



Human Factors for Health Technology Safety:

Evaluating & Improving
the use of
Health Technology
in the
Real World

Andrea Cassano-Piché, Patricia Trbovich,
Melissa Griffin, Ying Ling Lin and Tony Easty

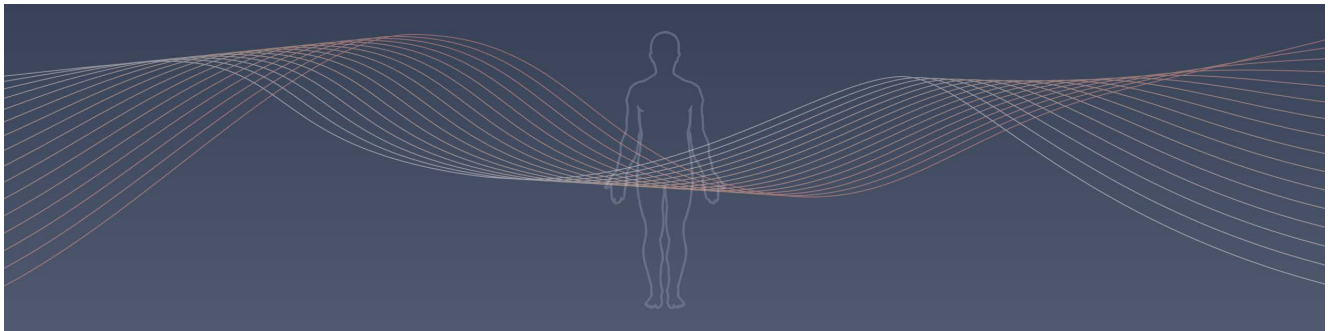
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Clinical Engineering Division

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Foreword

One characteristic of the healthcare field is its constant and extremely fast technological development. While in the past its progress relied on expertise coming mostly from medicine, today it receives contributions from many different areas of research such as electronics, chemistry, biology, physics, mathematics, mechanical engineering, materials engineering, and informatics.

Such fast development has produced an immense variety of well-accepted equipment and medical procedures for diagnosis and therapy. However, it also requires the development, transference and adaptation of safety programs, formerly developed in other industries, to be implemented in medical procedures as well as equipment operation, equipment design and production, hospital interoperability, medical records, cloud storage, and so on.

Clinical engineers, used to dealing mostly with medical equipment management techniques, found themselves overwhelmed by safety demands associated with the use of such technologies. Worse, few academics worldwide are familiar with safety programs applied to the healthcare area.

As one of the participants in the implementation of the academic curriculum for Clinical Engineering training courses, and the coordinator of one such training course for more than 20 years in Brazil, I am excited by the release of this book, explaining the practical use of safety tools by clinical engineers and technologists.

As a researcher and supervisor of a post-graduate Biomedical Engineering program at the University of Campinas for more than 30 years, I had several opportunities to discuss with my students and coordinators of Clinical Engineering training courses, subjects regarding risk management for the healthcare area. These discussions were about the urgent need to include safety tools and programs dedicated to healthcare environments within our Clinical Engineering academic program. Despite our belief of the urgency of this work, it was extremely difficult to find instructors familiar with this subject. The ones we found, despite great knowledge on very efficient safety tools, had no idea how to translate them to the healthcare area for practical use. It is important to mention that my participation as chairman of the Clinical Engineering Division of the International Federation for Medical and Biological Engineering – CED/IFMBE, showed me that this is not just a local problem but a worldwide lack of knowledge.

In 2011, I had the privilege to work with the HumanEra group, from the University Health Network in Toronto, Canada, that specializes in the use of human factors tools to develop their activities. I witnessed the important work they were leading for the Ministry

of Health and Long-Term Care of Ontario, regarding preventive studies and investigations on adverse events within the healthcare area. The results and conclusions they obtained produced very reliable recommendations to mitigate risks associated with the use of healthcare technologies.

I also became aware that some of the human factors engineering (HFE) tools could be used to develop safety programs with relative facility. From then on, I persistently asked HumanEra to write a book describing how these tools can be practically used by clinical engineers to develop and implement safety programs for the healthcare environment.

Fortunately in 2014, they found time to dedicate to the development of this book. With years of experience on the practical use of HFE tools, the HumanEra team knew exactly what kind of previous knowledge clinical engineers must have before learning about the use of such tools. Hence, the initial chapters of this book explain what it is necessary to learn before the presentation of the HFE tools.

The book also gives an explanation of other tools such as Failure Mode and Effect Analysis (FMEA) and Root Cause Analysis (RCA), that have also been adapted and used in the healthcare environment. It shows you how these tools can be applied in conjunction with other HFE tools, to uncover the underlying issues that compromise safety in healthcare.

I believe the best characteristic in this book is the way the HFE tools are presented. It explains not only “What” to do but also “How” to develop the activities needed to implement a safety program in the healthcare environment. Detailed examples are given on how to develop all documents as part of the investigative process, and what must be learned from people involved either in adverse events or simulations. It also provides, in straightforward language, all the necessary steps to develop the simulation tool, as well as when and how to conduct a task analysis. Together with the heuristic analysis, these three tools provide extensive possibilities for not only the investigation of adverse events but also their mitigation.

In summary, this book not only gives you a theoretical view of “What” to do when implementing the HFE tools but also “How” to implement them through detailed examples using case studies. After reading it, clinical engineers must move ahead to develop a safety program in the healthcare area they are working in.

The contents of this book can also be easily used and translated to lectures by Clinical Engineering scholars with the mission to design and implement a healthcare safety discipline within Clinical Engineering training courses.

Finally, regarding the implementation of safety programs within the healthcare environment, clinical engineers have now an extremely useful source of information that will be freely available on the Web, provided by the HumanEra Team and sponsored by the Clinical Engineering Division of the International Federation of Medical and Biological Engineering – CED/IFMBE.

Professor Saide Calil, UNICAMP, Campinas Brazil. May 2015

Preface

Thank you for taking a step toward exploring the positive role that human factors can play in helping to improve health technology safety by reading this book. Throughout the world the use of medical technology is on the rise, with many beneficial outcomes for patients. However, health technology does not always behave as intended, and can be awkward and confusing to use. Far too often, this leads to adverse events. The good news is that there are methods that can be applied to help to identify and overcome these problems, and that is the aim of this book.

Often, the people who are best-placed to engage in this approach are those who service and support technology in healthcare. In some settings, this will be a large team of people, including engineers and technologists. In others, this may be a lone technician doing what he or she can to provide support. This book refers to the “biomedical technology professional”. We chose this title carefully, wanting it to be as inclusive as possible, and relevant to many different settings in high-, medium-, and low-income healthcare environments.

No matter where you work, I encourage you to read this book and start applying some of the methods described here. At first, they may seem a little hard to follow, but there is nothing magic about them, and they can lead to surprising results. Once you get started and see for yourself how helpful these methods can be, I am sure you will be hooked, just as I was when I first started to use them. These methods change the way you view technology and its role in our world, and they can make a great difference to the safety of the healthcare system that you work in, too.

Many of the examples are based on our experiences in Canada but to some extent they reflect specific issues in our system, and so as you read the book, please substitute examples that you have experienced directly, in your own work environment. I am sure that you will quickly identify technologies that could benefit from the approaches described here, and I encourage you to make a start on applying them.

I would like to thank the co-authors of this book, who have worked hard to try to ensure that the methods described are as accessible as possible. I would also like to thank the reviewers, whose comments have helped in numerous ways to improve and clarify the messages that we sought to share. Any errors and omissions remain the sole responsibility of the authors. I owe a special thank you to Professor Kim Vicente of the University of Toronto, who first opened my eyes to the power and relevance of these methods, and helped me learn to apply them. A truly life-changing experience! Finally, I would like to thank the Clinical Engineering Division of the International Federation for Medical & Biological Engineering and its Chair, Professor Saide Calil, for commissioning us to write

this book. Without this invaluable support, we would not have been able to complete this work.

Tony Easty, Toronto, Canada. May 2015.

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We are extremely grateful to Professor Saide Calil for his vision and encouragement. Calil was the catalyst for this book and succeeded in securing funding for from the Clinical Engineering Division of the International Federation of Medical and Biomaterials Engineering, to whom we offer our sincere thanks.

While only some of the members of HumanEra formally authored this text, this book is truly the work of the entire team. Each team member, with their unique training, experiences and passion, has helped to evolve each of the methods presented in this book. Under the leadership of Tony Easty and Patricia Trbovich, HumanEra members include: Andrea Cassano-Piché, Christopher Colvin, Mark Fan, Rachel Gilbert (nee White), Melissa Griffin, Caterina Masino, and Sonia Pinkney. HumanEra has also had the privilege of working with many dedicated and talented students over the years, one of whom co-authored this book (YLL). Thank you to all of our students for their valuable contributions to our projects.

HumanEra has had the pleasure of collaborating with energetic and dedicated individuals and organizations in the realm of healthcare safety. Many of these people have contributed generously to the review of one or more sections of this text. These people are: Sandra Ahedo González-Zabaleta, Fernando Andrade, Guilherme Araujo Wood, Victor Batista Tsukahara, Ann Blandford, Saide Calil, Peter Doyle, Karina Gomide, Julie Greenall, Laura Herrero Urigüen, Sylvia Hyland, Leonardo Novaes Nascimento, Ryan Pinto Ferreira, Kim J. Vicente, and Carlos Alessandro Bassi Viviani.

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Finally, we wish to thank our families for their unconditional support of our work, our team and our vision for global healthcare safety. Thank you Chris Piché for being my champion and helping me to see the possibilities and Gus and Gabriella Cassano for being my example of doing whatever it takes to be the change (ACP). Thank you Gordon Lavergne for always injecting “joie de vivre” into our lives and for supporting me to pursue my passions (PT). MG thanks Mike Kozak for his encouragement and support, and for making me laugh. YL thanks Yen Chi Liu, Jiunn Long Lin and Steven Roy who consistently supported me without question and the HumanEra team for providing unique and outstanding mentorship. Many thanks to all the organizations who have supported our

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DISCLAIMER

Information included in this publication is intended to be used for informational purposes only. This publication is not to be used as a substitute for legal advice. It is not an official interpretation of the law

Introduction

When Technology Works... But Systems Fail

Adverse events can and do happen in every healthcare organization because individual healthcare workers are relied upon to bridge safety gaps, while working under extreme pressures in complex systems. This is especially noticeable when it comes to the use of health technology. Medical technology has become inherently complex, and the integration of health technology into broader information systems often leaves safety gaps that are filled by the vigilance of healthcare workers. Despite the heroic efforts of healthcare providers, it is inevitable that, as humans, they will make mistakes. Constant awareness and vigilance are not humanly possible. In these moments, whether or not mistakes translate into patient harm is dependent on the design of the system and its ability to detect and mitigate risks as they arise. This requires an understanding of human factors science. The following story, based on true events, illustrates how human factors plays a central role in health technology safety:

A very experienced nurse was working in the general ward of an urban hospital that had recently purchased and implemented new intravenous (IV) infusion pumps. The nurse was caring for an older patient who was receiving IV fluids through the new infusion pump at a rate of 40 mL/h. For patient comfort, the doctor had ordered morphine (1mg/mL) to be given intravenously at a rate of 2 mL/h. The nurse prepared the patient's medication and hung the 100 mL bag of morphine as a secondary infusion¹ ([Figure 1](#)). She programmed the pump to deliver the infusion at 2 mL/h, and although the volume of the bag was 100 mL, she intentionally entered the volume to be infused (VTBI) at just 10 mL because she wanted the pump to stop and alarm five hours later to remind her to check on the patient before the end of her shift. The nurse continued to care for this patient along with five others, and when her shift ended about five and a half hours later, she went home without remembering to check on the patient's morphine infusion.

¹ Secondary infusions are a common mode for delivering intermittent doses of medication in North America where volumetric infusion pumps are much more prevalent than syringe pumps.

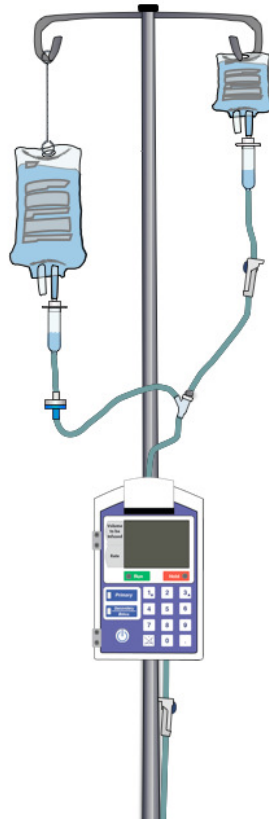


Figure 1. Secondary infusion setup to deliver morphine to the patient

A few hours after shift change, the patient's night shift nurse discovered the patient had died. The exact time of death was unknown and the patient's family had not been present, as was requested during advance care planning. A later investigation found the patient had received a morphine overdose. The nurse who programmed the infusion was devastated by the incident.

What went wrong in this case? A closer look reveals that the nurse, who programmed the infusion so she could safely monitor the patient's response to morphine, misunderstood how the secondary infusion mode on the pump worked.

Although the nurse had received training on the new infusion pump, it was only a short training session, and she did not get a chance to practice using the secondary infusion mode. Additionally, prior to the implementing these pumps, secondary infusions were administered using an entirely different type of infusion device, so the process of setting up and programming a secondary infusion on this type of pump was unfamiliar to the nurse. A *secondary infusion*, or piggyback, is an infusion setup where two infusions are run through a single pump by connecting the tubing of the secondary infusion to the port on the primary tubing set above the pump (see [Figure 1](#)). Due to hydrostatic pressure, the pump will deliver whichever fluid is highest in the infusion setup. Consequently, most infusion

pumps do not have the ability to identify whether fluid is being drawn from the primary or secondary bag; they simply draw fluid from above, and based on the fluid mechanics of the setup, fluid will flow from whichever bag has the higher hydrostatic pressure.

In this case the nurse expected that once the 10 mL volume of morphine had been delivered to the patient, the pump would stop running and then alarm, to alert the nurse to return to the bedside before resuming at the primary infusion rate; however the secondary infusion mode on this pump (and many other infusion pumps) is designed to sound an alert and automatically revert back to the primary rate once the secondary VTBI has been infused. Consequently, when the pump switched from the secondary rate of 2 mL/h to the primary rate of 40 mL/h, there were still 90 mL of morphine left in the bag, and since the morphine was hung higher than the other infusion, and had a greater hydrostatic pressure, the remaining 90 mL of morphine were delivered at a rate of 40 mL/h, causing the overdose.

Too often in healthcare today, the nurse would be blamed for incorrectly programming the secondary infusion. After an incident like this, the biomedical technology department would be brought in to determine whether the pump had malfunctioned. If no technical failure was found on the part of the pump, any further follow-up would be left to the clinical manager. The clinical manager would likely determine the cause of the incident to be human error, would reprimand the nurse, and then require the nurse to undergo additional training on the pump. In some cases, nurses have been punished by being terminated from their employment or worse, having their professional license revoked.

Although this approach to incident management may be well intentioned, it is unlikely to prevent similar future incidents from occurring. Having the nurse that was involved in the incident undergo additional training is a *person-focused* solution, and does not address any of the broader *system-level* factors that contributed to the incident. For example, in this case the organization had recently acquired new infusion pumps to replace their original pumps, which did not have a secondary infusion mode. Since staff were already familiar with using infusion pumps for single infusions, and there were few training resources available, staff received very little hands-on training. Another system-level contributing factor in this case was the inconsistent way in which VTBI information was handled by the pump. When running a single, primary infusion, the pump would stop running and alarm once the pump had delivered the programmed VTBI, but in contrast, when running a secondary infusion, the pump would sound an alert and then automatically switch to the primary rate and continue to pump whichever fluid had the higher hydrostatic pressure.

Because the nurse had to deliver a secondary infusion using the new pump but didn't have very much experience or training, she formed an understanding of how the

pump would handle VTBI information entered for a secondary infusion based on her experience both with the previous pump, and with the single, primary infusion mode. Unfortunately in this case however, her assumptions were incorrect.

To improve safety, a *human factors* approach to managing health technology is more impactful. Human factors is the science dedicated to designing systems that support safe and effective work based on an understanding of human strengths, limitations, biases and behaviours. Designing healthcare systems that support healthcare professionals in safely and effectively caring for patients is a means by which the safety of patients and staff may be improved. Taking a human factors approach means ensuring health technologies meet the needs of users, fit with the environment of use, minimize the opportunity for error, and promote feedback to enable continuous quality and safety improvements.

How to Use this Book

HumanEra was commissioned to write this book by the [International Federation for Medical and Biological Engineering's \(IFMBE\)](#) Clinical Engineering Division (CED) to support biomedical technology professionals in using human factors methods to improve the safety of health technology within a range of organizations. For the purposes of this book, a *biomedical technology professional* refers to any person, regardless of their title (e.g., clinical engineer, biomedical engineer, biomedical equipment technician, medical technology manager, materials manager, health technology manager, administrator, clinician), responsible for managing technology in a healthcare setting. While they are not explicitly referenced throughout the book, the intent is to support patient safety leaders of all roles and titles in their efforts to improve health technology safety, as well as students learning to master human factors methods for applications in healthcare.

Ideally, human factors professionals would work alongside biomedical technology professionals in every healthcare organization, but the reality is that human factors professionals are not an established resource in most hospitals. As a result, biomedical technology professionals have the opportunity to play an exciting and important role in leading the integration of human factors approaches into health technology management to improve the safe and effective use of health technology.

This book will provide practical, hands-on guidance for incorporating human factors methods into the daily activities and responsibilities of biomedical technology professionals. This book will also provide guidance to those looking to hire a human factors professional in terms of what services to request, and expected outcomes and outputs of various human factors analyses. It is important to note that this book is neither intended to be a comprehensive review of the literature, nor an academic discussion of human factors in healthcare. It is however, along with the additional resources listed in each *Resources* section, intended to cover the information needed to start using human factors methods in your organization. When human factors methods are used correctly, the safety of patients and staff related to the use of health technologies can be improved.

This book is separated into three main parts:

Part I: The Need For Human Factors in Health Technology Management provides some background about the disciplines of biomedical technology management and human factors, and discusses the need for these disciplines to come together to improve the safety of health technology.

Part II: Handbook of Human Factors Methods provides a detailed description of how to conduct selected human factors methods useful for identifying and mitigating health technology safety issues. These step-by-step descriptions are based on current best

practices, but if your organization does not have the resources required to carry out the methods exactly as described, it is recommended the method be adapted to suit the resources available, as opposed to not applying the method at all.

Part III: Applying Human Factors to Health Technology Management uses case studies to illustrate how human factors methods can be incorporated into the typical responsibilities of biomedical technology professionals.

In an effort to make the human factors methods presented more accessible and realistic for the global community, requirements for specialized or costly equipment have been reduced, and abridged approaches to the methods have been provided where possible.

Part I. The Need for Human Factors in Health Technology Management

“Fallibility is part of the human condition. Although we cannot change the human condition, we can change the conditions under which humans work.”

-James Reason, PhD

All people, no matter how careful, have the potential to make mistakes. Healthcare professionals enter the field out of a desire to help others, but because all humans have certain known strengths and limitations, people can often find themselves in situations where the systems in which they work lead them to make mistakes.

In 1999, the Institute of Medicine’s publication *To Err is Human* [1] revealed that approximately 44,000 to 98,000 preventable deaths take place each year in the United States, making it the 8th leading cause of death. A similar study in Canada showed even worse outcomes on a per capita basis, with between 9,000 and 24,000 preventable deaths occurring each year [2]. Other studies in the United Kingdom [3], New Zealand [4], and Australia [5] found that 8.7%, 12.9% and 16.6% of hospital admissions, respectively, were associated with an adverse event. In 2013, fourteen years after *To Err is Human* was published, an updated review of the literature provided higher estimates still, with between 210,000 and 400,000 preventable adverse events occurring in the United States annually[6]. Errors leading to adverse events and preventable patient deaths remain a serious, global issue.

An *adverse event* can be defined as an occurrence that results in unintended harm to a patient either by an *act of commission* or *omission* rather than by the underlying disease or condition of the patient [1]. Adverse events, or incidents, occur across the continuum of healthcare including in the operating room, emergency department, intensive care unit, general medical ward, laboratory, pharmacy, community clinic, and home care environment.

Many adverse events in healthcare organizations involve technologies. When a technology does not perform according to its technical specifications (e.g., there is an electrical, mechanical, or software failure) it can lead to an adverse event. Additionally, when a technology is not well-integrated with its environment of use, it can lead to an adverse event. For example a technology’s alarm function may work to specification, but when that technology is placed on the unit that alarm may no longer be audible over the regular background noise. These types of adverse events are also known as *use errors*.

Traditionally, adverse events involving technical device failures have been the primary concern of biomedical technology professionals, while incidents involving the context of use have not tended to be as much of a focus, with most healthcare organizations identifying these incidents as “user issues”, and then leaving the task of identifying solutions to clinical managers.

In response to the number of adverse events attributed to use error and evidence supporting the efficacy of applying human factors principles to the design of medical technologies, the United States Food and Drug Administration (FDA) has developed draft guidance [7] for the addition of human factors assessments to technology evaluations conducted as part of the FDA’s pre-market 510(k) approval process. While these guidance documents focus on human factors assessments as part of the design of healthcare technologies in the US, there are many ways biomedical technology professionals around the world can apply human factors methods and principles to technologies even after they have been implemented at a healthcare organization. By elevating the importance of having biomedical technology professionals identify use errors, and considering the relationship between users, technologies, and the use environment, preventable deaths can be avoided by ensuring a better fit between system components.

Chapters 1 and 2, will describe the traditional boundaries of biomedical technology professionals, introduce human factors, both from a general and a healthcare perspective, and describe how human factors can be applied to health technology management to reduce use errors and improve patient safety. Chapter 3 will provide an overview of some of the general principles associated with human factors science.

Chapter 1. Traditional Health Technology Management

A range of biomedical technology professionals undertake the management of healthcare technology. These professionals may include clinical engineers, biomedical engineers, biomedical equipment technicians, clinical equipment specialists, biomedical equipment specialists, laboratory technicians, and imaging technicians. Staff in these roles manage technologies in a range of healthcare settings, and are often responsible for planning, selecting, installing, calibrating, testing, maintaining, and repairing these devices. Professionals who manage healthcare technologies also play another important role as translator between clinical, administrative, and technical staff within a healthcare organization, often providing training and real-time technical assistance as required.

Typical tasks of a biomedical technology professional include:

- Participating in the planning and assessment process for new healthcare technologies.
- Assuring regulatory compliance of healthcare technologies through preventive and corrective maintenance
- Investigating adverse events involving the use of healthcare technologies.
- Participating actively in training and education of technical and medical personnel.
- Creating systems to manage the inventory of healthcare technologies.

The need for biomedical technology professionals has emerged in response to a requirement for better coordination between modern medicine and modern engineering. As healthcare technologies continue to become more complex, healthcare organizations need access to professionals who are able to advise and support clinicians and administrators about issues related to the assessment, implementation, maintenance, support, and management of these technologies.

Generally, biomedical technology professionals, who may come from a range of educational backgrounds, are trained to assess, manage and solve problems related to healthcare technology systems using knowledge based in mechanical, electrical, and software engineering, as well as medicine, and business [8]. Although some of the more formal engineering and technician training programs may provide a high-level introduction to human factors, there is little information available related to integrating human factors methods into traditional healthcare technology management tasks.

Given the unique role that biomedical technology professionals already play in many healthcare organizations, and the demonstrated value that applying human factors to healthcare systems can add, there is an opportunity for biomedical technology professionals to take on an expanded role. These professionals already help to bridge the

gap between technologies and users and to promote the safe and effective use of technology, both of which are complementary to the philosophy of human factors.

This is not to say that healthcare organizations should not employ human factors professionals, but that in the absence of these experts, a biomedical technology professional has many opportunities to apply human factors methods to improve the safety and effectiveness of healthcare technologies.

Chapter 2. Human Factors: Evolving from Cockpits to Operating Rooms

Section 2.1. Introduction

Human factors is a discipline dedicated to applying what we know about people's strengths and limitations to the technologies, processes, and environments we live and work within to try to make these systems safer, more intuitive, and robust. Within the science of human factors, many experts focus on designing technologies to suit the cognitive and physical attributes of people so that, rather than requiring people to adapt to the technology design, the technology is instead tailored to support people's capabilities. [9] By putting failsafe mechanisms in place to catch and correct inevitable mistakes before they result in harm, people can be supported in completing their tasks safely and successfully.

This may sound like common sense, but surprisingly, it is not how we tend to approach technology design in healthcare environments, or in our everyday lives [10]. We all make mistakes; we pull a door handle that needs to be pushed, we forget a password for an important account, or we phone one family member when we meant to phone another. When we do make mistakes, our response is usually to dismiss the error, attributing it to not paying enough attention, or not being careful enough. However, consider for a moment the aspects of the design of the device that influenced your behavior. The door handle looked as though it should have been pulled, the sheer number of passwords we have makes it difficult to remember them all, and your family members' names were right next to each other on your touchscreen phone.

When we begin to look at the world with a human factors lens we can go beyond the typical reaction of blaming ourselves for failing to be careful, or for not paying enough attention, and instead, begin to recognize opportunities where improvements to design can decrease errors. For example, when we can change the design of the door handle so we intuitively know it needs to be pushed, we don't have to worry about whether we are paying attention or being careful that day because the design of the door handle will naturally encourage us to interact with it correctly.

Section 2.2. History

The discipline of human factors emerged around World War II. At the time, aircraft technology had advanced significantly, resulting in more complex flight control systems. Although pilots were highly-trained, they did not easily adapt to these new control systems, resulting in crashes and the loss of many experienced pilots. [11] Psychologists at the time realized the design of cockpit control systems was confusing to even the most experienced of pilots, and so when cockpit controls were redesigned in an attempt to avoid this confusion, nearly all crashes were eliminated as a result.

Since then, the science of human factors has been applied to many other safety critical industries such as aerospace, [12] and nuclear power, [13, 14] where operational failures can result in loss of life. Healthcare, which is also considered to be a safety critical industry, has been comparatively slower to adopt the science of human factors [15]. However, steady progress has been made since about 1978, when early practitioners applied it to manage safety issues in anaesthesia [16].

Section 2.3. Why Apply Human Factors to Healthcare?

The importance of applying human factors to improve system safety in healthcare has reached a tipping point. There are a number of reasons for this, including several pivotal publications [1, 17, 18] that highlight the degree to which healthcare falls short as a safe system. From a healthcare technology standpoint, some of the factors contributing to this shortfall include an increase in: (1) the number of healthcare technologies present in patient care areas, (2) the complexity of healthcare technologies, and (3) the pace of technological change.

(1) Number of healthcare technologies present in patient care areas

An increase in the number of health technologies present in patient care areas adds to the mental burden put on healthcare providers, who are responsible for operating and monitoring these devices. The impact of this increased mental workload, or cognitive burden, on human performance has been widely studied, and the research indicates that when mental workload is high, human errors are more likely to occur.[19] In healthcare, when mental workload exceeds people's capabilities, devices may be set up incorrectly, used inappropriately, or trouble indicators may be ignored, and studies have confirmed this has a negative impact on patient safety. [20],[21]

(2) Complexity of healthcare technology

With a move towards increasingly complex healthcare technologies, the way in which humans interact with devices is changing. In the past, technology was designed so the technical functions of the device were controlled by the user, but more often now, user interfaces are designed to display only the settings and values that are intended to be controlled or observed by the user. As a result, the corresponding training users receive focuses on how to control the settings and values rather than understanding the technical principles that govern how the device is operating.

Over time, this will have the effect of preventing users from developing a mental model of how a device is functioning. This is of concern because when an unanticipated crisis situation arises, users are unable to adapt their interaction with the technology to handle complicated situations appropriately. In fact, without an understanding of the

technical principles behind the operation of a medical device, a users' response, although well intentioned, may do more harm than good.

(3) Pace of technological change

The fast pace of technological change has improved our capacity to provide more effective care to sicker patients, but has challenged us to continuously adapt our healthcare organizations to support these technologies appropriately. Technological changes greatly affect front line staff, who are forced to learn to use new devices, adapt their work practices, and maintain routine care operations, often without proper training, or the support of defined work practices or policies that reflect the changes needed to account for the new technology. These conditions have been connected to nurses' work stress and burnout [22], which are critical issues in healthcare.

Section 2.4. Observable Clues Pointing to Underlying Human Factors Issues

Applying human factors methods and principles can help in identifying where and when issues associated with a mismatch between users, technologies and environments are likely to occur. As a biomedical technology professional, there are a number of observable clues that can provide insight to underlying human factors issues associated with the use of a particular technology. Some of these clues include when:

No one wants to use the device or system

When users refuse to use, or go out of their way to avoid using, a particular technology, it suggests the technology may not: (1) be intuitive to use, (2) perform the required function, (3) fit well with users' workflow, or (4) have been introduced to users in a way that affords adequate familiarity and training.

The device turns up for service but no problem can be found

When no problem can be found after service has been requested, it can suggest a poorly designed technology, [23] or inadequate training, especially if the healthcare organization only recently implemented the technology.

The incorrect accessories are being used, or accessories are not properly installed

When the wrong accessories are being used, or accessories have not been properly installed, it is often a sign of a poor design without a clear physical match between the device and connecting components.

Displays are not easy to read

If during an inspection the displays on a device are difficult to read, it is likely those displays will also be difficult to read under clinical conditions, where darker lighting conditions sometimes exist and users are further away from devices.

Alarm/alert features have been adjusted to erroneous values

During an inspection, if the alarm or alert settings have been changed to values that do not make sense for the intent of the alarm, it is a clue that the alarm or alert settings are not appropriate for the clinical environment. In the case of alarms, this may point to a design issue, or it may be more of an issue with how the alarm settings have been configured, and whether staff understand how to configure the alarms.

Section 2.5. How Biomedical Technology Professionals Can Help Improve Patient Safety

If any of these observable clues are identified, biomedical technology professionals have an opportunity to apply human factors to improve effective use of the technology and reduce the risk of use errors. While applying human factors certainly expands the existing job responsibilities of a biomedical technology professional, with practice it can become a routine part of health technology management work, having tremendous benefit to both staff and patients in healthcare organizations.

The following case study illustrates how a biomedical technology professional could use human factors in their everyday work.

Case Study 1: Getting to the Bottom of a No Fault Found Issue

A defibrillator arrives in your biomedical engineering department for repair with a note taped on that says “broken”. Upon inspection, no fault can be found. The defibrillator is returned to the unit, only to arrive back a few days later with another “broken” note taped on. You inspect it again and the result is still ‘no fault found’. You wonder why front line staff think this device is broken when there is nothing technically wrong with it. Upon reflection, you suspect there must be some kind of an issue with how the device is being used, but you’re not exactly sure what the problem is. You decide you want to learn more about what might be going wrong, so you contact the cardiac arrest team to ask if you can observe the code situation from a safe distance the next time they go to assist a patient. That way you can watch the defibrillator in use to see whether staff run into any challenges.

You hear a code blue call a little while later and meet the cardiac arrest team in the catheterization lab. As you observe, you see the responder activate the defibrillator, but for some reason, it doesn’t discharge. The responder throws the defibrillator aside and finds a second defibrillator unit. When the responder activates this defibrillator, it does discharge as intended and she is able to restore the patient’s normal heart rhythm.

Once the cardiac arrest response is finished, the malfunctioning defibrillator is returned to its charger base on the crash cart. You inspect the malfunctioning defibrillator and notice the battery status light is not lit, meaning the battery is not charging. As you take a closer look, you notice the defibrillator is not fully engaged with the charger. You try pressing down on the defibrillator, and find you have to press down quite hard before you finally hear a click, and as you do, you see the battery status light illuminate. Problem identified – the defibrillator batteries were not charging because the chassis was not fully engaged with the charger.

Now that you've identified the problem, what should you do about it? You could simply tell staff that when they place the defibrillator back on the charger they have to remember to push down hard until they hear a click but, given our limitations on memory and attention, the chances of staff consistently remembering to do this are low. Cardiac arrest situations are known to be associated with a high cognitive workload, meaning staff are typically operating at the limits of memory and attention, and are under a great deal of stress. An optimal solution is to purchase defibrillators that easily attach to the charger. This however, is usually not an option until the end of the technology lifecycle when the healthcare organization purchases new devices. In the interim, a strategy to minimize the likelihood and increase the detectability that the defibrillator is not properly attached to the charger is to develop a re-stocking checklist for whoever is responsible for re-stocking and organizing the crash cart after the code blue and to include an inspection of the battery charging status of the defibrillator on the checklist. The checklist should be attached to the crash cart for easy reference.

As a biomedical technology professional, if you had not gone out into the field to observe the defibrillator in use, it likely would have been returned to your department many more times with the same “broken” sign on it. Observing how people interact with technology can be an extremely valuable and fruitful exercise.

Even more valuable is the application of similar human factors methods during procurement to help you identify these types of challenges before a device been selected. When issues like this are identified during procurement, either a different device can be selected to avoid the issue altogether, or solutions can be identified and implemented in advance of implementation of the device.

Case Study 1. Human factors in the everyday work of a biomedical technology professional

Chapter 3. Human Factors Thinking

Having an appreciation for the importance of human factors, and a basic understanding of the strengths and limitations that we as humans share, can go a long way in helping to shape how we think about the relationship between humans and technologies. Technologies should be designed and chosen to complement our natural abilities, supporting us in the things that are inherently more difficult for us to do. Just as the electrical and mechanical properties of technologies are constrained by the laws of physics, human performance is also constrained by known principles of cognitive and physical performance. When these constraints are ignored, systems failures can occur.

This chapter will provide a backdrop of human factors perspectives and frameworks to support the methods and applications described in the remainder of the book.

Section 3.1. The Mechanistic-Humanistic Divide

In his book *The Human Factor* [9], Kim Vicente describes that as a society, we have tended to learn about our world using a reductionist approach, whereby a “divide and conquer” mentality allows people to have a deep understanding about a particular topic. This is generally useful because we are able to learn a lot about a specific phenomenon, however, it can become problematic because many disparate silos of information are created in the process. As a result of this siloed approach, there has historically been a division between the human sciences (e.g., cognitive psychology), and the technical sciences (e.g., computer programming and engineering), with those coming from the human sciences (i.e., Humanists) having a good understanding of how people think, and those coming from the technical sciences (i.e., Mechanists), having a good understanding of how to make technology work.

Human factors serves to bridge the gap between the Humanists and the Mechanists by bringing together an understanding of natural human behaviour - how people think, our physical and cognitive strengths and limitations - *and* how to make technology work, so that technologies can better support how people tend to think and act. In the real world, people do not exist without technology, and technology does not exist without people, so it is important to consider what happens at the interface of these two entities.

This *systems view* is a foundational principle of human factors science, and is at the heart of every human factors method that will be explored in this book.

Section 3.2. The Human-tech Ladder

Applying human factors requires an understanding of the needs of all people in the system and the interaction between them. Vicente’s Human-tech ladder[9] ([Figure 2](#)) is helpful for visualizing the relationship that people across a system have with technologies

from a number of perspectives. The following descriptions of each rung of the Human-tech ladder have been adapted from the [Canadian Patient Safety Institute's Patient Safety Education Program \(PSEP\)](#).

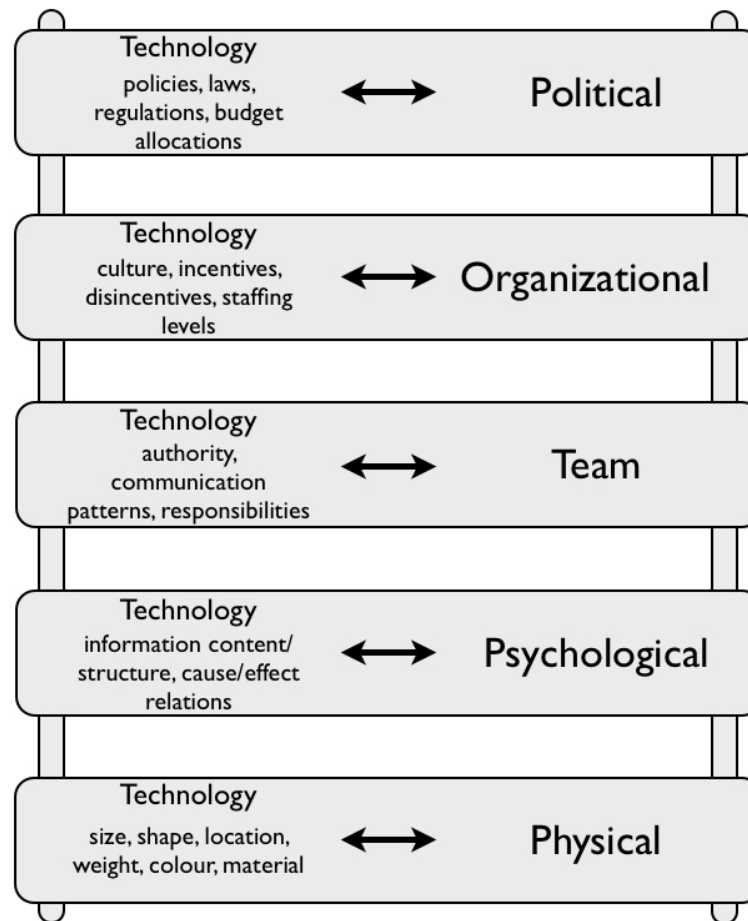


Figure 2. Vicente's Human-tech ladder [CPSI PSEP]

The *Physical* rung of the Human-tech ladder allows us to think about how humans interact with technologies on a physical level. When something is too heavy to be lifted or too far away to be easily reached, there is a clear mismatch between how the technology was designed and the intended end users.

The *Psychological* rung allows us to consider the cognitive fit between humans and technologies. If a technology requires more cognitive capacity of a user than is available during a task (e.g., remember a long series of numbers), or is counterintuitive to how people might expect to interact with a similar device, a mismatch between the technology design and user will result.

The *Team* rung causes us to think about how technologies must consider communication between multiple people in the system and facilitate the dynamics of

teams. Technologies should be designed to allow multiple people to work towards a common outcome.

The *Organizational* rung ensures that we consider that technologies must also fit well with work characteristics such as organizational culture, schedules, incentives, and disincentives.

Finally, the Political rung highlights that technologies must also fit well with people at the political level. This level incorporates attributes such as budgets, laws, regulations, and public opinion.

Section 3.3. Introduction to Cognitive Engineering

When thinking about the fit between humans and technologies a good starting point is on the bottom two rungs of the Human-tech ladder (i.e., the physical and psychological fit).

The physical fit between a person and a technology can usually be directly observed, for example a technology is too heavy for someone to lift. In contrast, the psychological, or cognitive fit between a person and a technology can be much more difficult to discern. How people perceive, process, and react to information is influenced by several factors, including cognitive ability (i.e. limitations and biases), and other external factors that are happening around us.

In general, humans are very good at cognitive tasks such as finding and interpreting patterns, but we struggle with things like mental arithmetic and remembering lists of information. Although we can perform these more challenging cognitive tasks, we are much more prone to making errors in these cases. Applying this knowledge to the analysis of the tasks required to use health technology can allow error-prone tasks to be identified and redesigned, or else safety support mechanisms to be added. The cognitive abilities and limitations described in this chapter are included to help you notice and consider them when conducting the human factors methods presented in Part III.

Section 3.3.1. Cognitive Ability

As humans, we have natural limitations when it comes to our cognitive abilities including limitations in memory, attention, and cognitive bias. When tasks require greater cognitive abilities than we have, or prime us in ways that invoke our cognitive biases, we fail to notice things, forget things, or make suboptimal decisions.

Section 3.3.1.1 Memory

Our memory is where information that is collected from the field is stored. There are two main types of memory: working, or short-term memory; and long-term memory.

Temporary information is stored in our working memory and we use this form of memory to process information by examining, evaluating, transforming, and comparing different mental representations of that information. The capacity of our working memory is limited and when our attention is drawn elsewhere, it can be especially vulnerable. We often rely on our working memory without even realizing it, which can be problematic given the number of things we have to remember and the many distractions, interruptions, and tasks going on at once.

Facts about the world and mental models of how to do things tend to be stored in our long-term memory. Initially, information is stored in our working memory and through repetition and training, some of this information is transferred over to our long-term memory where we can recall or recognizing it as needed. When we are unable to retrieve or recognize information it can be problematic, leading to errors or increased time to complete a task.

Section 3.3.1.2 Attention

In our daily lives we are bombarded with information but there is only so much we are able to pay attention to at any one time. Attention is the process we use to select what information we attend and respond to at any time. It is what enhances and inhibits information at any moment, given our intentions. [24]

While we have a variety of mechanisms to help us select, focus, and sustain our attention our total capacity for attention is limited. When we attempt to pay attention to something that requires more attention capacity than is remaining, we automatically stop attending to something else to free up the resources needed. This leads to *inattention blindness*, when we fail to notice things that are important and might seem obvious to others, or that might seem obvious after the fact, because our attention is focused elsewhere. [25] A good example of this is not noticing how close a car is in front of you until after you have hit it because your attention was on something else, such as the radio or phone.

Section 3.3.1.3 Cognitive Biases

Humans are wired to see the world according to a number of cognitive biases. Cognitive biases are acquired as a result of our tendency to use heuristics, or rules of thumb, when processing information as a means of decreasing the cognitive workload on our brains. Although helpful for producing short cuts for decision making by reducing cognitive workload, these biases increase the chance of drawing incorrect conclusions about information and introduce errors into our thought processes. There are many known cognitive biases, and a few examples are described in further detail below.

Confirmation Bias

A confirmation bias is the tendency for people to seek out, or to interpret information that confirms a preconceived notion. You see what you expect to see, not what is actually there.

Groupthink

Groupthink is the tendency for a group with similar interests to reach a consensus, even if no evidence is available to support that consensus, to minimize conflict within the group.

Omission Bias

An omission bias is the tendency for humans to believe that a harmful action is worse, or less moral, than an equally harmful inaction.

Framing Effect

The framing effect describes the tendency for people to draw different conclusions from the same set of information depending on how that information is presented.

Recency Bias

A recency bias is a tendency for people to place greater importance on something that has been observed or experienced recently.

For a more comprehensive list of cognitive biases see the Wikipedia entry for List of Cognitive Biases (http://en.wikipedia.org/wiki/List_of_cognitive_biases).

Section 3.3.2. External Factors Affecting Cognitive Ability

In addition to the aforementioned factors affecting cognitive ability, there are several external factors that influence how accurately and effectively we are able to process information including workload, and alertness and fatigue. These factors need to be considered when evaluating the fit between the cognitive resources required to complete tasks using technology and the cognitive resources available to complete that task.

Section 3.4. Reason's Swiss Cheese Model of Accident Causation

When we are challenged beyond our physical or psychological human limitations, errors are more likely to occur. In an attempt to prevent errors from leading to a system failure, many safety critical systems incorporate barriers to try to catch and prevent errors from ultimately leading to incidents. To consider how errors can propagate from the decisions and actions made upstream all the way to the patient, Reason's Swiss Cheese Model (Reason, 2000) can be used (adaptation shown in [Figure 3](#)).

This model shows that in healthcare, even when there are several barriers put in place to prevent errors from reaching patients, each barrier, no matter how well thought out or well intentioned, has inherent weaknesses. These weaknesses, which are constantly moving, will eventually align to create opportunities for hazards to propagate through the system and become adverse events. These weaknesses can originate from a number of sources along the rungs of the Human-tech ladder including the physical and psychological levels, as noted earlier, but also the team, organizational, and political levels.

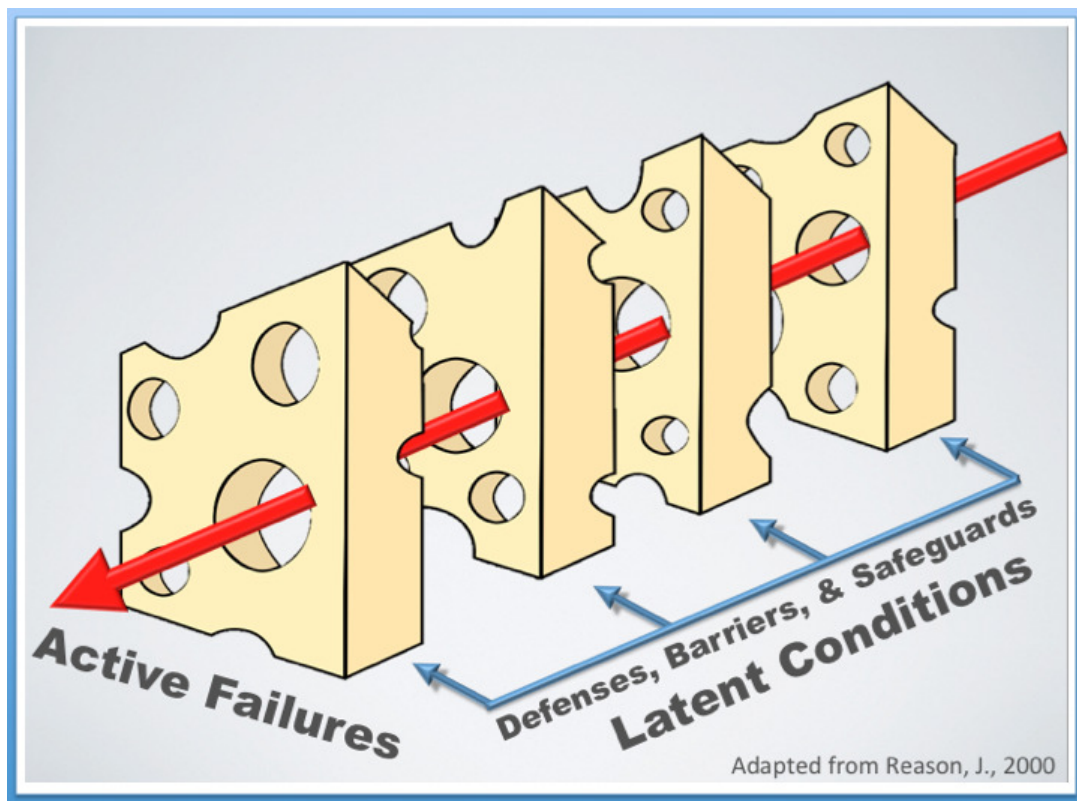


Figure 3. Adaptation of Reason's Swiss Cheese Model

In Reason's model ([Figure 3](#)), the cheese slices represent barriers put in place to try to make our healthcare system safer. Within each well-intentioned barrier, a number of weaknesses exist, represented by the holes in the cheese. Important to note, the holes, or weaknesses inherent to each barrier are not static, and so conditions in the system are always changing. When a hole in one slice lines up with cheese in the next, the error is caught, or mitigated. However, when a hole in one barrier lines up with a hole in the next, and so on, hazards have the opportunity to sneak through the barriers that have been put in place, and find their way to the patient.

Section 3.4.1. Active Failures

The holes at the very end of the system that come into contact with the patient are called *active failures*, typically involving staff at the bedside such as nurses, doctors, etc. Most analyses of errors tend to identify only the active failures, which results in the assignment of blame to those responsible for the active failures. These active failures result from different mechanisms including *slips, lapses, mistakes, or violations*.

Section 3.4.1.1 Slip

A slip occurs when perceived information is interpreted correctly, and the correct response is intended, but the wrong action is performed accidentally. An example is knowing a phone number but pressing an incorrect key on the phone when dialling.

Section 3.4.1.2 Lapse

A lapse occurs when the intended actions are correct, but there is a temporary lapse of memory or attention. An example is pressing a pen on paper to write something but forgetting to click the end of the pen to extend it first.

Section 3.4.1.3 Mistake

A mistake occurs when information is not interpreted correctly, which leads to an incorrect action. They usually happen when you misinterpret a situation or misapply a rule. An example is setting your alarm for 6:30 pm when you intended to set it for 6:30 am.

Section 3.4.1.4 Violation

A violation occurs when a choice is made to act contrary to accepted protocol. A violation can be well-intended when someone identifies that the rules are not likely to lead to the appropriate outcome. An example is a pilot choosing to ignore warnings from Air Traffic Control because they know that another aircraft that is on a collision path has already changed course.

Even when an error is identified as a slip, lapse, or mistake, it is sometimes difficult for organizations to identify it as a system error, particularly if there is a strong history or culture of blame in the organization. To facilitate identifying system failures when they occur, the Incident Decision Tree for Responding to Patient Safety Events ([Figure 26](#)) provided in Part III can be used as a guide to assessing culpability.

Section 3.4.2. Latent Failures

The holes that are upstream and in the middle of the system that do not come into direct contact with the patient are called *latent failures*. These weaknesses typically result from designs and decisions that are made further upstream in the system, such as decisions about which technology to purchase, training, scheduling, budgets, staffing levels, and policies. The presence of latent failures in an incident highlights that there are systems factors contributing to the incident.

Section 3.5. Hierarchy of Effectiveness

When applying human factors methods to health technology safety problems, it is not enough to simply identify human factors issues. Once an issue has been identified, a mitigating strategy needs to be developed and implemented to prevent such an issue from causing harm to patients and/or staff. However, not every mitigating solution is created equal. Unfortunately, a strategy that looks good on paper in terms of the resources required and ease of implementation does not always have the expected positive effect once implemented. The solution may not address the root cause of the problem, or may rely on the users to take on additional work, which usually leads to poor compliance over time or new, unanticipated issues arising from the added workload.

The hierarchy of effectiveness[26] ([Figure 4](#)) is a framework that will help you to consider the likely effectiveness of different mitigating strategies. It is a human factors-informed framework that can be used to consider how effective a design or error-mitigating strategy will be, based on the degree to which the solution is embedded in the system versus is reliant on behavioural changes of people.

