned for medical devices, equipment or technology that is deemed higher risk of contributing to harm (e.g., based on Appendices B or C and/or other *a priori* information such as adverse event or close call reports).
- Evaluation methods that are more robust or objective (see Table 1) may have higher weightings in procurement decisions.
- The weighting assigned to human factors evaluations should take into account other evaluations that may be carried out as part of the procurement activity. Other evaluations may include assessments by committee members, clinical trials, and evaluations by subject matter expert groups (i.e., clinical engineering, Infection Prevention and Control or IP&C).

The specific weighting approach should be based on discussions with procurement leads, committee members, and Human Factors Specialist(s).

Outcome: Procurement activity documentation (e.g., an RFP or RFI) with human factors requirements and evaluation information

Step 4: Conduct the human factors evaluation(s)

By Step 4, the procurement committee and Human Factors Specialist should have a plan developed in Step 2 for the type of human factors evaluation(s) that will be used for the procurement activity. In this section, the four recommended human factors evaluation methods will be described including timeline estimates, general approach, resources (both people and materials), how the specific evaluation can be scored and recommended weighting in procurement decisions. The four recommended human factors evaluation methods are:

1. Usability walkthrough
2. Heuristic evaluation
3. Usability testing
4. Field study

Usability Walkthrough¹⁵

Timeline: 1+ weeks (an estimate based on Western Human Factors Collaborative members' experiences)

Approach:

The usability walkthrough method provides answers to the question: Do users identify usability problems during exploratory use? In a walkthrough, users explore and informally interact with a device while commenting on their experiences. Non-users (such as biomedical engineering or clinicians from other programs) can also 'walkthrough' the device and verbalize their perspectives. Observers (typically Human Factors Specialists) can engage in probing questioning during the walkthroughs. Thus, a usability walkthrough can explore the clinical perspectives, task specifications, decision making and workflow of end-users, as well as the unique perspective of certain non-user groups. The resulting information is used to better understand workflow discrepancies, usability problems, workload, user frustrations and anticipated challenges with a medical device, equipment and technology. The results of usability walkthroughs can also guide the development and refinement of task scenarios for other human factors evaluations such as usability testing.

Resources:

- Human Factors Specialist (n = 1 – 2)
- End-user participants (n = 1 – 5 from each user group)
- [Optional] Non-user participants (e.g., nurses from other areas, biomedical engineering, educators) (n = 1 – 3)
- Full sets of configured medical devices, equipment, technology with accessories (minimum of 1)

Scoring:

Usability problems discovered using a walkthrough method can be scored in the same manner as heuristic evaluation. However, it is common to use usability walkthroughs for informational and exploratory purposes to identify safety or usability problems and confirm whether or not a medical device, equipment or technology is suitable for further human factors evaluation and/or clinical testing.

Weighting:

The specific weighting assigned to the results of any human factors evaluation must be agreed upon with the procurement leads, committee members and the Human Factors Specialist(s). Usability walkthroughs are typically given 10% to 15% when weighted in terms of an overall device score.

Heuristic Evaluation¹⁶

Timeline: 2+ weeks (an estimate based on Western Human Factors Collaborative members' experiences)

Approach:

Heuristic evaluation provides the answer to the question: Does the design of the device, equipment or technology violate any established usability principles or heuristics? Heuristic evaluation is an analytical process in which Human Factors Specialists (or trained evaluators facilitated by a Human Factors Specialist) compare the design of a device, equipment or technology against established design guidelines or device specific heuristics.

Usability heuristics can include:

- The device provides visibility of the system's status
- The device matches the real world
- The device gives the user control and freedom
- The device provides consistency
- The device is designed to minimize errors made by the user
- The device allows the user to recognize rather than to recall
- The device allows flexibility and efficiency of use
- The device helps users recognize, diagnose, and recover from errors
- The device provides help and documentation
- The device provides visual cues that provide meaning and context
- The device provides auditory feedback that is timely, accurate, and can be silenced when appropriate.
- The device has an aesthetic and minimalist design

For additional information on the heuristic evaluation method, please go to: <http://www.usability.gov/how-to-and-tools/methods/heuristic-evaluation.html>

Heuristic evaluation is useful for identifying design flaws and problems and is an excellent first step in evaluating the usability of a medical device, equipment or technology. However, the heuristic evaluation methodology may not take into account typical use in the users' actual working environment. Therefore, heuristic evaluation is often paired with usability testing and/or field studies.