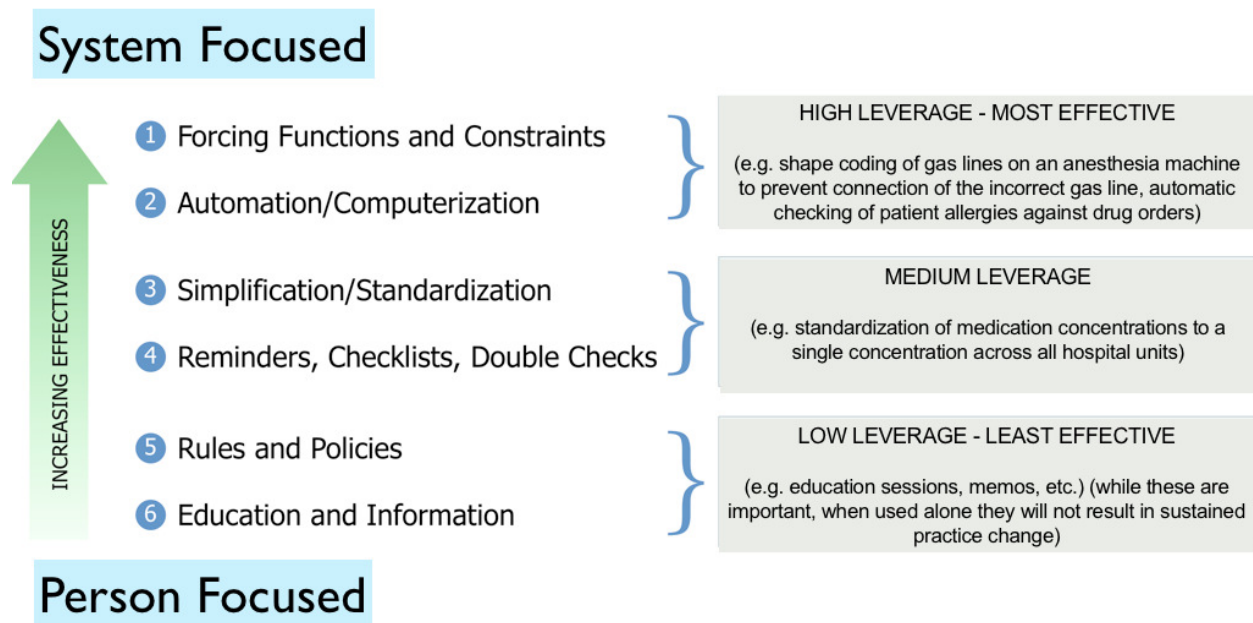


Figure 4. Hierarchy of Effectiveness (adapted from ISMP)

The hierarchy of effectiveness ranges from person-focused strategies at the bottom to system-focused strategies at the top. As the strategies go from person-focused up to system-focused, they generally become more effective as indicated by the green arrow in [Figure 4](#). However, note that it is most important to fit the solution to the problem than it is to solve a problem using strategies from the highest levels of the hierarchy. While person-focused strategies for preventing errors are easier to identify and implement, these types of strategies rely on vigilance, and so even when people have the best of intentions, work

efficiency pressure will eventually lead to the decay of these strategies and people will revert to accomplishing their work as efficiently as possible, regardless of how the work is expected to be done. This is especially true in healthcare where clinicians want to help patients as best as they can and are often overloaded with tasks and responsibilities. In contrast, more systems-focused strategies focus changing elements of the system itself to eliminate potential hazards all together. This is why system-focused strategies are typically more robust than person focused strategies; they support the decisions and actions of people and minimize the unrealistic requirement that people think, behave and act perfectly. The strategies represented at each of the levels of the hierarchy are described here:

Education and Information

According to the hierarchy of effectiveness, education and information is the least effective strategy for reducing errors. Although training is often used to familiarize people with new technologies and systems, and is a great way to practice the skills required to safely carry out a job, when implemented in response to a poor technology or system design, or to reinforce proper use of a technology, it is not very effective. Training that is meant to mitigate a poor technology or system design makes it the responsibility of the person to be vigilant. For example, even if a user was trained about how to get around a problematic device feature, it would still be possible for the user to make a mistake depending on the other cognitive and work pressures being experienced at the time.

Rules and Policies

Rules and policies are often implemented in healthcare organizations because they can be broadly disseminated and guide staff in appropriate conduct in the workplace. Rules and policies are often put into place as a result of an incident to control how people behave and act, but they do not always stop an action from being performed and do not get at the system level factors that contributed to an incident. Depending on the demands placed on a staff member, rules may not always be followed or followed correctly, especially if staff are unfamiliar, or if they do not think the rules and policies fit, or apply in a given situation.

Reminders, Checklists, Double Checks

Reminders, checklists, and double-checks can reduce errors by helping people to remember, and by involving multiple people in a process. Although these tools may seem useful, over time people can easily become desensitized when a checklist is routinely filled out or a reminder is routinely seen. Often, when double checks are carried out, they are not truly done independently, and even when they are, they are still susceptible to common cognitive biases like confirmation bias. It is not uncommon for more than one person to make the same mistake. Reminders, checklists and double-checks may help in identifying

errors, or reminding us to check for errors, however, they do not prevent errors from occurring.

Simplification and Standardization

Simplification and standardization tend towards more of a system focused strategy to preventing errors because these types of solutions tailor systems to match what people expect, and reduce the number of options and complexity presented, which helps people to focus on the important parts of a task instead of trying to sort through a collection of information. Although simplification and standardization can help in preventing errors, it is not a panacea because people are still prone to making mistakes, and these types of solutions will only address some of the issues within a system.

Automation and Computerization

Automation and computerization tends to be the second-most effective type of solution because some of the tasks we know to be potentially problematic for people can be shifted to computers. Those tasks that humans are not very good at, such as memorizing, calculating, or monitoring a situation for changes, can be transferred to computers, which are much more reliable for performing these types of activities. Although automation can be a reliable means of supporting the capabilities of people, it is still possible for errors to be introduced when a system has been automated or computerized. Since automated and computerized systems are designed and monitored by humans, errors could still be introduced at any interface between people and the automated system.

Forcing Functions and Constraints

According to the hierarchy of effectiveness, forcing functions and constraints are the most effective type of solution. Forcing functions and constraints are design features that force or prevent a user from carrying out an action that could lead to an error. They are considered the most robust method of preventing errors because by preventing people from continuing down the path of making an error, it is unlikely that error will actually occur. Although forcing functions are considered to be the most robust types of solutions, it can often be challenging to incorporate true forcing function solutions into the technology, process, or system being improved upon. Also, in healthcare it may be necessary to include an “override” function in some cases, which can encourage staff to sidestep forcing functions completely. An example of a forcing function would be the gas line connector coding on anesthesia machines. The nozzles for each gas line are designed to fit only in the matching socket ([Diameter Index Safety System](#)).

Part II. Handbook of Human Factors Methods

Human factors methods are varied and flexible in their application. They often resemble tasks that one would do naturally as part of an analysis of health technologies and health technology issues. However, each method has fundamental principles and underpinnings that need to be consciously applied to ensure the analysis is objective and the results are valid, so that the benefits of the methods are realized.

Part II will detail how to undertake each of the nine human factors techniques and methods selected to support the safe and effective use of health technology by health professionals. These methods are laid out as follows:

Data Collection to Understand Users and the Use Environment

- Observations
- Interviews, Focus Groups, and Surveys
- Task Analysis

Human Factors Evaluation Methods

- Heuristic analysis
- Usability Testing

Human Factors Informed Risk and Incident Analysis Methods

- Human Factors Informed Failure Mode and Effects Analysis (^{HF}FMEA)
- Human Factors Informed Root Cause Analysis (^{HF}RCA)

Human Factors Informed Procurement

- Human Factors Informed Procurement and Implementation Process (^{HF}PIP)

Once these human factors methods have been mastered, the biomedical technology professional will be able to effectively understand: user needs with respect to specific technologies; the use environment and environmental factors influencing user performance; how to evaluate technology to identify design issues likely to lead to human error; how to objectively evaluate user performance and determine its impact on patient safety; and how to investigate technology issues that could, or have already, led to patient harm.

Data Collection to Understand Users and the Use Environment



A typical intensive care environment requiring the coordinated efforts of many people and technology.

Chapter 4. Observations

Section 4.1. Setting the Stage

When people with similar training and experience are presented with a particular situation, it is not uncommon to find that they take fairly different approaches to managing the situation. This is not necessarily because one person has a better approach or more information than another, but because there are many factors that influence how people perform their work. In healthcare, we believe people inherently want to do their work safely and effectively, and that when their performance is unsafe or ineffective, there are factors, which they may or may not be aware of, that influence their performance.

These factors come from a combination of internal and external sources that can vary over time. Examples of external factors that can impact work include equipment design, the physical layout of a workspace, expected workflow and work practices, organizational policies, team dynamics, and organizational culture. Internal factors, or natural human limitations ([Chapter 3](#)), that can affect our work include our ability to remember multiple units of information, or to pay attention to many things that are happening at the same time. People also vary in terms of their skill level and ability to perform certain tasks based on factors like age, level of training, and experience.

Observing people as they interact with technologies, environments and each other provides us with a window into *how* people do things. Seeing the factors that shape how staff approach their work gives us insight into existing issues and possible areas of mismatch between people and the systems they are a part of.

Section 4.2. What are Observations

Observations, sometimes referred to as *ethnography* or *shadowing*, is a data collection technique where a human factors specialist watches, or observes people performing their regular day-to-day job duties in their normal work environment. A variety of data collection tools may be used to collect either structured or unstructured data while observing. Examples of these tools include note taking, photographs, task analysis software, artefact collection, and sometimes, video recording.

Section 4.3. Why use Observations

Conducting observations is a relatively low cost, valuable means of gathering rich information about users as they perform tasks in their work environment. Through observations, you can learn which clinical users are interacting with a device, what tasks are being performed, what other aspects of the environment are relevant to using a device, and see actual challenges, workarounds, and strategies as they are happening in real time. Observations provide essential context for defining problem scopes, and often lead human

factors practitioners down unexpected paths of discovery that end up being key to the issue at hand.

Observational data tend to be complementary to other qualitative data like interview, focus group, or survey data. Thus, interviews, focus groups and surveys should not be used in lieu of observations. Observations are essential for understanding *how* things happen, while interviews, focus groups, and surveys are more useful for better understanding *why* they happen from a subject's perspective.

It is important to observe rather than ask a subject how something happens because it is common for people to perceive step-by-step processes differently than they happen in reality. This is due to inherent human limitations like cognitive biases ([Section 3.4](#)) (e.g. confirmation bias, inattentional bias, groupthink), and because people do not tend to think about well-known processes in discrete steps. Through observations, the human factors specialist can identify gaps between perceived actions and actual events in an appropriate level of detail.

From the biomedical technology professionals' perspective, conducting observations will be helpful for:

- Identifying the different user groups of a device
- Understanding what a device must do to support users' tasks
- Understanding how users currently interact with a device
- Understanding how a device fits within the larger system (e.g., how it integrates with existing information systems, checklists, or related protocols and policies)
- Identifying challenges and risks with a device already in use
- Determining different levels of knowledge across users, and how well users understand device operation

Section 4.4. When to use Observations

Observations should be conducted whenever the human factors practitioner is unsure exactly how or why something is happening in the field. Observations should be considered the "go to" method, as almost always, it will be the starting point for any human factors analysis. Since observational data is complementary to data gathered using other qualitative data collection techniques, observations should be done whenever interviews, focus groups, or surveys have also been conducted.

Section 4.5. Preparing for Observational Data Collection

Section 4.5.1. How to structure data collection

Deciding whether to use a structured or an exploratory approach to data collection will depend on what you, the observer, already know about the users, devices, processes, and environments of interest. When a detailed understanding has already been achieved, a more structured data collection approach can be used; however, if little is known, an exploratory data collection approach should instead be taken. [Figure 5](#) provides some guidance about whether a structured or exploratory data collection approach should be taken based on what you already know about the users, devices, processes and environments of interest.

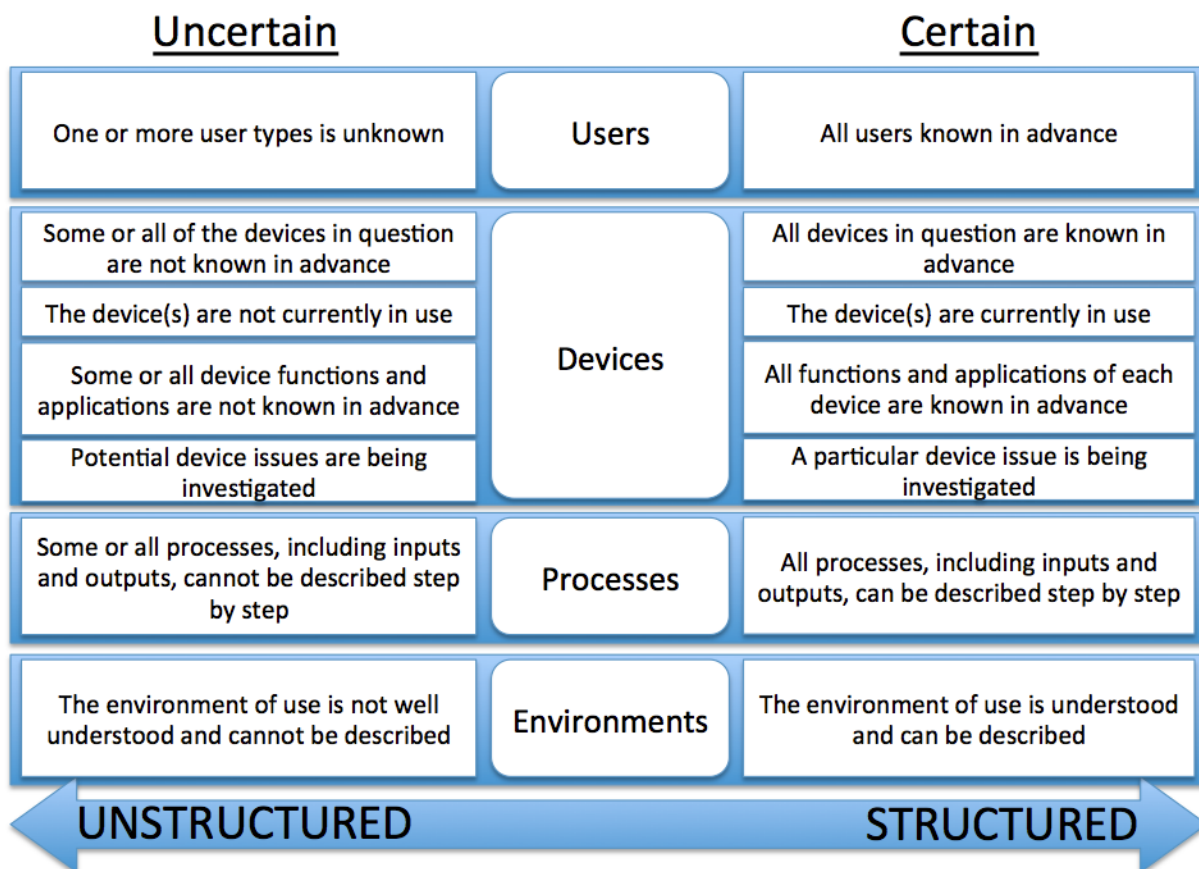


Figure 5. Considerations for a structured versus unstructured approach to data collection

Section 4.5.1.1 Exploratory data collection

When an exploratory approach to data collection is taken, it means that observations are aimed at developing a general understanding of factors that will influence how a technology is used and whether it will be used successfully. It starts with an understanding of who the users are, what tasks they perform, and potential issues related

to the use of a particular technology. A structured approach to data collection usually follows exploratory observations because a detailed baseline understanding of the system of interest is needed to be able to develop appropriate data collection tools (e.g., task/workflow checklists) to support the goal of the structured observations. When taking an exploratory approach, a formal data collection tool is not typically used. Instead, notes and photographs of what you are seeing should be recorded in real-time, or immediately following an observation session.

While conducting exploratory observations, make note of things like:

- What technologies are being used?
- When, why, and how are technologies being used?
- What are the environmental conditions in which the technologies are being used (noise, lighting)?
- What are the space configurations of the work environment?
- What processes are being carried out?
- What information (e.g., forms, charts, electronic interfaces, or policies) is being used?
- What knowledge, skills, training, or education is the user accessing?
- What are the goals of the user?
- What problems, challenges, workarounds or strategies are being used?
- What are the inputs and outputs of what you are observing?
- How do people work together relative to the device?

Section 4.5.1.2 Structured data collection

When a structured approach to data collection is taken during observations, it means that users are observed with a specific set of questions in mind, for example, what tasks do nurses perform with a particular telemetry monitor, and where do they perform those tasks? When taking a structured approach, a data collection tool is typically used to track observational data against a specific set of questions. The purpose of a data collection tool is to ensure each observer is capturing the same information during every observational session. The actual data collection tool you choose to use can vary, but generally, a simple paper tool with dedicated space for each required piece of information will be sufficient. The data collector usually designs the data collection tool based on what they expect to observe, and the goals of the observation sessions. Typically, preliminary exploratory observations will be required to determine which data elements you want to capture in a structured format. Once the data collection tool has been designed it is recommended that you pilot test it in the field prior to data collection to ensure it will meet your needs during observations.

Section 4.5.2. How to initiate contact

Before going into the field to conduct your observations, it is important to first contact the managers of the respective departments to explain the project and rationale for conducting observations. Getting managers to agree to support the project is critical to gaining access to front line staff, and ensuring these users are willing to participate in the observational sessions.

Once a manager has agreed to have their unit participate, it is advisable to:

- Plan the timing of your observations
- Determine whether there are any clothing or footwear requirements on the unit
- Determine whether a signed consent form will be required from each staff member and/or patient being observed (see [Appendix A](#) for description and sample)
- Introduce the project and any observers (data collectors) to staff, ideally as part of a staff meeting

Establishing a contact person, who may or may not be the manager, can be extremely helpful in accomplishing these tasks. A contact person will be required for each clinical area where you will be observing. In addition to these preparatory tasks, your contact person can also be called upon to help you collect artefacts such as forms, or disposables, and to verify the observational data after it has been summarized for accuracy.

Section 4.5.3. Timing

When planning the timing of your observations, you will want to discuss with the manager to find a time that works well for staff. You may also want to consider observing staff during the beginning of shift, the end of shift, at shift changeover, and during peak times. Observing during these more complicated times can provide unique insights in comparison to more typical non-peak times. Plan to meet your contact person in the unit on the day of your first observation session.

Section 4.5.4. Making participants feel comfortable

The most important aspect of conducting observations is to make sure staff feel comfortable while they are being observed. This means those being observed should know it is not their performance that is being evaluated, but rather, they are being observed to understand whether their needs are being met by the technologies, processes, and environments they interact with. If you see staff having difficulty, or working around aspects of a system, these are opportunities to learn about the challenges they are facing, and to think about solutions that could support them in making their work safer and more efficient.

Staff should feel comfortable knowing you will not share the details of their work practices, or opinions, to others, in particular with their superiors; if you can make staff comfortable as you are observing, they will be much more willing to participate in the observation process and to share information with you. One way to make this clear is to provide participants with a consent form for them to sign that explains how the information collected during the observation session will be used. Depending on the type of work you are doing, this may be required. [Appendix A: Confidentiality and Anonymity](#) describes how and when to get informed consent and provides a sample consent form template.

Staff can be a wealth of information and generally understand the issues better than anyone since they live and breathe these technologies every day. Although staff often have great ideas for solutions, sometimes they do not tend to bring them forward because there do not have any experience of their ideas resulting in changes, and may feel disempowered. When staff are observed and have the opportunity to bring their experiences, challenges, and ideas forward to someone who is responsible for incorporating their feedback into a change process (e.g., a procurement process) it can be a very empowering experience for all involved. Often staff who are more senior, extroverted or opinionated are given more opportunities to contribute. When possible it is advised to seek out staff participants who represent different perspectives (e.g., senior and novice, extroverted and opinionated as well as quiet and more reserved) to ensure a wide range of needs and ideas are included.

Section 4.5.5. What to bring

Helpful materials for conducting observations include:

- Appropriate clothing, ideally with pockets, that helps you blend in (e.g., a lab coat, scrubs, or whatever is generally worn in that area)
- Appropriate footwear (e.g., closed-toe shoes)
- An ID badge
- A clipboard, or light, hard surface for writing
- A notebook and/or data collection tool
- Consent forms (if required, see [Appendix A: Confidentiality and Anonymity](#))
- Two pens (different colors may be helpful)
- A camera
- Refreshments (e.g., coffee and muffins) for all staff on the unit (*optional*)

Ensure you are not planning to bring the following;

- Your own food/drink
- Heavy items, or things that are awkward to carry
- Uncomfortable clothing or footwear
- Scented items (items with heavy perfumes or deodorizers)
- People who are not part of the project team
- Vendors of the technology being investigated

Section 4.6. Observational Data Collection

Section 4.6.1. Initiating the observation session

Start by finding your contact person at the scheduled observation time. If you are unfamiliar with the clinical area, ask your contact person to take you on a quick tour of the facility to show you where things are located, and ask them to introduce you to a few of the staff members on shift. When you are ready to start observing, approach one of the staff members and provide a brief introduction to yourself and the project. Explain that you are hoping to observe how tasks or processes are conducted, and that you are not there to evaluate their performance, but rather, you would like to observe them to understand whether their needs are being met by the technologies, processes, and environments they are interacting with (you can state this more specifically in the context of the technology or system you are focusing on). Ask if they would feel comfortable being observed, and tell them they can stop the observation session at any time. If they are open to being observed and a consent form is required ([Appendix A](#)), ask them to sign it; if they say they would not like to be observed, approach another staff member and introduce yourself and the project again. A sample introductory script is provided in [Figure 6](#) below.

Sample Introductory Script

“Hi, my name is Charlie and I’m from the Biomedical Engineering department. Our hospital is buying new infusion pumps and I’m part of the team that is evaluating the available devices to see which would be best for our hospital. As part of my evaluation I’ll be looking at how well the different pumps meet your needs as a nurse, and how easy they’ll be to use.

What I’d like to do today is observe you and take notes as you use our current infusion pump. When I observe, I won’t be evaluating you, but rather, I’m interested in learning more about how our current pump fits into your workflow. I’ll be looking at things like the different ways you use the current pump, where you get the information required to program it, what documentation you have to fill out for each infusion, and what items you use in your environment, like orders, forms, labels, tubing, and cleaning supplies, that support your use of the pump. I’d also be happy to hear any of your thoughts about the current pump so we can consider these things going forward with the new pump. Any ideas you have about how the new pumps should work would also be extremely helpful.

It will probably feel a little strange to have me watch you at first, but if you agree, please know that I am not collecting any information about your performance, or evaluating you in any way, and I will not share my observations of you with your colleagues or your superiors. I am only interested in information related to the pumps and how to make the new pumps work best for you. In my notes, and when I share this information with the project team, you will never be identified by name. Also, you can stop the observation session at any time. Just tell me if you would like me to stop observing you. Does this all sound okay with you?”

“Yes, this is alright with me”

“Great, thanks! Also, would it be alright if I took some photos as we go? I will make sure not to take any pictures of patients, identifying, or personal health information. If any personal information is captured by accident, it will be blurred”

Figure 6. Sample introductory script to initiate observational session

Section 4.6.2. While Observing

At first, it is likely the person being observed will perform their tasks more carefully or consciously than normal (see discussion of Hawthorne Effect in [Section 4.8.1](#)), but over time, if you are able to observe without interfering and can make the staff member feel comfortable with your presence, they will begin to act normally and you will see a more accurate representation of how they work in reality. As you observe, try not to interfere, and make sure your observations are not impacting the staff member’s ability to provide patient care. Also, be sure to consider the comfort of any patients and family members

involved. It's generally a good idea to ask the nurse you are shadowing to introduce you to patients (if they are conscious) and their family so it is clear why you are there and recording notes. Also, be sure not to make any comments or raise any questions that could be perceived as alarming to patients or their family in front of them. Find a time away from the bedside to ask these questions.

If a structured approach is being taken while observing, use your data collection tool to record any observations. You may find it difficult to fill out a structured data collection form in the field, even if you have invested time to develop it. While shadowing, tasks may not happen in the sequence you are expecting, and challenges may arise that you never anticipated. Be prepared to adapt your approach to data collection as you are observing, to make the most of your time (e.g. take notes during shadowing and fill in the data collection form immediately after your observational session).

If an exploratory approach is being taken, use your notebook to record notes about what you are seeing as it is happening. A common pitfall while observing is to get caught up in “watching the show”, rather than recording notes about what is being observed. Another common experience at the start of exploratory data collection is a feeling of not knowing what to look for, or not seeing anything that seems relevant. These experiences are normal. It will take some time to become familiar with the environment and to differentiate what to focus on given the goals of your work. If you are not used to being in the clinical environment, it can take some time to get used to being around patients and understanding all the various equipment and systems before you can start to distinguish what is relevant to your project. If you are having difficulty identifying and recording what is relevant while observing, think back to the original reason for conducting observations and start there; keep in mind though, that you want to soak up as much as you can about what is happening around you. Although you may not see important issues right away, after some time observing the issues will begin to emerge.

Tip: It is common not to notice any issues during the first shadowing sessions at the start of a new project. This is true for both novice and expert observers and occurs because each project requires a certain amount of contextual understanding to be able to identify potential issues. As your contextual understanding grows, so too will your ability to identify issues. In a field study conducted by the primary author on multiple intravenous infusion safety, it took three days of observations in the intensive care setting before issues started to emerge. By the end of the project over 100 issues/contributing factors were identified.

If possible, having more than one data collector is extremely helpful because a lot of information is learned and processed by talking through what has been observed. Also, planning to have some downtime between observation sessions is important, to allow time

to think about what you have seen, identify additional things to look for, and to debrief, if possible. Since different activities may happen on different days and at different times of day, taking a break can facilitate observing different sets of tasks, or at more error prone times like shift-change (patient hand-offs). Record your observations, impressions, thoughts, questions, etc. immediately following a shadowing session to ensure you capture as much detail as you can before you begin to forget what you saw. This is especially important when conducting multiple shadowing sessions.

Observation sessions can vary in length depending on the arrangement made with the unit, but when the observer is saturated with information or the person being shadowed shows signs of not wanting to be shadowed any longer, the observer should take a break from shadowing, or move on to observing another person. A good rule of thumb for the length of an observation session is to aim for about three hours, but in reality, observation sessions could range anywhere from about an hour to eight or twelve hours, if an entire shift is being observed.

If you have questions as you are observing, it is important to ask them, but be careful not to interrupt the person you are observing at inappropriate times, especially if they are performing a task that is safety critical, or requires concentration. To ensure you ask questions at an appropriate time, it is recommended you write any questions in your notebook as they come up, and then ask the person you are observing to let you know when it is alright to ask questions.

Photographs can be a very effective source of data, and are especially helpful after you have completed your observations. Having access to photographic data can help you remember the details of complicated technologies and environments, and facilitate communication of your findings to the project team. While observing, try to photo-document as much as possible, but ensure the staff member (and patient, if applicable) are comfortable and give their permission before taking any photographs. Most healthcare organizations have strict privacy rules so make sure you know and work within these rules during data collection. When you do take photographs, try to avoid capturing any identifying, or personal health information of both patients and staff. If you do capture any identifying information, it will have to be covered or blurred during data analysis to maintain staff or patient confidentiality. If the person you are observing is uncomfortable with you taking photographs due to privacy concerns, offer to show them any photographs after they have been taken so they can approve them. Alternatively, you could ask the staff member to help you set things up so any identifying information is covered up (e.g., use a piece of paper to cover up a patient's name on a label). Having the unit manager's permission to take photographs is highly recommended, and may also help to make staff feel more comfortable. Prior to asking for the manager's permission it is good practice to

review your institution's policies regarding photos and voice recording (see [Appendix A: Confidentiality and Anonymity](#)).

Section 4.6.3. When to stop observing

After you have spent time observing and begin to understand the relevant tasks and issues given the context of your work, another challenge can be to know when to stop conducting your observations. Although there is no specific rule for stopping, when you can no longer identify new users, tasks, or issues, and reach saturation in terms of feedback from staff, these are key indicators that it is time to stop conducting observations. Of course, project timelines may also dictate when observations must stop. While it is not ideal to strictly limit observation time, remember that conducting some observations is better than none, and more is better than less.

Your understanding of the use environment will continue to develop even after the observational sessions have been completed, as the data are analyzed and additional human factors methods are applied. It is normal to uncover new things that are not well understood after your observations have been completed. If this happens, do not worry; with permission of the manager, you can always return to the unit to perform additional targeted observations.

Sending a note of thanks to your contact person, the manager, and the unit staff is highly recommended to let them know you appreciate and value their contributions to the project. Commit to sharing any outcomes with them if they are interested in learning how their input had an impact on the project.

Section 4.7. What to do with Observational Data

Whether observational data collection is exploratory or structured in nature, you will have a large quantity of descriptive data to work with. Figuring out how to analyze this data can be extremely daunting, and knowing where to start, especially for the novice observer, tends to be the biggest barrier to a successful analysis. Usually, a good first step is to organize the observational data into themes so they can be more easily managed. The themes chosen will depend on the data, and why they were collected in the first place. For example, themes could be chosen based on different:

- levels of the system (e.g., user, technology, process, clinical unit, hospital)
- parts of the system (e.g., user, technology, forms and documentation)
- user groups (e.g., nurses, doctors, pharmacists, clerks)
- areas of the hospital (e.g., intensive care unit, emergency department)

If the themes used to organize the data are quite broad, it may be useful to divide the data under each theme into sub-themes for improved granularity. An example of this preliminary step for data analysis is shown in [Figure 7](#). For the purposes of this example, an

exploratory approach was used to learn about issues related to administering multiple intravenous infusions. An excerpt of the observational data collected for the example is included.

Data Analysis Example

Excerpt: Raw Data

- *12 beds available in intensive care unit*
- *pumps show volume-rate in the largest font and the dose-rate in a small font at the bottom of the pump*
- *pharmacist is dedicated to the unit*
- *pharmacy technician restocks medication*
- *pharmacy technician delivers medication*
- *4-5 patients transferred to unit per day from surgery*
- *3 beds in cardiac surgery intensive care unit*
- *nurse has 2 patients*
- *pumps sometimes slow nurse down*
- *don't always use drug library*
- *pump responds slowly to key presses*
- *sometimes nurse has to re-press buttons when pump doesn't respond*
- *one time something was double entered because pump was slow to respond*
- *during arrests, drug library takes too long*
- *patients who are arresting need large volumes of fluid*
- *policy against agency nursing*
- *staff must have critical care experience*
- *medication order (artefact)*
- *photograph of pump interface screens*
- *photograph of medication label*

Excerpt: Raw Data Organized into Themes

Theme 1: Unit Structure

- *3 cardiovascular operating rooms send patients to the unit*
- *12 cardiac surgery ICU beds*
- *4-5 surgery patients transferred each day*

Theme 2: Staff

- *All staff have critical care experience*

Sub-Theme 2a: Nursing

- *Policy against using agency nursing*
- *Nursing to patient ratio is 1:2*

Sub-Theme 2b: Pharmacy

- *Dedicated unit pharmacist*
- *Pharmacy technician restocks and delivers medications*

Theme 3: Infusion Pump

Sub-Theme 3a: Pump Design

- *Pumps display volume-rate in a large font*
- *Pumps display dose-rate in a small font at the bottom of the pump*
- *Photograph of pump interface screens*

Sub-Theme 3b: Pump Issues

- *Large volumes of fluid are delivered quickly when a patient is arresting, and the drug library takes too long to use in these situations*
- *The pump responds slowly to key presses and if a button is re-pressed because the user doesn't think the first press was received, a programming error can occur; this has happened to nurses on the unit before but it was caught*

Theme 4: Information about Medication

- *Photograph of medication label*
- *Medication order (artefact)*

Figure 7. Organizing raw data into themes and sub-themes

Once observational data have been organized into themes, they are much easier to use as inputs to a range of other human factors methods, which will be presented throughout the rest of this handbook.

Section 4.8. Limitations of Observations

Before collecting observational data it is important to consider the following challenges and limitations :

Section 4.8.1. The Hawthorne Effect

As you can imagine, people are likely to improve or modify their behaviour if they know they are being observed. In the scientific literature, this behaviour change is referred to as the Hawthorne Effect [27]. While it may seem this effect would make the collection of reliable observational data challenging, ensuring the subject is comfortable and knows their skills and abilities are not being evaluated but rather the device, or system they are using, is being evaluated can help to minimize this effect. Behaviour modifications seen at the beginning of an observational period are likely to diminish over time if the observer can

consistently demonstrate that they are not evaluating the performance of those observed and are truly committed to understanding their environment, tasks and challenges. Also, any risks or concerns identified during observations (i.e., subject to the Hawthorne Effect) may be considered a conservative viewpoint into any challenges or issues experienced by subjects.

Section 4.8.2. The Time Investment Required

Depending on the goal of your observations, it may take several observational sessions with multiple staff, in various environments, to collect your data. These observational sessions may happen in quick succession or take place over a long period of time depending on the frequency with which certain tasks are done in the field. Often when observing, seeing unanticipated challenges will lead the human factors practitioner to expand the scope of their observations in order to more fully understand the factors affecting what has been observed. Ultimately, the time invested in observing may be dictated by external factors such as available resources, workload, or project timelines, but when possible, observational sessions should continue to be conducted until the use of the technology or the process can be clearly described and there are no outstanding questions to be answered.

Section 4.8.3. Observer Bias

As an observer, you will bring a biased viewpoint to your observations. All people have inherent human limitations affecting our ability to see, interpret, and remember what we have seen. Like all people, we see and interpret our world through a series of cognitive biases (see [Section 3.3.1.3](#)); we tend to see what we expect to see, and to collect information in a way that matches our own experiences and expectations. These inherent biases can be minimized through a greater awareness of our human limitations, and may be more systematically addressed through a structured data collection approach ([Section 4.6.1](#)).

Section 4.9. Additional Observations Resources

Articles

1. Diaz-Navarraz T, Pronovost P, Beortegui E, Segui-Gomez M. Benefits of Direct Observation in Medication Administration to Detect Errors. J Patient Saf. 3(4): pp200-207

Guides

2. Oullet M, Rainville M, Bouchard LM, Belley C. Guide to Direct Observation of Community Safety. 2009. Government of Québec. http://www.inspq.qc.ca/pdf/publications/1005_DirectObservation_Vol12_eng.pdf

Book Chapters

3. Clancey WJ. Observation of work practices in naturalistic settings. In: A. Ericsson, N. Charness, P. Feltovich & R. Hoffman (Eds.), *Cambridge Handbook on Expertise and Expert Performance*. New York: Cambridge University Press, pp. 127-145.
<http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.89.9513&rep=rep1&type=pdf>

Chapter 5. Interviews, Focus Groups, and Surveys

Section 5.1. Setting the stage

Data collection through observation yields rich information about *how* people do things, but this insight only provides part of the story. It is also important to understand *why* a system has been set up, or things are being done, in a particular way. Understanding why from the subject's perspective helps to prevent you, the observer, from introducing bias by assigning your own assumptions to something you have observed. It is also important to help you learn about people's mental models, preferences, and knowledge, in the context of technology use. Sometimes observations do result in an understanding of *why* the system functions as it does; namely, if you have the time and freedom to talk with, and ask questions of the people you are shadowing. However, in reality this is usually difficult because those being observed are busy, with little time to answer questions at length. This is why it is a good idea to plan to collect data in a number of ways, from multiple subjects, including using methods like interviews, focus groups, and surveys.

Interviews, focus groups, and surveys are all qualitative data collection methods used to gather information from subjects by asking them questions. They are useful for gathering data about participant perceptions, user preferences, or knowledge about a process, task or organizational issue, and are often applied in conjunction with observations ([Chapter 4](#)). However, they do not always correlate with optimized user performance and improved patient safety. This dissonance is an established human factors phenomenon called the performance versus preference paradox, [28] which states that users do not always perform better with items they prefer. As a result, make sure to interpret user preference data with caution, and in conjunction with supporting user performance data. For more information about generating user performance data, see [Chapter 8, Usability Testing](#).

Interviews, focus groups, and surveys may be used to collect data that range from being exploratory to structured in nature, and can be carried out in person, by phone, or electronically. Data collection tools for these methods vary depending on the type of data being collected, and could range from a blank notebook and pen to a formal series of electronic survey questions with predefined responses.

While planning for data collection through interviews, focus groups, or surveys, the project objectives, target subject group, and available resources should be considered to ensure relevant data are collected. Identifying interested participants can be a challenge, and before conducting interviews and focus groups, especially, it is important to first contact the managers of the departments you would like to include as part of your data collection. Introducing yourself during a staff meeting can be an excellent way to inform

staff of upcoming interview or focus group opportunities to boost interest and participation. For surveys, consider working with a manager, contact person, or organization familiar to your target participants to enhance your credibility, help you reach as many interested parties as possible, and improve the chances of people completing your survey.

Section 5.2. Interviews

Interviews are meetings, usually conducted either in person or by phone, where a data collector obtains information from one or more participants. Interviews can range from being exploratory, or semi-structured, to structured in nature, with questions prepared in advance by the interviewer being either more specific or open-ended. Depending on the nature and purpose of the interview, the same participant may be interviewed once or multiple times, and the interview length could last from just a few minutes to several hours.

Section 5.2.1. Why use them?

Interviews are an excellent way to understand a person's perceptions, preferences, and knowledge, as related to their roles and responsibilities. In addition to getting information about why systems function in a particular way, interviews can also provide insight to challenges, opportunities, and solutions from the perspective of an individual participant. Interviews allow some flexibility to the data collector, as topics of interest can be further probed and explored in real-time based on the responses of the interviewee.

Conducting interviews with staff prior to observing in the field can help acclimatize you to what you are about to see in advance, which can streamline your observation sessions. Interviews are also a great way to build rapport with a staff member who you will be observing later. In contrast, conducting interviews with staff after observing in the field can support the development of interview questions and provides an opportunity to get clarification of items not fully understood during the observation sessions.

From the biomedical technology professionals' perspective, conducting interviews can be helpful for getting:

- An overview of how a clinical area operates (e.g., funding, staffing, layout, patient flow)
- Information about policies and prescribed work practices (i.e., how people are instructed to carry out their work)
- Information about a subject's perspective, preferences, and experiences
- Historical information about a particular technology, issue, or incident
- Confirmation and clarification about observational data that have been collected

Section 5.2.2. When should they be used?

Interviews should be conducted before observing in the field if an understanding of the environment is required, or if the biomedical technology professional wants to build rapport with a participant before observing them. Additionally, if any confirmation or clarification is required based on what was observed in the field, conducting an interview is highly recommended.

Section 5.2.3. Preparing for Interview Data Collection

Regardless of whether interviews are open-ended, semi-structured, or structured in nature, a preliminary list of questions should be developed to serve as an interview guide, to ensure all required information is obtained from a participant at a minimum. This is especially important if the participant only has a limited amount of time available for the interview. No matter whether interviews are meant to be open-ended, semi-structured or structured, individual questions should be open-ended to avoid biasing or leading the participant and to solicit as much information and context from them as possible. Try to familiarize yourself with the set of questions, and to organize them in the interview guide so you can easily jump around from one to another as the conversation evolves. Keep track of any questions that have already been answered, as well as any outstanding questions, so you can optimize your time during the interview.

Think also about your strategy for recording information during the interview. If possible, arrange to have a second person attend the interview so one person can facilitate the session while the other records detailed notes. If it is not possible to have two people present, consider other strategies to capture data, like taking short-form notes, or using an audio recorder to tape the session. If an audio recorder is preferred, ensure you have proper permission (e.g., see discussion of consent and research ethics approval in [Appendix A: Confidentiality and Anonymity](#)), and that the participant is aware of the recorder, and gives their permission, before recording any part of the session.

Arrange to conduct the interview at a time and location convenient for the participant. Provide the participant with any background information such as the purpose of the interview or objectives of the project, and answer any questions they may have about the interview process. If the participant asks for a list of questions in advance, try to give them a general sense of what you will ask, but it is usually not necessary to share the exact questions with the participant in advance.

Section 5.2.4. Conducting Interview Data Collection

Introduce yourself and the project to the participant if they are not already familiar with the purpose and goals of data collection. Ensure they are still willing to participate, and if required, have them sign a consent form ([Appendix A: Confidentiality and Anonymity](#)). Using the interview guide, ask the participant the questions you prepared in advance. Keep track of the questions that have been asked, as well as the participant's

responses, so that if the participant volunteers an answer to a question that has not yet been asked, you do not ask the participant to answer the same question again.

Record the responses of the participant in real-time, and in as much detail as possible. If detailed notes cannot be taken during the interview, immediately following the interview, write down the participants' responses, and any thoughts or impressions you remember.

After the interview, send a thank you note to the participant to let them know you appreciate and value their contribution to the project. If they are interested in learning how their input impacted the project, commit to sharing any outcomes with them.

Section 5.2.5. Limitations of Interviews

While interviews are useful for learning about staff perspectives, experiences, and preferences, they should not be considered reliable for learning about how staff complete their work in reality. Many factors affect human behaviour and perceptions, and so when subjects are interviewed about how, or how often, they do a task or interact with a device, although they may be recounting things to the best of their ability, there will sometimes be a mismatch between what is shared during an interview and what is observed in reality.

Another limitation of interviews is that the interviewer can unintentionally introduce bias depending on how questions are posed to the subject. When questions are leading (e.g. 'don't you think that x is better than y?') or prompt subjects to provide only "yes" or "no" answers (e.g., 'is x time consuming for you?'), the data yielded from interviews will not be very useful at all. To avoid introducing bias based on the wording of the interview questions, as the interviewer, try to keep questions open-ended (e.g. ask 'what happened?' rather than 'did x happen?'), and avoid bringing assumptions into your interpretations. To ensure you fully understood what the subject said, verbally summarize what you think they said and ask them if you have interpreted correctly.

Bias can also be introduced by the order in which questions are asked. Where possible, balance topics in the interview to minimize this effect.

Section 5.3. Focus Groups

A focus group is essentially a group interview, typically done in person, where a data collector obtains information from multiple subjects at once. A facilitator or moderator (who may also be the data collector) leads a focus group, and although the size of a focus group can vary from just a few participants to many, a group size of about six to eight is ideal [29]. A general set of questions to promote discussion among focus group participants is prepared in advance, but questions can also be added or modified in real time as required. A focus group is different from an interview not only in terms of the number of people participating, but also because the data generated during the session is synergistic:

participants share their own perspectives and preferences and listen to others' viewpoints, which may ultimately change their own.

Section 5.3.1. Why use them?

Focus groups provide an opportunity for the human factors practitioner to become exposed to multiple participant perspectives in a relatively short amount of time. Perspectives, preferences, challenges, and opportunities can be explored based on the experiences of the participants. When presented with an issue or solution, focus group participants are likely to share multiple perspectives, and if the session is well facilitated, to talk through those perspectives as a group. As participants agree or disagree on topics, a clearer understanding of the differences within and between user groups, and the variations in practices, preferences, and knowledge within and between the groups can be achieved.

Focus groups are a great way to involve staff from across the organization in a project, and to share information across units, specialties, or departments, that would not typically work together. Participation in a focus group tends to improve staff interest and motivation in supporting subsequent steps of a project, especially if a focus group has been done early in the project. The opportunity to have staff build off one another's ideas in a collaborative manner can be a very positive experience for everyone involved.

From the biomedical technology professionals' perspective, conducting a focus group will be helpful for getting:

- Exposure to multiple participant perspectives and experiences in a short amount of time
- A multidisciplinary team to think about, and collaborate on, a common issue or solution
- Consensus from a group of stakeholders about a particular issue or solution
- Buy-in for a strategy or solution, especially if focus group participants helped to shape it

Section 5.3.2. When should they be used?

A focus group should be conducted when a range of perspectives or experiences is desired, when a range of candidate solution are sought after, or when consensus or group buy-in are required.

Section 5.3.3. Preparing for Focus Group Data Collection

For a focus group to be fruitful, similar to preparing for an interview, a preliminary list of questions should be developed in advance to ensure the required information is obtained from the group. Questions should be open-ended to encourage discussion among group members.

If possible, arrange to have a second person attend the focus group so one person can facilitate the discussion while the other records detailed notes. Facilitating a focus group requires quite a bit of skill to ensure each participant has a chance to share their opinion if they wish, and to help keep the discussion on track to get the required information. If it is not possible to have two people present, as for an interview, consider other strategies to capture data like taking short form notes or using an audio recorder to tape the session if it is allowed and if all the focus group members consent.

Arrange to hold the focus group at a time and location convenient for the participants to attend. Consider bringing coffee, juice, and snacks for participants, especially if the session is scheduled to last for more than about an hour. Be prepared to have participants join and leave the focus group throughout the session, especially if it has been scheduled during working hours.

Section 5.3.4. Conducting Focus Group Data Collection

At the start of a focus group, introduce yourself and the objectives of the session. Roundtable introductions, or an icebreaker activity can be helpful in making participants feel more comfortable, especially if they do not all know each other. Using the questions you developed in advance, ask the group a question and listen to the discussion that follows. Record the discussion in real-time and in as much detail as possible.

Facilitating a focus group requires specific communication skills to ensure each participant's ideas and opinions are respectfully heard. It is important to show participants you are actively listening and interested in what they have to say. If there is a designated note taker, it can be helpful to project typed notes, or to write participant's perspectives on a chalkboard or chart paper so everyone can see what has been discussed and the group can ensure each participant's thoughts have been captured accurately. Using probing questions and clarifying what participants have shared can be helpful in encouraging further discussion among focus group members.

Depending on the dynamics of the group, you may have to solicit responses, especially at the beginning of the session, by asking individual people if they would like to share. Often as a focus group progresses, people become more and more comfortable in sharing their perspectives.

When one or two participants dominate a focus group, it is the role of the facilitator to ensure that all participants' ideas and opinions are respectfully heard, and that everyone has the opportunity to contribute if they wish. As a facilitator, try to solicit responses from all participants by asking specific people open-ended questions to give them an opportunity to share.

For additional information and guidance on conducting focus groups, see the *Toolkit for Conducting Focus Groups* resource included in [Section 5.6](#).

Section 5.3.5. Limitations of Focus Groups

When one or two individuals dominate a focus group, it will fail to provide the biomedical technology professional with a balanced, or consensus view of the group's experiences, perspectives, and preferences. To avoid this either involve, or take on the role of, an effective facilitator who encourages all group members to share their opinions. This can be challenging depending on the different personalities, reporting relationships and organizational culture of the group. Encourage having a single person speak at a time and ensure group members are respectful of one another. Try to avoid having a staff member and their manager in the same focus group because the staff member may feel uncomfortable speaking freely due to the presence of their boss.

Section 5.4. Surveys

Surveys are data collection tools, administered by a data collector, to obtain information from subjects. Surveys include a written set of questions, prepared in advance, to gather a range of pre-defined and open-ended responses from subjects. Surveys can vary in content, format, length, and delivery mechanism, depending on the purpose of data collection and the intended subjects.

Section 5.4.1. Why use them?

Surveys can be an efficient and cost effective means of collecting data about many participants' perspectives, preferences, and knowledge in a relatively short amount of time, without having to coordinate the schedules or locations of participants. Exploratory, or open-ended survey questions help the data collector to understand the range of experiences and preferences of participants, while more structured questions shed light on the perceptions and preferences of the majority of subjects. Depending on the survey design, standardized information across multiple survey respondents can be compared and quantified using statistical analysis.

Some staff members may prefer completing a survey to participating in other data collection methods like interviews or focus groups, because survey responses can remain anonymous and participants can take time to reflect before responding to a question.

From the biomedical technology professionals' perspective, conducting a survey will be helpful for getting:

- Demographic information about a group of participants
- Information about the level of experience of a group of participants
- An understanding of the range of perceptions, preferences, or knowledge of respondents

- An understanding of the perceptions, preferences, or knowledge of the majority of respondents
- Standardized datasets to conduct descriptive statistical analyses about participants' perspectives and preferences

Section 5.4.2. When should they be used?

Surveys should be administered when the perspectives, preferences, or knowledge of many people is desired, or when it is difficult to schedule participants for interviews because of their availability or geographical location. Exploratory questions should be used when a range of perspectives is desired, and structured questions should be used when a more standardized understanding of the average or majority of respondents is required.

Section 5.4.3. Preparing for Survey Data Collection

Survey questions should be prepared in advance regardless of whether the survey will be presented in paper or electronic format. Questions should be tailored based on the target participant group, and whether open-ended (exploratory) or closed-ended (structured) responses are desired. An example of an exploratory versus a structured approach to a survey question is included in [Figure 8](#).

Exploratory Question

Which smart pump feature(s) do you use the most frequently?

Structured Question

Of the smart pump features listed below, which do you use the most frequently? (Check all that apply)

- ☐ Drug library
- ☐ Rate calculator
- ☐ Body surface area calculator
- ☐ Bolus function

Figure 8. Comparison of an exploratory versus a structured survey question

As you can see, with the more structured question, participants are prompted to choose their answers from the supplied list, while the exploratory version leaves it up to the participant to think of the most correct answers from their perspective. The

exploratory question is likely to extract a wide range of possible answers from participants, while the structured question is likely to cause participants to home in on one or more of the options provided.

If a goal of your survey is to be able to analyze data using descriptive statistics, a more structured survey approach will be required. In this case, in addition to questions about the project objectives and content of interest, it is also recommended that structured questions about a person's gender, age range, experience level, and unit type or specialty be included to provide additional demographic context to survey responses.

When developing your survey, another important consideration will be how to keep track of respondents to ensure duplicate responses can be accounted for. This tends to be easier when participants' identities do not need to be kept confidential, as the respondent's name can be used as an identifier. However, when participant's identities must remain anonymous, other approaches to tracking respondents will have to be used. A possible approach is to link a confidential participant name to an anonymous participant identification number so a respondent's identity is not directly included on the survey. Another option would be to use an electronic survey tool, that limits the number of responses coming from a single computer to one, and includes features like customized survey links to help manage tracking multiple respondents. If you are concerned about receiving duplicate responses, an affidavit or declaration could be included at the beginning or end of your survey, stating that by checking the box, the participant confirms they have not completed your survey already. The rigour with which responses are tracked, and restrictions for including personal information or tracking numbers, will depend on your institution, your subjects, and the objectives of the project.