Resources:

- Human Factors Specialist (n= 1 – 5) or trained evaluators with clinical or biomedical backgrounds (n= 3 – 5) and facilitated by Human Factors Specialist (n = 1 – 2)
- Full sets of configured medical devices, equipment, technology with accessories (minimum of 2)
- Heuristic evaluation template --- contact the Western Canada Human Factors Collaborative

Scoring:

A prioritization scale is typically used to assess the severity of each usability problem identified in the heuristic evaluation process. An example of a severity ranking and weighting approach is provided below.

Each usability problem is mapped to one or more heuristic violations. Then the problem is assigned a severity score and weighting (see Table 2). The weightings are similar to other risk management frameworks that provide greater weights for more significant effects and heuristic violations. The more severe violations have a higher likelihood of contributing to increased harm to the patient or user.

Table 2. Example of a Severity Score and Weighting Scale for Usability Problems.

Severity Score	Description	Severity Weighting	Severity Weighting
0	Not a Problem	Comments, features, positive elements.	0
1	Aesthetic Problem	Not satisfying to use.	1
2	Minor Usability Problem	Low Priority: Problem is a nuisance, but does not prevent accurate work. Many users will never realize or experience the problem.	10
3	Major Usability Problem	Medium Priority: Users are prevented from completing tasks related to high or medium priority user goals. May involve delays and frustration due to inadequate feedback, inefficient workarounds, or suboptimal task flow.	100
4	Severe Usability Problem	High Priority: Must fix before purchasing. Users are unsuccessful in completing tasks related to high priority user goals. Incorrect results and the potential for immediate harm to patient.	1,000

Table 3 shows the sum of the severity weightings for all the identified usability problems for three example devices. The first column shows the sum of severity weightings and the second column gives the number of evaluators. The summed severity weightings can be calculated as a percentage where the device with the lowest summed severity weighting score is awarded 100% and the other devices are scaled from the highest score. These calculated percentage values are shown in the third column. The percentage values can also be converted to the ‘points’ or ‘scale’ using the maximum number of points that the human factors evaluation was awarded in the overall procurement activity. In the example shown in Table 3, the heuristic evaluation findings were weighted as 15% of the overall score, as shown in the column ‘On a 15 Point Scale’. This method of scoring a heuristic evaluation provides the advantage of awarding the device with the lowest severity weighting score the highest number of points allowed for the human factors evaluation. However other scoring methods also exist and are acceptable.

Table 3. Example of a Final Heuristic Evaluation Scoring for 3 Devices

Device	Sum of Severity Weightings	Number of Evaluators	As a Percentage	On a 15 Point Scale
Device A	2339	7	100.00%	15.0
Device B	5404	7	43.28%	6.49
Device C	6000	7	38.98%	5.85

Weighting:

The specific weighting assigned to the results of any human factors evaluation must be agreed upon with the procurement leads, committee members and the Human Factors Specialist(s). Heuristic evaluations are typically given 10% to 15% when weighted in terms of an overall device score.

Usability Testing^{17,18,20}

Timeline: 4+ weeks (an estimate based on Western Human Factors Collaborative members' experiences)

Approach:

Usability testing provides the answer to the question: What usability problems can be identified when users act out or simulate realistic task scenarios? A usability test is an observational evaluation technique where a sample of representative end-users (nurses, technologists, physicians, pharmacists, etc.) complete realistic task scenarios with the device, equipment, or technologies in a simulated work environment. Scenarios require users to perform common device tasks, such as setting up the device, changing device settings, responding to unanticipated outcomes or, interpreting device feedback relevant to clinical practice. Human Factors Specialists observe each end-user and note any usability problems that users experience. The end-user may also 'think aloud' as they perform tasks, which may include what users are looking at, thinking, doing, and feeling. Thinking aloud gives observers insight into the user's experiences, expectations and cognitive processes.