Before distributing your survey to participants, it is highly recommended you validate it through pilot testing with one or more representative end users to ensure it is clear and covers material that is relevant to your target participants. This is because when surveys are unclear, the data collected may not accurately reflect the opinions or experiences of participants. If you have a project contact person, reach out to them to see if they would be willing to review your survey or if they know of a colleague who might review your survey instead.

Section 5.4.4. Conducting Survey Data Collection

Once your survey form is complete and has been validated, participants can be invited to complete your survey either in person or electronically, depending on your target population and the number of people you hope will complete your survey. If you can arrange to invite participants to complete your survey through a familiar and trusted source, such as a clinical colleague, clinical manager, or recognized organization, it is often easier to get your target population to participate. Alternately, if you can inform

participants about your survey in person, such as during a staff meeting, you can answer any questions about the survey or the project, and potential participants will later know to expect your invitation to complete the survey.

Section 5.4.5. Limitations of Surveys

When surveys are used in isolation of other data collection methods like observations, or even interviews and focus groups, there is a risk that an incomplete picture of a subject's perspectives, perceptions, and knowledge will be collected. Unlike interviews and focus groups, where the data collector can rephrase questions or probe deeper on a subject in real-time, surveys are static data collection tools. If questions are confusing or easily misinterpreted, the data collected through a survey will not be useful to the biomedical technology professional, and may even be incomplete or incorrect. Testing the validity of a survey (i.e., how well the survey measures what has been set out to measure) is highly recommended to ensure you get the most out of your survey tool. Pilot testing your survey with a small number of representative users to get feedback about the survey design and to determine how respondents interpreted questions as they were posed is a good way to validate your survey.

Another limitation of surveys is that when used to collect information about past issues and incidents, it can be difficult to design them to capture the level of detail required to understand the real root causes and contributing factors of those issues and incidents. Consequently, the human factors practitioner should almost always interpret this type of survey data in conjunction with data collected from other sources.

Although subjects may be more comfortable answering survey questions than participating in an interview or focus group, it can still be difficult to get participants to complete a survey. Surveys are less likely to be completed by participants if they are:

- Too long
- Have little perceived value to the participant
- Distributed from an unfamiliar source (e.g., a person or organization that is unknown to the participant)
- Accompanied by too short or too long a timeframe to respond (2 weeks is usually appropriate as it allows time for people who are on vacation or not on shift for a few days).
- Saturated with too many surveys
- Not presented in a timely manner (e.g., surveys about particular equipment are best distributed immediately after their use)

Again, pilot testing your survey with a small number of representative end users in order to solicit feedback is a good way to gain insight about whether any of these rules of thumb have been violated.

Section 5.5. What to do with Interview, Focus Group, and Survey Data

The methods chosen to analyze interview, focus group, and survey data will partially depend on the type of data that was collected (e.g., structured versus semi-structured interviews), and the objectives of the project. Qualitative data analysis techniques, such as the constant comparative method [30] are commonly used to examine these data. However, as a health technology manager, interview, focus group and survey data will usually be linked with observational data, and used as an input to other human factors analysis techniques and methods like task analysis, usability testing, ^{HF}FMEA and ^{HF}RCA. The subsequent sections of Part II of this book will discuss these human factors methods in greater detail.

Section 5.6. Additional Interview and Focus Group Resources

Toolkit for Conducting Focus Groups:

<http://www.rowan.edu/colleges/chss/facultystaff/focusgrouptoolkit.pdf>

Chapter 6. Task Analysis

Section 6.1. Setting the Stage

Once data have been collected in the field, you will need a way to make sense of the data, and to share it in a meaningful way with others. Completing a task analysis can be extremely helpful in accomplishing both of these goals. Taking the time to package your data into a task analysis format is an effective way of systematically identifying any assumptions being held, or any gaps in your own understanding.

Section 6.2. What is Task Analysis

A task analysis is a data documentation and analysis tool used to document the specific tasks of a process, a workflow, according to its constituent steps. Task analysis essentially decomposes an activity into smaller steps to analyze the sequence, conditions and performance criteria for completing a task.

Many frameworks and approaches to task analysis exist, with a comprehensive review included in Kirwan and Ainsworth 1992 [31]. Observational, interview, focus group, and survey data can all serve as inputs for a task analysis. The output of a task analysis is usually a diagram and/or a description of the individual steps required to carry out a workflow or process to complete a defined goal. In turn, this diagram often becomes an input for other human factors methods like heuristic analysis, usability testing, ^{HF}FMEA, or ^{HF}RCA.

Section 6.3. Why use Task Analysis

A task analysis is an excellent way to consolidate data from multiple sources, such as through observations, or interviews, focus groups, and surveys, and can serve as a framework for linking artefacts and photographs collected in the field to specific parts of the processes related to the technology being studied. Organizing your data in this way will help you to identify any gaps or uncertainties in your knowledge to ensure you have a clear understanding of the work that is being undertaken by staff.

Completing a task analysis will encourage the biomedical technology professional to:

- Systematically think through the actions and thought processes required of a subject in order for them to achieve a defined goal.
- Consider the boundaries of the defined workflow or process, and the relationships among different tasks.
- Define the scope of a system, process or problem.

- Think about the order in which tasks are completed, the required and available information at each task step, and how a subject proceeds from one task to the next to achieve their overall goal.
- Identify the conditions (knowledge, tools, etc.) and performance criteria for successfully completing each task step and the ultimate task goal.

In the context of health technology safety, the goal of a task analysis is to assess whether the demands being placed on the users of a technology are within the normal range of human capabilities, and if there are risks (human factors or other) associated with any of the tasks that can be mitigated. All the tasks described above will support the biomedical engineering professional in developing recommendations for task design/redesign and developing more effective procedures and instructions for use. They will also serve as the backbone for further human factors evaluation methods.

In addition to serving as input for other human factors methods, the output of a task analysis is helpful for communicating your understanding of the system to others. Often when processes are displayed step by step, as in a task analysis, even those intimately familiar with the documented process are surprised at just how many discrete steps are involved. A task analysis can be a catalyst for simplifying a workflow or process because when viewed diagrammatically, you may see entire branches or sections of the diagram that are not required to achieve the system goal. Thus, task analysis can help you to identify opportunities to optimize how work goals are achieved, with the ultimate aim of providing safer and more efficient care.

From the biomedical technology professionals' perspective, completing a task analysis will be helpful for:

- Consolidating, and organizing data from observations, interviews, focus groups, and surveys
- Highlighting any gaps in your understanding of a workflow or process that require further data collection in the field
- Making complex healthcare processes, workflows, and user interactions with technologies more understandable by breaking them down into smaller, more manageable parts
- Informing other human factors methods like heuristic analysis, usability testing, ^{HF}FMEA, and ^{HF}RCA

Section 6.4. When to Use Task Analysis

After you have collected observational, and interview, focus group, and/or survey data from the field, it can be consolidated, organized, and documented using a task analysis. The output of a task analysis can be an excellent communication and collaboration tool, so

if you would like to share your data with others, or get confirmation or clarification about what you learned in the field, this form of documentation and analysis is highly recommended. A task analysis should be completed prior to conducting an ^{HF}FMEA, ^{HF}RCA, and if desired, prior to a heuristic analysis or usability test.

Section 6.5. In Preparation for a Task Analysis

In preparation for a task analysis, the biomedical technology professional should spend time observing in the field ([Chapter 4](#)) to collect data that will serve as the basis for the task analysis. If applicable, interviews, focus groups, and/or survey should also be completed to serve as additional data sources ([Chapter 5](#)).

Once data have been collected it is a good idea to revisit the objectives of the project to get you thinking about the purpose and scope of your task analysis. Next, a framework should be chosen. There are several task analysis frameworks available, and the one you choose will depend on the purpose of doing a task analysis. Of note are the Decision-Action Diagram, or Activity Diagram; Hierarchical Task Analysis (HTA); Cognitive Task Analysis; Critical Incident Technique; and Link Analysis. A comprehensive review of the various task analysis frameworks are included in Kirwan and Ainsworth 1992 [31].

For the purposes of this book a single task analysis framework will be presented: the process flow diagram. The process flow diagram is likely to be the most useful task analysis framework for a biomedical technology professional because it is a flexible means of describing a wide range of workflows and processes. Typically, process flow diagrams are comprised of standardized shapes and arrows that represent tasks, and the flow between tasks, respectively. They provide a means of documenting actions, decisions, information flow and activities. In terms of notation for a process flow diagram, the Unified Modeling Language (UML) 2.0 is recommended because unlike most other notations, this graphical language allows the analyst to document activities occurring in parallel, which is a common occurrence in healthcare. An example of the output of a process diagram is shown in [Figure 9](#).

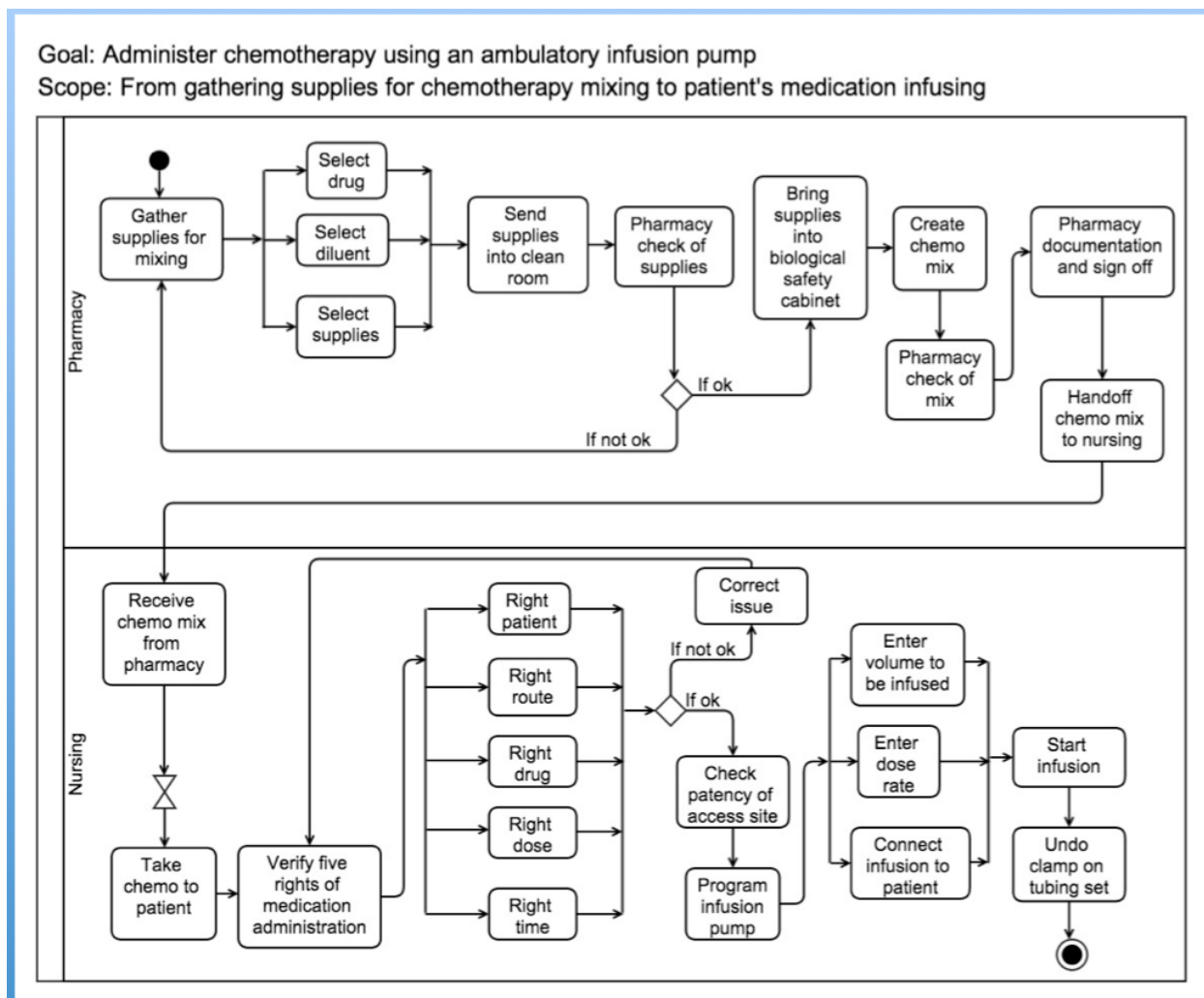


Figure 9. Example of a process flow diagram

In preparation for creating a process flow diagram, you will need to have access to the data collected in the field, including any notes, photographs and other artefacts, and either a large piece of paper and a pencil, or a computer program with diagramming capability. In terms of computer programs there are several options available, ranging from open source to professional suites. When selecting a computer program for your task analysis, ensure it can be used to create flowcharts. A program with a UML library is ideal because it allows you to easily drag and drop the boxes and arrows needed to represent the elements of a process flow diagram.

Section 6.6. Completing a Task Analysis

The first step when creating a process flow diagram is to define the goal and scope of the workflow or process being considered. Outlining the goal of the workflow will ensure the diagram covers the process of interest, especially when a process spans multiple clinical areas, and defining the scope of the workflow will provide the boundaries of the

diagram. In the case of the example in [Figure 9](#), the process goal is administering chemotherapy using an ambulatory infusion pump, and the process scope ranges from gathering supplies for chemotherapy mixing to the patient's medication infusing. Tasks that occur upstream and downstream of this scope (e.g., preparing chemotherapy order and discontinuing the pump after the medication is infused) are not included in the task analysis and are therefore not shown on the process flow diagram.

Determining what constitutes a task takes a bit of practice. One way to consider tasks is to think of them as a subject/verb/noun grouping. Essentially who does what action with/on what object. For example, a *nurse(subject) draws the diluent (verb) from the vial (noun)*. Some people may find it helpful to create a list of tasks in a tabular format before moving to a process flow diagram. [Figure 10](#) provides an example of what a task table could look like.

| Major Tasks | Sub-tasks | Conditions | Completion Criteria | Design | Instructional Consideration |
|--|-----------------------------------|--|---|---|--|
| 1. Pharmacy technician (PT) mixes Chemotherapy | 1.1 PT reviews chemotherapy order | 1. Order verified in electronic order system. 2. patient blood work is complete | 1. Blood work results are consistent with criteria for receiving chemotherapy | | 1. PT must know how to find blood work criteria for specific protocol ordered for the patient. |
| | 1.2 PT gathers supplies | 1. Containers for storing each patients medications are cleaned from previous use. | 1. All materials needed for the mix are in the storage container. | Baskets need separate compartments so bottles don't bang together | |

Figure 10. Tabular list of tasks and subtasks that help to organize information prior to creating a process flow diagram.

Each of the graphical symbols of a process flow diagram are described in this section and shown in [Figure 11](#). The starting point of the process flow diagram is the “initial node”: a box representing the first task in the process. From here, subsequent task steps are documented in boxes joined with arrows that indicate the sequence of the actions/decisions/information flow associated with the process goal and within the defined process scope. A “fork” and “join” are used in combination to indicate activities that may occur at the same time or in any order, with the stipulation that all activities must be completed before moving beyond the join. A “decision point” is indicated with a diamond, where only one of the available paths will be followed. To determine which path to follow

at a decision point, “decision criteria” are included to show the conditions under which that path should be taken. When either an elapsed time, or time to initiate an action is relevant, a “passing time” symbol is used. A “swim lane” is used to separate tasks that take place either in different clinical areas, or that are done by different people. Lastly, a “final node” is used to indicate the end of the process scope being diagrammed.

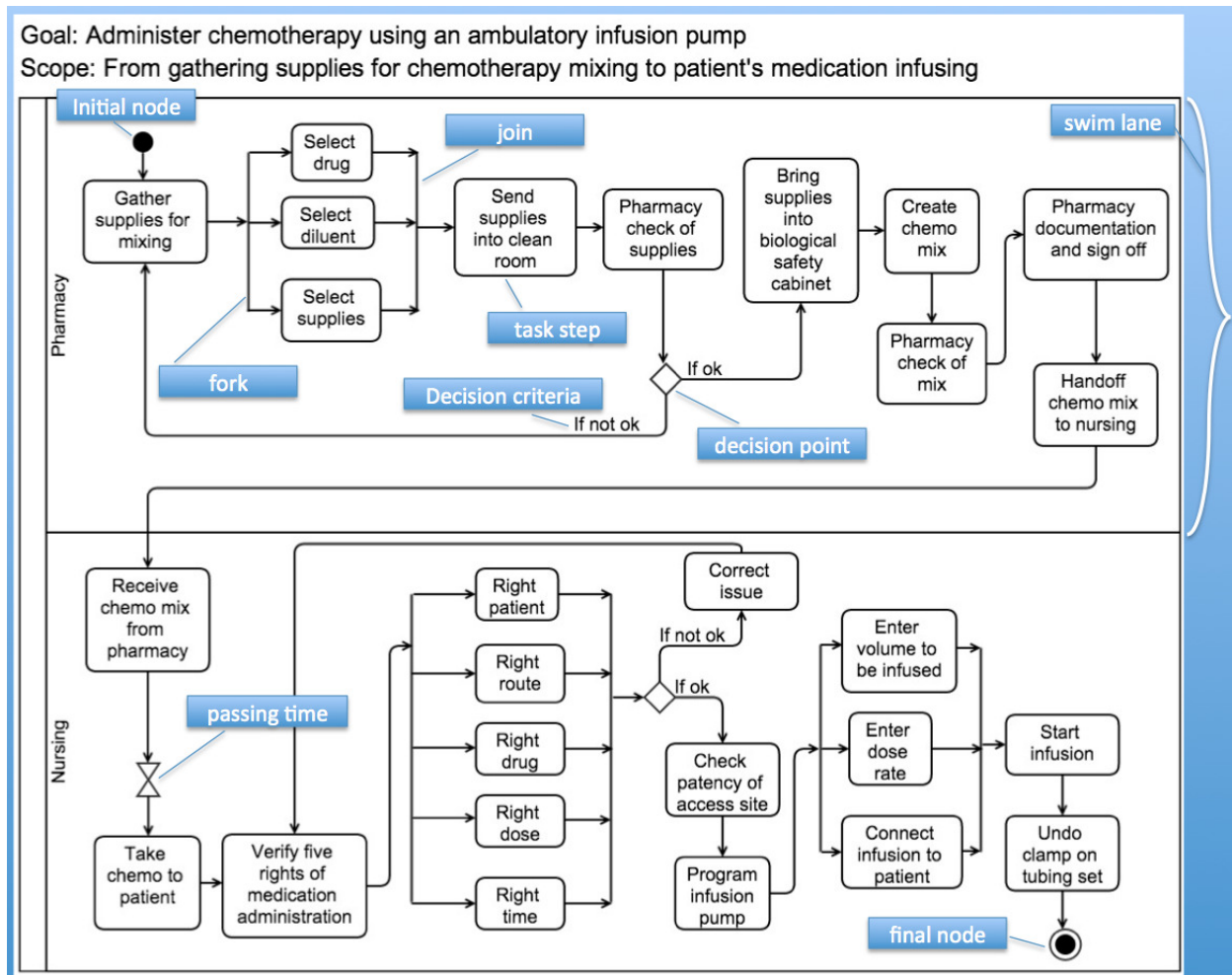


Figure 11. Process flow diagram with defined symbol types

As you work through adding nodes to the process flow diagram, refer to the data collected through your observations, or interviews, focus groups and surveys. If there is uncertainty surrounding a task step, it is important to make note of this and then to conduct targeted data collection activities to resolve the uncertainty and reflect the findings on the process flow diagram. Creating a process flow diagram is an iterative process, and it is normal to make a first draft of the diagram, to have gaps and questions about the process, and then to gather additional information to support an accurate diagram. One of the main challenges when creating a process flow diagram is knowing how much detail to include (see [Section 6.8](#) Limitations of Task Analysis). To assist in creating a

diagram at an appropriate level of detail keep in mind the purpose and resources available for the task analysis. Asking the question “does this task or sub-task fall within the defined goal and scope for this workflow” is another means of helping you to determine whether a task or subtask should be included.

Section 6.7. What to do with a Completed Task Analysis

A completed task analysis is required as an input to other human factors methods such as ^{HF}FMEA, ^{HF}RCA. It may also be used to help inform a heuristic analysis or usability test. Even if no further human factors analyses are to be conducted, a task analysis on its own can be an invaluable analysis and communication tool, especially to understand a process and to illustrate the complexity of a process to others. It can also inform development of procedures to compensate for poor design and is used to develop new processes when changing workflow or moving to a new building or workspace. Being able to see how different clinical units interface with one another adds a new and useful perspective.

Section 6.8. Limitations of Task Analysis

Although task analysis can be an extremely useful exercise, there are some limitations and common pitfalls to be aware of.

Section 6.8.1. The Time Investment Required

A task analysis is an iterative undertaking that requires several rounds of editing and updating as stakeholders review and provide feedback, based on their perspectives. It is important to include stakeholders who are involved in the process being documented as reviewers of your analysis and ask them to provide feedback to ensure your documentation is as accurate as possible. With practice, you will become more efficient at documenting and describing workflows or processes based on the data you have collected in the field.

Section 6.8.2. Knowing What Data to Include

A common pitfall when conducting a task analysis is knowing what data to include in the diagram or process description, both in terms of which content to include, and how detailed to be. This determination will partially depend on the content of the data you have to work with, as well as the goals of the task analysis, and project itself. Usually, actions that can be considered “constant” in that they would be required of any person in that role to achieve the defined goal, should be included in the task analysis. Actions that can be considered “context specific”, in that the subject you observed did something that was not related to the defined goal, should generally not be included in the task analysis. [Figure 12](#) includes an example for further clarification.

A nurse is preparing to administer chemotherapy to a patient using an ambulatory infusion pump, and you observe her do the following:

- Pick up the chemo from the pharmacy
- Talk with a nurse about another patient
- Take the chemo to the patient
- Verify the five rights of medication administration
- Answer a patient's question about side effects
- Check the patency of the patient's access site
- Program the infusion pump by entering the volume to be infused and the dose rate
- Connect to the patient
- Start the infusion
- Undo the clamp on the tubing set

You would want to include the following tasks in your task analysis:

- Pick up the chemo from the pharmacy
- Take the chemo to the patient
- Verify the five rights of medication administration
- Check the patency of the patient's access site
- Program the infusion pump by entering the volume to be infused and the dose rate
- Connect to the patient
- Start the infusion
- Undo the clamp on the tubing set

And you would want to exclude the following tasks from your task analysis:

- Talk with a nurse about another patient
- Answer a patient's question about side effects

The context specific tasks (talk with a nurse about another patient and answer a patient's question about side effects) should not be included in your task analysis because they do not directly lead to the process goal, of *administering chemotherapy to a patient using an ambulatory infusion pump* and thus would not have to be carried out by every person in this role.

Figure 12. Deciding what data to include as part of a task analysis

In terms of the level of detail to include, this will mostly depend on the purpose of the task analysis and the resources available. The larger the scope and more detailed the task analysis, the longer it will take to document. Not including enough detail in a task analysis, however, can lead to making assumptions about the process and a failure to

identify potentially problematic tasks, as well as possible opportunities for making improvements.

Section 6.8.3. Failing to Document the Actual Process

Another common pitfall with task analysis is failing to document the actual process followed by users of the technology, and documenting the ideal process instead. In healthcare it is common for work practices to change over time as a result of external time and cost pressures as well as changes to other components of the environment, and this means that people become creative and look for shortcuts, workarounds and new ways of accomplishing their goals. When a task analysis is completed for the ideal workflow or process, it often fails to capture the actual tasks that are being done, and it will not be an accurate, or useful description of what is truly happening in the field. A task analysis of the ideal process also limits its usefulness as an input for other human factors methods.

Additionally, there is often variability in how tasks are performed and this too needs to be captured in the task analysis.

For this reason it is extremely important to collect data using observations in the field rather than assuming staff are operating according to a policy or protocol. Although unintentional, it is common for people to describe what they do differently than how it is done in reality, because of limitations on memory and attention and cognitive biases ([Chapter 3](#)), and so interview, focus group, and survey data, although important, should always be supported by observational data prior to conducting a task analysis.

Section 6.9. Additional Task Analysis Resources

Articles:

- Human factors in anaesthetic practice: insights from a task analysis. British Journal of Anaesthesia 100 (3): 333–43 (2008)
<http://bj.a.oxfordjournals.org/content/100/3/333.full.pdf>
- [Vasilakis, C., Lecznarowicz, D., Lee, C., Application of unified modelling language \(UML\) to the modelling of health care systems: An introduction and literature survey. International Journal of Healthcare Information Systems and Informatics, 3\(4\), 39-52 \(2008\)](#)

White Papers:

- Embrey D, Task Analysis Techniques. 2000. Human Reliability Associates Ltd. Available at:
<http://www.cwsvt.com/Conference/Functional%20Assessment/Task%20Analysis%20Techniques.pdf>

Book Chapters:

- Fowler M, UML distilled third edition: A brief guide to the standard object modeling language: Chapter 1, Introduction. Third Edition ed., pp 1-16. Addison-Wesley, 2004

Books:

- Kirwan B, Ainsworth LK. A Guide to Task Analysis. London: Taylor & Francis, 1992

Human Factors Evaluation Methods



A Human Factors Engineer collects usability data on multiple intravenous infusion safety during a lab-based simulation with nurse from an intensive care unit.

Chapter 7. Heuristic analysis

Section 7.1. Setting the Stage

When a technology is poorly designed, it can lead people to make mistakes while interacting with it. In healthcare, this can be especially serious given the complexity of technology and what we need it to do. Many technologies in healthcare provide support life saving and supporting functions for complex patients with changing medical status. When this technology is poorly designed, it can be responsible for errors leading to patient safety events. Identifying technology designs, or aspects of design, that violate best practices for designing Human-tech[9] systems is a potentially life-saving undertaking. Heuristic analysis is one method by which technology design can be evaluated to determine whether users will find it challenging to operate.

Section 7.2. What is Heuristic analysis

A heuristic analysis is an analysis method whereby usability experts evaluate a design based on established “rules of thumb”. Historically, heuristic analyses were performed on human-computer interaction systems to evaluate software interfaces and determine whether such systems could be considered “usable”. Well-established guidance for designing good user interfaces has been developed by two leading experts, Nielsen, with his *10 Usability Heuristics for User Interface Design* [32] and Schneiderman with his *Eight Golden Rules of Interface Design* [33]. More recently, Zhang [34] combined and tailored these design principles into *14 Usability Heuristics* to facilitate the heuristic analysis of medical devices ([Table 1](#)).

During the analysis, design characteristics that violate one or more heuristics are identified. For each violation, the evaluator(s) identify what use problems will likely arise as a result of the violation and the potential impact of each use problem.

Table 1. Adaptation of Zhang et al's 14 Usability Heuristics for Medical Devices

| | | | |
|---|---|---------------------------------|---|
| Consistency & Standards | Users should not have to wonder whether an action or term is different than it was in a previous encounter. Standards and conventions in product design should be followed. e.g. color, font, capitalization, position, layout, sequences of actions, terminology, standards | Good Error Messages | Users should be provided with informative error messages in language they understand to allow them to learn and recover from errors. e.g. messages should be specific, clear, polite, constructive and in the language of the user |
| Visibility of System State | Users should know what is going on within a system based on feedback and information displays e.g. current system state, user options and possible actions, system acceptance or refusal of user input | Prevent Errors | The design and layout of the system should prevent users from making errors whenever possible. e.g. create interfaces that make user errors impossible, avoid text wrapping, design to account for common slips and mistakes |
| Match Between System & World | The mental model users maintain of the system should match the way the system is laid out and operates e.g. actions and options provided by system should match actions performed by user | Clear Closure | The system should clearly indicate to users when tasks have been started and ended and when goals have been achieved. e.g. clear feedback that goals have been achieved and that goal stacks can be released |
| Minimalist | Extraneous information should not be included in the system. Design should be streamlined to include only the information that is relevant. e.g. provide information tailored to a specific process step rather than more abstract or general information | Reversible actions | The system should allow users to undo actions to recover from errors, and to learn from these errors. e.g. When users perform a task with multiple steps, they should be able to go backwards as desired to change an action or outcome |
| Minimize Memory Load | Users should not have to remember information to carry out subsequent tasks. Recognition rather than recall is preferred. e.g. use a drop down list rather than an empty field that needs to be filled in | Use Users' Language | The system should always make use of language that is clear to the intended users. e.g. standard meanings of words, specialized language for specialized groups, language from the user's perspective |
| Informative Feedback | The system should provide informative and timely feedback in language that users can understand so users can progress through the system. e.g. concrete, specific feedback that takes the user's experience (i.e. novice vs expert) into account | Users in Control | Users should feel they are in control of the system. Users are initiators and not solely responders to actions. e.g. avoid tedious, surprising or unexpected actions and outcomes |
| Flexibility & Efficiency | The system should support a variety of users through customization and shortcuts so experts can accelerate their performance and novices can learn and improve. e.g. shortcuts, macros, history, abbreviations | Help & Documentation | The system should support the user by providing help and documentation, at the time it is needed, and in the language of the user. e.g. context specific and organized in a way that users expect, such as being searchable or listed alphabetically |

J Zhang et al. *Journal of Biomedical Informatics* 36 (2003) 23-30

Section 7.3. Why use Heuristic analysis

A heuristic analysis can be used to quickly identify usability issues with a technology that could have potential safety implications for patients and staff. Heuristic analysis is often preferred because it requires relatively few resources to identify design issues in comparison to many other human factors methods, such as usability testing.

From the biomedical technology professional's perspective, completing a heuristic analysis will be helpful for:

- Evaluating whether a technology design violates established best practices, which could increase the chance of a use error, and have a negative effect on patient safety
- Comparing the design of two similar technologies
- Predicting the types of use errors likely with a particular device design
- Suggesting device design improvements to vendors to make their products safer for your patients and other hospitals

Section 7.4. When to use Heuristic analysis

A heuristic analysis should be included as part of every technology procurement process. Before selecting a technology for implementation at your healthcare institution, it is crucial to ensure the device will not promote use error as a result of the way it has been designed. Having a sense of the design issues associated with a technology before choosing to implement it can help you to make a more informed decision, especially in the event you are comparing similar products. If several products are being considered as part of a procurement process, a heuristic analysis can help in reducing the total number of products that move forward as part of the procurement process, provided specific usability criteria are outlined in the request for proposals (see [Chapter 11](#) for more on human factors in procurement). If heuristic violations are identified in advance of a procurement decision you may have some leverage to suggest improvements to the vendor, and your healthcare institution has the opportunity to identify other types of mitigating strategies that can be implemented from within the organization.

After a near miss, or adverse event, heuristic analysis can be used to determine whether any design features of the device may have contributed to the incident. If a heuristic analysis does uncover design issues, immediate action should be taken to prevent a similar incident from happening to someone else. When it comes to issues with technology design it is important to note that training people to overcome poor design is not effective. For more information about the effectiveness of different mitigating strategies, see [Section 3.5](#).

Finally, if you ever design technology solutions as part of your role as a biomedical technology manager, having someone else conduct a heuristic analysis on your design provides an excellent opportunity to minimize use error as a result of a heuristic violation. Heuristic analysis done early in a *user centred design* process can streamline the development of your solution while ensuring it will meet user needs.

Section 7.5. In Preparation for Heuristic analysis

Section 7.5.1. Become Familiar with the Device

In preparation for a heuristic analysis, you should first become familiar with the technology by interacting with it to learn about its purpose, settings, screens, modes of operation, and any interfacing components.

In addition to learning about the device itself, it will also be important to understand the tasks that will be carried out with the technology. If the technology to be evaluated is already used in the field, it is highly recommended that observations and interviews be completed to learn about how it is typically used. If the device is not presently used in the field, try to observe and interview staff using a device having a similar purpose to the technology of interest, or try to observe in a different environment (e.g., another facility) where the device is currently being used. This information will be important for outlining a list of tasks that assessors will walk through as they complete their heuristic analysis. In addition to observation, reviewing the product manual and instructions for use is helpful for understanding the intended capabilities of the product. Doing this before observations will allow you to look for evidence of which features and functions of the device are utilized when you are conducting observations.

Section 7.5.2. Create a Task List

Using the observations and any interview data, create a step-by-step list or description of the tasks that are carried out with the technology. The tasks should include all tasks performed by all user groups, especially any safety critical or worst case scenario tasks. It is recommended that observations ([Chapter 4](#)) be conducted to support the development of the task list. If there is more than one user group of the technology, make sure to include all the tasks done by each unique user group as part of your task list. This task list will be used to guide each evaluator step-by-step through their heuristic analysis. It is important to consider the full range of tasks in the heuristic analysis since it is much easier to do so with this method than other human factors evaluation methods such as usability testing.

Section 7.5.3. Identify Your Evaluators

Once you are familiar with the technology to be evaluated and the tasks that are commonly performed, you will want to identify your evaluators. Ideally, people having knowledge of both the work being performed and human factors should be included as

evaluators for a heuristic analysis. However, if this is not possible, a combination of evaluators with either one of these areas of expertise can be included instead. Try to provide your evaluators with some time to familiarize themselves with the usability heuristics and severity rating scheme prior to conducting an analysis. If possible, have inexperienced evaluators practice applying the usability heuristics and severity rating scheme to a different device or object prior to carrying out the technology evaluation. Usually between three and five people should independently complete a heuristic evaluation to identify as many usability issues as possible given the objectives and resources available for your evaluation [35].

Section 7.5.4. Develop a Severity Rating Scale

The aim of the evaluation is to identify design issues that have the potential to result in safety and usability problems. For each safety and usability problem identified, a severity rating should be assigned to help identify the high priority issues and to help facilitate a comparison across products, if the analysis is being done to support a comparative evaluation. [Table 2](#) shows a severity rating scale that was adapted based on Zhang et al's work. However, each heuristic analysis should include the development of a rating scale that most appropriately categorizes the types of risks encountered for the technology being evaluated. [Table 3](#) shows a severity rating scale that incorporates both safety and usability concerns and is divided into only 3 severity categories: low, medium and high.

Table 2. Severity scale adapted from scale presented in Zhang et al (2003).

| Severity | Description |
|----------|--|
| 0 | Not a usability problem. No fix required. |
| 1 | Cosmetic problem only. Need not be fixed unless extra time is available. |
| 2 | Minor usability problem. Fixing this should be given low priority. |
| 3 | Major usability problem. Fixing this is important and should be given high priority. |
| 4 | Usability catastrophe. Fixing this is imperative and must be done before product can be released. |

Table 3. A severity rating scale that incorporates both usability and safety concerns.

| Severity | Description |
|----------|--|
| 1 | Low Severity: An issue that may be mildly frustrating to the user. |
| 2 | Medium Severity: A serious issue that may be very frustrating to the user and/or makes it difficult for the user to complete the task correctly and efficiently. |
| 3 | High Severity: A critical issue that may be highly detrimental to the user's ability to interact with the system and/or has potential for causing patient harm. |

Section 7.5.5. Prepare an Evaluator Reference Sheet and a Data Collection Template

Prepare a reference sheet for each evaluator that provides them with the framework for the analysis. This should include the following:

- A list of the 14 usability heuristics and definitions.
- The severity rating scale.
- The list of tasks they should perform to guide their interaction with the technology as they look for issues.

In addition to a reference sheet, evaluators should be given a template to record their findings, especially in the event an isolated heuristic analysis approach is desired, to ensure each evaluator provides adequate detail as part of their analysis. These materials should be given to the evaluators in advance so they have time to get familiar with them before the evaluation. Consider including space for assessors to provide four key pieces of information for each usability problem:

1. Where the usability issue occurred in the interface

When assessing a software component of the technology, this would be the screen where the violation exists. When assessing a hardware component of the technology, it is the physical location where a violation exists.

2. A description of the usability problem

For either a software or non-software application on a technology, a description of the violation in words to help differentiate between similar violations uncovered through the heuristic analysis.

3. A description of the potential consequences of the issue (if known)

A description of the potential impact of the issue on the user. For example the issue “it is not clear what the menu option ‘loading dose’ means” may have the impact “users may not be able to figure out how to administer what they refer to as a ‘bolus dose’ causing a delay in administering pain medication to the patient”.

4. The violation code for the usability problem (optional)

Including space for assessors to provide the number and letter combination representing the type of violation found is optional. In some cases, assessors may find usability issues that are not overtly included in [Table 1](#), so if you do provide space for the assessor to write the violation code, ensure they are aware they should still include any violations identified that are not specifically listed in the table.

5. The severity of the usability problem

The severity rating assigned to each violation based on the severity rating scale developed for the analysis.

A sample template to collect these four key pieces of information is shown in [Table 4](#).

Table 4. Example of a data collection template for evaluators

| Violation Code | Location of Usability Issue | Description of Usability Issue | Description of Potential Consequences | Severity Rating |
|----------------|-----------------------------|--|--|-----------------|
| 1b | Starting screen | Use of colour (red and green may be difficult to see if colour blind) | User may select wrong folder | 3 |
| 1d | | Multiple fonts/inconsistent font use on screen | User interprets fonts to have an implied meaning when they do not. Frustrating to users. | 2 |
| 2a | | Unsure of system state (not sure if system is starting up on its own or if it is waiting for an input from me) | User presses buttons while waiting and makes selections on the next screen without knowing what they have selected | 2 |
| ... | ... | ... | | ... |
| ... | ... | ... | | ... |

It is not necessary that a numeric score be allocated. Depending on the purpose of the heuristic analysis and how well the implications of the issues are understood, a

qualitative rating such as high, medium, and low severity (establish definitions for each that are relevant to the technology being evaluated) can be used. The benefit of a qualitative severity rating scale is that it reduces the likelihood that decision makers who are considering the results of the heuristic analysis (i.e., in a technology selection decision) will place a greater emphasis on the heuristic analysis results since than results from other human factors methods (e.g., usability testing) because it is easier to compare quantitative data than qualitative data.

Section 7.5.6. Decide on the Format for Heuristic analysis

A heuristic analysis can be organized in one of two ways: either the evaluator completes their evaluation in isolation; or the evaluator completes their analysis during a facilitated session while the facilitator observes the evaluator completing tasks and notes any issues, concerns, and preferences identified by the evaluator and later finalizes the evaluation by coordinating the observations with the heuristics. When assessors complete a heuristic analysis in isolation, it can help to reduce opportunities for unintentional bias to be introduced, including through interaction with the facilitator. Compiling information about violations and observations from each assessor, however, can be more resource intensive for the person in the facilitator role. When assessors complete a heuristic analysis during a facilitated session it may be easier for the facilitator to compile information about violations and observations because of the additional context provided by seeing evaluators go through each task. It is more likely however, that bias would be unintentionally introduced through interaction between the facilitator and evaluators. The approach you use will likely depend on the project objectives and resources available. Additional information about selecting an approach can be found in [Nielsen's How to conduct a heuristic analysis](#) ([Section 7.9 Additional Resources](#)).

Section 7.6. Completing a Heuristic analysis

For either an individual isolated heuristic analysis or a facilitated session, ensure the evaluator has all the information they need, as well as access to the technology being evaluated. Each assessor should use the reference sheet with the 14 usability heuristics and severity rating scheme, along with the task list, and data collection sheet to independently evaluate the technology design. Any violations or observations should be recorded on the data collection sheet by the evaluator or the facilitator, depending on how the heuristic analysis has been set up.

The evaluator should go through at least two rotations of the task list; first to become familiar with the device and to indicate any initial impressions and/or violations, and a second time to identify any violations that may have been missed during the initial review.

When describing the consequence of a violation or problem, it is important to do so in relation to the goals or the purpose of the technology. For example, if an intravenous infusion pump is being evaluated, its purpose is to support the administration of the correct: medication, dose, rate, route, time, etc. So the consequences of the issues identified should be identified in terms of their impact on these functions (e.g., wrong dose (too high), wrong dose (too low), delay in medication administration, etc), unless they are general ease of use issues in which case the consequence may be user frustration. Describing consequences in terms of the goals or purpose of the system makes it easier to assign severity ratings since the severity rating should be the same for all issues resulting in the same consequences.

Section 7.7. What to do with a Completed Heuristic Analysis

The goal of a heuristic analysis is to produce a single report that outlines all the issues identified, their potential consequences and the severity of those consequences to support one or more of the following aims:

6. To identify whether a health technology is likely to be safe and easy to use, provided there is a good fit between the device and the context of use (fit needs to be assessed using other methods such as usability testing)
7. To compare the relative safety and usability of two or more products

It is important to keep in mind that the primary focus of a heuristic analysis is on identifying and describing the issues, rather than identifying the correct heuristic violation that is causing the issue. The heuristics are a means to identifying issues, not the issues themselves.

Once each evaluator has completed their heuristic analysis, all the data must be collated into a single list of issues with a consequence description and a severity score assigned to each issue. This process is most efficiently done if one person inputs the data into a single spreadsheet and then all the evaluators come together to discuss each issue until the following is established:

- The usability problem description is clear and unique from all others
- The consequences are stated in terms that relate to the goal or overall function of the technology
- A single severity rating is assigned. Note, if consensus cannot be reached, you may want to use the weighted average of each evaluators score.

Once severity ratings have been determined for each usability issue, the data collection spreadsheet should be organized so the most severe violations are highlighted. Generating a list of recommendations or proposed actions to address each severe violation may be helpful depending on the context of the heuristic analysis. If possible, those violations found to be severe should be addressed immediately according to the identified recommended actions.

If the heuristic analysis has been done to either proactively or retrospectively identify whether an in-house technology has usability issues, concerns that have been identified with the technology design should be addressed. As stated in [Section 7.4](#), it is important to note that training people to overcome a violation in design is better than doing nothing, but is not a very effective solution. Similarly reliance on warning decals will not effectively mitigate the issues. If device-oriented changes are possible they will be more effective. Also, system changes that help to minimize the likelihood, and severity and/or improve detectability are recommended. For more information about the effectiveness of different mitigating strategies, see [Section 3.5](#).

If the heuristic analysis has been done for procurement purposes, the results of the heuristic evaluation can be used to determine whether any of the contending devices should be eliminated early on in the selection process as a result of any unfixable, catastrophic design flaws that have been identified before usability testing is done.

Section 7.8. Limitations of Heuristic Analysis

Although heuristic analyses are extremely useful for identifying usability issues with a technology, there are also several limitations to consider.

Section 7.8.1. Informal Evaluation Method

A heuristic analysis is not a systematic method, and is limited in that the only usability issues that will be detected are those encapsulated by the heuristics themselves. If a particular device design issue falls outside of the 14 heuristics, it is unlikely to be identified through a heuristic analysis. Further, assigning a severity score to each usability issue tends to be a subjective exercise. For these reasons, a heuristic analysis is generally considered to be an informal evaluation method.

Section 7.8.2. Multiple Assessors Are Required

Having a single assessor conduct a heuristic analysis will not uncover all the usability issues with a technology design. Since people have their own unique perspectives and experiences, different people will uncover different usability issues as they interact with a technology. Increasing the number of assessors, therefore, will increase the proportion of usability issues identified through a heuristic analysis. According to Nielsen, a single evaluator is likely to uncover only about 35% of the usability problems with a

technology design [35]. When the number of evaluators is increased to five, however, you can expect about 75% of the usability issues to be identified.

The relationship between the number of assessors and the proportion of usability issues identified is not linear, and so only minimal benefit will be seen as the number of evaluators is increased from five, to ten or 15. For this reason, and to help control costs, as a guideline it is recommended that between three and five evaluators be included when completing a heuristic analysis. Another possible approach would be to stop evaluating the technology once issue saturation has been reached, whereby subsequent independent assessors are not able to identify any more unique design issues. When evaluators uncover very different issues, and there is little consistency or overlap among the heuristic violations found, this is a key indicator that additional evaluators should be included. Results from a heuristic analysis should be treated with caution if there is little consistency in terms of issues found among those evaluating the technology or system..

Section 7.8.3. Experienced Assessors Should be Involved

Ideally, usability experts, such as human factors professionals, should carry out heuristic analysis because they are trained to see issues that violate best practice design principles. Additionally, subject matter experts (e.g., clinicians) should be included for their understanding of the processes that will be undertaken with the technology being evaluated. Pairing a usability expert and a subject matter expert for each evaluation can be an effective means of identifying a wider range of issues from each evaluation. If non-usability experts will be involved instead, it is recommended that prior to undertaking a heuristic evaluation, you dedicate some time to becoming familiar with and practicing how to apply the 14 heuristics to different devices. For less experienced evaluators, you may also want to consider including even more evaluators in an assessment than you would for experienced evaluators in order to improve the likelihood of uncovering usability issues.

Section 7.8.4. Technology is Evaluated in Isolation

Another limitation of a heuristic analysis is that the assessment is typically done on a technology in isolation, without considering the users, processes, or environments where that device will be used. As a result, some usability issues may only come to light once the technology is considered in the context of the system of use. For example, when evaluating an infusion pump in a well-lit office, a usability expert may not detect any issues with the contrast between the text and background, but when nurses use that same pump at night in the ICU, the text is found to be quite difficult to read. To help overcome these challenges, in addition to a heuristic analysis, usability testing is also highly recommended.

Section 7.9. Additional Resources

Journal Articles

- Using usability heuristics to evaluate patient safety of medical devices” by Jiajie Zhang et al.: Journal of Biomedical Informatics, 2003. 36: p. 23-30.
- “Human factors engineering: A tool for medical device evaluation in hospital procurement decision-making” by Gill Ginsburg: Journal of Biomedical Informatics, 2005. 38(3): p. 213-219.

Websites

- The Nielsen Norman group for heuristic assessment

<http://www.nngroup.com/articles/how-to-conduct-a-heuristic-evaluation/>

Chapter 8. Usability Testing

Section 8.1. Setting the Stage

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

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

Section 8.2. What is Usability Testing

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

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

Section 8.3. Why Use Usability Testing

No matter how closely biomedical technology professionals, human factors experts, or end users inspect a technology or process, they will never be able to identify all the possible problems and potential use errors that could occur. Often, this is because a device evaluated in isolation only provides a glimpse into the gamut of possible usability issues. It is not until the device is in the hands of the end user, who is carrying out realistic tasks and scenarios in a representative environment, that a truer picture can be seen. Similarly, no matter how many people’s thoughts and opinions are collected about a new technology or system change, it will never be adequate to form the basis of a meaningful decision. This is

because despite our best intentions, we are quite limited in our ability to reconcile our preferences and performance, often preferring products or changes leading to poorer performance (see Performance versus Preference Paradox [Section 5.1](#)).

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

Section 8.4. When to Use Usability Testing

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

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

Section 8.5. Preparing for a Usability Test

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

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

- Test tasks
- Test scenarios
- Test scripts
- Participant introduction
- Participant training
- Survey design

- Data documentation tools
- Test space setup
- Technology customization
- Pilot testing
- Participant recruitment

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

Section 8.5.1. Identifying Tasks to Include in a Usability Test

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

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

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

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

- Observation data,
- Focus groups, interview and survey results,
- Heuristic analysis results
- Past incident data (both from your own organization and other organizations that publish incident data).

Depending on the testing time available for each participant (should not exceed 3 hours), the set of tasks included in the scenarios may need to be trimmed based on the relative priority of each task (e.g., how safety critical the task is, how ubiquitous the task is, or how problematic the task is expected to be based on the results of other human factors methods, such heuristic analysis).

Section 8.5.2. Designing Usability Test Scenarios

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

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

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

- who the user group is,
- their goals associated with the technology,
- the tasks they would have to perform to achieve each of those goals,
- any supplemental or supportive equipment that would be required, and what environment(s) those tasks are completed in.

| | |
|-----------------------------------|---|
| Technology being procured: | - smart infusion pumps |
| User group: | - nursing |
| Goals: | - deliver medication to patients safely in order to improve their condition |
| Tasks: | <ul style="list-style-type: none"> - check medication order (<i>safety critical</i>) - complete positive patient identification (<i>safety critical</i>) - ensure patient has access - attach line to bag - hang bag on pole - check patency of patient line - turn pump on (<i>modified</i>) - choose clinical area (<i>new</i>) - go into drug library (<i>new</i>) - find drug in library (<i>new</i>) - confirm drug selection on pump matches medication order ... |
| Equipment: | - smart pump, infusion pump pole, IV bags, tubing, chair/bed, mock patient, medication order, ... |
| Environment: | - intensive care units, outpatient, chemotherapy daycare, emergency department |

Figure 13. Example of a summary sheet for a usability study of electronic smart pumps.

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

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

- Planted errors (optional)

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

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

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

(1) Accounting for different user groups

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

(2) Enhancing realism and reducing participant fatigue

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

provides participants with a chance to take a quick mental break and recharge before starting with the next set of tasks.

Scenario 1

User Group: ICU nurses

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

Environment Setup:

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

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

Initial Settings:

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

Tasks (in order):

Patient 1:

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

Patient 2:

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

Planted Errors:

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

(3) Counterbalancing to minimize learning effects

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

In addition to counterbalancing the scenarios, the planted errors within the scenarios should also be counterbalanced to minimize learning effects.

Section 8.5.3. Designing Usability Scripts

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

An excerpt of a usability script for the example in [Figure 14](#) is in [Figure 15](#) below.

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

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

[Participant] “Yes”

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

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

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

| | |
|---------------|--------------------------|
| Order: | Drug name: Ceftriaxone |
| | Concentration: 1 g/10 mL |

| | |
|---|--|
| | Order: 2 g in 100 mL NS, infuse over 2 hours |
| Programming: | Rate: 50 mL/h VTBI: 100 mL Duration: 2 hours |
| Participant: | Read medication order Verify the five rights Hang ceftriaxone Select intermittent (i.e., secondary) infusion Enter drug library Select ceftriaxone Program pump: Rate = 50 mL/h, VTBI = 100 mL Connect to the port above pump |
| [Nurse Actor] “Alright, that’s great! Thanks for your help with that. Come on over here and I’ll introduce you to Mrs. Sillian”... | |

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

Section 8.5.4. Designing Data Documentation Tools

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

When using a computer, the ability to add a time stamp of when each task is performed (or when difficulties were experienced) can be very useful, especially for

determining the order of tasks, and how long various tasks took participants to complete. Some spreadsheet computer programs provide keyboard shortcuts that allow you to capture a time stamp in a spreadsheet cell. Depending on the number of participants and the purpose of your usability test, you may want to have a single data documentation sheet per participant, or you may want to have a single spreadsheet for all participants.