Testing of devices by real users in realistic simulations can be invaluable and provides direct information about users' behaviours, which are often difficult for users to self-identify. Additionally, the simulation can prompt users to identify environmental factors that can affect the interaction of users with a device, such as other equipment that may be used in tandem or challenges integrating the new equipment into existing workspaces.

In usability testing, device training may be provided to end-users and could be facilitated by vendors, clinical leaders, clinical educators or human factors personnel. Standard in-service scripts could be used to ensure all users receive the same level of training, after which they perform the task scenario(s) with the device(s). Verbal protocols should be used to standardize all instructions provided to each participant.

Resources:

- Human Factors Specialist (n = 1–2)
- End-user participants (n = 5-10 from each user group)
- Full sets of configured medical devices, equipment, technology with accessories (minimum of 2)
- Training session (provided to end-user participants as needed)
- Post-test usability survey --- contact the Western Canada Human Factors Collaborative

Scoring:

Human Factors Specialists facilitate the usability testing and observe user interactions, which can yield a variety of results for scoring:

- Observed usability problems
- Error rates
- Scenario completion rates
- Post-test survey
- User preferences (including ranking of devices)

Usability problems discovered via usability testing can be scored in the same manner as heuristic evaluation. Errors are defined as any deviation from the ideal or recommended use (e.g., wrong button selections, incorrect value entries). Error rates are typically tabulated for each scenario and may be averaged or summed for a device, equipment or technology.

Scenario completion rates examine if users achieve the intended outcome as defined in each scenario. As an example a scoring approach for scenario completion rates could use 3 ratings: successful completion (2), partial completion (1) or failure (0).

Successful completion of a task (2)

- Correctly completed all steps in a task and achieved the intended outcome.

Partial completion of a task (1):

- Attempted the task more than once;
- Made multiple errors that had to be corrected;
- Took a significantly long time to complete the task (the time should be defined according to the device and task).

Failure to complete a task (0):

- Unable to complete all steps in the task to achieve the intended outcome;
- Abandoned the task or asked for help;
- Unintended outcome resulting in patient harm (adverse event) or potential harm (close call).

After completing the task scenario(s) with each device, participants can also rate the medical device, equipment or technology on specific usability criteria using a post-test survey. Responses for each usability criterion are typically averaged across participants for each medical device, equipment or technology. Preference rankings can also be provided by participants to help identify which medical device, equipment or technology users find most appropriate. Average or most common preference ranks can help determine how well usability ratings, observed usability problems, error rates and scenario completion rates align with overall participant preferences.

Weighting:

The specific weighting assigned to the results of any human factors evaluation must be agreed upon with the procurement leads, committee members and the Human Factors Specialist(s). Usability testing is typically given 20% to 25% when weighted in terms of an overall device score.

Field Study¹⁸

Timeline: 2+ weeks (an estimate based on Western Human Factors Collaborative members' experiences)

Approach:

A field study provides the answer to the question: Do factors such as the actual working environment and real clinical practice affect usability? A field study is a 'real-time' evaluation where a medical device, equipment or technology is used in a representative clinical work environment for a defined period of time (minimum of 1 week). The clinical work environment can affect use of a medical device but in a way that may not be recognized or understood by the user. For example, the presence of a room alarm with the same frequency as a device alarm could hinder a user perceiving the latter. Also, the clinical work environment can impair users' physical, perceptual and/or cognitive capabilities, which will then negatively affect their use of a device. For example, a dark, cluttered and noisy environment can not only restrict users' access to a monitor but also to users' recognition and responses to an alarm.

A field study enables users to try a medical device, equipment or technology (including related accessories) in their current clinical work environment. This evaluation has the benefit of allowing users to assess the appropriateness and ease of use of the medical device, equipment or technology in the actual use environment before selection and implementation. A field study also allows the clinical and technical teams to identify any implementation problems or product deficiencies that could affect overall usability.