An example of a data documentation spreadsheet can be found in [Table 5](#).

Section 8.5.5. Setting up the Testing Space

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

Section 8.5.5.1 Simulation Lab

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

Section 8.5.5.2 Unoccupied Clinical Environment

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

Section 8.5.5.3 Empty Office, Room, or Hallway

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

Section 8.5.6. Recording the Session

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

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

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

Section 8.5.6.1 Other Set-up Considerations

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

- A designated space for participants to store their belongings (e.g., phones, bags, drinks)
- A separate area for participant training if training and usability sessions will be happening for different participants at the same time

- Pens, paper, and a calculator for participants if there are any calculations or surveys included in your usability test

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

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

Section 8.5.7. Customizing the Technology

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

Section 8.5.8. Creating a Participant Introduction

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

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

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

A sample introduction text is shown in [Figure 16](#), based on the usability scenarios and script in [Figure 15](#).

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

General Introduction

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

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

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

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

Do you have any questions so far?”

Explanation of the Informed Consent Process

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

Explanation of the Usability Testing Process

“Thanks for completing the consent form. Now I’ll give you an overview of how this usability test has been set up. We will be testing two different smart infusion pumps today, and for each of those pumps, we’ll go through four main steps. First I’ll provide you with training on the pump, then I’ll ask you to fill out a survey about your experience and training related to smart

pumps, thirdly you'll be guided through a series of clinical scenarios with the pump, and finally, I'll ask you to complete a survey to share your thoughts and any comments about the smart pump. Then we'll repeat those four steps again for the second smart infusion pump.

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

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

Do you have any questions?"

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

Section 8.5.9. Designing Training

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

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

Although training is meant to be comparable to vendor training, a vendor should not provide it. This is because a vendor may not provide all the required information consistently across all participants and may not provide training specific to the tasks of the usability test. Ideally, when developing training materials for a usability test, the biomedical technology professional, or usability test facilitator, would receive training from

the vendor, and then develop a training program for the usability testing that is comparable in length and breadth and includes all the content necessary to carry out the tasks of the usability test. If participants are already quite familiar with the specific technology or system change being tested (e.g., it is already in use on their unit), training may not be required at all.

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

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

Section 8.5.10.1 Pre-Usability Test Survey

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

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

Gathering information about the level of background knowledge is also helpful in understanding the baseline understanding of participants related to the technology or system change being tested, especially if your test group of participants is representative of the general population. Conducting this survey prior to the training session, and then observing as participants complete each scenario after the training session can help to establish the effectiveness of the training. If several participants do not gain the knowledge required to complete the test scenarios through the training session, it can either point to a need to revise training content and delivery, or to design issues with the technology being tested.

| Demographics | Knowledge and Experience |
|---|--|
| <p>1. What best describes your role in the hospital?</p> <p><input type="checkbox"/> Registered nurse, full-time</p> <p><input type="checkbox"/> Registered nurse, part-time</p> <p><input type="checkbox"/> Other: _____</p> | <p>1. Do you know what a smart pump is?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> |
| <p>2. What is your age?</p> <p><input type="checkbox"/> 18-29 years old</p> <p><input type="checkbox"/> 30-39 years old</p> <p><input type="checkbox"/> 40-49 years old</p> <p><input type="checkbox"/> 50-64 years old</p> <p><input type="checkbox"/> 65 years old and over</p> | <p>2. Have you ever used a smart pump before?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not sure</p> |
| <p>3. How long have you been a registered nurse?</p> <p><input type="checkbox"/> Less than a year</p> <p><input type="checkbox"/> 1 to 4 years</p> <p><input type="checkbox"/> 5 to 9 years</p> <p><input type="checkbox"/> 10 to 20 years</p> <p><input type="checkbox"/> More than 20 years</p> | <p>3. What is a smart pump hard limit?</p> <p><input type="checkbox"/> A hardware feature meant to restrict programming parameters that fall outside of a safe window</p> <p><input type="checkbox"/> A hardware feature meant to verify whether users want to program the pump using the parameters they have chosen</p> <p><input type="checkbox"/> A software feature meant to restrict programming parameters that fall outside of a safe window</p> <p><input type="checkbox"/> A software feature meant to verify whether users want to program the pump using the parameters they have chosen</p> <p><input type="checkbox"/> Not sure</p> |
| <p>4. Which unit(s) do you typically work in (check all that apply):</p> <p><input type="checkbox"/> Outpatient</p> <p><input type="checkbox"/> ER</p> <p><input type="checkbox"/> OR</p> <p><input type="checkbox"/> NICU</p> <p><input type="checkbox"/> PICU</p> <p><input type="checkbox"/> SICU</p> <p><input type="checkbox"/> PACU</p> <p><input type="checkbox"/> Other: _____</p> | <p>4. Have you ever received training about how to use a smart pump?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not sure</p> |
| <p>5. How long have you been working in your current clinical area?</p> <p><input type="checkbox"/> Less than a year</p> <p><input type="checkbox"/> 1 to 4 years</p> <p><input type="checkbox"/> 5 to 9 years</p> <p><input type="checkbox"/> 10 to 20 years</p> <p><input type="checkbox"/> More than 20 years</p> | <p>5. In general, what is your preferred method to learn about how to use a new medical device? (rank options from 1 to 6, with 1 being most preferred, and 6 being least preferred)</p> <p><input type="checkbox"/> Read about the device</p> <p><input type="checkbox"/> Attend a hands on demonstration</p> <p><input type="checkbox"/> Attend a lecture or seminar</p> <p><input type="checkbox"/> Have access to the device to practice on your own and ask questions as needed</p> <p><input type="checkbox"/> Work side by side with an expert colleague</p> <p><input type="checkbox"/> Watch a training video</p> |

Figure 17. Sample demographics and knowledge and experience questions as part of a pre-usability test survey

Section 8.5.10.2 Post-Usability Test Survey

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

Section 8.5.11. Recruiting Participants

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

Section 8.5.11.1 Eligibility

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

Section 8.5.11.2 Staff Participation and Reimbursement

Staff participation in a usability test is usually set up in one of two ways, either staff participate in the test during work hours with their position being backfilled during the time of the testing, or staff participate in the test after work hours and are compensated for their time. Ideally, when a healthcare organization is planning to implement the new technology or system change being tested, a participant's position should be backfilled so they can take part in testing during work hours. However, if this is not possible, participants should be compensated for their time outside of work hours. Consider using gift cards as a means of compensating participants if the institution is not able to backfill positions during work hours.

| Participant Feedback | |
|--|---|
| <p>1. Using this smart infusion pump was intuitive:</p> <p><input type="checkbox"/> Strongly agree</p> <p><input type="checkbox"/> Agree</p> <p><input type="checkbox"/> Undecided</p> <p><input type="checkbox"/> Disagree</p> <p><input type="checkbox"/> Strongly disagree</p> <p>Additional comments:</p> <hr/> <hr/> | <p>5. Using this infusion pump in my unit will help to improve patient safety:</p> <p><input type="checkbox"/> Strongly agree</p> <p><input type="checkbox"/> Agree</p> <p><input type="checkbox"/> Undecided</p> <p><input type="checkbox"/> Disagree</p> <p><input type="checkbox"/> Strongly disagree</p> <p>Additional comments:</p> <hr/> <hr/> |
| <p>2. I have concerns about using this smart infusion pump in my nursing environment:</p> <p><input type="checkbox"/> Strongly agree</p> <p><input type="checkbox"/> Agree</p> <p><input type="checkbox"/> Undecided</p> <p><input type="checkbox"/> Disagree</p> <p><input type="checkbox"/> Strongly disagree</p> <p>Additional comments:</p> <hr/> <hr/> | <p>6. I found the set up tasks during the scenario to be difficult to complete:</p> <p><input type="checkbox"/> Strongly agree</p> <p><input type="checkbox"/> Agree</p> <p><input type="checkbox"/> Undecided</p> <p><input type="checkbox"/> Disagree</p> <p><input type="checkbox"/> Strongly disagree</p> <p>Additional comments:</p> <hr/> <hr/> |
| <p>3. This smart infusion pump will make my job easier as a nurse:</p> <p><input type="checkbox"/> Strongly agree</p> <p><input type="checkbox"/> Agree</p> <p><input type="checkbox"/> Undecided</p> <p><input type="checkbox"/> Disagree</p> <p><input type="checkbox"/> Strongly disagree</p> <p>Additional comments:</p> <hr/> <hr/> | <p>7. I am confident I completed all the tasks correctly during the scenario:</p> <p><input type="checkbox"/> Strongly agree</p> <p><input type="checkbox"/> Agree</p> <p><input type="checkbox"/> Undecided</p> <p><input type="checkbox"/> Disagree</p> <p><input type="checkbox"/> Strongly disagree</p> <p>Additional comments:</p> <hr/> <hr/> |
| <p>4. Using this smart infusion pump will change how I think about pump programming:</p> <p><input type="checkbox"/> Strongly agree</p> <p><input type="checkbox"/> Agree</p> <p><input type="checkbox"/> Undecided</p> <p><input type="checkbox"/> Disagree</p> <p><input type="checkbox"/> Strongly disagree</p> <p>Additional comments:</p> <hr/> <hr/> | <p>8. The training I received was comprehensive enough to allow me to complete all of the scenarios:</p> <p><input type="checkbox"/> Strongly agree</p> <p><input type="checkbox"/> Agree</p> <p><input type="checkbox"/> Undecided</p> <p><input type="checkbox"/> Disagree</p> <p><input type="checkbox"/> Strongly disagree</p> <p>Additional comments:</p> <hr/> <hr/> |

Figure 18. Sample questions as part of a post-usability test survey

Section 8.5.11.3 Recruitment Strategies

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

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

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

Section 8.5.11.4 Number of Participants to Recruit

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

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

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

subject will serve to strengthen the usability test by adding one more participant to the test population.

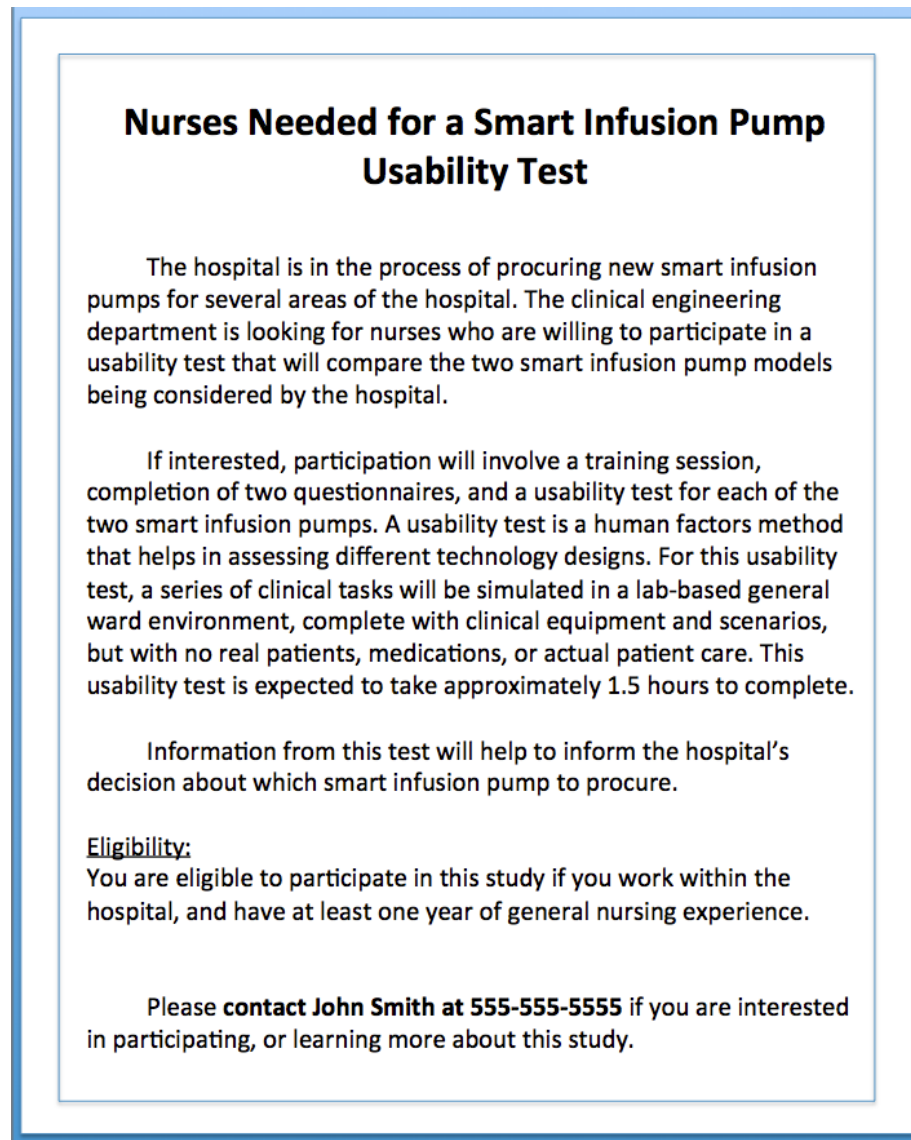


Figure 19. Example of a poster summarizing the usability test to be used for recruitment

Section 8.5.12. Conducting a Pilot Usability Test

Prior to usability testing, it is highly recommended that a practice, or pilot usability test, session be run either with your first participant, or ideally, with a colleague who is willing to pretend to be a participant. A pilot usability test session will serve to highlight any preparatory items that are either missing, or require modification, before the actual usability test sessions begin. Data collected from this pilot session should not be included as part of your actual usability test data, and you should allow enough time between the pilot session and the start of usability testing to incorporate any changes.

Completing a pilot usability test session allows you to ensure the environment, participant introduction, consent process, surveys, training, and usability test scenarios are prepared and that your presentation of each part and transition from one to the next flows smoothly. Running a pilot usability test session provides you with an opportunity to practice recording the session, using your data collection tool in real time, and, for a high-fidelity test, to communicate with the testing room facilitator.

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

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

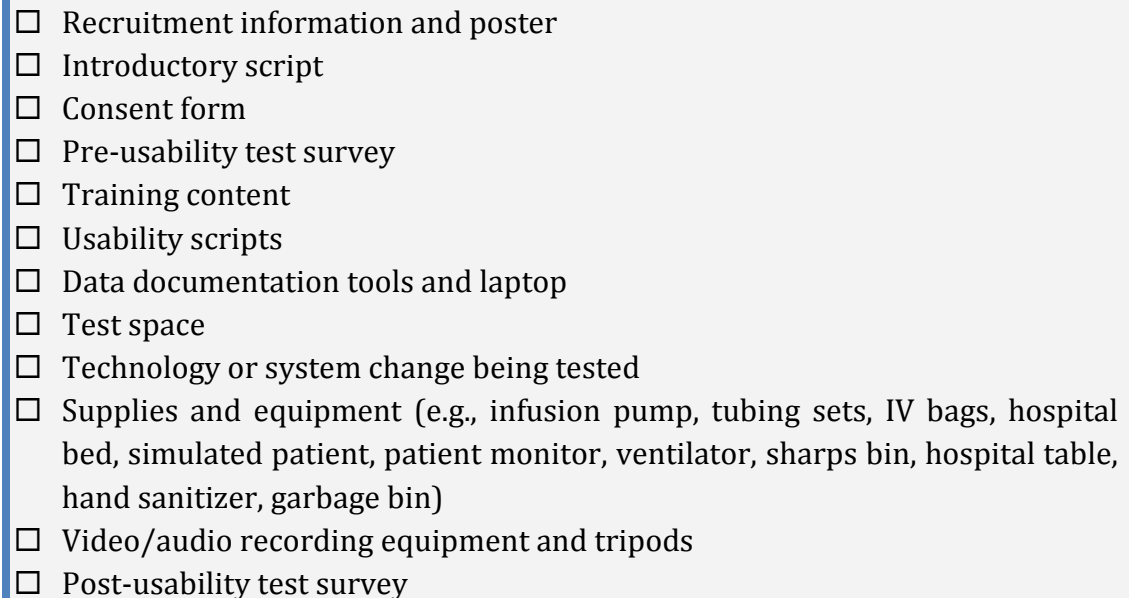
- 
- ☐ Recruitment information and poster
 - ☐ Introductory script
 - ☐ Consent form
 - ☐ Pre-usability test survey
 - ☐ Training content
 - ☐ Usability scripts
 - ☐ Data documentation tools and laptop
 - ☐ Test space
 - ☐ Technology or system change being tested
 - ☐ Supplies and equipment (e.g., infusion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

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

Section 8.6. Completing a Usability Test

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

Section 8.6.1. Overview of the Usability Test Session

Each usability test session should be completed by a single participant at a time, and every participant should go through the steps outlined in [Figure 21](#) below. A unique internal participant number should be assigned to each participant for inclusion on all information relating to the participant's session, including data documentation sheets and video recordings. Participants do not need to know or be made aware of their unique

internal participant numbers. These internal codes are simply meant to help you delineate between various participant sessions while maintaining confidentiality.

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

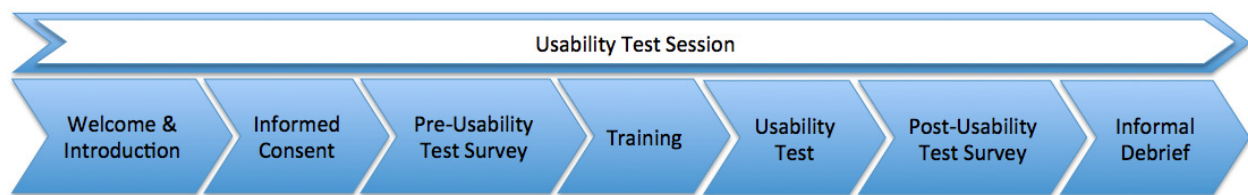


Figure 21. Overview of usability testing process

Section 8.6.2. Required Resources for Running A Usability Test Session

In order to get the most out of each session, it is highly recommended that in addition to the participant, a minimum of at least three people be present to help run each usability test session. A suggestion as to how to divide responsibilities during the usability test session is included in [Figure 22](#). Expecting a single person to facilitate the session, document observations in real time, and manage the cameras is *not* feasible. If only one person is available to run the usability test then it is best to set one or more cameras up in such a way that they will capture as much detail as possible without needing to be moved or zoomed and the facilitator should document observations in as much detail as they can during the session.

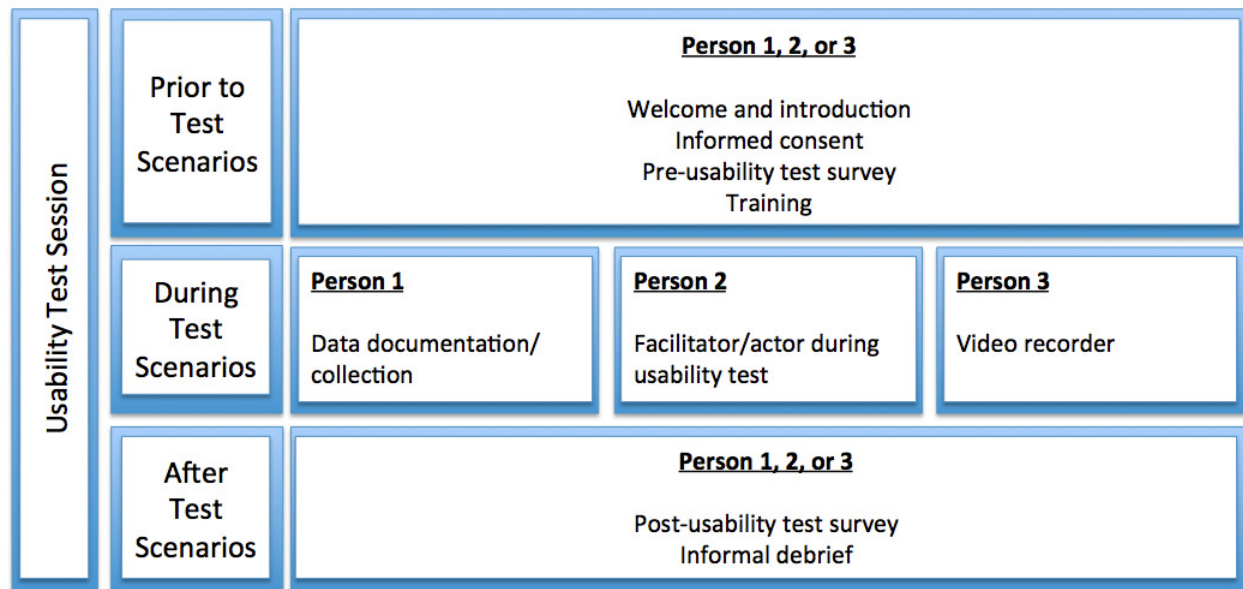


Figure 22. Suggested responsibilities during usability test session

Depending on the complexity of the usability test scenarios and script, it may be necessary to have more than one actor present to help facilitate the test scenarios. Depending on the purpose and context of your usability test, it may also be necessary to have more than one person collecting data.

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

Section 8.6.3. Data Collection During Usability Test Scenarios

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

After the participant has completed all the scenarios and the post-usability test survey, an informal debrief session can be conducted with the participant to solicit any feedback that goes beyond the scope of the surveys. This is a good time to ask participants

specific questions about their session. For example if you saw them do something surprising, or if they made an error and you are not sure what happened. When asking questions of the participant, ensure you do so in a way that does not make them feel uncomfortable if they performed a task incorrectly. Try to avoid telling them they made an error, and instead, ask open-ended questions about how they approached the task to get an understanding of the factors that contributed to the error. Also, ensure that any questions you ask of the participant are not leading in nature. See [Chapter 5](#), for more information about interviewing without introducing unintentional bias.

Section 8.7. What to do with Usability Test Findings

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

Section 8.7.1. User Performance Data

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

Section 8.7.1.1 Analysis of Use Errors

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

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

contributed to an error, the question you should continuously ask is ‘what features of the system are contributing to this error?’

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

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

| Severity | | |
|----------|-------------|-------------------------------------|
| Rating | Description | Definition |
| 1 | Minor | Patient unlikely to be harmed |
| 2 | Moderate | Patient could be temporarily harmed |
| 3 | Severe | Patient could be permanently harmed |
| 4 | Critical | Patient could die |

The next step is to consider how those use errors might be mitigated by the healthcare organization. This exercise should be done in collaboration with clinical experts and other representatives from the organization such as information technology specialists, risk managers, medication safety specialists, etc. Identifying proposed mitigating strategies is an extremely important exercise, especially if usability testing was done in the context of procurement. Unfortunately, there is no perfect technology, so it is likely the organization will have to accept a set of design issues that have the potential to lead to certain use errors. Having a sense of the mitigating strategies likely to address the set of design issues in advance is extremely helpful to decision makers who will benefit from being able to see the bigger picture implications when deciding on one technology over another.

Mitigating strategies that eliminate the possibility for an error occurring by forcing users to perform safely will be the most effective. However, it is important that these strategies are appropriate and users feel they are supportive or they will develop workarounds over time. Examples of these types of solutions include product customizations that limit certain features or options within the system, standardizing processes or systems, and automating tasks. Training is not typically considered an effective strategy for mitigating errors unless the error is caused by a lack of technical knowledge about the fundamental principles of the system. A framework for assessing the effectiveness of various types of mitigating strategies is presented in [Section 3.5](#) The Hierarchy of Effectiveness.

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

Section 8.7.1.2 Analysis of Time for Task Completion

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

Section 8.7.1.3 Analysis of Knowledge and Experience

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

Section 8.7.2. User Preference Data

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

Section 8.7.3. Communicating Findings to Others

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

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

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

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

Section 8.8. Comparative Usability Testing

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

Section 8.8.1. Introduction Script

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

Section 8.8.2. Scenario Design

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

Section 8.8.3. Counterbalancing

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

Section 8.8.4. Training

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

Section 8.8.5. Post-Test Questionnaire

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

Human Factors Informed Risk and Incident Analysis Methods



Two Human Factors Engineers working with an oncology pharmacist to understand failure modes associated with medication orders.

Chapter 9. Human Factors Informed Failure Mode and Effects Analysis

Section 9.1. Setting the Stage

Failure Mode and Effects Analysis (FMEA) is an engineering method for proactively assessing vulnerabilities in a system before the risks cause harm. It was first used in the late 1940's by the US Armed Forces to analyze various flight control systems (Amzen, 1996), as pilot error was leading to crashes and deaths. Since, FMEA has been adapted and used in several industries including military, aerospace, automotive, plastics, food service, and more recently, in healthcare. FMEA has been promoted by several national healthcare quality and safety organizations in Canada and the United States including: the Veterans Health Administration [37], the Institute for Safe Medication Practices [38], the Institute for Safe Medication Practices Canada [39], and the Institute for Healthcare Improvement [40].

Carrying out an FMEA is a means for hospitals to satisfy accreditation standards in the US and Canada including The Joint Commission's patient safety standard LD.5.2 in the Leadership chapter of the Hospital Accreditation Manual [41] and Accreditation Canada's Required Operating Practice that hospitals conduct at least one proactive risk assessment of a high-risk process each year [42].

Many versions of the FMEA method exist across multiple industries, including Healthcare Failure Mode and Effects Analysis (HFMEA). This chapter will present a human factors informed FMEA method (^{HF}FMEA) tailored to proactively analyzing healthcare systems and ensuring human factors considerations are included in the process.

Section 9.2. What is ^{HF}FMEA?

^{HF}FMEA is a human factors analysis method used to identify risks within a system proactively. It is carried out by a multidisciplinary team, and can be used to assess workflows, or technology-focused processes. ^{HF}FMEA helps you to consider:

- What can go wrong (failure mode)
- What happens if it goes wrong (effects)
- If it were to go wrong, how severe, likely, and detectable would it be (prioritizing what to focus on)
- Why could it go wrong (causes)
- What strategies could prevent it from going wrong (mitigating strategies)

The ^{HF}FMEA aims to improve on the more traditional FMEA method by incorporating a range of human factors methods during the analysis to:

- Enable the identification of failure modes from a human factors perspective

- Take our natural human strengths and limitations into account when rating and prioritizing issues
- Identify causes from a human factors perspective
- Identify human factors informed mitigating strategies and set expectations about how much risk is likely to be mitigated given the proposed solutions

Further to incorporating human factors methods throughout the analysis, ^{HF}FMEA also supports the biomedical technology professional in ensuring critical issues surface more readily, and that resources are focused on the highest risk/highest reward issues and solutions, so the overall effort required can be optimized.

Section 9.3. Why use ^{HF}FMEA?

^{HF}FMEA provides a means of understanding the potential risks that exist within a system in a proactive manner, and from a human factors perspective. The ability to identify and address risks before they lead to a patient or staff safety issue is a golden opportunity to reduce actual harm.

^{HF}FMEA can unite staff from across the organization who have different professional backgrounds and who work in different environments, by bringing them together to identify and solve problems as a group. This kind of undertaking can strengthen organizational culture and help to create a feeling of unity among staff. Involving a range of staff will serve to generate a more robust analysis and mitigating strategies than any one clinical group or unit could achieve on their own, and will help in achieving buy-in when it comes time to implement mitigating strategies identified through the analysis.

From the biomedical technology professional's perspective, completing an ^{HF}FMEA will be helpful for:

- Proactively examining and managing risks to patient safety
- Comparing the risks associated with multiple comparable technologies or processes when deciding which should be implemented e.g., for procurement
- Identifying system weaknesses that may be related to, but not directly involved in an incident
- Meeting accreditation requirements for completing at least one proactive risk assessment annually

Section 9.4. When to use ^{HF}FMEA?

^{HF}FMEA can be used to support several key responsibilities of a biomedical technology professional including risk management, procurement, incident management, and meeting accreditation requirements.

To manage risk proactively, a potentially problematic or high-risk process should be selected and analyzed, with any mitigating strategies identified through the analysis being implemented to prevent patient and staff harm from ever being realized. Establishing mitigating strategies before any harm is experienced is the best case scenario for patient safety and incident management.

For procurement, the processes undertaken by staff when interacting with the technologies being considered can be analyzed and compared using ^{HFFMEA}. Applying this human factors analysis tool allows the set of failure modes and proposed mitigating strategies to be compared across the possible technologies so an informed decision can be made about the level of resultant risk the healthcare organization is willing to take on.

After an incident, or a root cause analysis (RCA) ([Chapter 10](#)), ^{HFFMEA} can be applied to uncover more general system weaknesses that go beyond the failure modes that led directly to the incident. Casting your net more widely using ^{HFFMEA} can highlight other parallel and surrounding risks that would not come to light using ^{HFRCA} alone.

Many accreditation bodies require that at least one proactive risk assessment be completed by a healthcare organization annually. ^{HFFMEA} can be used to analyze a process deemed risky by the organization, or as a result of a safety incident, to fulfill this requirement.

Section 9.5. Completing an ^{HFFMEA}

The ^{HFFMEA} process is comprised of seven steps, outlined in [Figure 23](#). Each step will be outlined and described in this section.

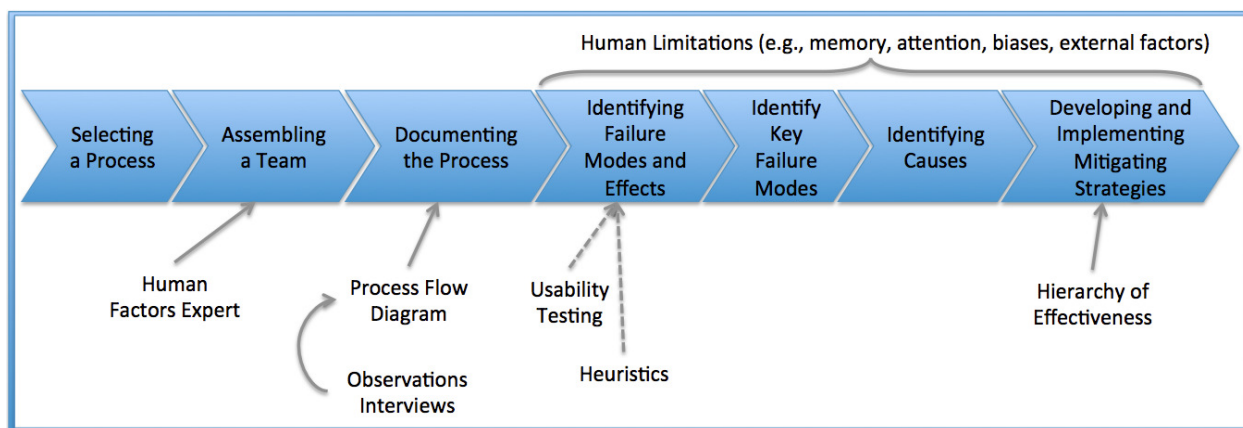


Figure 23. The seven steps and opportunities to incorporate human factors as part of an ^{HFFMEA}

Section 9.5.1. Select A Process

The first, and most critical step of an ^{HFFMEA} is to select a process to analyze. In the context of this type of analysis, a process can be considered a series of tasks undertaken to

achieve a goal with a defined beginning and end. A process may be focused around a technology, or may define a series of workflow tasks required to accomplish a goal.

When choosing a process, it should be sufficiently high-risk and error prone to justify the effort involved in conducting an analysis. Comparing the residual risk associated with different technology options for procurement, and analyzing the general risks related to a critical incident usually justify an ^{HF}FMEA. To identify failure modes prospectively and independently of an incident or procurement exercise, consider reviewing incident databases from your healthcare organization or other organizations that collect incident report data like the Institute for Safe Medication Practices, FDA, ECRI Institute, Institute for Healthcare Improvement, the National Health Service (NHS) (UK), Australia Patient Safety Foundation, and reviewing guidance documents from health technology safety advocate organizations like ECRI Institute, the Association for the Advancement of Medical Instrumentation, INAHTA, and accreditation bodies like The Joint Commission. If trying to decide between two candidate processes for analysis consider the following factors, which will influence the likely success of an ^{HF}FMEA.

- Is the clinical area(s) associated with the process committed to participating? Clinical areas that have had incidents related to the process being investigated are usually willing to commit to supporting the analysis and implementing mitigating strategies.
- Is there an obvious champion on the unit(s) who will participate as part of the ^{HF}FMEA team and act as a liaison with the clinical area(s)? Having a champion from within the clinical unit is key to gaining access to the clinical area, observing the work system, and collecting artefacts in order to support an ^{HF}FMEA.
- Is the clinical area preparing to undergo a change related to the process being evaluated? If the unit is already preparing for a related change (e.g., purchasing and implementing a new device associated with the proposed process) they may be more likely to support an ^{HF}FMEA.
- Is the process pervasive across the organization (i.e., does it affect many clinical areas)? If the results of the ^{HF}FMEA will benefit many clinical areas, the effort may have a greater payoff.
- Is the process aligned with broader organizational priorities? Choosing a topic related to something the organization is actively measuring will make it easier to gain support from senior management.

Section 9.5.1.1 Defining the Starting and Ending Points of the Process

To support a successful ^{HFF}FMEA the process scope included for analysis must be clearly defined. To do this, the starting and ending points of the process must be established, as these are the boundaries that will define the scope of the analysis. A well-defined and manageable process scope is essential to prevent the required resources and scope from escalating out of control. When defining a process scope for analysis, always lean towards too narrow a process, rather than a process that may be too broad, as there is almost no process that is too narrow for the application of ^{HFF}FMEA.

Section 9.5.1.2 Defining Inclusion and Exclusion Criteria

To help define the process scope for an ^{HFF}FMEA, consider the proposed process on a number of levels and explicitly define what will be included and excluded. Categories of information to include or exclude depend on the process under consideration, but some common ones include: Patient population, care area, technology. [Table 7](#) provides an example of some of the variables that might be considered for inclusion/ exclusion when defining scope for the process *administering chemotherapy using an ambulatory infusion pump*.

Section 9.5.2. Assemble a Team

Once the process, starting and ending points, and inclusion and exclusion criteria have been defined, a team must be assembled to conduct the analysis. Teams should be multidisciplinary, representing a range of knowledge, experiences, backgrounds, and perspectives. The people you choose to invite to participate on an ^{HFF}FMEA team will depend on the process and scope being analyzed. As much as possible, team members should be chosen who are knowledgeable about the defined process scope, and who will think critically, and provide input, feedback, guidance, and buy-in at various stages of the ^{HFF}FMEA exercise.

Table 7. Example of variables that might be explicitly included or excluded from an ^{HF}FMEA when defining scope for the process *administering chemotherapy using an ambulatory infusion pump*.

| Defined Process: Administering chemotherapy with an ambulatory infusion pump | | |
|---|-----------------|-----------------|
| | Included | Excluded |
| Patient Population | | |
| Adult | ✓ | |
| Paediatric | | ✓ |
| Clinical trials | | ✓ |
| Delivery Devices | | |
| Electronic ambulatory infusion pump | ✓ | |
| Elastomeric ambulatory infusion pump | | ✓ |
| Large volume infusion pump | | ✓ |
| IV push | | ✓ |
| Environment | | |
| Inpatient hospital | | ✓ |
| Outpatient hospital | ✓ | |
| Community | | ✓ |
| Home | | ✓ |
| Task Steps | | |
| Ordering chemotherapy | | ✓ |
| Selecting the correct pump | | ✓ |
| Mixing chemotherapy for pump | | ✓ |
| Five rights before connecting | ✓ | |
| Connecting patient to the pump | ✓ | |
| Pump programming | ✓ | |
| Starting the pump | ✓ | |
| Pump infusing | ✓ | |
| Disconnecting the pump | ✓ | |
| People | | |
| Medical oncology | | ✓ |
| Pharmacy | ✓ | |
| Nursing | ✓ | |
| Patients | | ✓ |
| Families and lay public | | ✓ |

Section 9.5.2.1 Team Member Roles

Individual team members need to fulfill a number of different roles in order to ensure a successful project. Each ^{HF}FMEA team should include individual members who can serve as subject matter or process experts, process reviewers, and senior advisors. Additionally, some of these same team members will have to take on the roles of team leader or facilitator, scribe, and human factors expert.

Subject Matter, or Process Experts

Subject matter or process experts are individuals who have a detailed understanding of any technologies, processes, and environments being studied. These team members will be central to mapping the process being analyzed, identifying potential risks, assessing and rating risks, and providing input when proposing and identifying the impact of mitigating strategies.

Process Reviewers

Process reviewers are individuals who are less familiar with the process being analyzed, but who have experience and knowledge in a related field. Process reviewers are important for providing a critical review of practices and standards that are accepted by the community. Team members fulfilling this role are more likely to identify vulnerabilities that are not detected by process experts.

Senior Advisors

Senior advisors tend to be a hospital executive, or a senior staff member, who can provide a broad organizational perspective to the team. These individuals help to facilitate access to the resources, such as people and financial support, which are needed to conduct an ^{HF}FMEA. Senior advisors also play a key role in achieving buy-in from areas in the healthcare organization where changes will be implemented based on the mitigating strategies identified in the analysis, and for facilitating any policy changes.

Team Leader, or Facilitator

The team leader or facilitator is a member of the team who is responsible for keeping the discussion during meetings moving and on target. The team leader should encourage participation from team members who may be more reluctant to express their ideas. The team leader should be confident, good at managing people, group dynamics, and able to facilitate group consensus building. The team leader does not have to be the same person as the project leader or coordinator.

Scribe

The scribe is responsible for capturing the discussion and decisions made at each meeting and circulating meeting minutes to the entire team.

Human Factors Expert

Ideally, one of the ^{HF}FMEA team members will have human factors training. The human factors perspective for an ^{HF}FMEA is important because human strengths and limitations are considered when identifying and rating failure modes, and when identifying

causes and recommendations. Applying a human factors lens, as described for this method, will yield additional insights for each of these ^{HF}FMEA steps. If it is not possible to include a human factors expert, a health technology professional can apply their newfound human factors lens (provided by this book and additional resources referenced in this book) to the process in order to fulfill this role and develop human factors experience. Another more cost effective option to consider is to bring in a graduate student of human factors and their advisor to help provide this perspective.

Section 9.5.2.2 Team Size

^{HF}FMEA teams generally range in size from about three to eight people, but the exact number will depend on the process scope and how many stakeholders are affected by the process being analyzed. When too few team members are included in an ^{HF}FMEA, the analysis will be less robust, with the possibility of being incomplete, if relevant perspectives are not included. When too many team members are included, it can be increasingly difficult to schedule meetings, coordinate and compile team member's process work, and reach consensus.

An effective balance can be reached by tending towards a larger team, but then breaking that team into a *work team* and an *advisory team*. The work team should consist of two or three people who are responsible for conducting the detailed analysis and reporting back to the larger team. The work team should meet several times and dedicate their time to leading the hands-on work including creating diagrams, formulating the analysis and producing reports. This portion of the team can be considered the “doers”. The advisory team, who make up the balance of the entire ^{HF}FMEA team, is responsible for reviewing the analysis of the work team and providing guidance and resources as required during several key meetings. This portion of the team can be considered the “enablers”. Key meetings take place throughout a ^{HF}FMEA to ensure the perspectives, experience and ideas of all stakeholders are included in the analysis. In this section each of the key meetings are outlined using callout boxes to highlight their purpose and structure. The first meeting takes place once the team is selected and a process is proposed.

Team Meeting # 1:

Attendees: work and advisory teams

Purpose: meet and greet; review the process scope

Estimated duration: 1-2 hours

Once the work and advisory teams have been identified, the first meeting should focus on reviewing and getting consensus for the chosen process, starting and ending points, and the inclusion and exclusion criteria.

Section 9.5.3. Document the Process

Once the team has been assembled and consensus has been reached on the process scope (i.e., start and end points, inclusion and exclusion criteria), the process must be documented. Documenting the process means creating a graphical representation of the steps and sub-steps required to complete your chosen process scope. Any style of graphical representation can be created, but for the purposes of this handbook a process flow diagram is recommended. To learn how to create a process flow diagram, see [Chapter 6 Task Analysis](#).

Creating a process flow diagram is an iterative, rather than a linear, undertaking. To create a process flow diagram for an ^{HFF}FMEA, first the work team members should create a diagram based on an initial understanding of what happens as part of the process. Next, any advisory team members who are also considered to be process reviewers should review this diagram. Then, the work team should go into the field to conduct observations ([Chapter 4](#)), and interviews ([Chapter 5](#)) in order to validate the process flow diagram. It is extremely important that the actual process, as opposed to the ideal process, be documented, as this will form the basis of the ^{HFF}FMEA. This iterative approach of reviewing the diagram, going into the field to clarify and validate, and updating the diagram should be repeated until there are no discrepancies between the diagram and what happens in the field.

For a successful ^{HFF}FMEA, it is essential that observations and interviews be conducted for a number of reasons. First, it is almost certain that going into the field will yield new information that could affect your process scope. As observations and interviews are conducted you may learn of interfacing equipment, supplies, new user groups, or different areas of the hospital, for example, which have an impact on the process being studied. In these cases your process scope may have to expand for a successful analysis. In contrast, through observations it may become evident that the original process scope chosen is too large and complex to manage with the available time and resources. In this case your process scope may have to be narrowed. Either way, any changes in process scope should be clearly defined in terms of starting/ending points, and inclusion/exclusion criteria, and also be supported by both the work and advisory teams.

In addition to re-evaluating process scope, observations and interviews are also helpful for adding detail, filling gaps in understanding, and avoiding situations where assumptions are being made about a process. Processes are almost always more detailed and complex than originally assumed, so it is important to get into the field to support the creation of an accurate diagram. Although an accurate diagram is important, it is possible to include too much detail. Knowing just how much detail to document (i.e., whether to include or exclude certain subtasks) can be a real challenge when creating a process flow diagram to support an ^{HFF}FMEA. To support the creation of a diagram that is at an

appropriate level of detail, for each task and sub-task, ask yourself the question “does this task or sub-task fall within the scope of this ^{HF}FMEA”. A clearly defined scope, with start and end points as well as inclusion and exclusion criteria, can go a long way in supporting this approach.

To make the process flow diagram as useful as possible for the purposes of an ^{HF}FMEA it is highly recommended that each step and sub-step be numbered to make it easier for the group to discuss individual steps throughout the analysis process. When there are different variations on the same steps of the process, each variation should be documented on the process map and labelled so that it is clear that one of the variations will take place. Labelling the variations with letters, in addition to numbers, may help to illustrate this (e.g., Sub tasks 1.2.a, 1.2.b, 1.2.c represent the three different ways that subtask 1.2 is achieved). Using swim lanes, which allow a process to be mapped to represent different clinical areas or people in a process, is also highly recommended for improved clarity.

Once the final draft of the process flow diagram has been created using the iterative approach of reviewing, going into the field, and updating the diagram, it should be shared with front line staff who are familiar with the process. Because reading a process flow diagram can be quite tedious, it is recommended that one or more meetings be set up so you can walk any reviewers through the diagram step by step. During this exercise, notes should be made directly on the diagram about any areas where changes may be required. If new information comes to light that significantly changes the process flow diagram, it is recommended further observations be conducted to validate any changes.

After any further updates have been made, the process flow diagram should be circulated among the advisory team at least a week prior to Team Meeting #2. Providing both an electronic and a paper version of the document is recommended to facilitate review and editing by team members.

Team Meeting # 2:

Attendees: work and advisory teams

Purpose: review process flow diagram

Estimated Duration: half a day

The final draft of the process flow diagram should be discussed in detail, with a member of the work team walking the group through the diagram step by step. Each team member should have a printed copy of the process flow diagram that can be used for notes and to follow along with during the session. Based on discussion during the meeting, further changes to the process flow diagram, including change in scope, are likely.

Allow ample time for this meeting, especially for a larger process scope, and consider bringing in refreshments for team members.

Section 9.5.4. Identify Failure Modes and Effects

Once the process flow diagram has been finalized and approved by the work and advisory teams, the next step is to identify potential failure modes (FM) and effects for the defined process scope. The Veteran's Affairs National Centre for Patient Safety defines a failure mode as "different ways that a process or a sub-process can fail to provide the anticipated result" [43]. In other words, a failure mode is a description of *how* things fail. It is important to highlight that *how* things fail is different than *why* things fail. For example, when making toast, a failure mode would be *the toast burns*. Why things fail describes the cause of a failure mode. In the toast example, a possible *why* could be that the toaster darkness setting was too high. Understanding *why* things fail is important, but will be considered later on in the ^{HF}FMEA process. The reason for this distinction is because identifying a comprehensive list of causes is extremely time consuming. The ^{HF}FMEA method focuses the time spent identifying causes only on the most serious and important failure modes as determined through the failure mode rating process.

To facilitate the identification of failure modes, and to support the remainder of the ^{HFF}FMEA method, a member of the work team should convert the final process flow diagram into a spreadsheet format. To do so, each numbered task and subtask from the process flow diagram, along with corresponding task descriptions, should be entered into rows on the spreadsheet. See [Table 8](#) for an example of an ^{HFF}FMEA spreadsheet template with process flow description steps entered into rows.

Table 8. Example of an ^{HFF}FMEA spreadsheet with process flow description information entered

| Task # | | Failure Mode (FM) | | Effect | Scoring | | | Key Failure Mode (KFM) | | | | | |
|--------|-----------------------------|-------------------|-------------|--------|--------------|-----------------|-------------------|------------------------|--------|------------|------------|-----------------------------|-------|
| # | Description | # | Description | | Severity (S) | Probability (P) | Hazard Score (HS) | S x P | HS x 8 | Controlled | Detectable | Single Point Weakness (SPW) | KFM ? |
| 1.0 | Check right patient | | | | | | | | | | | | |
| 2.0 | Check right drug | | | | | | | | | | | | |
| 3.0 | Check right dose | | | | | | | | | | | | |
| 4.0 | Check right route | | | | | | | | | | | | |
| 5.0 | Check right time | | | | | | | | | | | | |
| 6.0 | Attach IV tubing to patient | | | | | | | | | | | | |
| 7.0 | Turn pump on | | | | | | | | | | | | |
| 8.0 | Enter drug library | | | | | | | | | | | | |
| 9.0 | Select drug | | | | | | | | | | | | |
| ... | ... | | | | | | | | | | | | |
| ... | ... | | | | | | | | | | | | |
| ... | ... | | | | | | | | | | | | |
| ... | ... | | | | | | | | | | | | |
| ... | ... | | | | | | | | | | | | |
| ... | ... | | | | | | | | | | | | |
| ... | ... | | | | | | | | | | | | |
| ... | ... | | | | | | | | | | | | |

Once the ^{HFF}FMEA spreadsheet has been initialized, the work group should meet and systematically review each task step and sub step to identify any potential failure modes. For every step and sub step, the question *how could this step or sub step go wrong* should be answered, with the answer going in the failure mode description column.

If there is more than one possible failure mode for a given task step or sub step, they should all be included. The more failure modes that can be identified and listed, the better, because when a comprehensive list is developed, the potential to reduce the risk of the failure modes identified is increased. When identifying failure modes, note that it is common for the same failure mode to be associated with different task steps and sub steps. To assist in generating a comprehensive list of failure modes, the following questions can be posed:

- How could this step or sub step be performed incorrectly?
- How could this step or sub step be performed incompletely?

- If this step or sub step is attempted correctly, what could prevent it from being completed correctly?
- What would happen if a task that is part of this step or sub step were omitted?

Including a human factors expert, or incorporating what you know about human factors when identifying failure modes, will result in a more comprehensive list of failure modes, and a more robust analysis. Consider inherent human limitations like memory, fatigue, and cognitive biases ([Chapter 3](#)).

Table 9. Example of an ^{HF}FMEA spreadsheet with process flow description, and failure modes entered

| Task # | | Failure Mode (FM) | | Effect | Scoring | | | Key Failure Mode (KFM) | | | | | |
|--------|-----------------------------|-------------------|--------------------------------|--------|--------------|-----------------|-------------------|------------------------|--------|------------|------------|-----------------------------|-------|
| # | Description | # | Description | | Severity (S) | Probability (P) | Hazard Score (HS) | S x P | P x HS | Controlled | Detectable | Single Point Weakness (SPW) | KFM ? |
| 1.0 | Check right patient | 1 | Right patient not checked | | | | | | | | | | |
| 2.0 | Check right drug | 2 | Right drug not checked | | | | | | | | | | |
| 3.0 | Check right dose | 3 | Right dose not checked | | | | | | | | | | |
| 4.0 | Check right route | 4 | Right route not checked | | | | | | | | | | |
| 5.0 | Check right time | 5 | Right time not checked | | | | | | | | | | |
| 6.0 | Attach IV tubing to patient | 6 | Tubing not attached to patient | | | | | | | | | | |
| 7.0 | Turn pump on | 7 | Pump is not turned on | | | | | | | | | | |
| 8.0 | Enter drug library | 8 | Do not enter drug library | | | | | | | | | | |
| 9.0 | Select drug | 9 | Drug not selected | | | | | | | | | | |
| | | 10 | Wrong drug selected | | | | | | | | | | |
| ... | ... | ... | ... | | | | | | | | | | |
| ... | ... | ... | ... | | | | | | | | | | |
| ... | ... | ... | ... | | | | | | | | | | |

It is important to reiterate that ^{HF}FMEA is a *prospective* risk analysis method, meaning that regardless of whether a failure mode has actually happened, or how unlikely it may seem, it should still be included in the spreadsheet for further consideration.

To identify the possible effects of each failure mode, the work team should think through what could happen if the failure mode occurred. When several different effects are possible, rather than listing out every possibility, include the most serious possible effects to be as conservative about the risk as possible.

When identifying effects, think about the overall goal of the process being analyzed, rather than just the most immediate effect. For example from [Table 10](#) if the process being analyzed is *administering chemotherapy with an ambulatory infusion pump*, and a failure mode is #6, *tubing is not attached to the patient*, an immediate effect is that *the patient does not get connected to their infusion*, but in the context of the overall process goal, the effects are *medication leak*, and *the patient does not receive their chemotherapy*. Avoid taking the effect any further than this, (e.g., patient dies), because this extends beyond the goal of the process as defined (e.g., administer chemotherapy to the patient using an ambulatory infusion pump). The effect of the patient not receiving their chemotherapy (e.g., patient dies) will be captured as part of the risk rating process for the severity of the effect.

Table 10. Example of an ^{HF}FMEA spreadsheet with process flow description, failure modes, and effects entered

| Task # | | Failure Mode (FM) | | Effect | Scoring | | | Key Failure Mode (KFM) | | | | | | |
|--------|-----------------------------|-------------------|--------------------------------|--|--------------|-----------------|-------------------|------------------------|---|----|------------|------------|-----------------------------|-------|
| # | Description | # | Description | | Severity (S) | Probability (P) | Hazard Score (HS) | S | P | HS | Controlled | Detectable | Single Point Weakness (SPW) | KFM ? |
| 1.0 | Check right patient | 1 | Right patient not checked | Wrong patient | | | | | | | | | | |
| 2.0 | Check right drug | 2 | Right drug not checked | Wrong drug | | | | | | | | | | |
| 3.0 | Check right dose | 3 | Right dose not checked | Wrong dose | | | | | | | | | | |
| 4.0 | Check right route | 4 | Right route not checked | Wrong route | | | | | | | | | | |
| 5.0 | Check right time | 5 | Right time not checked | Wrong time | | | | | | | | | | |
| 6.0 | Attach IV tubing to patient | 6 | Tubing not attached to patient | Medication leak | | | | | | | | | | |
| | | | | Patient does not receive medication | | | | | | | | | | |
| 7.0 | Turn pump on | 7 | Pump is not turned on | Patient does not receive medication | | | | | | | | | | |
| 8.0 | Enter drug library | 8 | Do not enter drug library | Nurse not alerted to possible wrong dose | | | | | | | | | | |
| 9.0 | Select drug | 9 | Drug not selected | Pump alarm goes off | | | | | | | | | | |
| | | 10 | Wrong drug selected | Patient receives wrong drug | | | | | | | | | | |
| ... | ... | ... | ... | ... | | | | | | | | | | |
| ... | ... | ... | ... | ... | | | | | | | | | | |

Once the work team has identified as many potential failure modes, and resultant effects as possible for each step and sub step of the process, the spreadsheet should be circulated to the advisory team for review.

Team Meeting # 3:

Attendees: work and advisory teams

Purpose: review and expand upon potential failure modes and effects

Estimated Duration: 1 day

The failure modes and effects for each process step and sub step should be reviewed, discussed, and expanded upon during this meeting. The facilitator should walk the group through each step and sub-step and elicit any feedback or additional failure modes for each step. Every team member should have a printed copy of the spreadsheet and process flow diagram that can be used for notes, and to follow along with during the session. If possible, project a working copy of the spreadsheet so the entire team can see it, and have the scribe type any new or modified failure modes and effects in real time so the team can ensure the discussion is being captured accurately.

In addition to failure modes and effects, it is likely that causes will be also be brought forth. To keep this meeting on track any causes should be recorded in a separate file, or on chart paper, for future use and the facilitator should steer the group back towards the identification and review of failure modes and effects.

It is normal for further modifications to the process flow diagram to occur as a result of this meeting. Have the scribe, or another dedicated team member capture any required edits on a paper copy of the process flow diagram so they can be incorporated following the meeting.

This will be the longest meeting of the ^{HF}FMEA, and an entire day should be scheduled, especially for a larger process scope. If it is not possible to schedule a meeting this long, plan to have several shorter meetings instead. Organize refreshments for team members, and make sure to schedule several short breaks throughout the day.

Section 9.5.5. Rate Failure Mode Effects and Determine Key Failure Modes

A long list of failure modes and resultant effects will have been generated following Team Meeting #3. With unlimited resources, one would try to mitigate every failure mode identified, but since in reality most healthcare organizations do not have the capacity to do this, it is important to focus on fixing those failure modes that carry the highest risk. To identify which failure modes are the highest priority issues, and thus require the most attention, each failure mode and effect will be rated using risk-scoring matrices and assessed to determine if it is a key failure mode (KFM). Once the KFMs have been identified, the team can then focus on determining causes and creating mitigating strategies targeted towards these high priority issues so available resources can be used in the most efficient manner possible.

Risk-scoring matrices are rubrics that support the assignment of risk scores to each failure mode effect. In the ^{HF}FMEA framework two matrices are required to support the identification of key failure modes, a Severity-Scoring Matrix and a Probability-Scoring Matrix.

The ratings and definitions used to evaluate the severity and probability of each failure mode should be tailored to the process being analyzed, but suggested severity and probability scoring matrices are included in [Table 11](#) as examples.

It is important that the definitions and scale chosen be appropriate and meaningful for the process scope being evaluated. For example, if several of the failure modes being considered are likely to happen daily, the definition of “Frequent” in [Table 12](#) should be adjusted to take this into account.

The process of creating risk-scoring matrices may be most efficient if the work team develops proposed matrices and circulates them and receives comments by email, rather than meeting in person.

Once the risk-scoring matrices have been developed and approved by the work and advisory teams the work group should meet several times to assign severity and probability scores to each failure mode and effect in the ^{HF}FMEA spreadsheet. When rating severity, consider the effect of the failure mode, and when rating probability, consider the failure mode itself ([Table 13](#)).

If possible, include a human factors expert in this rating exercise because having this perspective will enable the consideration of people’s inherent strengths and limitations, possibly affecting the scores assigned to different issues. Think about inherent human limitations like memory, fatigue, and cognitive biases ([Chapter 3](#)). A common pitfall when rating failure modes and effects is to assume that people should just be vigilant when it comes to a potential issue, or that they should remember to do something, but a human factors lens will help to remind the group that in reality, this is not possible.

Once the work team has rated each failure mode and effect, the ^{HF}FMEA spreadsheet should be circulated to the advisory team for review and feedback. A meeting should be scheduled for both the work and advisory teams to review and discuss the assigned severity and probability scores in person, so that any disagreements can be discussed until consensus is reached.

Table 11. Example severity-scoring matrix

| Severity | | |
|----------|-------------|-------------------------------------|
| Rating | Description | Definition |
| 1 | Minor | Patient unlikely to be harmed |
| 2 | Moderate | Patient could be temporarily harmed |
| 3 | Severe | Patient could be permanently harmed |
| 4 | Critical | Patient could die |

Table 12. Example probability-scoring matrix

| Probability | | |
|-------------|-------------|--|
| Rating | Description | Definition |
| 1 | Remote | Unlikely to occur (may happen once in 5-30 years) |
| 2 | Uncommon | Possible to occur (may happen once in 2-5 years) |
| 3 | Occasional | Probable to occur (may happen more than once in 1-2 years) |
| 4 | Frequent | Likely to occur (may happen several times within the year) |

Table 13. Severity and probability scores for each failure mode and effect

| Task # | | Failure Mode (FM) | | Effect | Scoring | | Key Failure Mode (KFM) | | | | | | | |
|--------|-----------------------------|-------------------|--------------------------------|--|--------------|-----------------|------------------------|-----|-----|-----|------------|------------|-----------------------------|-------|
| # | Description | # | Description | | Severity (S) | Probability (P) | Hazard Score (HS) | S | A | 3 | Controlled | Detectable | Single Point Weakness (SPW) | KFM ? |
| 1.0 | Check right patient | 1 | Right patient not checked | Wrong patient | 3 | 3 | | | | | | | | |
| 2.0 | Check right drug | 2 | Right drug not checked | Wrong drug | 3 | 3 | | | | | | | | |
| 3.0 | Check right dose | 3 | Right dose not checked | Wrong dose | 3 | 3 | | | | | | | | |
| 4.0 | Check right route | 4 | Right route not checked | Wrong route | 3 | 3 | | | | | | | | |
| 5.0 | Check right time | 5 | Right time not checked | Wrong time | 2 | 4 | | | | | | | | |
| 6.0 | Attach IV tubing to patient | 6 | Tubing not attached to patient | Medication leak | 1 | 2 | | | | | | | | |
| | | | | Patient does not receive medication | 3 | 2 | | | | | | | | |
| 7.0 | Turn pump on | 7 | Pump is not turned on | Patient does not receive medication | 3 | 1 | | | | | | | | |
| 8.0 | Enter drug library | 8 | Do not enter drug library | Nurse not alerted to possible wrong dose | 3 | 4 | | | | | | | | |
| 9.0 | Select drug | 9 | Drug not selected | Pump alarm goes off | 1 | 2 | | | | | | | | |
| | | 10 | Wrong drug selected | Patient receives wrong drug | 3 | 2 | | | | | | | | |
| ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... |
| ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... |

Team Meeting # 4:

Attendees: work and advisory teams

Purpose: Determine risk scoring matrices and reach consensus about severity and probability ratings for failure modes and effects

Estimated Duration: 3 to 4 hours

Now that the failure modes and effects have been reviewed, the work team should present the proposed risk scoring matrix for review and discussion. Any modifications to the risk scoring matrix should be made based on group consensus about the rating scale and definitions.

Severity and probability ratings will be assigned to each pair of failure modes and effects during this meeting. The facilitator should walk the group through each failure mode and the proposed scoring determined by the work group. The advisory and work teams should vote to determine whether the assigned scoring is acceptable as is. Any disagreements should be resolved through discussion to reach consensus. Every team member should have a printed copy of the ^{HF}FMEA spreadsheet with proposed scoring, as well as a copy of the risk scoring matrices for severity and probability. If possible, project a working copy of the ^{HF}FMEA spreadsheet so the entire team can see it, and have the scribe update scoring in real time.

Depending on the process scope and the number of failure modes and effects to rate, between three and four hours should be scheduled. Bring refreshments for team members if possible.

Section 9.5.5.1 Applying the Three Tests

Once the severity and probability of each failure mode and effect has been rated using the severity and probability rating matrices, a series of three tests are applied to determine the key failure modes. The three tests are the Severity Test, the Hazard Score Test, and Single Point Weakness Test. The tests should be applied according to the decision tree process outlined in [Figure 24](#).

Test 1: Severity Test

A severity threshold is chosen by looking at the failure modes associated with each score value (or range of score values, depending on the range of your score matrices) and determining which types of failures associated with each score/score range are important to mitigate. Note that if a failure mode has multiple effects, each effect will have its own severity rating. Any failure mode and effect having a severity above or equal to the chosen threshold will automatically become a key failure mode that gets analyzed further. In [Table](#)

11, the severity threshold is 3, and so all failure modes associated with a severity rating of 3 or more are classified as KFMs.

Table 14. Applying the severity test

| Task # | | Failure Mode (FM) | | Effect | Scoring | | | Key Failure Mode (KFM) | | | | | |
|--------|-----------------------------|-------------------|--------------------------------|--|--------------|-----------------|-------------------|------------------------|-------|------------|------------|-----------------------------|-------|
| # | Description | # | Description | | Severity (S) | Probability (P) | Hazard Score (HS) | S < 3 | S ≥ 3 | Controlled | Detectable | Single Point Weakness (SPW) | KFM ? |
| 1.0 | Check right patient | 1 | Right patient not checked | Wrong patient | 3 | 3 | | Y | | | | | Y |
| 2.0 | Check right drug | 2 | Right drug not checked | Wrong drug | 3 | 3 | | Y | | | | | Y |
| 3.0 | Check right dose | 3 | Right dose not checked | Wrong dose | 3 | 3 | | Y | | | | | Y |
| 4.0 | Check right route | 4 | Right route not checked | Wrong route | 3 | 3 | | Y | | | | | Y |
| 5.0 | Check right time | 5 | Right time not checked | Wrong time | 2 | 4 | | N | | | | | |
| 6.0 | Attach IV tubing to patient | 6 | Tubing not attached to patient | Medication leak | 1 | 2 | | N | | | | | |
| | | | | Patient does not receive medication | 3 | 2 | | Y | | | | | Y |
| 7.0 | Turn pump on | 7 | Pump is not turned on | Patient does not receive medication | 3 | 1 | | Y | | | | | Y |
| 8.0 | Enter drug library | 8 | Do not enter drug library | Nurse not alerted to possible wrong dose | 3 | 4 | | Y | | | | | Y |
| 9.0 | Select drug | 9 | Drug not selected | Pump alarm goes off | 1 | 2 | | N | | | | | |
| | | 10 | Wrong drug selected | Patient receives wrong drug | 3 | 2 | | Y | | | | | Y |
| ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... |
| ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... |

Test 2: Hazard Score Test

To determine the hazard score of each failure mode and effect, the severity and probability scores are multiplied together. Note that if a failure mode has multiple effects, each effect will have its own hazard score. Once hazard scores have been determined, a threshold is again chosen based on of the type of failure modes associated with each hazard score. Any failure mode and effect having a hazard score above or equal to the chosen hazard threshold will be further considered, ([Table 15](#)) although it may not become a KFM.

Table 15. Applying the hazard score test

| Task # | | Failure Mode (FM) | | Effect | Scoring | | | Key Failure Mode (KFM) | | | | |
|--------|-----------------------------|-------------------|--------------------------------|--|--------------|-----------------|-------------------|------------------------|------------|-----------------------------|-------|--|
| # | Description | # | Description | | Severity (S) | Probability (P) | Hazard Score (HS) | Controlled | Detectable | Single Point Weakness (SPW) | KFM ? | |
| 1.0 | Check right patient | 1 | Right patient not checked | Wrong patient | 3 | 3 | 9 | Y | Y | | Y | |
| 2.0 | Check right drug | 2 | Right drug not checked | Wrong drug | 3 | 3 | 9 | Y | Y | | Y | |
| 3.0 | Check right dose | 3 | Right dose not checked | Wrong dose | 3 | 3 | 9 | Y | Y | | Y | |
| 4.0 | Check right route | 4 | Right route not checked | Wrong route | 3 | 3 | 9 | Y | Y | | Y | |
| 5.0 | Check right time | 5 | Right time not checked | Wrong time | 2 | 4 | 8 | N | Y | | ? | |
| 6.0 | Attach IV tubing to patient | 6 | Tubing not attached to patient | Medication leak | 1 | 2 | 2 | N | N | | | |
| | | | | Patient does not receive medication | 3 | 2 | 6 | Y | N | | Y | |
| 7.0 | Turn pump on | 7 | Pump is not turned on | Patient does not receive medication | 3 | 1 | 3 | Y | N | | Y | |
| 8.0 | Enter drug library | 8 | Do not enter drug library | Nurse not alerted to possible wrong dose | 3 | 4 | 12 | Y | Y | | Y | |
| 9.0 | Select drug | 9 | Drug not selected | Pump alarm goes off | 1 | 2 | 2 | N | N | | | |
| | | 10 | Wrong drug selected | Patient receives wrong drug | 3 | 2 | 6 | Y | N | | Y | |
| 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | |
| 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | |

For those failure modes with scores above or equal to the chosen hazard threshold, two considerations will have to be made to determine whether it is a KFM.

Consideration 1: Is the failure mode effectively controlled?

An effectively controlled failure mode has an intervention that is inherent to the system that eliminates or substantially reduces the likelihood of a system failure or adverse event. For example, for the failure mode associated with process step #8 in [Table 16](#), “Do not enter drug library”, some organizations may effectively control this failure mode through the use of a bar code system that identifies the care provider each time the pump is programmed. If a quality lead on the unit follows up with staff each time the drug library is escaped, this failure mode will likely occur infrequently and only with appropriate rationale. In this case, the answer to consideration 1 is yes.

Consideration 2: Is the failure mode detectable?

A detectable failure mode is considered to be an obvious hazard that is likely to be detected and mitigated, and as a result, not requiring an effective control measure.

To determine whether a failure mode is detectable, the following questions should be considered. If any of the following statements are true, the failure mode is NOT detectable and should be analyzed further:

1. There is no possible way to detect the error
2. The failure can be detected only through inspection and is not feasible or readily done
3. Error can be detected with manual inspection but there is no process in place so the detection is left to chance
4. There is a process for double-checks or detection but the process relies on vigilance and/or is applied only to a sample

Those failure modes having a hazard score above the chosen threshold and that are neither effectively controlled nor detectable, are considered KFM, and will be analyzed further.

If a failure mode has a hazard score above the chosen threshold and is either effectively controlled, detectable, or both, it will be documented but will not be analyzed further ([Table 16](#)).

Table 16. Identifying effectively controlled and detectable failure modes

| Task # | | Failure Mode (FM) | | Effect | Scoring | | | Key Failure Mode (KFM) | | | | | | |
|--------|-----------------------------|-------------------|--------------------------------|--|--------------|-----------------|-------------------|------------------------|-------|--------|------------|------------|-----------------------------|-------|
| # | Description | # | Description | | Severity (S) | Probability (P) | Hazard Score (HS) | S ≥ 3 | P ≥ 3 | HS ≥ 9 | Controlled | Detectable | Single Point Weakness (SPW) | KFM ? |
| 1.0 | Check right patient | 1 | Right patient not checked | Wrong patient | 3 | 3 | 9 | Y | Y | | | | | Y |
| 2.0 | Check right drug | 2 | Right drug not checked | Wrong drug | 3 | 3 | 9 | Y | Y | | | | | Y |
| 3.0 | Check right dose | 3 | Right dose not checked | Wrong dose | 3 | 3 | 9 | Y | Y | | | | | Y |
| 4.0 | Check right route | 4 | Right route not checked | Wrong route | 3 | 3 | 9 | Y | Y | | | | | Y |
| 5.0 | Check right time | 5 | Right time not checked | Wrong time | 2 | 4 | 4 | N | Y | | Y | N | | N |
| 6.0 | Attach IV tubing to patient | 6 | Tubing not attached to patient | Medication leak | 1 | 2 | 2 | N | N | | | | | |
| | | | | Patient does not receive medication | 3 | 2 | 6 | Y | N | | | | | Y |
| 7.0 | Turn pump on | 7 | Pump is not turned on | Patient does not receive medication | 3 | 1 | 3 | Y | N | | | | | Y |
| 8.0 | Enter drug library | 8 | Do not enter drug library | Nurse not alerted to possible wrong dose | 3 | 4 | 12 | Y | Y | | | | | Y |
| 9.0 | Select drug | 9 | Drug not selected | Pump alarm goes off | 1 | 2 | 2 | N | N | | | | | |
| | | 10 | Wrong drug selected | Patient receives wrong drug | 3 | 2 | 6 | Y | N | | | | | Y |
| ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | | ... | ... | ... | ... |
| ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | | ... | ... | ... | ... |

Test 3: Single Point Weakness Test

The last test to be applied is the single point weakness test. This test is applied to the failure modes with a hazard score that is less than the chosen threshold. A single point weakness is a failure that on its own would result in a system failure or an adverse event. If a failure mode is identified as a single point weakness, the same two considerations will have to be made as for the hazard-scoring test to determine whether it is a KFM.

Consideration 1: *Is the failure mode effectively controlled?*

Consideration 2: *Is the failure mode detectable?*

If the single point weakness is not effectively controlled or detectable, it will be considered a KFM and analyzed further.

If the single point weakness is either effectively controlled, detectable, or both, it will not be considered a key failure mode. It will be documented, but will not be analyzed further ([Table 17](#))

Table 17. Single point weakness test

| Task # | | Failure Mode (FM) | | Effect | Scoring | | | | | Key Failure Mode (KFM) | | | |
|--------|-----------------------------|-------------------|--------------------------------|--|--------------|-----------------|-------------------|-----|-----|------------------------|------------|-----------------------------|-------|
| # | Description | # | Description | | Severity (S) | Probability (P) | Hazard Score (HS) | SAS | HSI | Controlled | Detectable | Single Point Weakness (SPW) | KFM ? |
| 1.0 | Check right patient | 1 | Right patient not checked | Wrong patient | 3 | 3 | 9 | Y | Y | | | | Y |
| 2.0 | Check right drug | 2 | Right drug not checked | Wrong drug | 3 | 3 | 9 | Y | Y | | | | Y |
| 3.0 | Check right dose | 3 | Right dose not checked | Wrong dose | 3 | 3 | 9 | Y | Y | | | | Y |
| 4.0 | Check right route | 4 | Right route not checked | Wrong route | 3 | 3 | 9 | Y | Y | | | | Y |
| 5.0 | Check right time | 5 | Right time not checked | Wrong time | 2 | 4 | 4 | N | Y | Y | N | | N |
| 6.0 | Attach IV tubing to patient | 6 | Tubing not attached to patient | Medication leak | 1 | 2 | 2 | N | N | N | Y | Y | N |
| | | | | Patient does not receive medication | 3 | 2 | 6 | Y | N | | | | Y |
| 7.0 | Turn pump on | 7 | Pump is not turned on | Patient does not receive medication | 3 | 1 | 3 | Y | N | | | | Y |
| 8.0 | Enter drug library | 8 | Do not enter drug library | Nurse not alerted to possible wrong dose | 3 | 4 | 12 | Y | Y | | | | Y |
| 9.0 | Select drug | 9 | Drug not selected | Pump alarm goes off | 1 | 2 | 2 | N | N | | | N | N |
| | | 10 | Wrong drug selected | Patient receives wrong drug | 3 | 2 | 6 | Y | N | | | | Y |
| ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... |
| ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... |

Only those failure modes and effects deemed to be KFM through this rating and ranking process will be considered going forward for the ^{HF}FMEA.

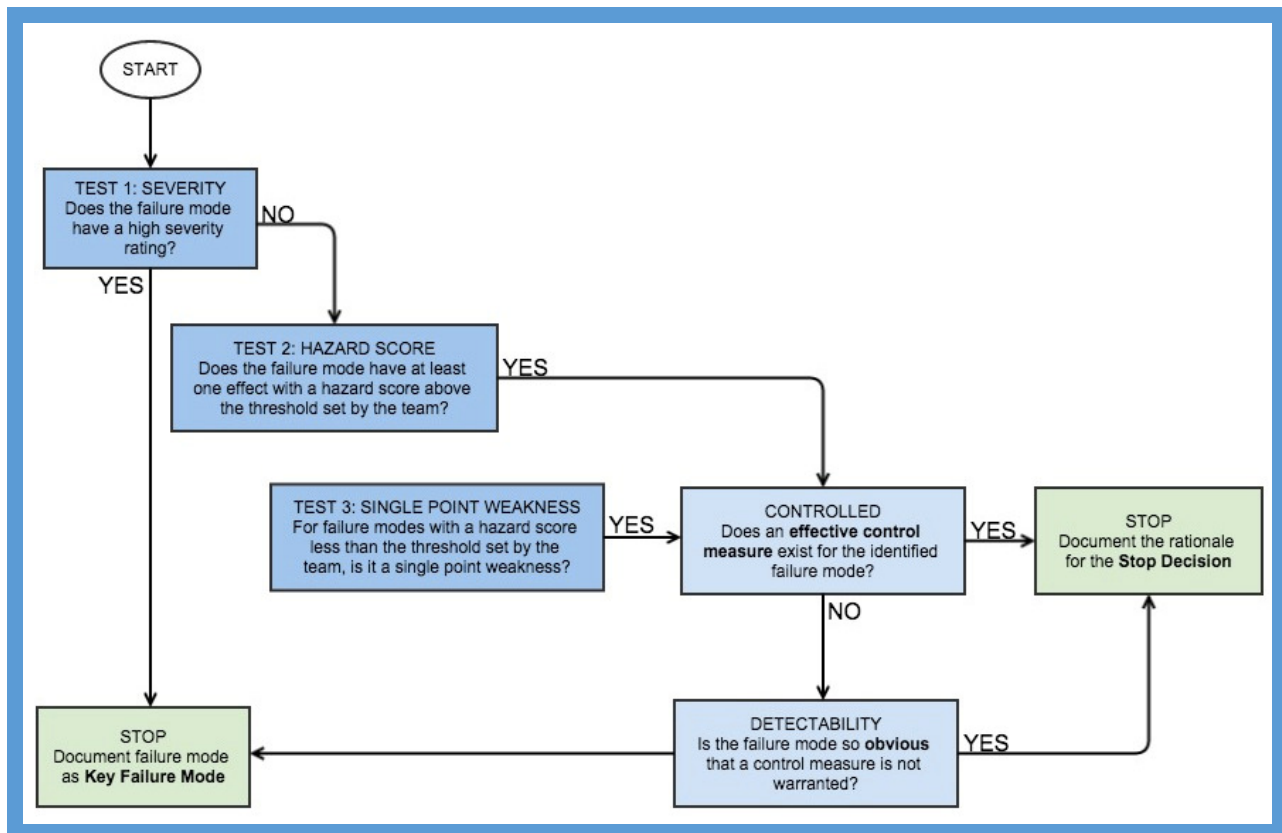


Figure 24. Decision tree used to determine whether a failure mode is a key failure mode

Section 9.5.6. Identify Causes

Only those failure modes determined to be KFM will be considered for the remainder of the analysis. Once the KFMs have been identified, the work team should meet to review the KFMs and begin to identify the causes, or the *whys* behind each KFM. At this stage of the analysis, it is likely the work and advisory teams will have identified a number of causes, which should be captured in the team meeting notes. Any causes should be reviewed, and if relevant, incorporated into the analysis in the ^HFFMEA spreadsheet next to any of the pertinent KFM and effects.

The work team should then systematically review each KFM and effect and think about the possible causes of that failure mode. When thinking about the possible causes, or the *whys* behind each key failure mode, it is important to go beyond the first, most proximal why, because it is the root causes rather than the proximal causes that are of interest for an ^HFFMEA. It is important to go deeper than that first, most proximal why, because if the root causes can instead be identified and addressed, you are much more likely to address the real problem, rather than simply adding a patch to the surface of the problem. Identifying and addressing the root causes will increase the chance the risk associated with the KFM will be reduced.

Some common pitfalls to avoid when identifying causes are (1) only thinking about the human-centric causes, and (2) focusing on compliance with established protocols and procedures.

Think Beyond the Human-Centric Causes

We are all human and we all make mistakes. Consequently, as the work team thinks about the potential causes of each KFM, make sure to go beyond simply saying the user could perform the wrong action, and consider the underlying reasons why an incorrect action might be performed. Failing to think beyond the human-centric causes will not lead to meaningful system change as is intended for the ^HFMEA. To support thinking beyond the human-centric causes continue to ask *why* after a human cause has been identified. For example, for the *administering chemotherapy with an ambulatory infusion pump* process, a cause of the failure mode *tubing not attached to the patient* might be *nurse gets distracted*. Rather than stopping here, the work team should ask why the nurse could get distracted. Perhaps in this case, each nurse is responsible for several patients who all tend to interrupt with questions about their medication. Going beyond the human-centric cause (i.e., distraction in this case) to a system-level cause (i.e., frequent interruptions by patients and high nurse workload), means that mitigating strategies can be developed to lead to meaningful system change. Perhaps if patients were given a dedicated opportunity to talk with a doctor or pharmacist prior to receiving their medications, they would have fewer questions for nurses as their infusions are being set up.

Think Beyond Compliance with Established Protocols and Procedures

Staff compliance issues will surface as causes to certain KFM in almost every ^HFMEA, however, it is important to note that failing to comply with established protocols and procedures is rarely as a result of rebellion or ill will on the part of staff. Instead, there are almost always broader systems issues at play such as staffing levels, scheduling, unfamiliarity with protocols, unworkable protocols, differing work practices, and other work pressures that enable these deviations. When identifying causes, ensure the work team thinks beyond any compliance issues to identify those underlying system pressures so that meaningful system change can be accomplished through tailored and appropriate mitigating strategies.

When identifying causes, if the work team is unable to think beyond the human-centric or compliance focused causes, it is highly recommended other human factors methods, such as observations ([Chapter 4](#)), interviews ([Chapter 5](#)), heuristics ([Chapter 7](#)) or usability testing ([Chapter 8](#)) be used to get to the root causes of why a failure mode could occur.

Once the work team has identified causes for each KFM, the ^{HF}FMEA spreadsheet should be circulated to the advisory team for review and any feedback. A meeting with the work and advisory teams should be scheduled to review and discuss the root causes identified for each KFM.

Team Meeting # 5:

Attendees: work and advisory teams

Purpose: finalize root causes for each key failure mode

Estimated Duration: 2 to 3 hours

Root causes for each key failure mode will be reviewed, discussed, and finalized during this meeting. The facilitator should walk the group through the causes for each key failure mode. The advisory and work teams should discuss and refine causes with any disagreements being resolved through discussion to reach a consensus.

Every team member should have a printed copy of the ^{HF}FMEA spreadsheet. If possible, project a working copy of the ^{HF}FMEA spreadsheet so the entire team can see it, and have the scribe update causes in real time.

Depending on the process scope and the number of key failure modes to review, between two and three hours should be scheduled. Bring refreshments for team members if possible.

Section 9.5.7. Develop and Implement Mitigating Strategies

The final step of an ^{HF}FMEA is to develop and implement mitigating strategies that address the root causes of the key failure modes in order to reduce the severity, or likelihood, or increase the detectability of a failure mode. Developing strategies that focus on changing the system, rather than strategies that focus on changing the person, is of the utmost importance. If mitigating strategies aim to change how a person behaves, or how they interact with the system, there may be a temporary improvement, but over time, work pressures and inherent human limitations will drive people towards their former work behaviours to allow them to meet work demands. In contrast, when mitigating strategies focus on the system, sweeping improvements can be made, rather than trying to make changes person by person. Implementing a system-level mitigating strategy means that regardless of the person, or their knowledge of policies, or their awareness or vigilance on a given day, the system is set up to guide people to perform correctly and safely.

To support the development of system-focused, rather than person-focused, mitigating strategies, as well as to compare the relative potential effectiveness of different strategies, it is highly recommended that the Hierarchy of Effectiveness ([Section 3.5](#)) be used. The Hierarchy of Effectiveness should be distributed to work and advisory team

members and a meeting should be scheduled for both groups to work together to start to develop mitigating strategies to address the root causes of the KFM.

Team Meeting # 6:

Attendees: work and advisory teams

Purpose: develop mitigating strategies to address root causes for each key failure mode

Estimated Duration: 2 to 3 hours

Ideas about how to mitigate the root causes for each key failure mode will be shared and discussed at this meeting. The facilitator should encourage a range of ideas and ensure team members consider the Hierarchy of Effectiveness when proposing and discussing strategies. A strong facilitator will be required to keep the discussion inclusive and moving forward, while still reminding team members to think about the effectiveness of proposed solutions using the Hierarchy of Effectiveness.

Every team member should have a printed copy of the ^{HFF}FMEA spreadsheet. If possible, project a working copy of the ^{HFF}FMEA spreadsheet so the entire team can see it, and have the scribe update ideas for mitigating strategies in real time.

Depending on the number of key failure modes, between two and three hours should be scheduled. Bring refreshments for team members if possible.

In addition to how effective a mitigating strategy is likely to be, it is also important to consider whether implementing it is feasible, given the resources available. Once the work and advisory teams have identified a number of possible mitigating strategies that are likely to be effective, the next step is to consider the required resources for proper implementation. A prioritization exercise that weighs the likely effectiveness, required resources, and available resources/feasibility for each mitigating strategy, will have to be completed by the work and advisory teams. There is no prescribed process for prioritizing the implementation strategies; however, a good guiding principle for choosing mitigating strategies is that it is more effective to implement fewer, more resource intense, mitigating strategies that will address higher risk issues than implementing many low-resource mitigating strategies that addresses lower risk issues.

To support this prioritization exercise, a copy of the ^{HFF}FMEA spreadsheet with possible mitigating strategies should be circulated to the work and advisory teams for review. A meeting should be scheduled to discuss and decide upon which of the proposed strategies will be pushed forward for implementation.

Team Meeting # 7:

Attendees: work and advisory teams

Purpose: prioritize mitigating strategies, create implementation plans, conclude ^{HFF}FMEA

Estimated Duration: 2 to 4 hours

The mitigating strategies put forth in Team Meeting #6 will be reviewed and prioritized based on the likely effectiveness, required resources, and available resources/feasibility in each case. It is important to have senior advisors present at this meeting as they will have the broad organizational knowledge and authority required to decide which mitigating strategies should be implemented.

Once the group has determined which mitigating strategies to move forward with, the team should develop an implementation plan ([Section 9.6, What to Do With a Completed ^{HFF}FMEA](#)).

The scribe should capture all discussion and any decision points in real-time, ideally, with any notes being projected so all team members can see them.

Depending on the number of mitigating strategies being considered, and how many are likely to move forward for implementation, between two and four hours should be scheduled. Bring refreshments for team members if possible.

Although implementation work will continue, this is the last official meeting of the ^{HFF}FMEA team.

Section 9.6. What to do with a Completed ^{HFF}FMEA

As part of Team Meeting #7, once mitigating strategies have been prioritized and a decision has been made about which solutions will be implemented, a plan needs to be developed to support the successful implementation of each strategy. The plan for each strategy should outline (1) the individuals responsible for implementing the strategy, (2) the outcome measures that will be used to assess success, (3) anticipated timelines, and (4) a plan for proactively evaluating the new failure modes that are likely to be associated with the system changes made through implementing the mitigating strategy.

Each agreed upon mitigating strategy should then be implemented at the healthcare organization using the plan developed during Team Meeting #7. Although no further meetings are typically scheduled for the ^{HFF}FMEA team beyond Team Meeting #7, those responsible for implementing the mitigating strategies will likely find it helpful to keep in

touch with various team members for support and guidance throughout the implementation process.

It is highly recommended that a summary document be prepared by the work team that outlines the ^{HF}FMEA process, team members, key decisions, lessons learned, and progress implementing mitigating strategies to date. This document should be circulated to the advisory team for review and approval before sharing more broadly with the healthcare organization and others. Having such a document can provide a wealth of information for future ^{HF}FMEAs and accreditation activities, and is a means of capturing how mitigating strategies came to be implemented

Section 9.7. Limitations of ^{HF}FMEA

Prior to conducting an ^{HF}FMEA it is important to consider some of the criticisms and limitations of this method.

Section 9.7.1. The Resources Required

Like all approaches to FMEA, the resources required to conduct an ^{HF}FMEA can be substantial. A team consisting of several professionals is required to meet regularly, and carry out a number of steps to complete an analysis. To address this challenge, the ^{HF}FMEA method aims to somewhat reduce the resources required in comparison to the more traditional FMEA methods. This is achieved by moving the failure mode ranking exercise earlier in the analysis so the bulk of the time invested by the group is spent examining those failure modes considered to be the highest risk. Further, to help control the required resources, it is highly recommended that a well-defined process scope be chosen prior to undertaking an ^{HF}FMEA.

Section 9.7.2. Impossible to Identify Every Failure Mode

No matter how much time and effort is spent identifying failure modes, it is impossible to identify every failure mode that could occur. Healthcare systems are extremely complex in comparison to many other industries in which FMEA is used because of the variability introduced by patients and changing patient conditions, and the knowledge, experience, and mental models held by staff. Although every possible failure mode will not be uncovered using this technique, ^{HF}FMEA can be relied upon to highlight many failure modes with the potential for serious consequences that are not readily apparent prior to applying the method. If resources allow, applying other human factors methods such as heuristic evaluation ([Chapter 7](#)), and usability testing ([Chapter 8](#)) during the ^{HF}FMEA process can increase the chances of identifying as many failure modes as possible.

Section 9.7.3. Hazard Scoring is Subjective and Only Allows for Relative Ranking

Assigning hazard scores to each failure mode is subjective, and as such, different analysis teams could assign different hazard scores to the same failure mode. Thus, hazard

scoring only allows for the relative ranking of failure modes. To make the scoring process as robust as possible, it is important that the ^{HF}FMEA team score hazards as a group, and that any disagreements are discussed until consensus is reached. The dynamics of the team should also be considered to avoid a situation where a few individuals have a strong influence on scoring. Further, the same team should score all hazards for consistency across the analysis, rather than having different team members rate different groups of failure modes. The hazard scoring process should only be used to help the ^{HF}FMEA team separate the high- and low-risk failure modes relative to each other rather than as an absolute or quantitative measure of risk at each process step.

Section 9.7.4. Potential for False Positives

The way in which scoring is done for a traditional FMEA means that it is possible for a high severity, low probability failure mode to yield the same risk score as a failure mode that is low severity, but high probability. This can be problematic in healthcare because when evaluating risks to patient safety, a failure mode that is unlikely, but high in severity, is likely to require more attention than a failure mode that is likely, but low in severity. Even one serious patient safety issue is still one too many, and so should be emphasized through this type of analysis. To help address this challenge, the ^{HF}FMEA makes use of a rating process that incorporates every high severity failure mode for further consideration regardless of how frequently it might happen.

Section 9.7.5. No Guidance for Developing Mitigating Strategies

Traditional FMEA methods do not provide any guidance for developing effective mitigating strategies to address identified failure modes. As such, it is up to the analysis team to propose solutions that will successfully prevent failure modes from occurring. Further, the actual effort required to implement a proposed mitigating strategy and the hazard score attributed to a failure mode do not always match, meaning that at times the score will indicate a need for action, but the cost and effort required are not justified by the risk. To help weigh the benefits and costs, as well as set expectations about how likely a solution is to mitigate a failure mode, the ^{HF}FMEA incorporates a hierarchy that can be used to assess a solution's likely effectiveness.

Section 9.8. Additional Resources

Journal Articles

1. ECRI. (2004). Failure mode and effects analysis: A hands-on guide for healthcare facilities. *Health Devices*. 33(7); pp.233-243.
2. De Rosier J, Stalhandske E, Bagian JP, Nudell T. (2002). Using health care failure mode and effect analysisTM: The VA National Centre for Patient Safety's prospective risk analysis system. *Journal of Quality Improvement*. 28(5); pp. 248-267.

Web Tools

1. Institute for Healthcare Improvement Failure Modes and Effects Analysis Tool.

<http://www.ihp.org/knowledge/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx>

Chapter 10. Human Factors Informed Root Cause Analysis

Section 10.1. Setting the Stage

Root Cause Analysis (RCA) is a retrospective incident investigation framework, initially developed as a quality management engineering tool, that is now widely used in many industries to support the improved safety of systems following an accident or incident. In healthcare, regulators such as The [Joint Commission](#) have mandated immediate investigation and response following a sentinel event, which is “an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof” [44]. RCA is a means by which this type of investigation and response can be accomplished.

Like the other human factors methods presented in this handbook, a central tenet of RCA is that in healthcare, inherently people do not want to cause harm. Consequently, this method focuses on identifying the system factors and issues contributing to an incident, rather than what a person might have done wrong. The root causes inherent to the system, and not the people, are the factors that will need to be addressed to improve overall system safety. When individuals are blamed for an incident, remedial action tends to focus on the person or people involved, but this represents a missed opportunity to make wider reaching changes to the system, aimed at preventing future occurrences of the same, or a similar error. Unfortunately, there are many examples of healthcare professionals who have unintentionally made errors as a result of a poor system design, and who have received harsh punishments such as losing their professional license, or being criminally charged [45, 46]. These punishments are in addition to the guilt, mental anguish, and loss of self-confidence experienced as a “second victim” of the incident [47, 48]. In the case of one such second victim blamed for an accidental calcium chloride overdose that led to the death of an eight month old patient, the emotional stress of the aftermath of the incident led her to commit suicide [49].

These types of tragic outcomes for staff involved in an incident are not inevitable. Rather than assigning blame, if one instead applies systems thinking and views an incident as a series of system failures ultimately contributing to a sentinel event, identifying and addressing those system failures will serve to strengthen the system and improve the likelihood that future similar incidents will be eliminated.

To support the completion of an RCA several quality and safety organizations, such as The [Joint Commission](#), the [VA National Centre for Patient Safety](#), [ISMP Canada](#), the [Canadian Patient Safety Institute](#), and the NHS (UK) have developed different RCA frameworks and tools. For example, the [Joint Commission offers an online RCA framework](#), along with publications about specific sentinel events that have been investigated using RCA[50]. Additionally, the VA has online tools and triage cards[51], ISMP Canada has

published several high profile RCA investigations[52], ISMP Canada and CPSI have jointly authored the comprehensive Canadian Incident Analysis Framework [53] and the NHS (UK) has an online Root Cause Analysis Toolkit and eLearning Programme [54].

For the purposes of this handbook, portions of these RCA frameworks will be combined and various human factors methods will be incorporated to create an ^{HF}RCA framework.

Section 10.2. What is ^{HF}RCA

^{HF}RCA is a human factors analysis method used to retrospectively identify root causes and contributing factors leading to a incident. A *root cause* can be considered an initiating factor leading to a particular effect or outcome and a *contributing factor* can be considered a condition that influences a particular effect or outcome. Ideally, a multidisciplinary team works together to collect information, document the incident, identify the root causes and contributing factors, and identify mitigating strategies targeted at improving the system in order to prevent similar incidents from happening again.

The ^{HF}RCA aims to improve on the more traditional RCA method by incorporating a range of human factors methods during the analysis to:

- Determine whether an ^{HF}RCA should be completed at all
- Promote the collection of accurate and quality data and artefacts from the field in a tactful manner
- Document the events leading up to the sentinel event
- Enable the identification of root causes from a human factors perspective by taking our natural human strengths and limitations into account
- Identify human factors informed mitigating strategies and set expectations about how much risk is likely to be mitigated given the proposed solutions

Section 10.3. Why use ^{HF}RCA

After a sentinel event, or a near miss that could have negatively impacted patient safety, an ^{HF}RCA should be conducted to examine and identify the root causes that contributed to the event. Completing an ^{HF}RCA is strongly recommended because this method allows the biomedical technology professional to go beyond the surface level contributing factors, to the true underlying root causes of the issue. It is only when the true root causes are addressed, that a reliable improvement to safety can be realized. These more surface level contributing factors, called *active failures*, tend to be focused on a person's actions and are highly dependent on the context of the specific incident. When an investigation stops here, it means that when other people find themselves in the same or a similar situation, the sentinel event is likely to recur because the system factors that were in place during the incident, still exist. In contrast, when the underlying root causes, also

called *latent failures*, can be identified and addressed, the design of the system is inherently improved to support staff in performing safely, making the occurrence of a similar sentinel event unlikely.

When done well, an ^{HF}RCA can unite staff from across the organization who have been touched by a patient safety incident. Organizational culture can be strengthened when staff work together to identify the root causes that contributed to an incident, which can lead to a strong resolve among staff members to improve the system in order to promote patient safety.

From the biomedical technology professional's perspective, completing an ^{HF}RCA will be helpful for:

- Preventing similar sentinel events from recurring
- Retrospectively examining and managing the root causes contributing to a sentinel event
- Retrospectively examining and managing the root causes contributing to a near miss
- Meeting accreditation requirements following an incident

Section 10.4. When to use ^{HF}RCA

An ^{HF}RCA should be conducted following a sentinel event, an incident that resulted in serious harm or death, or a near miss that could have resulted in serious patient harm. Completing an ^{HF}RCA on a serious near miss that was caught can be an excellent opportunity to proactively prevent other similar events from occurring.

Prior to conducting an ^{HF}RCA, the biomedical technology professional should ensure they have the support and buy-in of management to increase the chance for uptake and positive changes stemming from the analysis. In the case of a near miss, although an ^{HF}RCA may not be required from a regulatory body perspective, a strong case can still be made based on the liability associated with a possible future sentinel event with a history of near misses.

Completing an ^{HF}RCA following an incident can be a cathartic experience for those involved, providing an opportunity to strengthen workplace culture and unite staff in the face of a tragedy.

Section 10.5. In Preparation for an ^{HF}RCA

There is little that can be done in preparation for an ^{HF}RCA. Often sentinel events seem to occur suddenly, and so just being familiar with the ^{HF}RCA framework and being prepared to work with senior leaders and act quickly once an incident has occurred, is the best approach.

Section 10.6. Completing an ^{HF}RCA

The ^{HF}RCA process comprises six steps, outlined in [Figure 25](#). Each step will be outlined and described in this section.

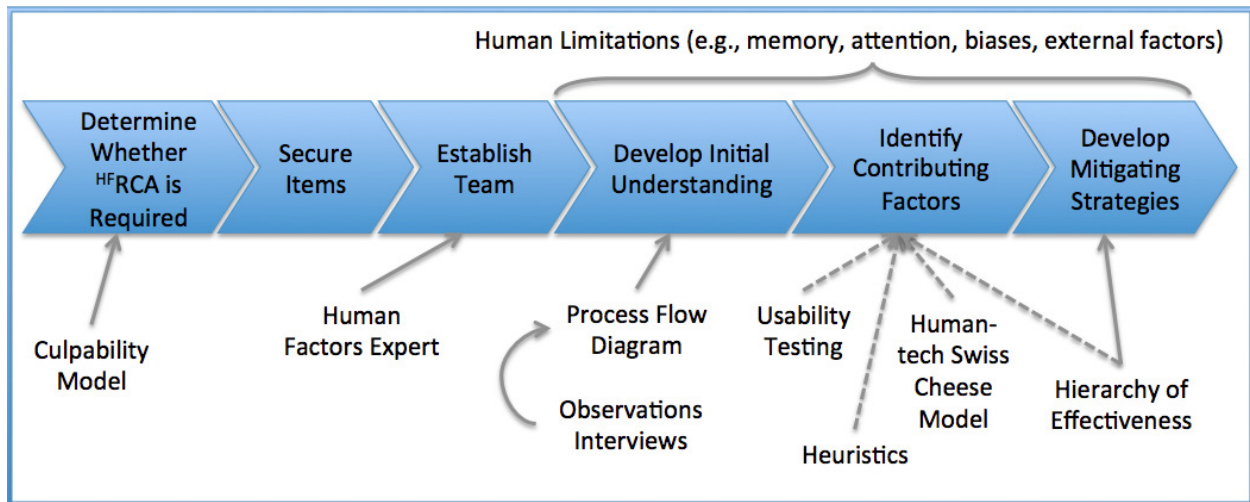


Figure 25. The six steps and opportunities to incorporate human factors as part of an ^{HF}RCA

Section 10.6.1. Determine Whether an ^{HF}RCA is Required

Following a sentinel event, the first step is to determine whether an ^{HF}RCA is required. This should be done as quickly as possible to increase the chance of collecting all equipment, supplies, and as much information as possible from the location of the incident before anything is adjusted or removed by others.

As noted previously, a determination of whether the incident is considered unintentional will have to be made. To assist with this determination, an Incident Decision Tree developed by the NHS (UK) [55] and adapted for this text ([Figure 26](#)) should be used. The decision tree is a tool that guides the process of determining whether an individual or the system is culpable for a sentinel event.

To apply the incident decision tree, each of the four tests from [Figure 26](#) should be applied sequentially. If the actions were as intended and/or there is evidence of ill health or substance abuse, the incident may have stemmed from a wilful action, and is not a good candidate for analysis using ^{HF}RCA. In these cases, consult with the appropriate regulatory bodies and union representatives, if applicable, and consider how the situation will be handled by the healthcare organization.

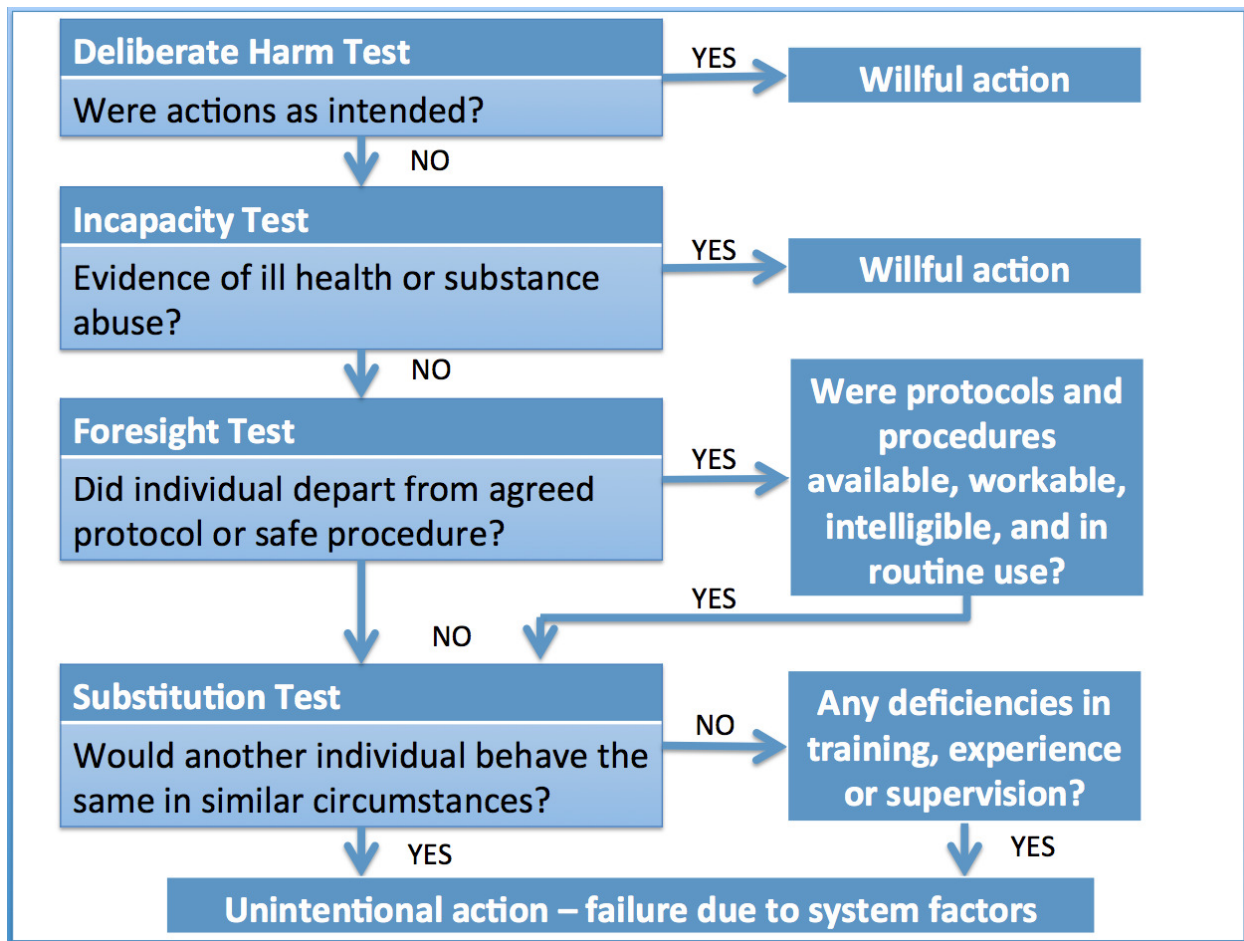


Figure 26. Incident Decision Tree For Responding to Patient Safety Events. Reprinted with permission (adapted from the UK National Health Service).