Agreement from all procurement stakeholders should be reached before any medical device, equipment or technology is evaluated in a real clinical work environment. All team members should be confident that the medical device, equipment or technology is safe and effective for use. A prospective risk analysis may

be used to identify and mitigate risks. Once the team agrees to proceed with the field study, vendors must ensure the medical device, equipment or technology is programmed as it would be if it were to be implemented in a specific clinical work setting, comprehensive training is provided to all users, and 24-hour support is available if required.

Resources:

- Human Factors Specialist (n = 1)
- End-users in a specified unit or location (n = 3 – 10 from each user group)
- Full sets of medical devices, equipment or technology with accessories configured to be used in specified settings (minimum quantities will vary by clinical work environment)
- Full in-servicing for use on patients (provided to end-users)
- Means of capturing usability problems or incidents (journal, diary or logbook)
- Post-test usability survey --- contact the Western Canada Human Factors Collaborative

Scoring:

Results from a field study can be scored in a few different ways:

- Usability problems experienced by users
- Incidents experienced by users
- Post-test survey (same that is used in usability testing)

Usability problems or incidents could be captured by users via a journal, diary or other documentation tool. Users should note problems and incidents shortly after they occur. Failure to do so could mean that users forget to log the problem / incident or do not fully remember all the circumstances. Incidents could require further investigation by Human Factors Specialists to uncover the specific usability problems that contributed to the incident. Usability problems discovered through field studies can be scored in the same manner as heuristic evaluation. Participant users often also complete post-test surveys at the end of the field study period. Surveys can be scored in the same manner as surveys for usability testing.

Weighting:

The specific weighting assigned to the results of any human factors evaluation must be agreed upon with the procurement leads, committee members and the Human Factors Specialist(s). Field studies are typically given 15% to 25% when weighted in terms of an overall device score.

Outcome: Human factors evaluation results and scores for each device, equipment, or technology

Step 5: Share human factors evaluation results and provide recommendations to the procurement committee

Once the human factors evaluation(s) and analysis have been completed, a final weighted score and/or recommendation is provided to the procurement committee. A report, briefing note, one-page summary, or PowerPoint presentation can be an appropriate way to share evaluation findings. Ideally, the manner in which results and recommendations will be delivered should be defined in Step 3. However, there may be instances where the final deliverable format must be finalized after the human factors evaluation(s) has been completed.

The final deliverable should provide recommendations for which medical devices, equipment or technologies are acceptable and safe for use. The report should also include an overview of the findings, highlighting positive design features as well as usability problems or safety issues identified by the human factors evaluation(s). Of note, some of the findings may be used to inform education, workarounds, or other strategies to proactively address any usability issues identified in purchased devices. A one-page summary can be provided by the procurement lead to the vendors, if agreed ahead of time and deemed appropriate by the procurement committee. The purpose of this summary is to communicate both positive and negative features identified in the evaluations, and typically is written to be vendor specific so information is not shared between vendors.

Outcomes: Human factors evaluation results and recommendations have been shared with procurement committee members

Challenges When Integrating Human Factors Evaluations in Procurement

Members of the Western Canada Human Factors Collaborative have experienced a number of challenges when integrating human factors evaluations in to the procurement process. Table 4 lists the most common challenges that have been experienced and ways to mitigate any negative effects. Organizations that are interested in integrating human factors in to procurement activities should consider putting strategies in place to mitigate the challenges that have been identified.

Table 4. Challenges and Mitigation Strategies for Integrating Human Factors Evaluations in Procurement