If the individual's actions were not as intended and there is no evidence of ill health or substance abuse, the foresight test is applied. In cases where an individual departed from an agreed upon protocol or safe procedure, it is important to consider whether (1) the protocols and procedures make sense, (2) they were readily used, and (3) they were readily available to staff. Remember that given what we know about inherent human limitations, trying to influence behaviour by writing expected actions in a protocol is not a very robust strategy to prevent errors.

The final test requires the biomedical technology professional to consider whether another individual in similar circumstances is likely to behave in the same way. It is important to approach this final question from a human factors perspective, that is, to consider the system factors that may have led someone to behave in a certain way. Keep in mind our inherent human limitations ([Chapter 3](#)) and consider whether there might be any deficiencies in training, experience, or supervision. In most cases, the biomedical

technology professional will find that sentinel events are a result of unintentional actions leading to system failures, rather than from wilfully harmful actions.

When the incident decision tree points to an unintentional action resulting in a failure, it indicates it is the system that has failed. These types of events are good candidates for analysis using an ^{HF}RCA. In these cases, the healthcare institution will have to determine whether the sentinel event will move forward for investigation using an ^{HF}RCA. This decision will likely be based on many factors including legislative requirements, accreditation standards, hospital policies, and resources. Since conducting an ^{HF}RCA can be resource intensive, this kind of undertaking is more likely to be supported when the organization is required to perform this type of analysis.

Section 10.6.2. Secure Items

As soon as the decision has been made to move forward with an ^{HF}RCA, it is critical that all items used at the time of the incident, and any used shortly beforehand, be collected and secured. If a technology is involved, the device must immediately be taken out of use and the logs retained to ensure this information is available to the team going forward. Other things to collect might include, but are not limited to:

- All medications and fluids, including packaging and sharps
- Copies of medication orders
- Medication labels
- Scrap paper used for calculations
- Any other supplies and packaging
- Photographs of the environment
- Photographs of the technology set up
- Screen shots from any electronic systems
- The patient's health record

If the patient's health record is obtained, make a copy for the unit to continue using if the patient is receiving ongoing care and be sure to follow all privacy regulations when handling the health record. Information about the unit such as a schedule, any shift changes, new procedures, changes to equipment or supplies, organizational practices, and policies can also be quite valuable if they are available.

Once these things have been collected from the field, a photograph should be taken of each item and all lot numbers, serial numbers, and expiration dates should be recorded. The items should be reviewed, and the biomedical technology professional should consider whether there is any evidence of items that are inherently confusing, complicated, or seem to be outside of what would be considered normal procedure (e.g., handwritten changes to

an order, look alike sound alike medications). Any of these types of observations should be noted for future reference.

It is important to collect and document this information (e.g., through photographs and written records) in a timely manner to ensure it is as accurate as possible because in stressful situations especially, humans have inherent limitations in memory.

Section 10.6.3. Establish the Team

Once items have been secured from the field, a core analysis team must be established to conduct the ^{HF}RCA. Team members should be knowledgeable about one or more topics related to the sentinel event, be analytical, and have a mindset that supports a just culture where health care organizations are accountable for the systems they have designed and staff are accountable for their behavioural choices and reporting errors and system vulnerabilities [56, 57]. Core team members should participate over the course of the entire analysis but others may be involved as team members on an as needed basis to support certain aspects of the analysis. For example, patients and family members, and some subject matter experts, may only be involved while an initial understanding of the incident is being developed. Thus, the size of the larger team will vary not only depending on the context of the incident, but also the stage of the analysis.

Generally, teams should be multidisciplinary, including both clinical and non-clinical staff, to represent a broad range of perspectives, and to provide valuable insight and leadership to support the analysis.

Section 10.6.3.1 Complete a Confidentiality Agreement

Depending on the policies of your healthcare organization, team members may have to sign a confidentiality agreement prior to participating as part of an ^{HF}RCA team. Signing this kind of agreement can serve as a reminder of team members' responsibility to protect any information obtained as part of the ^{HF}RCA. [The Canadian Incident Analysis Framework](#) [53] provides a sample confidentiality agreement in the event your healthcare organization does not have a template prepared.

Section 10.6.3.2 Team Member Roles

Individual team members will need to fulfill a number of roles to ensure a successful ^{HF}RCA. These roles include a *leader*, a *facilitator*, and a *senior leadership representative*. In addition, you will need *subject matter experts* who are knowledgeable and can provide information and think critically about the system factors that may have led to the sentinel event such as technologies, processes, environmental factors, policies, training programs, organizational changes, etc. One team member should take on the role of *scribe*, and ideally, a *human factors expert* should also be included as part of the ^{HF}RCA team.

Finally, depending on your institution, you may want to reach out to the *patient and family* to see if they are willing to participate as part of the ^{HF}RCA team. Patients and family members can provide an essential perspective that will be unique from that of any of the clinical team members. In addition, involving patients and family members can provide a needed sense of closure and contribution in some cases. It is essential to note, however, that including those who were directly involved in the incident, whether they are patients and family members or staff, can be difficult, and will have to be approached with extreme sensitivity to ensure the experience is positive and not defensive or punitive.

Team Leader

According to the [Canadian Incident Analysis Framework](#) [53] a leader is someone who has a general understanding of the incident that occurred, and has the authority to undertake an investigation. An individual in a senior clinical management role who possesses strong clinical and analytical skills would be a good candidate. The leader will be responsible for:

- Keeping the team focused
- Supporting cultural change
- Supporting other team members in their analysis
- Removing barriers encountered by other team members

Facilitator

A facilitator is someone who can manage group dynamics, delegate tasks, and facilitate group consensus building. An individual that is a specialist in quality or risk management, who possesses confidence and has expertise in analytical methods, would be a strong candidate. The facilitator will be responsible for:

- Coordinating team meetings
- Ensuring the team stays focused
- Facilitating constructive discussion among team members
- Monitoring timelines
- Ensuring the analysis process follows the healthcare organization's protocol and policies
- Ensuring the completion of a final report, if applicable

Senior Leadership Representative

A senior leadership representative is someone who has the authority for decision-making, and helps to drive a culture of safety. An individual who is a senior manager for the

organization will be a strong candidate. The senior leadership representative will be responsible for:

- Ensuring any actions and mitigating strategies are implemented
- Authorizing scheduled time away from staff member's regular duties to participate in the analysis
- Encouraging and supporting the broad communication of the results and mitigating strategies
- Ensuring those involved in the sentinel event, including patients and families, and staff, are supported so the experience is as positive as possible

Subject Matter Experts

Subject matter experts are individuals who are knowledgeable about one or more topics related to the sentinel event. They should have a detailed understanding of any technologies, processes, environments, policies, training, and organizational structures or changes that may have contributed to the incident. Subject matter experts should be critical thinkers, capable of providing feedback and input over the course of the ^{HF}RCA. These team members will carry out the bulk of the hands-on analysis including developing an initial understanding of the incident, identifying root causes and contributing factors, and developing mitigating strategies.

Scribe

The scribe is responsible for capturing any discussion or decisions made whenever the team convenes. The scribe should circulate meeting minutes to the entire team and an agenda of what the team hopes to accomplish prior to each meeting.

Human Factors Expert

Ideally, the ^{HF}RCA team will include at least one human factors expert. The human factors perspective is important for an ^{HF}RCA because this will facilitate the inclusion of various human factors methods, and ensure the analysis takes our inherent human limitations into account, especially when thinking through the root causes and contributing factors to the sentinel event. If it is not possible to include a human factors expert, the health technology professional can apply their newfound human factors knowledge (supported by this book and the additional resources highlighted in this book) during the ^{HF}RCA in order to fulfill this role. Another more cost effective option to consider is to bring in a graduate student of human factors and their advisor to help provide this insight, if available.

Patient and Family

If the patient and family are included as part of the ^HF RCA team, they will be able to provide invaluable information about the sentinel event from a unique perspective that no other team member will have. They will serve as subject matter experts from the perspective of the ones receiving care.

Section 10.6.4. Develop Initial Understanding of Incident

Developing a thorough and accurate initial understanding of the incident will be key in supporting the identification of the actual root causes and contributing factors, and the development of robust and effective mitigating strategies.

Section 10.6.4.1 Create an Initial Process Flow Diagram

To start, create a process flow diagram ([Chapter 6](#)) based on your preliminary understanding of the incident. This initial understanding should be informed with any information collected from the staff who were involved, information from any incident reports, a chart review, history logs of any devices, any information that can be acquired from hospital systems, and artefacts. The defined goal for this task analysis should match that of the individual(s) at the time of the sentinel event. The scope for this task analysis should also match the conditions and context present at the time of the sentinel event. The initial process flow diagram should describe the *actual*, rather than the ideal or prescribed process and sequence of events.

As the diagram is being created, keep track of any questions that arise or areas of uncertainty, as these will have to be addressed as the diagram is updated iteratively.

Section 10.6.4.2 Iteratively Update the Process Flow Diagram

Once this initial diagram has been created to describe the sequence of events, it is essential the diagram be shared with the ^HF RCA team to get any feedback. As with any task analysis, the creation of a process flow diagram is an iterative one, requiring multiple rounds of sharing, incorporating feedback, and review. To support the ^HF RCA method, in addition to sharing the diagram with the ^HF RCA team for feedback, observations ([Chapter 4](#)), and interviews ([Chapter 5](#)) should also be done to further improve the process flow diagram. Once several rounds of iteration have been completed and the diagram reflects the actual workflow during the sentinel event as closely as possible, the diagram can be considered complete; in the event new information comes to light, however, this diagram should be updated no matter what point of the ^HF RCA the team is at to ensure the diagram reflects the most accurate information possible.

Section 10.6.4.3 Layer Other Contextual Information on to the Process Flow Diagram

This process flow diagram can be used as the backbone for developing an initial understanding of the incident. In addition to an overview of the tasks leading up to the sentinel event, this diagram can also be used to document the timing of various tasks and

events, and as a legend or key to link to artefacts, policies, procedures, and other contextual information that was collected as items were secured.

The biomedical technology professional may also find it helpful to indicate not only the actual events leading to the sentinel event, but also the “expected working process” and the “typical working process” so that any deviations can be highlighted. The expected working process is the series of steps that should be performed by staff as outlined by a healthcare organization’s policies and procedures. The typical working process is the series of steps most staff carry out as a result of the reality of daily operations including factors such as work, time, and cost pressures. Expected and typical working processes are likely to differ, as typical working processes will include things like workarounds and shortcuts that most staff use to try to get their work done as efficiently and safely as possible. Adding information about the expected and typical working processes to the diagram of the actual events leading to the sentinel event can be extremely helpful because any points at which there are deviations serve as clues that the system as designed is failing to support the people working within it. The policies and procedures that have been developed may look right on paper, but when the context and reality of the front lines are taken into account, policies and procedures can be cumbersome to follow.

Section 10.6.4.4 Finalize the Process Flow Diagram

Once the diagram has been created, updated iteratively, and used as a basis for linking artefacts and other contextual information, including any deviations from expected and typical workflows, it should be circulated to the core ^{HF}RCA team for any additional feedback. This diagram will be used as the basis for identifying the root causes and contributing factors leading to the sentinel event.

Section 10.6.4.5 Create a Factual Description of the Events Leading to the Incident

Based on the finalized process flow diagram, a written, factual description of the events that led up to the sentinel event should be created. This description will be more accessible for staff who are outside of the core and extended ^{HF}RCA teams when it is time to share information about the incident with them.

Section 10.6.5. Identify Contributing Factors

Once the team has a clear initial understanding of what happened leading up to the incident, the next and most important step of an ^{HF}RCA is to understand the root causes and contributing factors leading to *why* the incident happened. It is critical to note that a sentinel event is almost always caused by multiple factors, rather than just a single root cause. The root cause is typically considered to be only the first in a chain of contributing factors leading to the incident. The contributing factors can be considered circumstances, actions, or other influential factors that are likely to have played a role, or increased the chance of, the incident occurring [53].

A helpful starting point when identifying causes can be to write down the task or action that went wrong, and then to keep asking *why* it went wrong using the process flow diagram and any artefacts as you go. This approach will allow the team to build an understanding of the system context that surrounded the incident. At this point it will already have been established that the individuals involved in the sentinel event did not intend to cause harm, so as is the case for ^{HF}FMEA, it is important to avoid focusing only on the human centric causes, and failures of individuals to comply with established protocols and procedures ([Section 13.2.6](#)). If an individual makes a mistake or fails to comply with an established protocol or procedure, the job of the ^{HF}RCA team is to ask why that might have been. The systems we work within should not require us to be superhuman, but rather, systems should be designed to take our human limitations into account. Features of a system that do not support us in our inherent strengths and limitations have the potential to lead us to make mistakes, and thus should be thought of as contributing factors.

Section 10.6.5.1 Human-tech/Swiss Cheese Model Framework

To help in identifying the system features contributing to a sentinel event, several human factors methods, such as observations ([Chapter 4](#)), interviews ([Chapter 5](#)), heuristics ([Chapter 7](#)), or usability testing ([Chapter 8](#)) can be used. In addition, a combination of the Human-tech ladder ([Section 3.2](#)), and Reason's Swiss Cheese Model of Error ([Section 3.4](#)) is highly recommended as a guiding tool ([Figure 27](#)).

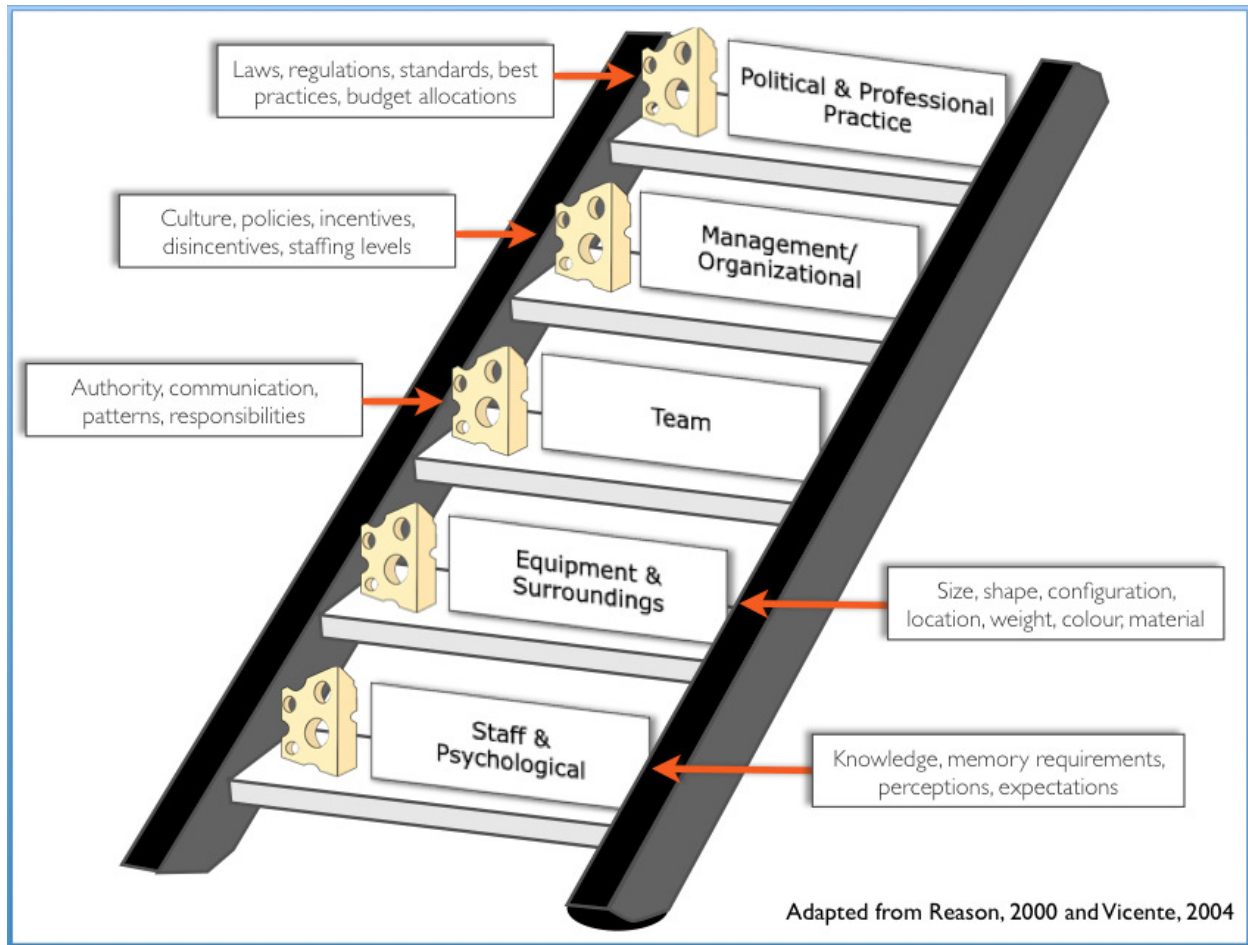


Figure 27. Human factors framework adapted from Reason's Swiss Cheese Model, 2000 and Vicente's Human-tech ladder, 2004

This human factors framework illustrates the importance of thinking beyond the human centric causes, to thinking about contributing factors related to the physical, psychological, team, organizational, and political levels of the system. Latent factors at each of these levels typically translate into system weaknesses that can combine to allow a sentinel event to occur. For example, if an ^{HF}RCA team is trying to identify contributing factors leading to an incident where a calculation error was made leading to a patient overdose, the adapted human factors framework could be used as follows ([Figure 28](#)).

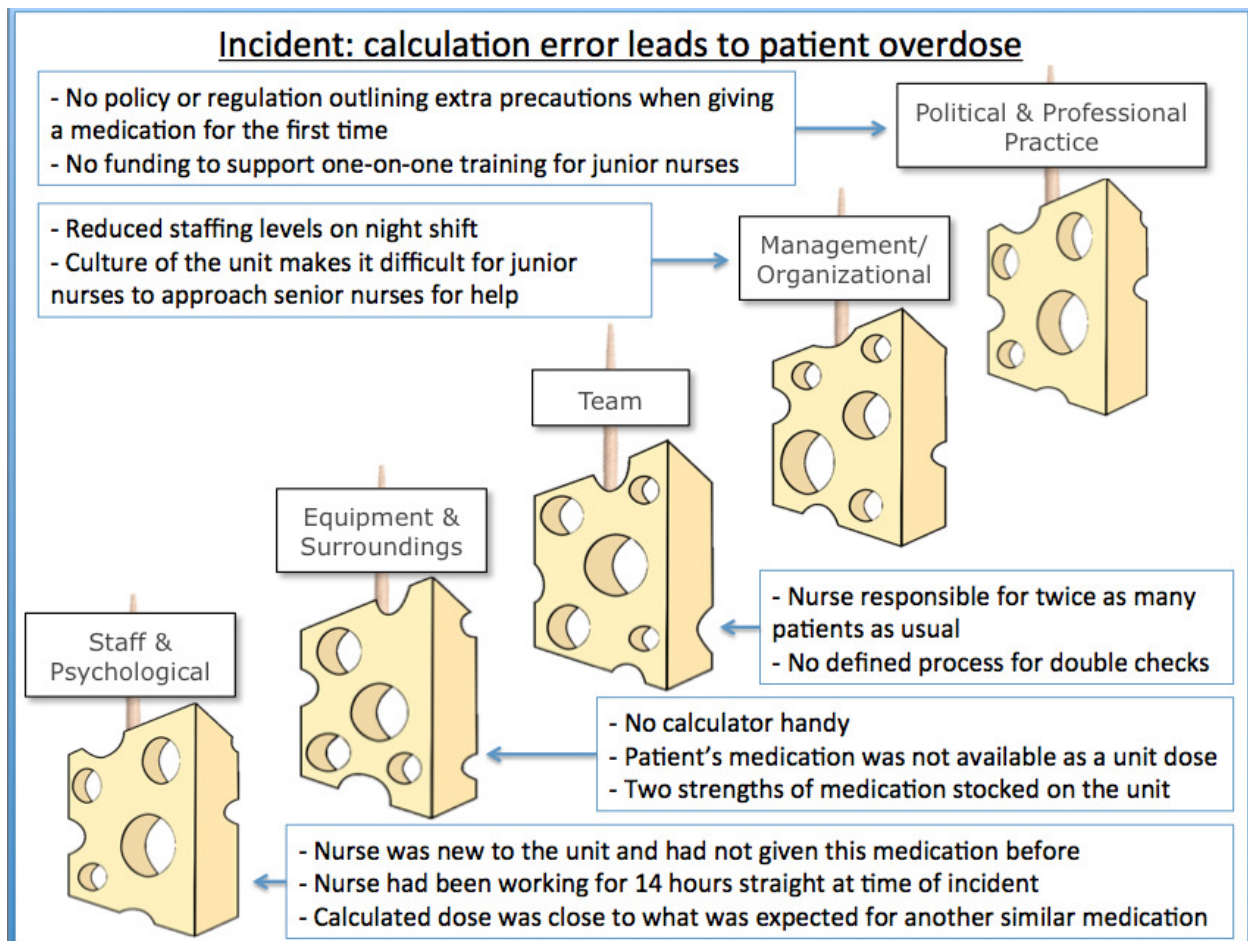


Figure 28. Using Reason's Swiss Cheese Model and Vicente's Human-tech ladder to identify contributing factors to a sentinel event

In addition to this human factors framework, and the other human factors methods mentioned above (i.e., observations, interviews, heuristics, usability testing), The [Joint Commission's RCA Framework](#) [50], [Table 18](#), provides a series of helpful prompts to encourage the ^{HF}RCA team to think through a wide range of potential contributing factors.

Table 18. RCA Action Plan Tool (© The Joint Commission, 2013. Reprinted with permission.)

| | Analysis Question | Prompts |
|---|---|--|
| 1 | What was the intended process flow? | <p>List the relevant process steps as defined by the policy, procedure, protocol, or guidelines in effect at the time of the event. You may need to include multiple processes.</p> <p>Note: The process steps <i>as they occurred in the event</i> will be entered in the next question.</p> <p>Examples of defined process steps may include, but are not limited to:</p> <ul style="list-style-type: none"> • Site verification protocol • Instrument, sponge, sharps count procedures • Patient identification protocol • Assessment (pain, suicide risk, physical, and psychological) procedures • Fall risk/fall prevention guidelines |
| 2 | Were there any steps in the process that did not occur as intended? | <p>Explain in detail any deviation from the intended processes listed in Analysis Item #1 above.</p> |
| 3 | What human factors were relevant to the outcome? | <p>Discuss staff-related human performance factors that contributed to the event.</p> <p>Examples may include, but are not limited to:</p> <ul style="list-style-type: none"> • Boredom • Failure to follow established policies/procedures • Fatigue • Inability to focus on task • Inattentional blindness/ confirmation bias • Personal problems • Lack of complex critical thinking skills • Rushing to complete task • Substance abuse • Trust |
| 4 | How did the equipment performance affect the outcome? | <p>Consider all medical equipment and devices used in the course of patient care, including AED devices, crash carts, suction, oxygen, instruments, monitors,</p> |

| | | |
|---|---|---|
| | | <p>infusion equipment, etc. In your discussion, provide information on the following, as applicable:</p> <ul style="list-style-type: none"> • Descriptions of biomedical checks • Availability and condition of equipment • Descriptions of equipment with multiple or removable pieces • Location of equipment and its accessibility to staff and patients • Staff knowledge of or education on equipment, including applicable competencies • Correct calibration, setting, operation of alarms, displays, and controls |
| 5 | What controllable environmental factors directly affected this outcome? | <p>What environmental factors within the organization's control affected the outcome?</p> <p>Examples may include, but are not limited to:</p> <ul style="list-style-type: none"> • Overhead paging that cannot be heard • Safety or security risks • Risks involving activities of visitors • Lighting or space issues <p>The response to this question may be addressed more globally in Question #17. This response should be specific to this event.</p> |
| 6 | What uncontrollable external factors influenced this outcome? | <p>Identify any factors the organization cannot change that contributed to a breakdown in the internal process, for example natural disasters.</p> |
| 7 | Were there any other factors that directly influenced this outcome? | <p>List any other factors not yet discussed.</p> |
| 8 | What are the other areas in the organization where this could happen? | <p>List all other areas in which the potential exists for similar circumstances. For example:</p> <ul style="list-style-type: none"> • Inpatient surgery/outpatient surgery • Inpatient psychiatric care/outpatient psychiatric care <p>Identification of other areas within the organization</p> |

| | | |
|----|---|---|
| | | that have the potential to impact patient safety in a similar manner. This information will help drive the scope of your action plan. |
| 9 | [Were]... staff properly qualified and currently competent for their responsibilities at the time of the event? | <p>Include information on the following for all staff and providers involved in the event. Comment on the processes in place to ensure staff is competent and qualified. Examples may include but are not limited to:</p> <ul style="list-style-type: none"> • Orientation/training • Competency assessment (What competencies do the staff have and how do you evaluate them?) • Provider and/or staff scope of practice concerns • Whether the provider was credentialed and privileged for the care and services he or she rendered • The credentialing and privileging policy and procedures • Provider and/or staff performance issues |
| 10 | How did actual staffing compare with ideal levels? | <p>Include ideal staffing ratios and actual staffing ratios along with unit census at the time of the event. Note any unusual circumstance that occurred at this time. What process is used to determine the care area's staffing ratio, experience level and skill mix?</p> |
| 11 | What is the plan for dealing with staffing contingencies? | <p>Include information on what the organization does during a staffing crisis, such as call-ins, bad weather or increased patient acuity.</p> <p>Describe the organization's use of alternative staffing. Examples may include, but are not limited to:</p> <ul style="list-style-type: none"> • Agency nurses • Cross training • Float pool • Mandatory overtime • PRN pool |
| | Were such contingencies a | If alternative staff were used, describe their orientation to the area, verification of competency |

| | | |
|----|--|--|
| 12 | factor in this event? | and environmental familiarity. |
| 13 | Did staff performance during the event meet expectations? | Describe whether staff performed as expected within or outside of the processes. To what extent was leadership aware of any performance deviations at the time? What proactive surveillance processes are in place for leadership to identify deviations from expected processes? Include omissions in critical thinking and/or performance variance(s) from defined policy, procedure, protocol and guidelines in effect at the time. |
| 14 | To what degree was all the necessary information available when needed? Accurate? Complete? Unambiguous? | <p>Discuss whether patient assessments were completed, shared and accessed by members of the treatment team, to include providers, according to the organizational processes.</p> <p>Identify the information systems used during patient care.</p> <p>Discuss to what extent the available patient information (e.g. radiology studies, lab results or medical record) was clear and sufficient to provide an adequate summary of the patient's condition, treatment and response to treatment.</p> |
| 15 | To what degree was the communication among participants adequate for this situation? | <p>Describe staff utilization and adequacy of policy, procedure, protocol and guidelines specific to the patient care provided.</p> <p>Analysis of factors related to communication should include evaluation of verbal, written, electronic communication or the lack thereof. Consider the following in your response, as appropriate:</p> <ul style="list-style-type: none"> • The timing of communication of key information • Misunderstandings related to language/cultural barriers, abbreviations, terminology, etc. • Proper completion of internal and external hand-off communication • Involvement of patient, family and/or significant other |
| | Was this the appropriate | Consider processes that proactively manage the |

| | | |
|----|--|--|
| 16 | physical environment for the processes being carried out for this situation? | <p>patient care environment. This response may correlate to the response in question 6 on a more global scale.</p> <p>What evaluation tool or method is in place to evaluate process needs and mitigate physical and patient care environmental risks?</p> <p>How are these process needs addressed organization-wide?</p> <p>Examples may include, but are not limited to:</p> <ul style="list-style-type: none"> • alarm audibility testing • evaluation of egress points • patient acuity level and setting of care managed across the continuum, • preparation of medication outside of pharmacy |
| 17 | What systems are in place to identify environmental risks? | <p>Identify environmental risk assessments.</p> <ul style="list-style-type: none"> • Does the current environment meet codes, specifications, regulations? • Does staff know how to report environmental risks? • Was there an environmental risk involved in the event that was not previously identified? |
| 18 | What emergency and failure-mode responses have been planned and tested? | <p>Describe variances in expected process due to an actual emergency or failure mode response in connection to the event.</p> <p>Related to this event, what safety evaluations and drills have been conducted and at what frequency (e.g. mock code blue, rapid response, behavioural emergencies, patient abduction or patient elopement)?</p> <p>Emergency responses may include, but are not limited to:</p> <ul style="list-style-type: none"> • Fire • External disaster • Mass casualty |

| | | |
|----|---|---|
| | | <ul style="list-style-type: none"> • Medical emergency <p>Failure mode responses may include, but are not limited to:</p> <ul style="list-style-type: none"> • Computer down time • Diversion planning • Facility construction • Power loss • Utility issues |
| 19 | How does the organization's culture support risk reduction? | How does the overall culture encourage change, suggestions and warnings from staff regarding risky situations or problematic areas? |
| 20 | What are the barriers to communication of potential risk factors? | <ul style="list-style-type: none"> • How does leadership demonstrate the organization's culture and safety values? • How does the organization measure culture and safety? • How does leadership establish methods to identify areas of risk or access employee suggestions for change? • How are changes implemented? <p>Describe specific barriers to effective communication among caregivers that have been identified by the organization. For example, residual intimidation or reluctance to report co-worker activity.</p> <p>Identify the measures being taken to break down barriers (e.g. use of SBAR). If there are no barriers to communication discuss how this is known.</p> |
| 21 | How is the prevention of adverse outcomes communicated as a high priority? | Describe the organization's adverse outcome procedures and how leadership plays a role within those procedures. |
| 22 | How can orientation and in-service training be revised to reduce the risk of such events in the future? | Describe how orientation and ongoing education needs of the staff are evaluated and discuss its relevance to event. (e.g. competencies, critical thinking skills, use of simulation labs, evidence based practice, etc.) |

| | | |
|----|--|--|
| 23 | Was available technology used as intended? | <p>Examples may include, but are not limited to:</p> <ul style="list-style-type: none"> • CT scanning equipment • Electronic charting • Medication delivery system • Tele-radiology services |
| 24 | How might technology be introduced or redesigned to reduce risk in the future? | Describe any future plans for implementation or redesign. Describe the ideal technology system that can help mitigate potential adverse events in the future. |

In addition to the Human-tech/Swiss Cheese Model Framework ([Figure 27](#)) and The [Joint Commission's action plan tool](#), the [Canadian Incident Analysis Framework](#) outlines a set of guiding questions that can encourage the ^{HF}RCA team to identify potential contributing factors at various levels of the system ([Table 19](#)).

Table 19. Guiding questions to support identifying contributing factors²

| |
|---|
| Task (care/work process): |
| <ul style="list-style-type: none"> • Were there previous or predicted failures for this task or process? • Were specialized skills required to perform the task? • Was a fixed process or sequence of steps required (e.g. order sets, checklists)? • Did it exist and was it followed? • Was a protocol available, was it up-to-date, and was it followed in this case? • Were there constraints or pressures (e.g. time, resources) when performing the task? • Was the information required to make care decisions available and up-to-date (e.g. test results, documentation, patient identification)? • Was there a risk assessment/audit/quality control program in place for the task/process? • Other? |
| Equipment (including information and communication systems): |
| <ul style="list-style-type: none"> • Were the displays and controls understandable? • Did the equipment automatically detect and display problems? • Was the display functional? • Were the warning labels, reference guide and safety mechanisms functional and readily visible/accessible? • Were the maintenance and upgrades up-to-date? • Was the equipment standardized? • Would the users describe this equipment as “easy-to-use”? • Were the communication systems (phone, pager, software, hardware, etc.) available and operational? • Other? |
| Work environment: |
| <ul style="list-style-type: none"> • Did noise levels interfere with the alarms? • Was the lighting adequate for the task? • Was the work area adequate for the task(s) being performed (e.g. space, layout, location and accessibility of resources)? • Other? |
| Patient(s) characteristics: |
| <ul style="list-style-type: none"> • Did the patient(s) have the information to assist in avoiding the incident? • If not, what would have supported the patient in assisting their care team? • Did factors like age, sex, medications, allergies, diagnosis, other medical conditions, contribute to the incident? How did they contribute? • Did any social or cultural factors contribute to the incident? • What factors? In which way? • Was language a barrier? • Other? |

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Care team: Caregiver(s):

- Were the education, experience, training and skill level appropriate?
- Was fatigue, stressors, health or other factors an issue?
- Was the workload appropriate?
- Were appropriate and timely help or supervision available?
- Other?

Care team: Supporting team (all involved in care process):

- Was there a clear understanding of roles and responsibilities?
- Was the quality and quantity of communication (verbal and/or written) between team members appropriate (clear, accurate, free of jargon, relevant, complete and timely)?
- Were there regular team briefings/debriefings about important care issues?
- Was team morale good? Do team members support each other?
- Were the communication channels available and appropriate to support the needs of the team (e.g. email, pager, and phone)?
- Other?

Organization: Policies and priorities:

- Were the relevant policies and procedures available, known, accessible, and did they meet the needs of users
- Were there workarounds to the documented policy/procedure?
- Was there a mechanism in place to identify and resolve gaps between policy and practice?
- Were the strategic priorities of the organization clear to all?
- Other?

Organization: Culture:

- Was everyone (patients, clinicians, other staff) comfortable to speak-up about safety concerns?
- Was there visible support from leadership and board for safe patient care?
- Was communication between staff and management supportive of day-to-day safe patient care?
- Were incidents considered system failures with people not blamed?
- Other?

Organization: Capacity (resources):

- Did scheduling influence the staffing level, or cause stress, fatigue?
- Was there sufficient capacity in the system to perform effectively (e.g., access to resources)?
- Were formal and/or incentives appropriate?
- Other?

Other - consider:

- Were there any local conditions or circumstances that may have influenced the incident and/or an outcome?
- Were there any sector specific conditions or circumstances that may have influenced the incident and/or outcome?
- Other?

Section 10.6.5.2 Traditional RCA Tools for Documenting Contributing Factors

The ^{HF}RCA team may also find other types of diagrams useful for documenting contributing factors identified at different levels of the system. Many documentation tools and approaches may be used, but three examples often used as part of a traditional RCA method are included here: the Ishikawa Diagram, the Tree Diagram, and the Constellation Diagram. Further detail about these diagrams is available as part of the [Canadian Incident Analysis Framework](#).

Ishikawa Diagram⁴

An Ishikawa diagram, named for its' creator, is also known as a fishbone diagram. To create this type of diagram a straight line that ends in a box containing the incident is drawn ([Figure 29](#)). Next categories representing contributing factors are indicated and connected to the straight line leading to the incident ([Figure 30](#)). Finally, more detailed information about the contributing factors is noted under each category of contributing factor ([Figure 31](#)). Ishikawa diagrams do not generally allow for a clear understanding of the order in which contributing factors occur, but rather, they provide a means of categorizing and summarizing contributing factors at a glance.



Figure 29. Ishikawa Diagram: Straight line ending in a box containing the incident

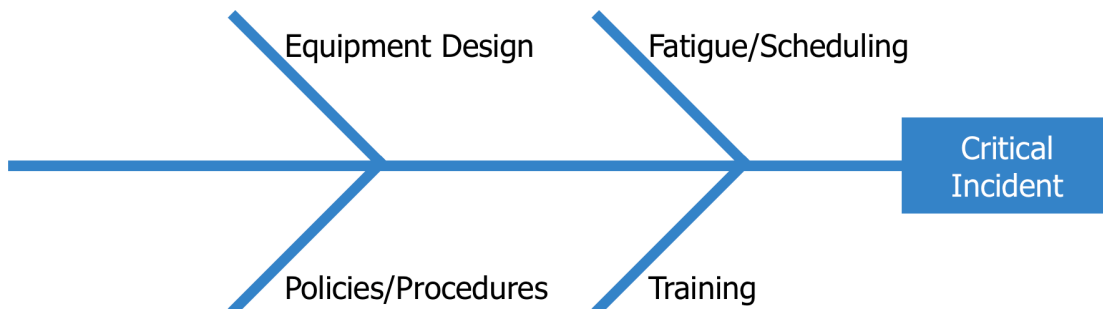


Figure 30. Ishikawa Diagram: Categories of contributing factors

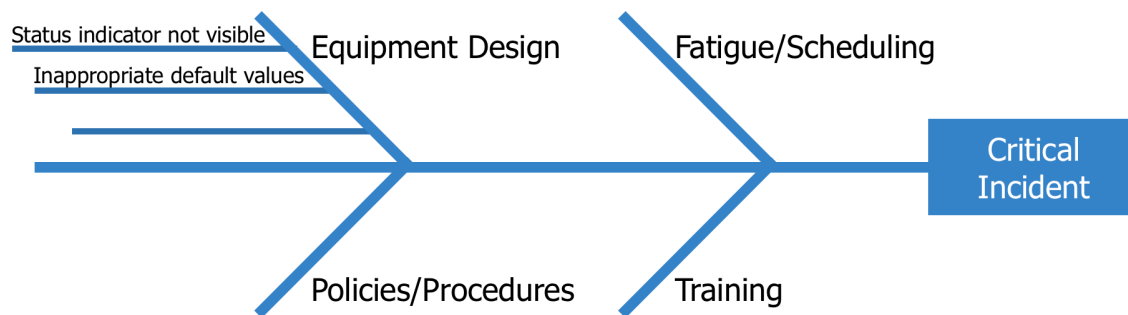


Figure 31. Ishikawa Diagram: Detailed information about contributing factors by category

Tree Diagram⁴

A tree diagram ([Figure 32](#)) is a linear cause-consequence diagram that starts with the incident and grows backwards as the actions or conditions leading to the preceding action are documented. Unlike Ishikawa Diagrams, tree diagrams allow causal chains to be denoted, where the respective causes and effects of a series of actions can be traced from root cause to incident. In most cases however, tree diagrams will be too simplistic as a documentation tool because in reality, incidents result from multiple contributing factors, rather than a one-to-one cause and effect relationship.

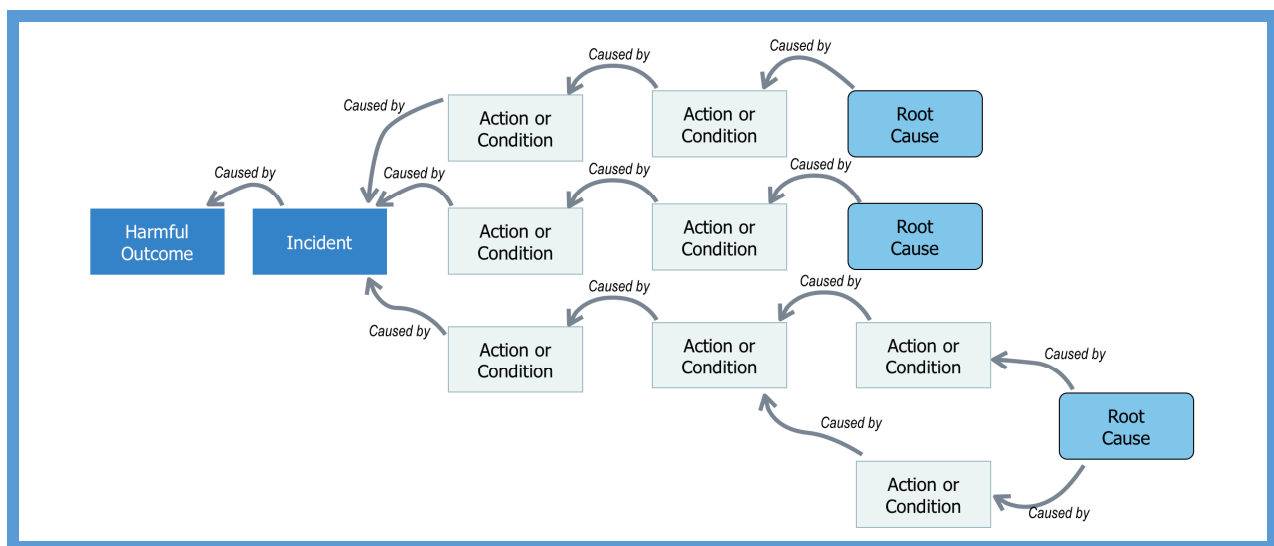


Figure 32. Tree diagram⁴

Constellation Diagram⁴

A constellation diagram ([Figure 33](#)) is a more versatile documentation tool than either the Ishikawa diagram or tree diagram that allows one to categorize and illustrate the causal relationships between all the identified contributing factors.

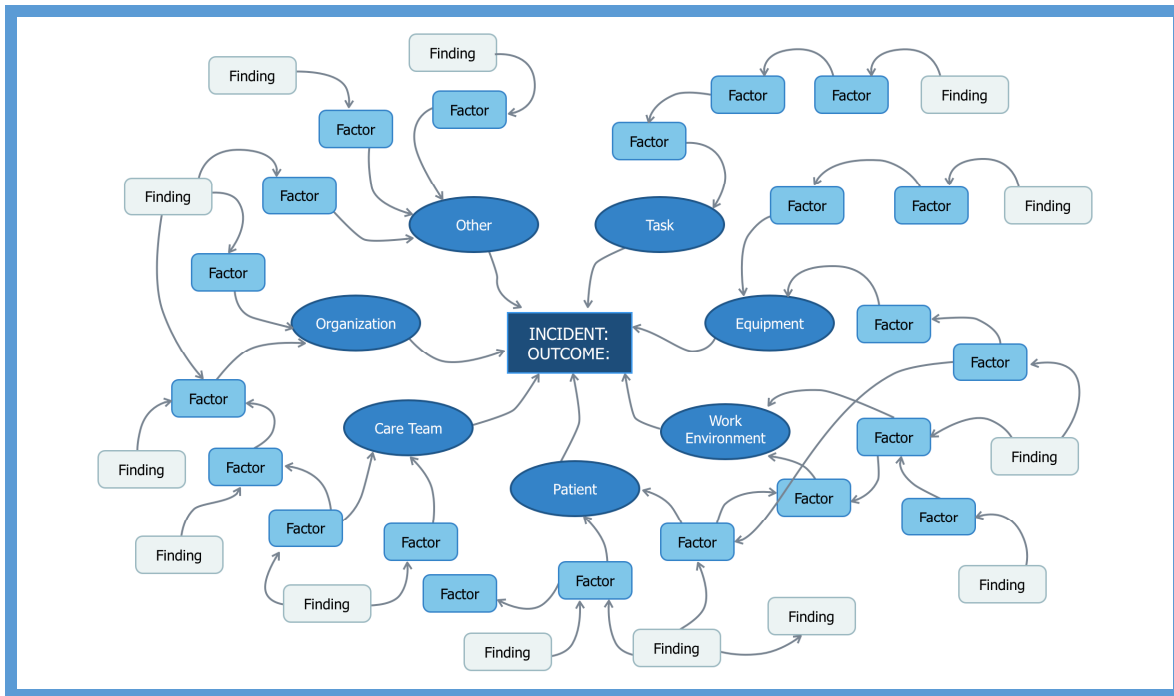


Figure 33. Constellation Diagram⁵

This type of diagram will likely be the most useful to the biomedical technology professional once the Human-tech/Swiss Cheese Model framework ([Figure 27](#)) has been applied, as the levels of the Human-tech ladder can be used as categories, and the causal relationships between contributing factors can be indicated in a flexible way ([Figure 33](#)). With a constellation diagram, every contributing factor should be connected to at least one other factor, or a category of factors. If a contributing factor does not connect to either another factor or a category, a new category will have to be created, or the factor does not belong in the analysis.

Section 10.6.5.3 Finalize Documentation of Contributing Factors

Once the root causes and contributing factors have been identified and documented, the analysis should be shared with the ^{HF}RCA team to gather any feedback. As the analysis is reviewed, the ^{HF}RCA team should consider three main questions:

What are the factors that:

1. If corrected, would have prevented the incident or mitigated the harm?
2. If corrected, would NOT have prevented the incident or mitigated the harm, but are still important to enhance patient and/or staff safety in general?
3. Prevented the incident from having more serious consequences, and thus, represent safeguards that should remain in place?

Regardless of the approach to documenting contributing factors, these three questions should be used as the basis for prioritizing which factors warrant the further consideration and development of recommendations and mitigating strategies.

Section 10.6.6. Develop Mitigating Strategies

After the root causes and contributing factors leading to the incident have been identified, documented, and prioritized using the three questions from [Section 10.6.5.3](#), mitigating strategies will have to be developed. Since most healthcare organizations have limited resources, a selection, rather than every root cause and contributing factor, will end up being addressed. The number and types of mitigating strategies implemented will depend on the context of the incident, your healthcare organization, and the resources available. To help guide the ^HFRCA team in figuring out which root causes and contributing factors to address, a number of tips are included below.

Section 10.6.6.1 Use the Hierarchy of Effectiveness to Develop System-Focused Strategies

Focus on system-level mitigating strategies rather than person-centered solutions. Use the Hierarchy of Effectiveness ([Section 3.5](#)) to determine whether a proposed solution is system focused. Person-centered solutions will not result in system improvements, and when person-centered solutions are implemented without addressing the system issues, the same, or a similar incident is likely to happen again.

Section 10.6.6.2 Quality Over Quantity

Rather than trying to implement many, lower impact mitigating strategies, aim to implement a few, well thought out recommendations that target system change. A well planned and carefully executed mitigating strategy that targets system improvement will be a more robust and long-term solution to prevent similar incidents from occurring again.

Section 10.6.6.3 Use the SMART framework

When drafting recommendations ensure they are SMART [58] ([Table 20](#)):

Table 20. SMART framework[58] [101]

| | |
|-------------------|--|
| Specific | Target a clearly defined issue with known scope |
| Measurable | Demonstrate an impact on outcomes through an indicator or progress |
| Attainable | Can be achieved given the available resources |
| Realistic | Results are possible given the available resources |
| Timely | Achievable in the defined implementation timeframe |

As part of the SMART framework, try to ensure any primary mitigating strategies fall within the locus of control of the healthcare organization, rather than an outside group,

such as a manufacturer or vendor. Although it may be necessary to work closely with a manufacturer to implement a mitigating strategy, solutions that originate outside of the healthcare organization will naturally be much harder to advance and control. When it is necessary to implement a solution that originates outside the healthcare organization, working closely with regulators, policy makers, and other healthcare organizations experiencing similar challenges, can help sustain momentum for a change to be realized.

Section 10.6.6.4 Validate Potential Mitigating Strategies

Prior to implementing a mitigating strategy, it should be validated to ensure it will have the intended effect without introducing other unintended consequences into the system. Gathering evidence from the literature, experiences from other healthcare organizations, and recommendations from professional and safety organizations can be a useful exercise to get a baseline understanding of potential implications. When little evidence exists, or there are features or factors that make your healthcare institution unique, applying human factors methods such as observations ([Chapter 4](#)), interviews, focus groups and surveys ([Chapter 5](#)), heuristics ([Chapter 7](#)), usability testing ([Chapter 8](#)), or a ^{HF}FMEA ([Chapter 9](#)), are recommended.

The [Canadian Incident Analysis Framework](#) provides templates both for assessing potential mitigating strategies while taking these considerations into account ([Table 21](#)), and tracking progress during the implementation of mitigating strategies ([Table 22](#)). The individual responsible for implementing each strategy that is agreed upon by the ^{HF}RCA team should put a plan together that outlines a project plan, timelines, required resources, and measures of success. The individual or team that implements each mitigating strategy does not have to be the same as the ^{HF}RCA team; however, depending on the incident and mitigating strategy, it may be helpful to keep the ^{HF}RCA team involved as an advisory group to maintain some consistency and oversight.

Table 21. Prioritized list of RCA actions [99]

| Recommended Action (category) | Risk (severity assessment) | Hierarchy of Effectiveness (high, medium, low leverage) | Predictors of Success (alignment, existing mechanisms, quick wins) | System Level Targeted | Evidence Available? What Type? | Confirm Validity, Feasibility | Order of Priority or Time Frame |
|-------------------------------|----------------------------|---|--|-----------------------|--------------------------------|-------------------------------|---------------------------------|
| | | | | | | | |

Table 22. Follow through actions from a RCA [99]

| # | Recommendation | Source and ID # | Date Entered | Progress Status | Timeframe (end date) | Target Area | Risk Level | Individual Responsible |
|---|----------------|-----------------|--------------|-----------------|----------------------|-------------|------------|------------------------|
| | | | | | | | | |

Section 10.7. What to do with a Completed ^{HF}RCA

Section 10.7.1. Create a Draft Report

Once the ^{HF}RCA has been completed and a decision made about which mitigating strategies the healthcare organization will move forward with, a report should be created that summarizes the incident and ^{HF}RCA process. Remove as much identifying information about the patient and staff involved in the incident as possible for privacy purposes.

Once drafted, the report should be labeled “Draft” and “Confidential” and then shared with any key stakeholders for review. Preparing a report following an incident that includes information about the information gathering, documentation, analysis, and mitigating strategy development process can contribute to organizational learning and memory when another sentinel event occurs. When shared with staff, this type of report can provide helpful context so those responsible for and affected by mitigating strategies understand the rationale driving any changes.

Consider sharing de-identified information about the incident, analysis, and planned mitigating strategies, beyond your healthcare institution if senior management supports this type of dissemination. If this type of sharing is supported, it can be an invaluable opportunity for other organizations to learn from the incident so similar events can be avoided in other institutions.

Section 10.7.2. Conduct an ^{HF}FMEA

Depending on the context of the incident and findings from the ^{HF}RCA, the ^{HF}RCA team may want to consider conducting an ^{HF}FMEA to identify more general risk factors not

immediately implicated in the sentinel event, but that could contribute to a future incident. See Chapter 12 for information about how to conduct an ^{HF}FMEA.

Section 10.8. Limitations of ^{HF}RCA

Although ^{HF}RCA can be an excellent means of understanding the root causes that contributed to a sentinel event, there are also some challenges and limitations to consider.

Section 10.8.1. The Resources Required

Properly carrying out an ^{HF}RCA is resource intensive, as it can be time consuming for a multi-disciplinary team to identify the root causes of a sentinel event. For an ^{HF}RCA to have impact, the multi-disciplinary team will also have to dedicate time to identifying and implementing mitigating strategies to address the identified root causes. Although ^{HF}RCA can be resource intensive, the benefits to successfully completing this type of analysis are substantial. Preventing future patients from being harmed as a result of a similar event is an invaluable opportunity.

Section 10.8.2. ^{HF}RCA is not Appropriate for Every Incident

Given that ^{HF}RCA is intended to identify system level root causes and contributing factors, incidents where a person wilfully causes harm are not appropriate for analysis using ^{HF}RCA. Examples of such circumstances include criminal acts, purposely unsafe acts, substance abuse by staff, and patient abuse of any kind. To determine whether an incident falls into the category of unintended harm caused by system factors or wilful harm, the Incident Decision Tree ([Figure 26](#)) is recommended.

Section 10.8.3. Completing an ^{HF}RCA Requires Tact

Following a sentinel event, it is normal for staff involved in the incident to be upset and scared about potential punitive actions towards them, or towards their colleagues, particularly if this approach was used historically. Consequently, it is of the utmost importance that those conducting the investigation are sensitive, and recognize that any interactions should leave staff feeling supported, rather than perpetuating any feelings of fear or paranoia. Follow the guidance provided for conducting observations ([Chapter 4](#)) and interviews ([Chapter 5](#)) such that staff do not feel they are being audited or judged, but rather that you are there to learn from them to make the system around them safer.

Section 10.9. Additional Resources

Reports

1. Incident Analysis Collaborating Parties. Canadian Incident Analysis Framework. Edmonton, AB: Canadian Patient Safety Institute; 2012. Incident Analysis Collaborating Parties are Canadian Patient Safety Institute (CPSI), Institute for Safe Medication Practices Canada, Saskatchewan Health, Patients for Patient Safety

Canada (a patient-led program of CPSI), Paula Beard, Carolyn E. Hoffman and Micheline Ste-Marie. Available at www.patientsafetyinstitute.ca

Tools and Frameworks Available Online

1. Veterans Affairs National Centre for Patient Safety Root Cause Analysis Tools
<http://www.patientsafety.va.gov/CogAids/RCA/index.html#page-4>
2. Veterans Affairs National Centre for Patient Safety Root Cause Analysis Triage and Triggering Questions
<http://www.patientsafety.va.gov/CogAids/Triage/index.html>
3. The Joint Commission Framework for Conducting a Root Cause Analysis and Action Plan
[http://www.jointcommission.org/Framework for Conducting a Root Cause Analysis and Action Plan/](http://www.jointcommission.org/Framework%20for%20Conducting%20a%20Root%20Cause%20Analysis%20and%20Action%20Plan/)
4. National Health Services (UK) Root Cause Analysis Toolkit
<http://www.nrls.npsa.nhs.uk/resources/rca-conditions/>

Examples of Root Cause Analyses

1. ISMP Canada published RCA's:
 - Fluorouracil Incident Root Cause Analysis
<http://www.ismp-canada.org/download/reports/FluorouracilIncidentMay2007.pdf>
 - Hydromorphone/Morphine Event
http://www.ismp-canada.org/download/Hydromorphone_Morphine_RCA_Report_final12.pdf
 - The Joint Commission - Sentinel Event Data: Root Causes by Event Type
http://www.jointcommission.org/sentinel_event.aspx
 - The Joint Commission - Sentinel Event Data: Root Causes by Event Type

Human Factors Informed Procurement



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 ^{HF}PIP 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 ^{HF}PIP

The ^{HF}PIP 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 ^{HF}PIP framework to incorporate human factors methods as part of the procurement process.

Section 11.5. In Preparation for ^{HF}PIP

In preparation for an ^{HF}PIP, 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 ^{HF}PIP

The ^{HF}PIP framework is outlined in [Figure 34](#). Each step will be outlined and described in this section.

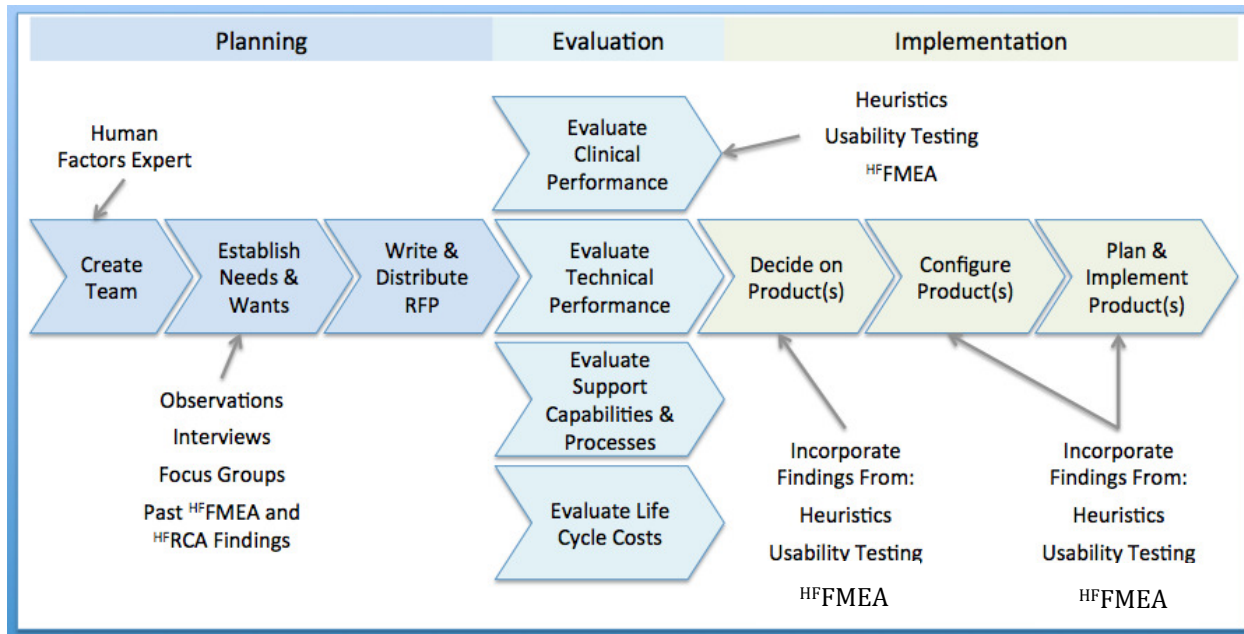


Figure 34. The Human Factors Procurement and Implementation Process (HFPIP)

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 ^{HF}PIP 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 ^{HF}PIP, 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 ^{HF}FMEA ([Chapter 9](#)) and/or ^{HF}RCA ([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 | <i>Human factors engineering – Design of medical devices</i> | 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, 3 rd ed. | <i>General safety & essential performance standard for medical electrical equipment</i> | Introduction to standard with subparts for a variety of electrical medical devices. |

| | | |
|--------------------------------------|---|---|
| IEC 60601-1-8: 2006 | <i>Collateral to IEC 60601-1:2005 on general requirements, tests and guidance for alarm systems</i> | 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 | <i>Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied</i> | 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 | <i>Medical devices -- Application of risk management to medical devices</i> | The definitive standard on principles of risk management, e.g. FTA, FMEA to medical devices |
| IEC 60601-1-11: 2011 | - <i>Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment</i> | 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 | <i>TRF – Test Report Forms</i> | 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 ^{HF}PIP 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 of 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 [^{HF}FMEA](#), 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 ^{HF}PIP 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 ^{HF}FMEA ([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 ^{HF}FMEA 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 ^{HF}PIP 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 ^{HF}FMEA

When applied during a procurement process, ^{HF}FMEA ([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 ^{HF}FMEA 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 ^{HF}PIP 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 ^{HF}PIP 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 ^{HF}FMEA). The procurement team may find it helpful to summarize the human factors issues found as part of the ^{HF}PIP either in categories across the technologies considered, and/or using an ^{HF}FMEA-style scoring matrix to assess potential usability issues based on their relative risk.

If a prospective risk assessment such as ^{HF}FMEA 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 ^{HF}FMEA](#), 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 ^{HF}PIP, 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, ^{HF}FMEA) 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 ^{HF}PIP 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 ^{HF}PIP, 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 ^{HF}PIP 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 ^{HF}PIP Findings

Once the ^{HF}PIP has been completed and the technology implemented, a report should be created that summarizes ^{HF}PIP 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 ^{HF}PIP

Although ^{HF}PIP 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 ^{HF}PIP 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. ^{HF}PIP May Not be Feasible for Every Medical Device

Due to the resources required, it will not be feasible to undergo the ^{HF}PIP process for every technology being procured. To help determine whether ^{HF}PIP should be used, refer to [Section 11.4 When to Use ^{HF}PIP](#).

Section 11.8.3. Implementation is Rarely, if Ever Seamless

Even when the ^{HF}PIP 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/generalthospitaldevicesandsupplies/infusionpumps/ucm202496.htm#3>

Part III. Case Studies: Applying Human Factors to Health Technology Management

“What looks like a people problem is often a situation problem... When you shape the [situation], you make change more likely...”

-Chip and Dan Heath, authors of Switch: How to Change Things When Change is Hard

Biomedical technology professionals already play an important role in promoting patient safety by integrating healthcare technologies so they fit well with clinical workflows, existing devices, and the environment of use. The philosophy of human factors is well aligned with these objectives because human factors focuses on improving the fit, or relationship, between various system-level components, and some readers may actually find they have been using human factors methods without realizing they are considered as such.

Part III of this book aims to connect the human factors methods described in Part II to the tasks of a biomedical technology professional. It is comprised of two case studies that illustrate how human factors methods can be incorporated into typical tasks of the biomedical technology professional. Chapter 12 introduces a case study to show how human factors can be incorporated into the procurement process and Chapter 13 uses a second case study to highlight opportunities to apply human factors methods during incident analysis.

We recognize that some biomedical technology professionals may not have the organizational authority to pursue human factors analyses. It is our intention to support these professionals by providing examples that will help them to outline human factors projects (including methods, resources and timelines), and describe the expected benefits so they can enroll senior leadership in the expansion of their role to include human factors analyses.

Chapter 12. Procurement Support Case Study

Biomedical technology professionals are often involved when a healthcare organization decides to procure a new medical technology. As such, technical professionals in these roles are well positioned to apply human factors methods throughout the procurement process to ensure that whatever technology is chosen by the healthcare organization fits well with the people who will use it given the context of use.

To illustrate how biomedical technology professionals can approach procurement using human factors methods, the *human factors informed procurement and implementation process* (^HFPIP) will be applied to a case study (see *Case Study 2*) that occurred in the United States in 2000.

Human Factors Not Considered in Design of Patient-Controlled Analgesia Pump

On February 27, 2000, at 2:34 AM, nineteen-year-old Danielle McCray was admitted to the Tallahassee Memorial Hospital in Florida to have her baby. After a long labour, a healthy baby girl was delivered by Caesarean section at approximately 4:30 PM. About two hours later, Danielle complained of pain, and at 7:00 PM she was connected to a patient-controlled analgesia (PCA) pump. A PCA pump is a special type of infusion pump that delivers small doses of pain medication at the request of a patient via a remote button.

A nurse programmed the PCA pump so Danielle could self-administer small doses of morphine as prescribed by her physician. At 8:30 PM, Danielle was awake, alert, and feeding her newborn. Six hours later, following a 30-minute resuscitation effort, Danielle had died.

The autopsy results showed Danielle had experienced a morphine overdose, with almost four times the lethal dose of morphine in her bloodstream. Upon further investigation, the cause of the overdose was found to be a programming error. Specifically, the nurse programmed the pump for a 1 mg/mL morphine concentration, but Danielle was receiving morphine at a concentration of 5 mg/mL. This meant that each time Danielle requested morphine she received a 5-fold overdose compared with the prescribed amount.

Case Study 2. Morphine Overdose of Danielle McCray

The events of this case study are described in the book *The Human Factor* [9] and a journal article published in the *Canadian Journal of Anesthesia* [84].

After reviewing this case, it may not seem obvious how an error like this could have occurred. A concentration of 5 mg/mL is obviously more potent than a concentration of 1 mg/mL, and programming the pump for a lower concentration than is loaded means that

more volume of the drug is released with each dose, which, given the concentration used, will result in a medication overdose. One of the likely contributing factors to this error is that in the factor preset configuration, the pump sequentially offers four default concentration settings during the programming sequence (morphine 1mg/mL, morphine 5mg/mL, morphine 0.5 mg/mL, and meperidine 10 mg/ml). The nurse in this case was required to reject the first default option, and select the second option, but most likely selected the first option. The concentration selection error is more likely in this particular case because the hospital stocks 1mg/mL morphine and 5mg/mL morphine, but the 1 mg/mL concentration was unavailable, so the nurse had to obtain a 5mg/mL drug container. It is likely that 1mg/mL morphine was the standard concentration for obstetric patients and the nurse was conditioned to programming the pump for 1mg/mL morphine (although these facts were not confirmed in the reports).

What makes Danielle's death even more upsetting, is that this particular model of PCA pump had been implicated in several other morphine concentration programming errors due to incorrect selection of the default concentration, ultimately leading to several patient deaths. Further, three years prior to Danielle's death, a medical device alert was issued for the pump because of the default concentration issue [85-87].

Since then, human factors researchers have estimated this model of PCA pump, which is no longer available for purchase, was responsible for between 65 and 667 deaths due to programming errors [84]. A human factors analysis of the user interface found the PCA pump programming sequence to be complex and confusing, requiring as many as 27 distinct programming steps for proper operation. A redesigned interface proposed by human factors researchers required a maximum of only 12 programming steps in comparison. A controlled experiment comparing the two designs showed the human factors-informed design led to fewer errors, faster task completion times, and lower mental workload [88].

This incident serves to highlight that adverse events can be expected when devices have not been designed, selected, and implemented using human factors principles [84, 89-91]. Perhaps Danielle and others would be alive today if the manufacturer of the PCA pump had incorporated human factors methods when designing the PCA pump, or if the hospital had been able to incorporate human factors into the procurement process.

To illustrate how a biomedical technology professional can apply the HFPIP presented in Chapter 11, this chapter presents a case study applying the framework to the procurement of a new type of PCA pump to replace a hospital's existing PCA devices. The rationale for the purchase was that the current PCA devices were very old and it was becoming increasingly difficult to get replacement parts to service the pumps. Additionally,

the current pumps had usability issues that were implicated in several medication incidents that resulted in patient harm.

Section 12.1. Create Team

Once the hospital made a decision to move forward with procuring a new PCA pump, a multidisciplinary team was created to undertake the ^{HF}PIP ([Table 24](#)). In this case, the team consisted of representatives with the following areas of expertise:

Table 24. PCA Procurement Decision Team

| Direct Stakeholders | Indirect Stakeholders |
|----------------------------|-------------------------|
| Anaesthesia | Biomedical technology |
| Post-anaesthetic care unit | Human Factors |
| General ward | Clinical education |
| Pain management | Risk management |
| Pharmacy | Informatics |
| Cleaning and maintenance | Legal |
| | Central stores |
| | Hospital administration |

The clinical representatives included on the ^{HF}PIP team included a combination of front line staff and managers. In many cases it is also advantageous to include a patient representative. The list of stakeholders above included both direct and indirect stakeholders.

Section 12.2. Establish Needs and Wants

Once the procurement team was established, the biomedical technology professional, human factors specialist, and post-anaesthesia care unit nurse on the ^{HF}PIP team conducted observations ([Chapter 4](#)) of the current PCA pumps in use to learn more about the types of users, and how those staff were interacting with the pump. Informal interviews ([Chapter 5](#)) were held with staff as observations were being done to gather information about the types of tasks they perform, features they rely on, features they wish they had, and any general frustrations with their current devices.

A list of all user groups who interacted with the current PCA pump was created, and a task analysis ([Chapter 6](#)) was completed to describe the tasks conducted with the current pump by each user group. Following data collection and documentation, another round of interviews and focus groups ([Chapter 5](#)) were done with staff, to validate the task analysis

and to collect information about other desired features and capabilities that an ideal PCA pump would have.

The biomedical technology professional from the ^{HF}PIP team reviewed a previous ^{HF}RCA ([Chapter 10](#)) that had been completed following an incident involving the hospital's current PCA pumps. Internal and external incident reporting systems were also reviewed to search for PCA pump-related incidents.

For each outlined user group, established needs and wants were sorted into functional requirements (what the pump must do) and implementation considerations (what the hospital must consider and/or adapt prior to implementing). A small subset of the user needs were identified as a result of this process ([Figure 35](#)).

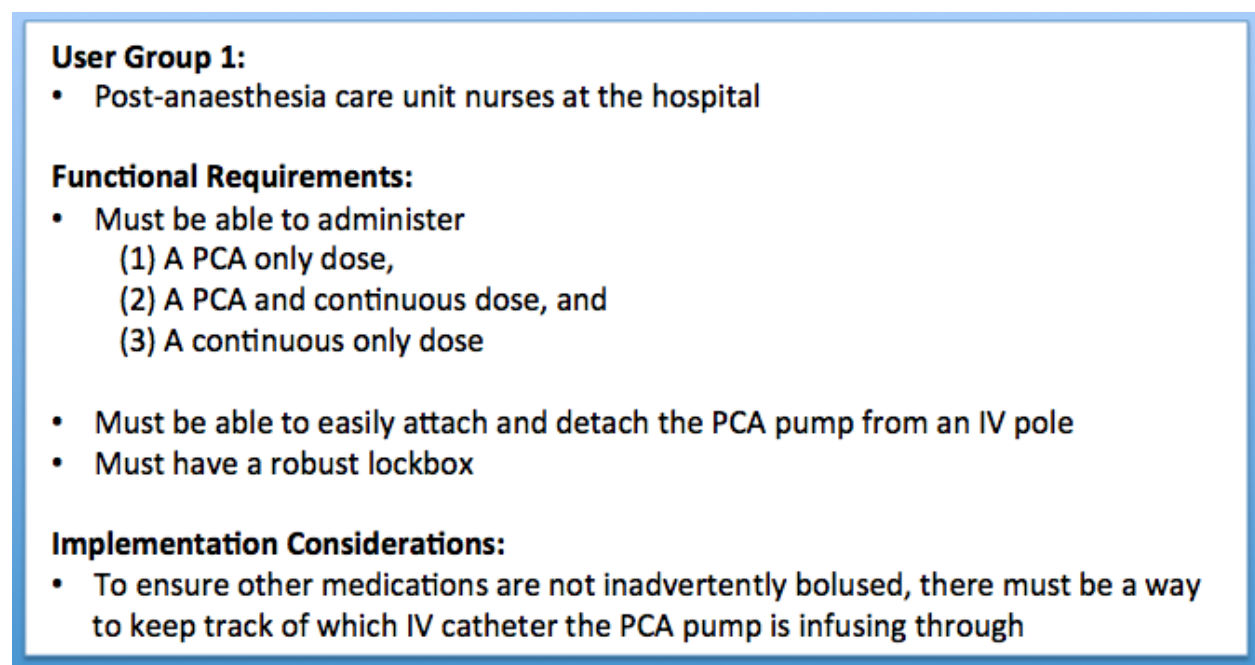


Figure 35. Selection of user needs and wants divided into functional requirements and implementation considerations.

Section 12.3. Write and Distribute RFP

Once the needs and wants of each user group were established, the procurement team wrote and distributed a request for proposal (RFP) to several vendors. In addition to standard RFP components, the ^{HF}PIP team also included a request for documentation from each vendor outlining how the human factors standard [HE75](#)[73] had been interpreted and incorporated into the design of the PCA pump [Table 23](#). In this case, rather than highlighting specific parts of the standard in the RFP, a more general inquiry was made using the following request: “Please indicate how the design of the technology has fulfilled the AAMI/ANSI Standard HE75”. Additionally, the RFP requested that the vendor provide

evidence of how usability testing results ([Chapter 8](#)) were incorporated into the design of the product.

The RFP also included a description of the human factors evaluation methods that were planned as part of the ^{HF}PIP ([Figure 36](#)).

“Each product that is shortlisted for evaluation will undergo human factors testing, which will include a heuristic evaluation¹ and usability testing².

Vendors will not be invited to participate directly in these evaluations, but will be expected to provide the healthcare organization with 3 PCA pumps and 50 primary tubing sets to enable this testing. Additional support may be required to train procurement team staff members who will be running these evaluations. Finally, assistance may be required to upload customized drug library software, and to download specified drug libraries into the test pumps.

¹Heuristic Evaluation: A heuristic evaluation is a structured comparison of a user interface, or product design with established human factors design principles, or heuristics [3]. This method is generally carried out by one or more usability experts. A heuristic evaluation is helpful for identifying design issues likely to lead to use-errors.

²Usability Testing: A usability test is a human factors evaluation method where representative end users interact with a system in a simulated environment. Data from representative end users can be collected about safety, appropriateness, and ease of use of a system prior to its selection and implementation in the real world.

Figure 36. Description of human factors methods to be applied to shortlisted technologies

Section 12.4. Evaluation

The ^{HF}PIP team received four responses to the RFP. After reviewing each vendors’ proposal against the RFP, and re-examining the needs and wants of users established earlier in the ^{HF}PIP, it was found that three out of the four vendor submissions met the requirements outlined in the RFP. Thus, the PCA pumps from each of these three vendors were shortlisted and moved forward into the evaluation phase of the ^{HF}PIP, while the PCA pump from the vendor that did not meet the requirements did not progress any further as part of the ^{HF}PIP.

As outlined in the RFP, the ^{HF}PIP team requested 3 PCA pumps, and 50 primary tubing sets from each shortlisted vendor so the heuristic analysis and usability testing could take place.

Section 12.4.1. Heuristic analysis

The human factors specialist conducted an independent heuristic analysis ([Chapter 7](#)) using the Zhang et al. heuristics for assessing the usability of medical technology ([Table 1](#)), and then led several clinical representatives in turn through a heuristic analysis by sitting with them and asking them to complete a wide range of tasks on the PCA pump while they identified anything that seemed unclear, awkward, or difficult. The task list was created based on the user's manual for each pump and the observation data collected during the user needs assessment. Since not every PCA pump had the same features, the task lists were somewhat different for each pump, although there was a common set of basic tasks across each pump. The human factors specialist documented the underlying design issue and the heuristics that were violated. Once all the tasks were complete, the human factors representative reviewed the list of issues with the clinician and asked the clinician to identify the impact (worst possible outcome) as a result of the issue. The severity of each outcome was rated using pre-defined scoring criteria similar to that shown in [Table 2](#).

A list of usability issues considered to be 'severe' based on the scoring criteria in [Table 2](#), were compiled from across the heuristic analyses completed by each team member. A list of recommended changes or actions was identified for each of these issues. A sample of some of the severe issues identified on each of the three PCA pumps is shown in [Table 25](#).

Table 25. A sample of the severe usability issues found by five independent reviewers during a heuristic analysis of the three shortlisted PCA pumps

| <i>Pump A</i> | | |
|--|--|--|
| <i>Issue</i> | <i>Heuristic Violated</i> | <i>Recommended Changes or Actions</i> |
| Pump can start infusing with the cover closed but not locked. | Prevent Errors Feedback | Pump should have a sensor on the lock, and not just the cover, to ensure safety given the high-risk nature of medications such as narcotics. |
| Cannot change the delivery parameters once the pump is programmed and running. Users have to re-program all information and any shift information is lost. | Flexibility and efficiency Users in control | Pump should allow users to adjust parameters in the setup menu once the pump is running. A code or key should be required. |
| There are two different task sequences associated with changing a syringe depending on whether the same drug is continued or not. | Minimize memory load | Task sequences for changing a syringe should be consistent regardless of whether a new syringe contains the same drug. |

| <i>Pump B</i> | | |
|---|--|---|
| <i>Issue</i> | <i>Heuristic Violated</i> | <i>Recommended Changes or Actions</i> |
| Pump does not require the barcode to be scanned. Manual drug selection is always available. | Prevent Errors | An option should be available to make the barcode scan mandatory prior to loading the syringe. Scanner should detect and indicate a faulty barcode. |
| After the barcode is scanned, the drug name and concentration can be manually changed. | Prevent Errors | Once a barcode has been scanned, the drug menu should only show the scanned drug. All other drug names should be eliminated. |
| Pump does not prompt users to systematically review the settings before starting the pump. | Prevent Errors | On the Run screen users should be forced to confirm each setting. |
| There is only one lock level that provides access to all functions. | Prevent Errors | Create at least two lock levels. One that unlocks all functions and one that unlocks everything but the clinician bolus so that ward nurses cannot accidentally give boluses. |
| When the pump is unlocked with a code it remains unlocked for one minute. Patients could tamper with the pump during this time. | Prevent Errors | Pump should automatically re-lock once it starts running, or after 30 seconds of being idle during programming. |
| The 4-hour limit does not have fixed units. Users can select mcg/kg, mcg, mg/kg, mg. | Prevent Errors | Units for the 4-hour limit should be fixed as part of the drug protocol. |
| <i>Pump C</i> | | |
| <i>Issue</i> | <i>Heuristic Violated</i> | <i>Recommended Changes or Actions</i> |
| Button key press is not visible to user right away. | Informative Feedback | CPU should update screens much faster to prevent users from selecting the wrong button. Buttons on second screen should be carefully placed so that selecting a button quickly twice in a row either (a) selects nothing (i.e., no button underneath on second screen) or (b) selects a safe second action that is easy to exit from if desired. |
| No clear way to exit the Bolus Dose screen without giving a patient a bolus. The user must press Cancel twice to exit. The pump will not accept 0 mg. | Reversible actions Users in control Minimize memory load | Provide a clear exit (add "Exit" key to bottom of screen with a screen asking user to confirm that they do not want proceed with a bolus). Allow the user to enter 0 mg as a dose and again confirm that they are not giving any dose before asking user to close and lock door. |

Section 12.4.2. Usability Testing

Following the heuristic analysis of each of the three PCA pumps, the human factors specialist, biomedical technology professional, and acute care pain nurse prepared for, and conducted usability testing ([Chapter 8](#)). They conducted the usability test in an empty patient room in the general ward at the healthcare organization. The environment doubled as both a ward environment and a post-anaesthetic care unit ([Figure 37](#)).



Figure 37. Usability testing environment for PCA usability testing

Section 12.4.2.1 In Preparation for Usability Testing

Data gathered during the process of (1) establishing the needs and wants of the user (observations), (2) conducting the task analysis, and (3) conducting the heuristic analysis were used as a basis for developing the usability testing scenarios ([Section 8.5.2](#)). Each participant was required to complete four different scenarios on each pump to ensure the following list of tasks was completed on each pump:

1. Setting up and programming a PCA for a new patient
2. Replacing an empty medication container and restarting the pump
3. Changing to a new medication and re-programming the pump
4. Titrating the dose and checking the medication history.

Three sets of different but equivalent scenarios were developed so that participants would be able to complete the same set of tasks on each pump but with a different context so that testing each of the three products would not seem repetitive or familiar.

The assignment of each set of scenarios to each pump was counterbalanced, as was the order that each participant tested each pump. The counterbalancing schedule is shown in [Figure 38](#). For each participant (i.e., Participant 1-10) the schedule illustrates the order each pump is tested (e.g., First A, Second B, Third C) and the scenario group applied to each pump (i.e., S1, S2, S3).

| | Pain Management Participants | | | | | Post-Anaesthetic Care Unit Participants | | | | |
|--------|------------------------------|--------|--------|--------|--------|---|--------|--------|--------|---------|
| | Part 1 | Part 2 | Part 3 | Part 4 | Part 5 | Part 6 | Part 7 | Part 8 | Part 9 | Part 10 |
| First | A/S1 | B/S3 | C/S2 | A/S1 | B/S3 | C/S2 | A/S1 | B/S3 | C/S2 | A/S1 |
| Second | B/S2 | C/S1 | A/S3 | B/S2 | C/S1 | A/S3 | B/S2 | C/S1 | A/S3 | B/S2 |
| Third | C/S3 | A/S2 | B/S1 | C/S3 | A/S2 | B/S1 | C/S3 | A/S2 | B/S1 | C/S3 |

A, B, C = pump A, pump B, pump C

S1, S2, S3 = scenario group 1, scenario group 2, scenario group 3

Figure 38. Assignment of the order of pumps and scenario groups to each participant to achieve counterbalancing

Usability scenarios were reviewed with clinical members of the ^{HF}PIP team, including those from anaesthesia, the post-anaesthesia care unit, pain management, the general ward, and clinical education, to ensure they were as realistic as possible. Two of the usability test scenarios that were developed are included in [Figure 39](#) as an example.

Scenario Group 1

Scenario 1: Setting up a new PCA Infusion

New patient, Mr. Ricardi, arrives to the post-anesthetic care unit (PACU) following a total hip replacement surgery. The patient is 76 years old and stable. His pain score is 6/10 when resting.

Task 1: Program the PCA pump so the patient receives morphine 2mg/mL at a continuous dose of 5mg/hr with a bolus dose of 2mg. The bolus lockout time is 5 min and the 4-hour limit is 40mg.

Scenario 2: Replacing an empty medication container

Mr. Ricardi is ready to move from the PACU to the ward. Upon arrival at the ward you notice the morphine container in his pump is almost empty.

Task 2: Remove the empty drug container, replace with a new one, re-start the pump.

Scenario 3: Changing to a new medication

Mr. Ricardi is starting to complain he is itchy. You notice he is developing hives on his torso and they are spreading. You speak to his wife and she says that he had a similar reaction to morphine when he fell and bruised his hip several years ago. Although his chart has no allergies listed, you consult with his doctor and she decides to switch him to hydromorphone.

Task 3: Change the morphine drug container to hydromorphone, re-program and start the pump.

Scenario 4: Titrating the infusion and documenting shift totals

About an hour after the hydromorphone was started, Mr. Ricardi pain's score is still 5/10. His heart rate is elevated and he is visibly uncomfortable. His medication orders allow the continuous dose of hydromorphone to be increased from 1mg/hr to 1.5mg/hr. Since you are at the end of your shift, you decide to first document your shift totals and then titrate the hydromorphone.

Task 4: Document the shift totals in the medication administration record, and then titrate the hydromorphone.

Figure 39. Scenarios in scenario group 1 for PCA usability testing

Once the scenarios were finalized, scripts were written to facilitate each task. A sample script based on the first scenario in [Figure 39](#) is shown in [Figure 40](#). A data documentation tool ([Section 8.5.4](#)) was also developed based on the tasks and subtasks of each scenario.

Each of the three PCA pumps was customized to suit the usability scenarios and user groups. In this case, the drug library for each pump was customized to match the drugs and concentrations given by PCA on wards and in the post-anaesthetic care unit. Representative end users including anaesthetists, nurses from the post-anaesthesia care unit, nurses from pain management, and nurses from the general ward were included in the study. The vendors of each of the three PCA pumps were contacted for assistance with creating appropriate drug libraries for each of these four services.

| |
|---|
| <p>[Nurse Actor] “Hi _____, I’m Carol, nice to meet you. Thanks for coming in on short notice, we’ve been swamped all morning and our resource nurse didn’t show up. We just got 3 patients back from the OR and all of them need meds started right away. Since you haven’t worked on this unit before there are a couple of things I’ll show you before I get you start one of our PCA’s. First, here is our medication administration cart where you can find the patient’s records and medication orders. You’ll be responsible for administering the IV medications, but I can take care of any documentation. There is a formulary of IV medications in the binder on the cart if you need it and you can also access it online.”</p> <p>Any questions?”</p> <p>[Participant] “<i>No...not that I can think of...</i>” [or answer whatever question they have]</p> <p>[Nurse Actor] “Great! lets get started. Our first patient is Mr. Ricardi. He is a 76 year-old male who underwent a total hip replacement. No complications or relevant medical history to report. His heart rate is 62, his respiratory rate is 14, his temperature is 37.8°C, and his blood pressure is 110/70. He is conscious, but is currently sleeping and has been complaining of post-operative pain (6/10 at rest and hasn’t tried moving). He needs an IV PCA started. His morphine orders are in his chart.</p> <p>I’m just going to be over there with Ms. Wu so holler if you need anything, but hopefully you’ll be okay on your own.</p> <p>[Participant]: Sure</p> <p>[Nurse Actor]: Great, thanks! I’ll be back in a little bit.</p> |
|---|

Figure 40. Script developed based on the usability test scenarios

Pre- and post-questionnaires ([Figure 41](#) and [Figure 42](#)) were then designed in order to collect direct feedback and information from each representative user group.

| | |
|---|---|
| <p>Demographics</p> <p>1. What best describes your role in the hospital?</p> <p><input type="checkbox"/> Medical doctor</p> <p><input type="checkbox"/> Registered nurse</p> <p><input type="checkbox"/> Other: _____</p> <p>2. What is your age?</p> <p><input type="checkbox"/> 18-29 years old</p> <p><input type="checkbox"/> 30-39 years old</p> <p><input type="checkbox"/> 40-49 years old</p> <p><input type="checkbox"/> 50-64 years old</p> <p><input type="checkbox"/> 65 years old and over</p> <p>3. How long have you been in your current role?</p> <p><input type="checkbox"/> Less than a year</p> <p><input type="checkbox"/> 1 to 4 years</p> <p><input type="checkbox"/> 5 to 9 years</p> <p><input type="checkbox"/> 10 to 20 years</p> <p><input type="checkbox"/> More than 20 years</p> <p>4. Which unit(s) do you typically work in (check all that apply):</p> <p><input type="checkbox"/> OR</p> <p><input type="checkbox"/> PACU</p> <p><input type="checkbox"/> General Ward</p> <p><input type="checkbox"/> ER</p> <p><input type="checkbox"/> SICU</p> <p><input type="checkbox"/> PICU</p> <p><input type="checkbox"/> Outpatient</p> <p><input type="checkbox"/> Other: _____</p> | <p>5. How long have you been working in your current clinical area?</p> <p><input type="checkbox"/> Less than a year</p> <p><input type="checkbox"/> 1 to 4 years</p> <p><input type="checkbox"/> 5 to 9 years</p> <p><input type="checkbox"/> 10 to 20 years</p> <p><input type="checkbox"/> More than 20 years</p> <p>Knowledge and Experience</p> <p>1. Do you know what a PCA pump is?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>2. Have you ever used a PCA pump before?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not sure</p> <p>3. Have you ever received training about how to use a PCA pump?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not sure</p> <p>4. In general, what is your preferred method to learn about how to use a new medical device? (rank options from 1 to 6, with 1 being most preferred, and 6 being least preferred)</p> <p><input type="checkbox"/> Read about the device</p> <p><input type="checkbox"/> Attend a hands on demonstration</p> <p><input type="checkbox"/> Attend a lecture or seminar</p> <p><input type="checkbox"/> Have access to the device to practice on your own and ask questions as needed</p> <p><input type="checkbox"/> Work side by side with an expert colleague</p> <p><input type="checkbox"/> Watch a training video</p> |
|---|---|

Figure 41. Sample of pre-questionnaire for PCA pump usability testing

| Participant Feedback | |
|---|--|
| <p>1. Using this PCA pump was intuitive:</p> <p><input type="checkbox"/> Strongly agree</p> <p><input type="checkbox"/> Agree</p> <p><input type="checkbox"/> Undecided</p> <p><input type="checkbox"/> Disagree</p> <p><input type="checkbox"/> Strongly disagree</p> <p>Additional comments:</p> <hr/> | <p>5. Using this PCA pump in my unit will help to improve patient safety:</p> <p><input type="checkbox"/> Strongly agree</p> <p><input type="checkbox"/> Agree</p> <p><input type="checkbox"/> Undecided</p> <p><input type="checkbox"/> Disagree</p> <p><input type="checkbox"/> Strongly disagree</p> <p>Additional comments:</p> <hr/> |
| <p>2. I have concerns about using this PCA pump in my clinical environment:</p> <p><input type="checkbox"/> Strongly agree</p> <p><input type="checkbox"/> Agree</p> <p><input type="checkbox"/> Undecided</p> <p><input type="checkbox"/> Disagree</p> <p><input type="checkbox"/> Strongly disagree</p> <p>Additional comments:</p> <hr/> | <p>6. I found the set up tasks during the scenario to be difficult to complete:</p> <p><input type="checkbox"/> Strongly agree</p> <p><input type="checkbox"/> Agree</p> <p><input type="checkbox"/> Undecided</p> <p><input type="checkbox"/> Disagree</p> <p><input type="checkbox"/> Strongly disagree</p> <p>Additional comments:</p> <hr/> |
| <p>3. This PCA pump will make my job easier as a healthcare practitioner:</p> <p><input type="checkbox"/> Strongly agree</p> <p><input type="checkbox"/> Agree</p> <p><input type="checkbox"/> Undecided</p> <p><input type="checkbox"/> Disagree</p> <p><input type="checkbox"/> Strongly disagree</p> <p>Additional comments:</p> <hr/> | <p>7. I am confident I completed all the tasks correctly during the scenario:</p> <p><input type="checkbox"/> Strongly agree</p> <p><input type="checkbox"/> Agree</p> <p><input type="checkbox"/> Undecided</p> <p><input type="checkbox"/> Disagree</p> <p><input type="checkbox"/> Strongly disagree</p> <p>Additional comments:</p> <hr/> |
| <p>4. Using this PCA pump will change how I think about delivering infusions:</p> <p><input type="checkbox"/> Strongly agree</p> <p><input type="checkbox"/> Agree</p> <p><input type="checkbox"/> Undecided</p> <p><input type="checkbox"/> Disagree</p> <p><input type="checkbox"/> Strongly disagree</p> <p>Additional comments:</p> <hr/> | <p>8. The training I received was comprehensive enough to allow me to complete all of the scenarios:</p> <p><input type="checkbox"/> Strongly agree</p> <p><input type="checkbox"/> Agree</p> <p><input type="checkbox"/> Undecided</p> <p><input type="checkbox"/> Disagree</p> <p><input type="checkbox"/> Strongly disagree</p> <p>Additional comments:</p> <hr/> |

Figure 42. Sample of post-questionnaire for PCA pump usability testing

The training protocol for the testing was developed by members of the HFPIP team. First, the HFPIP team members received training from each of the vendors at the level of depth that would typically be given by the vendor during an inservice. The HFPIP team then developed a training protocol for the usability testing that included all the information required to complete each of the scenarios. The length and depth of the training protocol for the usability testing was similar across all three pumps.

Introductory scripts and consent forms were also created to ensure each participant would receive all the necessary information prior to the start of the usability test session.

For testing, a total of five nurses from the post-anaesthesia care unit and five nurses/nurse practitioners from the acute pain team were recruited.

Two pilot usability tests were completed: one with the acute pain nurse from the HFPIP team; and one with the general ward nurse from the HFPIP team, to ensure everything had been organized properly and was ready to go. The human factors specialist and biomedical technology professional filled out the usability test checklist ([Section 8.5.13](#)) prior to conducting the first official usability test session.

Section 12.4.2.2 Conducting Usability Testing

Upon arrival, each participant was welcomed by the facilitator. The facilitator delivered the introductory script ([Section 8.5.8](#)) and reviewed the consent form ([Appendix A](#)) with the participant, and then asked the participant to complete the pre-usability test survey ([Figure 41](#)). The facilitator then delivered the training associated with the first pump being tested to the participant.

Following the training session for that pump the facilitator introduced the participant to the first scenario acting as the actor (confederate) nurse, and the participant completed the four test scenarios associated with each pump. The testing was videotaped using a video camera on a tripod. A biomedical technology student helped to do the video recording during the sessions. During the test, the human factors specialist documented any issues that were observed or actions that were unexpected in the data documentation sheet. Following the completion of the scenarios, the facilitator asked the participant to fill out the post-training questionnaire ([Figure 42](#)), and conducted an informal debrief session. This process was repeated on the other two PCA pumps using the other two scenario groups to minimize familiarity with the tasks. At the very end of the usability test, after testing all three pumps, a slightly longer debrief session was held with the participant to gather more general thoughts about the test session and the three PCA pumps used.

The usability test team analyzed the data collected from the usability test sessions by evaluating user performance and preferences for each of the three PCA pumps ([Section 8.7.1](#)). The performance data was used to determine issues and their severity. The preference data was used to identify any additional potential issues or user needs not previously captured.

Questionnaires and notes taken during each usability session were compiled across participants. Data documentation spreadsheets that were completed during testing were also compiled across participants, and a determination of which tasks were passed and failed was made. Tasks that participants had difficulty completing were considered in further depth by the ^{HF}PIP team.

Results from usability testing uncovered several new issues and validated many of the findings from the heuristic analysis. Each error was rated using a severity scale similar to that in [Table 11](#) with the most severe errors being extracted and compiled for each of the three PCA pumps tested ([Table 26](#)). Descriptive statistics were used to summarize user performance on each pump, for example how many errors occurred on each task for each pump and, of those, how many had potentially harmful consequences.

Table 26. Summary of issues with potentially severe safety consequences identified during usability testing

| Pump A | | |
|--|---|---|
| Issue | Description of Error | Impact to Safety |
| Input mechanism (scroll wheel) is not intuitive. | User selects the wrong drug (either because they press the wheel trying to scroll, or they accidentally press and turn the wheel at the same time). | Patient receives over/under infusion depending on the concentration to dose ratio if the user does not detect the error. |
| Pump terminology inconsistent with terminology used at healthcare organization. | User sets the “background rate” at 1.0 mg/hr instead of the bolus dose. | Patient receives over infusion. Consequences depend on the rate entered but could be severe. |
| Technical software glitch. | When the pump is first turned on, totals showing are 0.0 mg, 42.2 mL. They should both be zero. | Consequences unclear but could potentially result in incorrect tracking of drug volume administered, which could lead to inappropriate changes to the medication order. |
| Users cannot remember the task sequence for changing a syringe to a new drug since it is different than changing a syringe when the drug remains the same. | When changing the syringe to a new drug, users forgot to stop the pump in order to access the drug list. One user changed a syringe to a new drug but kept the old drug protocol. | New drug may run using the previous drug protocol. Patient would receive an over/under infusion depending on the concentration to dose ratio. |
| User is not forced to verify settings. | User did not verify each parameter selected. They scrolled directly to Confirm. | Protocol parameters could be incorrect. Severity of impact depends on the range of values allowed for the protocol. |
| Pump B | | |
| Issue | Description of Error | Impact to Safety |
| Barcode scanner difficult to activate. | User is unsuccessful at scanning the barcode (not holding it in the right position after pressing the top knob). | Manual selection of drug allows the potential for the wrong drug to be selected. Patient could receive over/under |

| | | |
|--|--|---|
| | User manually selects drug. | infusion depending on the concentration to dose ratio. |
| User is not alerted that the pump is running. | Pump is stopped and user does not restart. User thinks the pump is running. | Patient does not receive medication. |
| Pump terminology is inconsistent with user experience. | User increases bolus dose to 1.5 mg instead of the PCA dose because she interprets bolus to mean PCA dose. | Patient does not receive the increased dosage. |
| Unclear how to clear shift totals. | User gives an accidental clinician bolus when trying to clear the shift totals. | Patient receives an unintended dose that is not included in the 4-hour limit and is not prescribed. |
| Easy to confuse modalities since they are selected using one knob. | User accidentally purges the pump after it is connected to the patient while trying to start the pump. | Patient receives an unintended dose that is not included in the 4-hour limit and is not prescribed. |
| User is not alerted that pump is not running. | User programmed the pump but did not press start. The pump was not running but the user thought it was. | Patient does not receive medication. |

Pump C

| Issue | Description of Error | Impact to Safety |
|---|--|---|
| It is not clear to users what "Anaesthesia Mode" is or how it affects the pump. | User incorrectly selects "Options" when trying to review the setup parameters. User selects "Anesthesia Mode" and enables it without knowing what it does. | Patient could receive an overdose since medication limits are broadened in this mode. |
| Pump buttons are difficult to press. | User entered a dose of 0.2 mg but the pump only registered 2 because the buttons are hard to press. User noticed and mitigated the error. | If a dose of 2 mg is inside the programming limit, a 10-fold overdose would occur each time the patient requested a dose. |
| Visual parallax effect on pump | User selected the wrong drug three times because of a | Pump programmed incorrectly resulting in over/under |

| | | |
|--|--|-------------------------------------|
| screen. | parallax effect on the screen. If the user is not standing directly in front of, and at the same height as the screen, the buttons do not line up with the screen options. | infusion. |
| Pump response to key press is delayed. | User pressed the same button several times because the pump did not respond quickly to the initial key presses. Subsequent presses were applied to the next screens without the user knowing what was selected. In one case the user inadvertently gave the patient a 1.5 mg bolus because of this design issue. | Unintended over dose of medication. |

The HFPIP team reviewed each of the issues in [Table 26](#) and discussed potential mitigating strategies for each one to see whether the risks could be addressed in a systematic way prior to implementation. Risks that could not be suitably mitigated (i.e., mitigated using a systems approach rather than a person approach as described in the [hierarchy of effectiveness](#)) were compared across the three pumps to identify which of the three pumps was the safest and best fit for the organization. [Table 27](#) shows the mitigating strategies that were identified for the issues associated with each of the three pumps.

Table 27. Mitigating strategies strategies for the severe issues identified during usability testing

| Pump A | | | |
|---|---|---|--|
| Issue | Description of Error | Impact to Safety | Mitigating Strategy |
| Pump terminology inconsistent with terminology used at healthcare organization. | User sets the “background rate” at 1.0 mg/hr instead of the bolus dose. | Patient receives more pain medication than prescribed. Consequences depend on the rate entered but could be severe. | Change wording on the pre-printed medication order to match the pump terminology |
| Technical software | When the pump is first turned on, totals | Consequences unclear but could potentially | No effective mitigating strategy |

| | | | |
|---|---|---|--|
| glitch. | showing are 0.0 mg, 42.2 mL when they should both be zero. | result in incorrect tracking of drug volume administered. | from within the organization. Ensure vendor fixes technology glitch |
| Task sequence for changing a syringe to a new drug is different that changing a syringe when the drug remains the same. | When changing the syringe to a new drug, users forgot to stop the pump in order to access the drug list. One user changed a syringe to a new drug but kept the old drug protocol. | New drug may run using the previous drug protocol. Patient would receive an over/under infusion depending on the concentration to dose ratio. | No effective mitigating strategy from within the organization. Recommend that the vendor review the workflow and improve consistency. |

| Pump B | | | |
|--|--|---|--|
| Issue | Description of Error | Impact to Safety | Mitigating Strategy |
| User is not alerted if the pump is programmed but not running. | Pump is stopped and user does not restart. User thinks the pump is running. | Patient does not receive medication but user thinks it's running | No effective mitigating strategy from within the organization. Recommend that vendor review the alerts. |
| Task sequence for clearing the shift totals is not intuitive. | User gives an accidental clinician bolus when trying to clear the shift totals. | Patient receives an unintended dose that is not included in the 4-hour limit and is not prescribed. | No effective mitigating strategy from within the organization. Recommend that vendor reviews the menu structure of the user options. |
| Easy to confuse modalities since they are selected using one knob. | User accidentally purges the pump after it is connected to the patient while trying to start the pump. | Patient receives an unintended dose that is not included in the 4-hour limit and is not prescribed. | No effective mitigating strategy from within the organization. Recommend that vendor review technology design to ensure users are aware of which modality has been selected |

| Pump C | | | |
|---|--|--|---|
| Issue | Description of Error | Impact to Safety | Mitigating Strategy |
| It is not clear to users what “Anaesthesia Mode” is or how it affects the pump. | User incorrectly selects “Options” when trying to review the setup parameters. User selects “Anesthesia Mode” and enables it without knowing what it does. | Anaesthesia Mode removes many of the safety limits built into the drug templates. This mode could be removed from the pump so this option would never be inadvertently selected. | Remove Anaesthesia mode from drug library template to prevent this use error since it is not needed for PCA. |
| Pump buttons are difficult to press. | User entered a dose of 0.2 mg but the pump only registered 2 because the buttons are hard to press. User noticed and mitigated the error. | If a dose of 2 mg is inside the programming limit, a 10-fold overdose would occur each time the patient requested a dose. | No effective mitigating strategy from within the organization. Recommend that vendor reviews button design to reduce force required to register key press. |
| Visual parallax effect on pump screen. | User selected the wrong drug three times because of a parallax effect on the screen. If the user is not standing directly in front of, and at the same height as the screen, the buttons do not line up with the screen options. | Pump programmed incorrectly resulting in over/under infusion. | No effective mitigating strategy from within the organization. Recommend that vendor reviews screen design to reduce parallax effect. |
| Pump response to key press is delayed. | User pressed the same button several times because the pump did not respond quickly to the initial key presses. Subsequent presses were applied to the | Incorrect selections made which could result in giving drug to a patient inadvertently. | No effective mitigating strategy from within the organization. Recommend that vendor reviews button |

| | | | |
|--|---|--|---------|
| | next screens without the user knowing what was selected. In one case the user inadvertently gave the patient a 1.5 mg bolus because of this design issue. | | design. |
|--|---|--|---------|

During this ^{HF}PIP, neither an ^{HF}FMEA ([Chapter 9](#)) nor in-use trials ([Section 11.6.2.4](#)) were conducted. Since the healthcare organization's policy allowed it, the ^{HF}PIP team shared some feedback with each vendor to highlight design issues that were uncovered on their product during the evaluation process. The team was extremely careful when sharing results, ensuring that information was kept confidential between the ^{HF}PIP team and each individual vendor.