Challenge	Mitigation Strategy
Longer procurement evaluation timelines	<ul style="list-style-type: none"> • Determine whether to include human factors evaluations early in the planning process and adjust timelines accordingly. • Conduct human factors evaluations concurrently with other planned procurement evaluations.
Limited human factors resources	<ul style="list-style-type: none"> • Include human factors evaluations only on procurement activities that are deemed highest priority (see Appendix B and C). • Estimate the level of effort required for human factors evaluations based on a schedule of procurement activities for the next several years and hire human factors resources accordingly. • Use external human factors resources (consultants / contractors) to fill capacity gaps.
New way of interacting with vendors	<ul style="list-style-type: none"> • Include the intent and requirements for the human factors evaluation in the procurement documentation so that vendors are aware of the need to provide sample products, etc. • Include a description of human factors and the rationale for the evaluations in the procurement documentation to manage vendor expectations and perceptions.
New way of doing business	<ul style="list-style-type: none"> • Use this guidance document to identify the steps for integrating human factors evaluations in to procurement. • Start by doing an initial pilot project to determine how best to integrate human factors evaluations in to procurement activities. • Seek guidance from members of the Western Canada Human Factors Collaborative.

Conclusions

Traditional procurement processes thoroughly evaluate the utility of a device (i.e., can the device perform the required functions) and the financial feasibility (i.e., pricing options and competitive bids). However, a third criterion to consider in procuring medical devices, equipment and technologies is usability.^{9,10} Therefore, in addition to verifying that a device can do what we need it to do (i.e., utility), we should evaluate characteristics of a device that relate to its potential to reduce use errors as well as effectiveness, efficiency, and user satisfaction (i.e., usability). Furthermore, we should try to determine areas of concern with a device that may need to be either further vetted or focused on during implementation, so as to decrease the probability of patients and personnel suffering harm, and damage to equipment and/or working environment (i.e., risk mitigation). The usability criterion should be examined using human factors evaluations that objectively assess usability and may identify potential areas of risk for medical devices, equipment or technology to inform the procurement decision-making process.

Over the past 10 years members of the Western Canada Human Factors Collaborative have allocated almost 10,000 hours of effort completing procurement related human factors evaluations. Members' experiences and lessons learned helped identify the five major steps for integrating human factors evaluations into procurement activities:

- Step 1: Identify if a human factors evaluation should be included
- Step 2: Determine which human factors evaluation method(s) is appropriate given the specific procurement context
- Step 3: Incorporate human factors requirements and evaluation information into procurement activity documentation
- Step 4: Conduct the human factors evaluation(s)
- Step 5: Share human factors evaluation results and provide recommendations to the procurement committee

The incorporation of human factors evaluations into procurement activities may be challenging but can help provide health authorities with validated methodologies and expertise to independently evaluate the usability of medical devices, equipment and technologies. The goal is to proactively identify and mitigate potential harm to patients prior to implementing any medical device, equipment or technology.

References

1. Chapanis A. Ergonomics in product development: a personal view. *Ergonomics*. 1995;38(8):1625-1635.
2. Nielsen J. Usability engineering. Boston: AP Professional; 1994
3. International Standards Organization International Electrotechnical Commission. IEC 62366: 2015. Medical devices – application of usability engineering to medical devices. Geneva, Switzerland: IEC; 2015.
4. U.S. Food and Drug Administration. Human factors implications of the new GMP rule overall requirements of the new quality system regulation [Internet]. Silver Springs (MD): U.S. Food and Drug Administration; 2015. Available from: <http://www.fda.gov/medicaldevices/deviceregulationandguidance/humanfactors/ucm119215.htm>
5. Zhang J, Patel VL, Johnson, TR, Chung, P, Turley, JP. Evaluating and predicting patient safety for medical devices with integral information technology. In: Henriksen K, Battles JB, Marks ES, Lewin DI, editors. *Advances in patient safety: from research to implementation (volume 2: concepts and methodology)*. Rockville (MD): Agency for Healthcare Research and Quality; 2005.
6. Institute for Safe Medication Practices Canada. Fluorouracil incident root cause analysis [Internet]. Toronto: Institute for Safe Medication Practices Canada; 2007. Available from: <http://www.ismp-canada.org/download/reports/FluorouracilIncidentMay2007.pdf>
7. Donawa, ME. European medical device usability requirements. *Eur Med Dev Tech*. 2011; 12-14.
8. Health Quality Council of Alberta. Rockyview General Hospital and Calgary Laboratory Services Diagnostic and Scientific Centre and Royal Alexandra Hospital: Review of the quality of anatomical pathology specimen preparation and interpretation [Internet]. Calgary (AB): Health Quality Council of Alberta; 2012. Available from: https://d10k7k7mywg42z.cloudfront.net/assets/532203e9f002ff53d9000038/HQCA_Review_Anatomical_Pathology_November_2012.pdf
9. Namshirin P, Ibey A, Lamsdale A. Applying a multidisciplinary approach to the selection, evaluation, and acquisition of smart infusion pumps. *J Med Biol Eng*. 2011;31(2):93-98.
10. Davies JM, Caird JK, Chisholm S. Trying before buying: human factors evaluations of new medical technology. In: Anca J, editor. *Multimodal safety management and human factors. Crossing the borders of medical, aviation, road and rail industries*. Ashgate: Aldershot; 2007; 316-323.
11. Carayon P. *Handbook of human factors and ergonomics in health care and patient safety*. 2nd ed. Boca Raton (FL): CRC Press; 2012.
12. Rosenorn-Lanng D. *Human factors in healthcare*. New York: Oxford University Press; 2014.
13. Lin L, Isla R, Doniz K, Harkness H, Vicente KJ, Doyle DJ. Applying human factors to the design of medical equipment: patient controlled analgesia. *J Clin Monit Comput*. 1998;14:253-263.
14. Garmer K, Lilijegren E., Osvalder AL, Dahlman S. Application of usability testing to the development of medical equipment. Usability testing of a frequently used infusion pump and a new interface for an infusion pump developed with a Human Factors approach. *Int J Ind Ergon*. 2002;29:145-159.
15. Bias RG. The pluralistic usability walkthrough: coordinated empathies. In: Nielsen J, Mack R, editors. *Usability inspection methods*. New York: John Wiley and Sons; 1994.

16. Nielsen J. Heuristic evaluation. In: Nielsen J, Mack R, editors. Usability inspection methods. New York: John Wiley and Sons; 1994.
17. Dumas JS, Redish J. A practical guide to usability testing. Portland: Intellect Books; 1999.
18. Israelski E. Testing and evaluation. In: Weinge MB, Wiklund ME, Gardner-Bonneau DJ, editors. Handbook of human factors in medical device design. Boca Raton: CRC Press; 2010.
19. Association for the Advancement of Medical Instrumentation. ANSI/AAMI HE75:2009/(R)2013. Human factors engineering – design of medical devices. Arlington (VA): Association for the Advancement of Medical Instrumentation; 2013.
20. Center for Devices and Radiological Health. Applying human factors and usability engineering to medical devices. Guidance for industry and food and drug administration staff. Rockville (MD): U.S. Food and Drug Administration; 2016.

Appendices

Appendix A – Members of the Western Canada Human Factors Collaborative

Last updated: May 19, 2017

Name	Organization	Email
Susan Biesbroek	Alberta Health Services	Susan.biesbroek@ahs.ca
Katherine Bubric	Alberta Health Services	Katherine.bubric@ahs.ca
Jan Davies	University of Calgary/W21C	jdavies@ucalgary.ca
Greg Hallihan	University of Calgary/W21C	gmallih@ucalgary.ca
Pamela Heinrichs	Pamela Heinrichs	Pamela.Heinrichs@saskatoonhealthregion.ca
Wrae Hill	Vancouver Island Health Authority	Wrae.Hill@viha.ca
Jessica Jones	Alberta Health Services	Jessica.jones3@ahs.ca
Jason Laberge	Alberta Health Services	Jason.laberge@ahs.ca
Shaunna Milloy (co-chair)	Alberta Health Services	Shaunna.milloy@ahs.ca
Allison Muniak	Vancouver Coastal Health	Allison.Muniak@vch.ca
Claire Munro	Alberta Health Services	Claire.munro@ahs.ca
Lenore Page	Alberta Health Services	Lenore.page@ahs.ca
Amanda Raven	Alberta Health Services	Amanda.raven@ahs.ca
Emily Rose (co-chair)	Vancouver Coastal Health	Emily.Rose3@vch.ca
Jonas Shultz	Health Quality Council of Alberta / University of Calgary	Jonas.shultz@hqca.ca

Appendix B – Highest Priority Devices for Human Factors Evaluation in Procurement

Provided by: Western Canada Human Factors Collaborative

The following devices are highest priority for including human factors evaluations as part of procurement.

The devices are listed alphabetically by category and emphasize devices with a user interface. The list is based on past human factors evaluation experience, known adverse events and patient safety incidents in Canada and elsewhere, and is cross-referenced with published information (i.e., FDA, ECRI, ISMP, ISMP Canada, Health Canada).

- 1) Computerized information systems:
 - i. Clinical decision support systems
 - ii. Computerized physician order entry systems (CPOE)
 - iii. Electronic health records (EHR)
 - iv. Electronic information handover devices
 - v. Medication control systems
 - o Automated medication dispensing cabinets (ADC)
 - o Computerized medication carts
- 2) Fluid delivery devices:
 - i. Fluid injectors:
 - o Contrast injectors
 - o Rapid infusers
 - ii. Infusion devices:
 - o Enteral feeding pumps
 - o Epidural infusion pumps
 - o Large volume / general purpose infusion pumps
 - o Patient-controlled analgesia (PCA) pumps (IV, Subcutaneous, Ambulatory)
 - o Syringe infusion pumps
 - iii. Other electromechanical infusion devices
 - o Fluid / blood warmers
 - o Hemodialysis / dialysis / peritoneal units
- 3) Life supporting equipment:
 - i. Anaesthetic gas machines
 - ii. Defibrillators
 - o Acute care defibrillators
 - o Automated external defibrillators (AED)
 - iii. Mechanical ventilators (most all are complex micro-processor controlled)
 - o Transport ventilators
 - iv. Monitors
 - o Patient monitoring equipment
 - o Transport monitors
- 4) Surgical devices:
 - a. Cardiovascular perfusion control system (roller/ centrifugal / ECMO / heart-lung machines)
 - b. Electrocautery devices
 - c. Robotically assisted or virtual guided surgical systems
 - d. Tourniquet systems
 - e. Warming and cooling devices

Appendix C – Human Factors in Procurement Checklist

If a device is not on the list in Appendix B, then the following questions can help determine if a medical device, equipment or technology requires a human factors evaluation as part of procurement.

‘Yes’ to any question indicates that a human factors evaluation is recommended (high, medium or low priority) for a procurement activity. If you are unsure of any answers to these questions, please contact your local Human Factors Specialist or the Western Canada Human Factors Collaborative (Appendix A).

Highest priority for human factors evaluation

Is the device used to maintain life supporting measures or monitoring of patients?	Yes	No
Does the device infuse fluids (medications, blood, nutrients) into patients?	Yes	No

Medium priority for human factors evaluation

Are patients required to interact with the device?	Yes	No
Does the user need to program information into the device?	Yes	No

Lower priority for human factors evaluation

Does the device have a visual display?	Yes	No
Does the device employ alarms to alert users to problem situations?	Yes	No

Appendix D – Additional Optional Human Factors Questions

1. Is this device new to the market?

- a. If yes, has the device undergone formal human factors testing in any other jurisdiction or country?
- b. With which human factors standards does the device comply?
- c. When were evaluations conducted and how (methodology)?
- d. What were the results?

2. Is this device marketed as an upgrade, a modification or a new model of a previous device?

- a. If yes, what was the previous Model Name or Number?
- b. If yes, what were the changes?
- c. If yes, did the device undergo formal human factors testing in any other jurisdiction AFTER it was upgraded or modified? Provide:
 - i. With which human factors standards does the device comply?
 - ii. When were evaluations conducted and how (methodology)?
 - iii. What were the results?

3. Are there reports of problems (from Close Calls to harm to patients/users) with this device?

If yes:

- a. Where reported: Peer-reviewed journal, Health Canada alert, FDA, MAUDE database etc
- b. Where and when did the problems occur: Location (Jurisdiction/Country)
- c. What was the problem: Close Call, harm to patient, harm to user
- d. What were the results of any investigation and remedial actions