In addition to the aforementioned human factors-informed evaluations, the biomedical technology department conducted technical assessments of each pump to confirm that each PCA pump operated according to specification. All three products met the technical specifications, and no products were eliminated on this basis.

The hospital's purchasing department also conducted a financial review of each product. Pump C was more expensive than either of Pump A or Pump B, and fell outside of the hospital's budget, however this vendor indicated a willingness to negotiate on price in exchange for being a beta test site if there was interest in purchasing the product. No products were eliminated from the evaluation based on financial concerns.

Section 12.5. Decide on Product(s)

To make the final decision about which PCA pump to procure, the ^{HF}PIP team weighed several factors including findings from the human factors evaluations, and the technical and financial reviews. Since there were no major technical or cost constraints, the most significant differentiating factors were the results of the human factors evaluations. Each of the three PCA pumps being considered had safety issues that could not be effectively mitigated by the healthcare organization. Since these issues had the potential to cause serious patient harm, discussion was initiated with each of the three vendors to determine whether software and other design changes could be made to address the concerns. None of the three vendors were able to make the requested changes and so the ^{HF}PIP team decided not to purchase any of the three PCA pumps evaluated.

The available funds for the capital expenditure were held by the healthcare organization, and the purchase decision was deferred for about a year. During this time, another vendor introduced a new PCA pump to the marketplace that was licensed for sale and that met the criteria set out in the RFP. The ^{HF}PIP team evaluated the new PCA pump using the same process described in this chapter. The results of the human factors evaluations showed fewer usability issues, and none of the issues identified had potentially serious safety implications. The ^{HF}PIP team selected this pump (Pump D) for procurement.

It is recognized that many hospitals are required to make purchasing decisions based primarily on cost. In these cases it is even more important to ensure that user needs, particularly those associated with product features and functions that can impact safety, are translated directly into the request for proposals so that products can be eliminated from contention that do not support safe use. If the final decision is primarily determined by cost, it is recommended that a usability evaluation be conducted on that product to identify potential issues and training requirements so that mitigating strategies and appropriate training can be developed as part of the implementation strategy.

Section 12.6. Configure Product(s) and Environment

Findings from the human factors evaluations conducted on Pump D were used to help inform how to configure the pump for each representative user group. For example, alarm settings were adjusted based on the number of air-in-line alarms experienced during the usability testing. Additionally, the pre-printed medication orders were re-designed to ensure the wording matched the wording used on the pump and the order of information on the pre-printed order form was consistent with the programming sequences to minimize data entry errors.

Section 12.7. Plan and Implement Product(s)

Making Changes to the Work System

Findings from the human factors evaluations conducted on Pump D were used to help inform the types of changes required at the work system level. For example, a worksheet was implemented to help support and guide nurses through some new documentation steps that were required for verifying the rights of medication management [92, 93], and the storage locations of intravenous tubing for PCA pumps and large volume infusion pumps were changed because of a near miss during usability testing where the wrong tubing was almost used by a participant.

Training and Education

Several training sessions were provided to staff beginning a few months prior to the date the PCA pump was to be implemented. Members of the ^{HF}PIP team, including the clinical educator, created a training program tailored to the needs of each representative

user group. The human factors representative was also very instrumental in the design of the training and communicated what aspects of the pump needed to be highlighted in the training based on the results of the usability testing. The training was administered jointly by the vendor and the clinical educator. Information was presented not only about the 'knobology', (e.g., what button to press to start the PCA pump), but also the underlying principles governing how the PCA pump worked so staff would understand why a process had to be done in a certain way. Hands on "training clinics" were held regularly leading up to the implementation date so staff could practice using the PCA pump in a simulated setting. Prior to receiving sign-off to use the PCA pump in practice, each end user had to successfully complete a set of hands-on tasks to demonstrate their ability to perform each required task.

Implementation

The new PCA pump was implemented by the healthcare organization, and although the transition was somewhat stressful for staff, highly trained clinical champions on each unit were available to support staff during the implementation.

Transitional and Ongoing Support

Even after the PCA pumps had been implemented, occasional "training clinics" were held where staff could come in to practice on the new PCA pump in a simulated environment. A competency-training program was established at the healthcare institution so staff could regularly brush up on the requirements when using these pumps and new staff could be trained in a systematic way.

The implementation was highly successful. Nurses transitioned to the new devices with ease, and the pumps were used safely and effectively by all user groups.

Chapter 13. Identifying Issues and Investigating Incidents Case Study

Biomedical technology professionals are often the first people to identify issues with a technology. Sometimes they identify them proactively, during regular inspections, and sometimes they find them retrospectively, when they are contacted by front line staff for assistance. In both of these scenarios, biomedical technology professionals are well positioned to apply human factors methods to identify human factors issues. This chapter will use case studies to showcase two human factors informed methods that can be used to help identify human factors issues with technology either retrospectively (^{HF}RCA), or prospectively (^{HF}FMEA).

Section 13.1. Retrospective Incident Investigations: ^{HF}RCA

To illustrate how the biomedical technology professional can approach incident investigations from a human factors perspective, the human factors informed root cause analysis (^{HF}RCA) framework will be applied to a case study (Case Study 3) that occurred in Canada in 2006.

Chemotherapy Overdose Results in Patient Death

On July 31, 2006, a 43-year old woman underwent her first cycle of adjuvant intravenous (IV) chemotherapy treatment to reduce the likelihood of recurrence of nasopharyngeal cancer. Previously, she had received two months of combined chemotherapy and radiation treatment, and although her cancer was advanced, the planned treatment was expected to be effective.

On the morning of her first cycle of adjuvant treatment, she arrived at the cancer centre and received hydration and anti-nausea medications intravenously, followed by the intravenous chemotherapy drug, cisplatin. This drug was followed by a post-hydration medication and another chemotherapy drug, fluorouracil. A high dose of fluorouracil was to be given to the patient slowly, over the course of four days. So the patient would not have to stay in the hospital for this infusion, the fluorouracil was to be given intravenously using an ambulatory infusion pump.

The nurse calculated the required medication delivery rate for the fluorouracil, programmed the ambulatory infusion pump, and asked a second nurse to double check her calculation and that the pump had been programmed correctly. Both nurses signed off on the required documentation, and the patient's nurse connected the patient to the ambulatory infusion pump and started the infusion. The nurse instructed the patient to

return in four days, at which point she would be disconnected from the ambulatory infusion pump.

The patient left the clinic, and about four hours later she heard the infusion pump beeping. When she checked the pump she saw that the entire bag of fluorouracil was already empty. Instead of infusing over four days, the medication had been delivered to the patient in just four hours.

The patient returned to the cancer centre where the pump was disconnected and her line was flushed. The physician on call was notified and he indicated that unfortunately nothing could be done to reverse the overdose, as there was no antidote. Tragically, the patient died on August 22, 2006 from “complex causes, including a failure of multiple organs, as well as widespread internal bleeding”.

From: [ISMP Canada Fluorouracil Incident Root Cause Analysis](https://www.ismp-canada.org/download/reports/FluorouracilIncidentMay2007.pdf), May 2007. Available at <https://www.ismp-canada.org/download/reports/FluorouracilIncidentMay2007.pdf>

Case Study 3. Chemotherapy overdose resulting in patient death

Shortly after this tragic incident, ISMP Canada was asked to investigate and identify underlying factors that could have contributed to the event, in the hope that other similar events could be prevented in the future. Correspondingly, when a sentinel event occurs in your own healthcare organization, it is highly recommended that an ^{HF}RCA be completed, not only to fulfill legislative or accreditation requirements, but also to reduce the likelihood of other similar events occurring again.

Prior to conducting an ^{HF}RCA, the biomedical technology professional should ensure they have the support and buy-in of senior level management to increase the chance for positive change as a result of the analysis. It may be helpful to share RCA reports from other investigations, such as the ISMP Canada RCA cited in Case Study 4, to illustrate the possible output and impact. In the case of the fluorouracil incident described above, the Chief Medical Officer of the organization took immediate action by declaring the tragedy a systems failure, apologizing to the family, and requesting that [ISMP Canada](#) conduct a formal RCA. Senior management in this case was keenly aware of the importance of managing risk at a systems level, rather than at a person level.

The [ISMP Canada RCA](#) [94] of the fluorouracil incident is an excellent example of how to conduct a RCA. While ISMP Canada does not refer to it as an ^{HF}RCA, a human factors specialist was asked to participate on the ISMP Canada RCA team, and he performed several HF methods covered in this book including Observations ([Chapter 4](#)), Interviews ([Chapter 5](#)) and Usability Testing ([Chapter 8](#)). The report, therefore, included a description

of many human factors issues that were deemed to have contributed to the identified systems failures.

Section 13.1.1. Determine Whether ^{HF}RCA is Required

To determine whether it is appropriate to conduct a RCA in this case (i.e., there are systems issues that must be identified and addressed) the Incident Decision Tree ([Figure 26](#)) should be applied. It is clear in this case that conducting a ^{HF}RCA is appropriate because: the nurse did not intend to cause harm, there was no evidence of ill health or substance abuse, the nurse does not appear to have departed from agreed protocols or safe procedures, and others in a similar situation could make the same mistake. Consequently, this sentinel event is a systems failure rather than a person-centered issue and thus requires an analysis of the risks in the system to identify mitigating strategies.

Section 13.1.2. Secure Items

Based on the description of the case, the items considered important to secure were:

- The ambulatory infusion pump
- The bag of chemotherapy
- The tubing sets used
- All medication labels
- The medication order
- The patient's records
- Any notes or papers used for the calculation

After securing these items, photographs were taken, and lot numbers, serial numbers, and expiration dates were recorded. Pump logs were saved for future review.

Section 13.1.3. Establish the Team

If a ^{HF}RCA were conducted by an internal team at the healthcare facility, it should include a pharmacist, one or more oncology nurses, an oncologist, a risk manager, a biomedical technology professional, and someone with human factors expertise (could be the biomedical technology professional). The team should be assembled at the request of a senior hospital administrator who will also receive reports on the activities of the team.

In the case of the RCA conducted by [ISMP Canada](#), the team consisted of five health care professionals: three pharmacists with expertise in medication safety; an oncology nurse; and a physician who was also a human factors engineer.

A senior leadership representative from the healthcare institution would be an excellent addition to the team. In the case of this incident, the Chief Medical Officer fully supported the completion of this RCA. Support and awareness of RCA activities by senior leadership is essential to realizing positive change at the healthcare organization following a sentinel event.

Section 13.1.4. Develop Initial Understanding of Incident

The initial understanding of the incident described in the [ISMP Canada RCA](#) [52] as follows:

“A woman in her 40s died last week after she was mistakenly given a lethal overdose of a standard chemotherapy drug while undergoing treatment at the XXXX Cancer Institute. Instead of receiving the intravenous drug continuously over four days, the woman received the dose over four hours on July 31 from a pump that had been programmed in error. She died Aug. 22 at the University of XXXX Hospital from complex causes, including a failure of multiple organs, as well as widespread internal bleeding.”

From: XXXX. We cannot eliminate human error. XXXX Journal, Thursday, August 31, 2006.

To help create this succinct statement, a process flow diagram was created to support the development of the initial understanding of the incident ([Figure 43](#)). The information used to create this type of process flow diagram is usually generated by conducting observations of the work environments responsible for all tasks related to ordering, preparing and administering ambulatory intravenous chemotherapy and conducting interviews with staff about what happened on the day of the incident. Conducting interviews following an incident can be difficult, both for the interviewer and especially for the interviewees. Careful consideration should be given to who conducts the interviews, where the interviews take place, the specific questions that are asked, and how the interview is positioned to the interviewee.

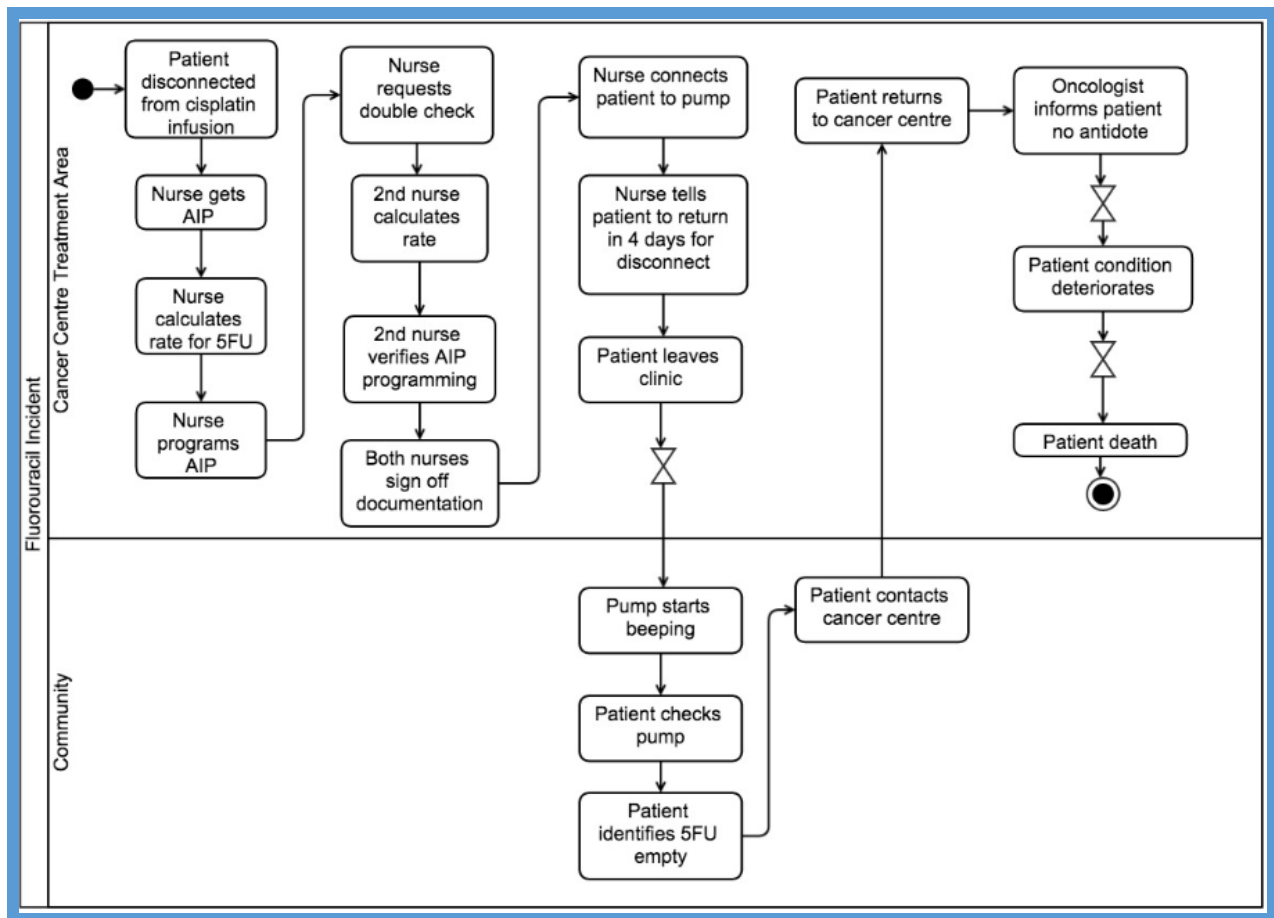


Figure 43. Process flow diagram based on the teams' initial understanding of the incident

Creating this diagram was just the first step in understanding the incident. Once created, it was enhanced iteratively through subsequent interviews, an examination of the physical environment, usability testing, and a search for information about other similar incidents.

In the case of the RCA conducted by ISMP Canada, the initial understanding of the incident was informed by:

- Interviews with:
 - Corporate executive team members
 - Senior leadership
 - Pharmacy administrators
 - Internal critical incident review team members
 - Nursing and medical staff directly involved in the incident
 - Nursing and medical staff indirectly involved in the incident
 - Nursing and medical staff knowledgeable about the typical care process

- Front line staff
 - Biomedical engineering manager
 - Medical staff from the Intensive Care Unit where the patient was transferred following the incident
 - Staff from the patient residence in the community, where the patient had stayed during the ambulatory portion of her chemotherapy treatment
 - A representative from the provincial Health Quality Council, who also conducted an external review of the incident
- An examination of the physical environment where the incident took place
 - Observations of typical work processes in the Medical Clinic, Treatment Area, and Pharmacy
 - A usability test of the tasks associated with setting up and programming the ambulatory infusion pump.
 - A search for information about similar incidents that may have occurred nationally, or internationally.

In addition to incorporating information from these data collection exercises, other contextual information was included in the process flow diagram such as notes about artefacts, timing, and a comparison of the actual, typical and expected workflows ([Figure 44](#)). In this case, one of the many factors identified as contributing to the incident was a missed step in the calculation resulting in the programming of a medication delivery rate that was 24 times too fast. [Figure 44](#) shows this missed calculation step on the diagram, but does not tie it in with the actual events. Time data indicated on the process flow diagram in [Figure 44](#) are not accurate, and have been included for illustrative purposes only.

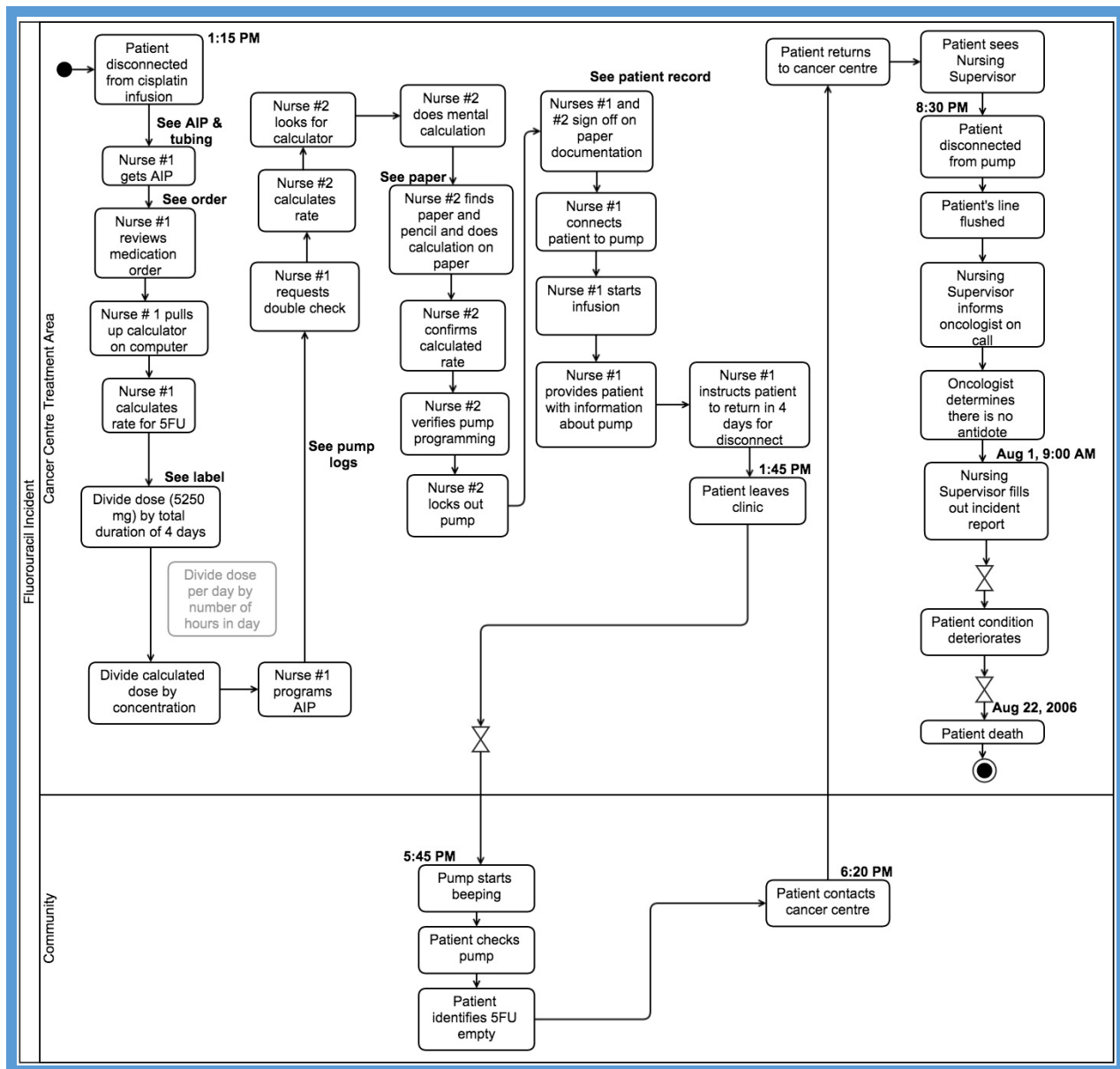


Figure 44. Updated process flow diagram based on data collected through interviews, observations, usability testing, and information searches.

In addition to a process flow diagram, a factual description of the events leading to the incident should then be created. These descriptions are useful to aid in systematically thinking through potential failure modes across the entire workflow. The following list provides an abridged summary of the events leading to the adverse event, with a more complete summary available in the ISMP RCA report [94].

- The patient received her pre-hydration, pre-medications, cisplatin, and post-hydration according to the typical prescribed protocol.

- Following the post-hydration infusion, nurse #1 calculated the required medication delivery rate for the patient's fluorouracil infusion. To do so, she used the dose ordered over four days (5,250 mg), the total duration of the infusion (4 days), and the final concentration (45.57 mg/mL). A rate of 28.8 mL/h was calculated, and was observed to match a number printed on the pharmacy drug label. The calculation was done using a calculator available on a computer.
- Nurse #1 entered the rate of 28.8 mL/h into the ambulatory infusion pump.
- Nurse #1 requested a second check to verify the correctly calculated rate of drug delivery and pump programming.
- Nurse #2 came to do the check but could not find a calculator, so she did the calculation both mentally and on paper. Nurse #2 confirmed the calculation and pump programming before locking the pump.
- Nurses #1 and #2 each signed the handwritten medication administration record, documenting the total dose of fluorouracil as 5,250 mg.
- Nurse #1 signed off electronically on the total dose in the computer.
- Nurse #1 started the infusion, reviewed the pump functionality with the patient, and instructed her to return to the cancer centre in 4 days.
- About four hours after the patient left the cancer centre the pump started beeping because the bag of fluorouracil was empty.
- The patient contacted the cancer centre, and later returned to the cancer centre, where the evening shift Nursing Supervisor disconnected the pump and flushed the patient's line.
- The Nursing Supervisor contacted the physician on call, who advised that nothing could be done. The Nursing Supervisor completed a paper incident report and submitted it, with the pump, to the Chemotherapy Treatment Clinic.
- The following morning, the Unit Manager and Nurse #1 reviewed the pump history and verified that the pump had been programmed at the incorrect rate. The pump should have been programmed at a rate of 1.2mL/h, but was programmed at 28.8mL/h - a rate that was 24 times higher than intended.

Section 13.1.5. Identify Contributing Factors

The factual description of events highlights that several contributing factors across the system led to the occurrence of this incident. The human factors framework adapted from Reason's Swiss Cheese Model and Vicente's Human-tech ladder (Section 10.6.5.1) is helpful for identifying and documenting contributing factors across the levels of the system. The Swiss Cheese/Human-tech illustration for this incident is included in Figure 45.

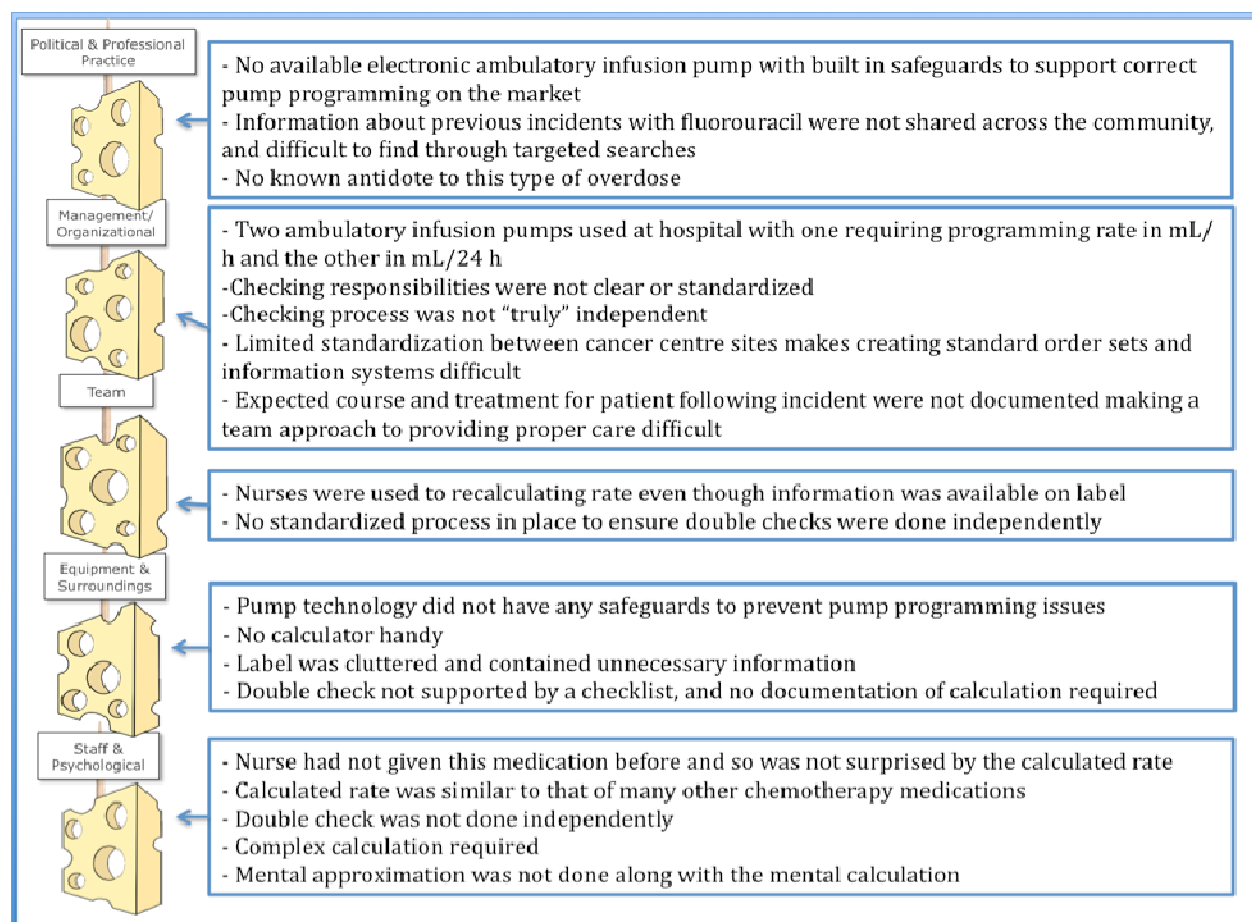


Figure 45. Using Reason's Swiss Cheese Model and Vicente's Human-tech ladder to identify contributing factors to a sentinel event.

Additionally, the Joint Commission RCA Action Plan Tool helps to systematically identify contributing factors by asking a series of questions. A brief excerpt of the analysis questions from the Joint Commission RCA Action Plan Tool that were used to help identify additional contributing factors are included below in Table 28.

Table 28. Excerpt of analysis questions from the Joint Commission RCA Action Plan Tool for the fluorouracil incident

| | Analysis Question | Description based on incident |
|-----|--|--|
| 2 | Were there any steps in the process that did not occur as intended | Nurse #2 looked for a calculator to do her calculation, but could not find one ... |
| 3 | What human factors were relevant to the outcome? | Confirmation bias: Information about rate per hour and rate per 24 hours was available on label, and matched what both nurses calculated ... |
| ... | ... | ... |

Other tools that are helpful for analyzing and document contributing factors include an Ishikawa diagram, a tree diagram, or a constellation diagram ([Section 10.6.5.2](#)).

In this case, the ISMP Canada RCA team also created a number of causal statements to summarize the contributing factors leading to the incident. A selection of the most critical factors that contributed to (1) the miscalculation, (2) the false confirmation of the information on the label and (3) the pump being programmed in accordance with the miscalculation, are included here.

(1) Factors contributing to the miscalculation

- Nurses were used to performing complex calculations involving multiple dimensions, even though the information was available on the medication label. The nurses at this institution did this calculation as a double check to catch any issues that might have been introduced upstream.
- Nurse #1 had never administered fluorouracil in this way before and so was not suspicious of the calculated value; this was the first time the nurse had ever administered this protocol.
- The calculated rate of 28.8 mL was not unusual for other intravenous infusions administered in the chemotherapy treatment clinic.

- Nurse #1 did not verify the calculated rate with a mental approximation (e.g., if the total volume in the bag was 130 mL, and the infusion was to be given at a rate of approximately 30 mL/h, the infusion would only last for about 4 hours rather than the intended 96 hours).

(2) Factors contributing to a false confirmation of the miscalculation

- The medication label ([Figure 46](#)) contained information about two different rates, including a rate per hour and a rate per 24-hours, increasing the opportunity for a false confirmation of the miscalculated rate.
- Ambulatory infusion pumps used previously at the institution were programmed in mL/24 h.

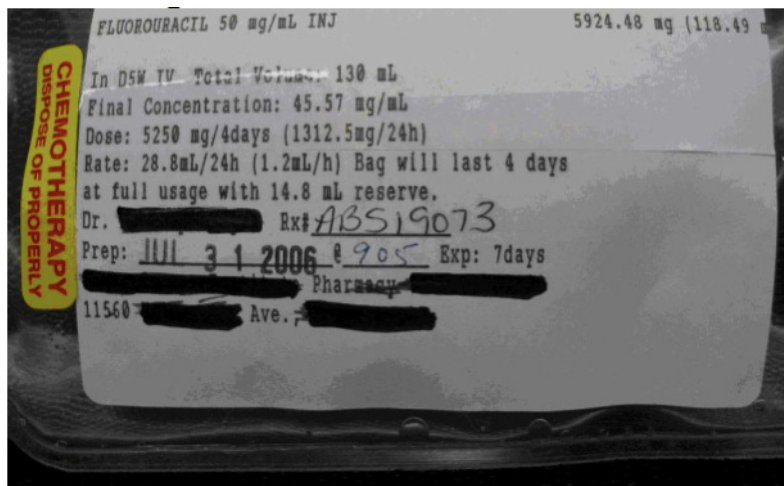


Figure 46. Medication label for fluorouracil infusion containing two different rates

- The double-checking process was not standardized to support an independent check by Nurse #2, and there was no checklist or documentation required to support the calculation.
- The double-checking process was not truly independent with documentation of independent mathematical calculations.
- Nurse #2 did not verify the calculated rate with a mental approximation. (e.g., if the total volume in the bag was 130 mL, and the infusion was to be given at a rate of approximately 30 mL/h, the infusion would only last for about 4 hours rather than the intended 96 hours).
- There was no calculator readily available to Nurse #2, so the calculation was done on a scrap piece of paper.

- The format of the medication label reflected pharmacy’s interpretation of the legal requirements and professional guidelines for labeling medications. Human factors principles were not taken into account to ensure the contents reflected pump programming requirements and that other factors, such as optimal font size, style, appropriate use of white space, etc., were incorporated.

(3) Factors contributing to the pump’s inability to detect the calculation error

- The pump used at the cancer centre did not have built-in safeguards to prevent users from programming a rate exceeding a specified maximum value for a particular drug. This was true of all electronic ambulatory infusion pumps available on the market at the time.

Section 13.1.6. Develop Mitigating Strategies

Once the contributing factors are identified, mitigating strategies to address those factors must be identified. There is no single approach for developing mitigating strategies, and often this is an iterative process, and one that requires careful consideration of resources, feasibility, accountability and, most importantly, effectiveness. [Section 10.6.6](#) describes several approaches to developing mitigating strategies and potential pitfalls associated with this task.

Several recommendations were put forth to address the contributing factors identified through the ^{HF}RCA. For a complete listing of the recommendations identified by ISMP Canada, see the [ISMP Canada RCA](#) [69]. One such recommendation was that in the absence of “smart pump” technology for ambulatory infusion pumps, other safeguards should be put in place to ensure that programming parameters fell within a safe range for high-risk medications. Since no electronic pumps on the marketplace had this capability at the time, another option was to migrate to the use of elastomeric, rather than electronic pumps. When this solution was considered in the context of the Hierarchy of Effectiveness ([Chapter 3](#)) it was determined to be a systems-focused solution, and so likely to be more effective than some of the other person-focused solutions the team had identified. It turned out, however, to be less of a fail-safe solution than anticipated, as is discussed in the [FMEA case study](#) in the next section.

In a typical RCA, a list of prioritized RCA action items ([Table 28](#)) is captured with progress being tracked using a spreadsheet outlining necessary follow through actions and timing ([Table 29](#)).

Table 29. Excerpt of prioritized list of ^{HF}RCA actions

| Recommended Action (category) | Risk (severity assessment) | Hierarchy of Effectiveness (high, medium, low leverage) | Predictors of Success (alignment, existing mechanisms, quick wins) | System Level Targeted | Evidence Available? What Type? | Confirm Validity, Feasibility | Order of Priority or Time Frame |
|--|----------------------------|---|---|---|--------------------------------|---|---------------------------------|
| Migrate from electronic AIPs to elastomeric AIPs | Medium | High | Recent pump procurement project in another unit could be used as a basis for evaluation | Unit-wide rather than organization wide | Little evidence found | Talk with other hospitals using elastomer-ics | Inter-mediate |

Table 30. Excerpt of follow through actions and timing for ^{HF}RCA

| # | Recommendation | Source and ID # | Date Entered | Progress Status | Timeframe (end date) | Target Area | Risk Level | Individual Responsible |
|---|--|-----------------|--------------|-----------------|----------------------|----------------------|------------|------------------------|
| 1 | Migrate from electronic AIPs to elastomeric AIPs | 1A | 09/09/06 | | 03/01/07 | Chemo Treatment Area | Medium | Peter |

A report is created to summarize the process, findings, and action items stemming from the ^{HF}RCA. The final ISMP Canada RCA report [94] is an excellent resource that contains further detail.

Section 13.2. Proactive Systems Improvement Following an Incident (^{HF}FMEA)

Following a retrospective analysis such as an ^{HF}RCA, it can be beneficial to conduct a prospective analysis using ^{HF}FMEA. When a prospective technique is applied following a retrospective analysis, the opportunity to identify general risks, not directly involved in the incident, is presented. Further, a prospective analysis method like ^{HF}FMEA can be applied following an ^{HF}RCA to examine the potential for new risks to be introduced into the system as a result of planned changes and mitigating strategies. Case Study 4 expands on Case Study 3 and will be used to illustrate how the biomedical technology professional can use ^{HF}FMEA to conduct a prospective risk analysis.

Implementing Elastomeric Ambulatory Infusion Pumps

Following the incident described in Case Study 3 (Chemotherapy Overdose), a retrospective analysis was conducted using ^{HF}RCA ([Chapter 10](#)). One of the root causes identified through the analysis was that the electronic ambulatory infusion pumps in use at the time of the incident did not have built-in safeguards to prevent programming errors from occurring. Based on this issue, a recommendation was put forth that the healthcare organization should start using pumps with built-in safeguards to prevent programming errors.

At the time of the incident, there were no electronic ambulatory infusion pumps with built-in safeguards available on the market. Consequently, the healthcare organization considered other options, such as elastomeric pumps ([Figure 47](#)). Unlike electronic pumps, elastomeric pumps are mechanical and do not require any pump programming. However, prior to moving from electronic to elastomeric ambulatory infusion pumps, the healthcare organization wanted to understand what risks were associated with the use of these devices, and so an ^{HF}FMEA was to be undertaken at the healthcare organization.

Case Study 4. Identifying Risks Associated with Elastomeric Ambulatory Infusions Pumps



Figure 47. An elastomeric ambulatory infusion pump

Section 13.2.1. Select a Process

The chosen process for this particular ^{HF}FMEA was *administering chemotherapy using an elastomeric ambulatory infusion pump*. This process was chosen because from the fluorouracil incident it was known that the electronic ambulatory infusion pumps in use at the time did not contain any built-in safeguards to ensure the parameters entered for pump programming fell within acceptable ranges. The reason the institution was considering

switching to an elastomeric pump was to prevent these types of pump programming errors from occurring as chemotherapy was set up and administered using the pump.

Consequently, the starting point for the process was chosen to be *as the nurse received the pump filled with chemotherapy from pharmacy*, and the ending point for the process was chosen to be *as the patient left the chemotherapy treatment chair*.

To keep the analysis focused and scope manageable, the following inclusion and exclusion criteria were defined ([Table 31](#)):

Table 31. Inclusion and exclusion criteria to define process scope

| Inclusion and Exclusion Criteria | |
|---|--|
| Patient Population | |
| Inclusions: Adult patients receiving chemotherapy | |
| Exclusions: Adult patients not receiving chemotherapy, paediatric patients, clinical trials patients, and other special cases | |
| Location/Environment: | |
| Inclusions: Outpatient treatment clinic of cancer centre | |
| Exclusions: Inpatient cancer treatment areas, pharmacy, physician's clinics, community, home | |
| Staff Population: | |
| Inclusions: Chemotherapy nurses working in the outpatient treatment clinic | |
| Exclusions: Chemotherapy nurses not working in the outpatient treatment clinic, pharmacists, physicians/oncologists, community health care workers, home care workers | |
| Tasks: | |
| Inclusions: Receive filled elastomeric pump from pharmacy, check five rights, connect pump to patient, start infusion, check the pump is infusing | |
| Exclusions: Ordering chemotherapy, checking order, picking supplies to make chemo order, mixing chemotherapy order, checking chemotherapy mix | |
| Equipment: | |
| Inclusions: Elastomeric ambulatory infusion pumps and associated tubing/supplies | |
| Exclusions: Large volume infusion pumps, electronic ambulatory infusion pumps | |

Thus, the process scope was to include adult patients receiving chemotherapy treatment at the outpatient treatment clinic of the cancer centre, from the time the nurse receives the mixed chemotherapy and elastomeric ambulatory infusion pump from the pharmacy to the point at which the patient leaves the treatment chair with the infusion running.

Section 13.2.2. Assemble a Team

Although the process scope only included chemotherapy nurses and processes contained within the chemotherapy treatment clinic, it was essential that people from outside of this process scope were included as part of the ^{HF}FMEA team.

To complete this ^{HF}FMEA, the following team members were chosen and recruited:

Work Team:

- Front line chemotherapy nurse
- Biomedical technology professional
- Human factors specialist

Advisory Team:

- Nursing manager for outpatient chemotherapy treatment clinic
- A second front line chemotherapy nurse
- Oncology pharmacist
- Pharmacy technician
- Oncologist
- Clinic nurse
- Clerk
- Risk manager
- Cancer centre chief nursing officer

Team Meeting # 1:

Attendees: work and advisory teams

Purpose: meet and greet; review the process scope

Date: May 2, 2007

Time: 12:00-14:00

Meeting Notes:

-Roundtable introductions

- Decided on responsibilities including: team leader (biomedical technology professional), scribe (front line chemotherapy nurse), and facilitator (human factors expert)
- Explained the difference between the work and advisory groups and set expectations for frequency of meetings for advisory group (about 7 meetings of varied length over the course of the analysis)
- Gave overview of planned process scope, start/end points, and inclusion and exclusion criteria
- Had a group discussion about whether the scope should be expanded to include pharmacy; decided to keep it the same for now, but to revisit this at next meeting once the work team has conducted observations and created a draft of the process flow diagram

Section 13.2.3. Document the Process

An initial process flow diagram was created based on an understanding of the tasks that would be required to administer chemotherapy to an adult patient using an elastomeric ambulatory infusion pump ([Figure 48](#)).

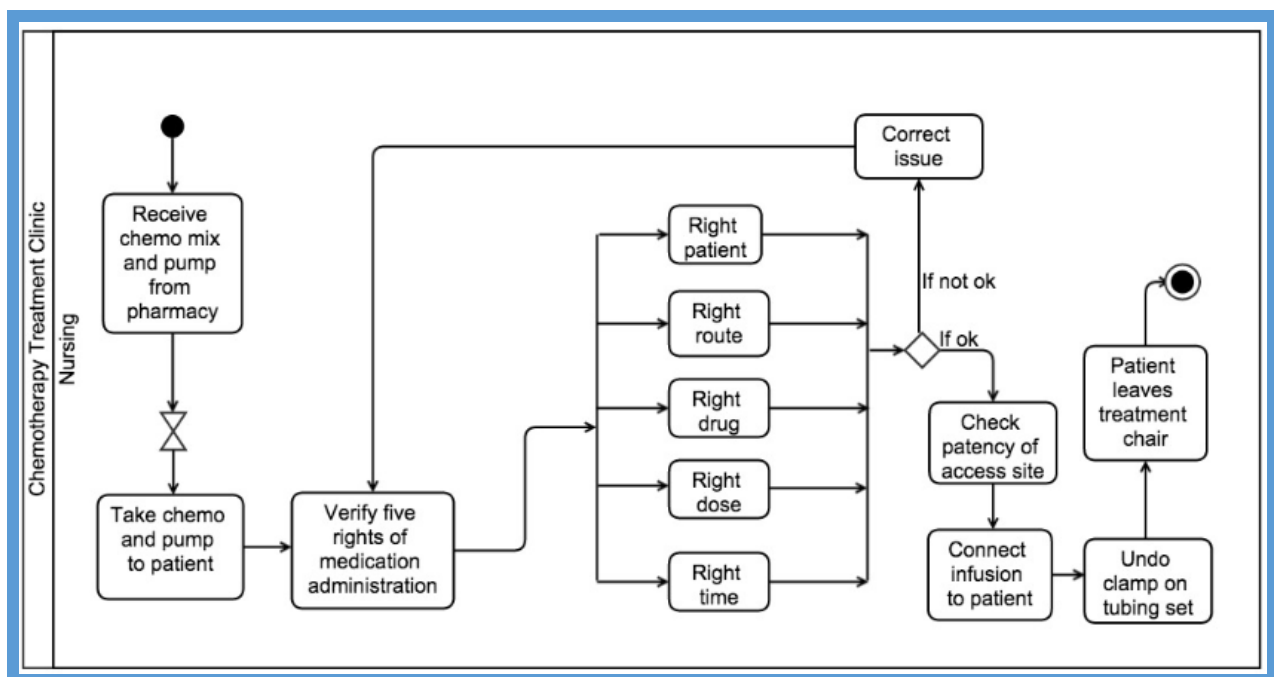


Figure 48. Initial process flow diagram for administering chemotherapy to an adult patient with an elastomeric ambulatory infusion pump

After creating the initial process flow diagram, several questions and areas of uncertainty remained. Work team members raised questions about how to control the rate of medication delivery, what type of tubing to use, and whether there were any special

considerations for nursing for the elastomeric pump. Since these devices were not currently being used at the healthcare organization, the work team contacted the vendor to get more information about the devices. The vendor agreed to provide samples of the elastomeric pump to the healthcare organization so they could better determine how they might fit with the in-house workflow.

The work team also decided to contact another local organization that was using the elastomeric pumps to see if they could come and observe staff, to see how the pumps fit into their workflow. The work team planned a visit to this institution and learned through observations and interviews of nurses that the stated flow rate of the pump seemed to depend on a number of physical factors including a patient's temperature, the head height between the pump and the infusion port, and the patient's catheter size. They also learned that several models of elastomeric ambulatory infusion pump had to be purchased and stocked because each model of pump delivered medication to the patient at a different flow rate.

Based on this information, the work team decided to schedule a second visit to the local institution to learn how the pumps were stored, and how the pharmacy made sure the proper elastomeric pump model was chosen for a particular patient's chemotherapy.

During this second visit, the work team learned through observations and interviews in the pharmacy that pump storage and selection was sometimes challenging because there were many models that looked similar, with the only differences being a small printed label on the device, and differently coloured plastic top. One pharmacist also mentioned that the flow rate stated on the side of the pump could be affected depending on the diluent that was used by the pharmacy technician when mixing a patient's chemotherapy.

The work team updated the initial process flow diagram based on the information learned through observations and interviews ([Figure 49](#)). Through the visits to the field, it also became apparent to the team that it would be important to expand the scope of the analyzed process to include: (1) tasks in pharmacy related to picking the right pump, and (2) mixing with the correct diluent to ensure chemotherapy is delivered to the patient at the intended rate.

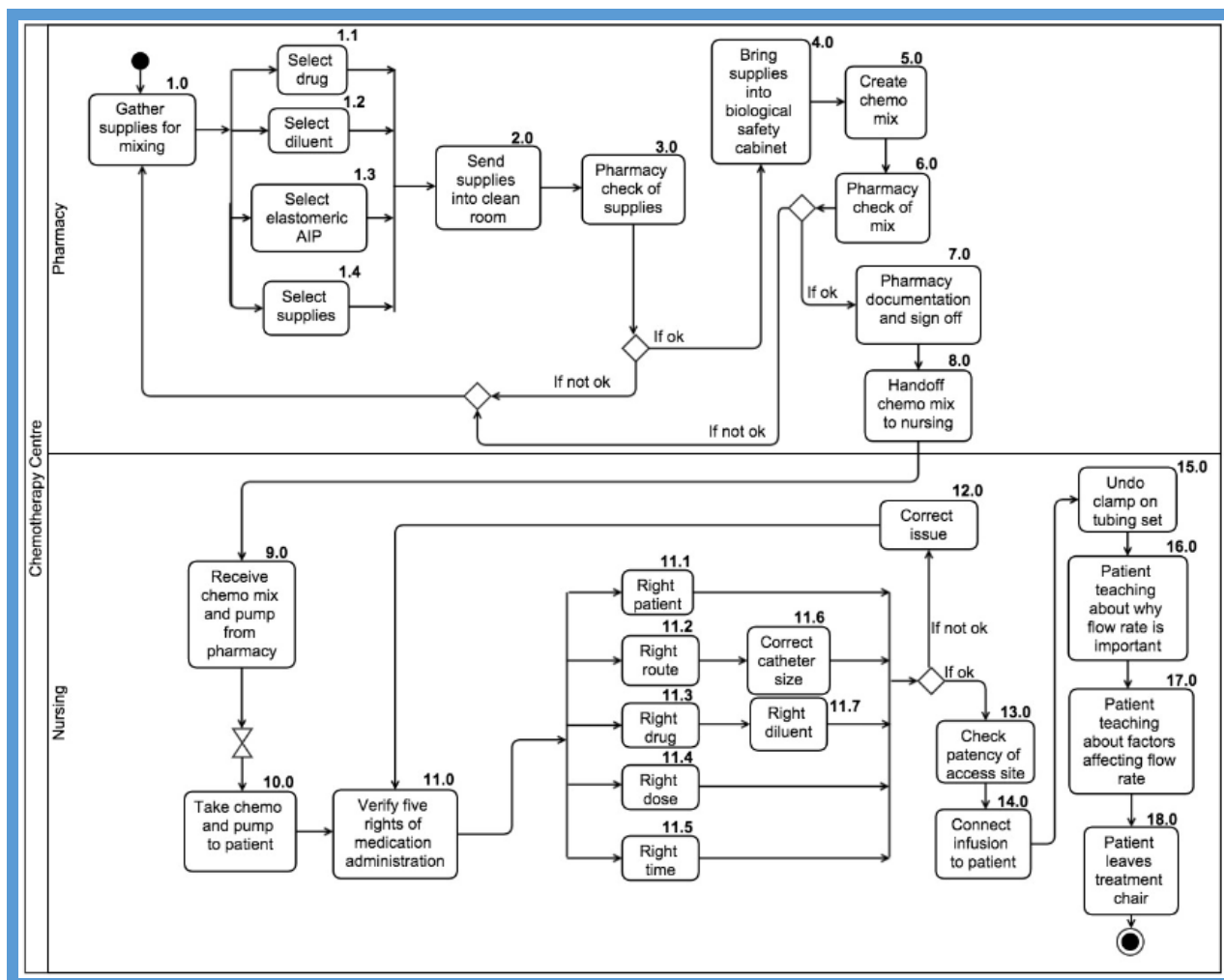


Figure 49. Updated process flow diagram based on information learned through observations and interviews in the field

Team Meeting # 2:

Attendees: work and advisory teams

Purpose: review process flow diagram

Date: May 25, 2007

Time: 8:00–12:00

Meeting Notes:

-Asked team members to help themselves to coffee and snacks

-Verified that all team members received a copy of the updated process flow diagram for review

-Updated advisory team on what the work team has been doing since the last meeting. Work team created an initial process flow diagram, contacted the manufacturer of the elastomeric ambulatory infusion pump to get more information and samples, and contacted another local institution using elastomeric pumps. Work team conducted two field visits where observations and interviews were conducted. Learned that several factors affect the flow rate of these pumps and that many models of pumps need to be purchased and stored as each model delivers medication at a different rate.

-Reviewed updated process flow diagram with the advisory team

-Discussed and came to consensus that process scope should be expanded to include pharmacy based on observations and interviews

-Reviewed membership of work and advisory team to ensure pharmacy expertise was accounted for; since pharmacist and pharmacy technician are already part of team, agreed that no new members are required at this point

-Feedback acquired from the advisory team about updated process flow diagram steps; several minor modifications were agreed upon based on subject matter expert input

-Next steps: work team will update process flow diagram based on feedback from today's meeting and will recirculate within two weeks for independent review and approval by advisory team members.

Section 13.2.4. Identify Failure Modes and Effects

The work team converted the final process flow diagram approved by the advisory team into a spreadsheet format, a portion of which is shown in [Table 32](#).

Table 32. Part of the spreadsheet created based on the approved process flow diagram

| Task # | | Failure Mode (FM) | | Effect | Scoring | | | Key Failure Mode (KFM) | | | | | | |
|--------|---|-------------------|-------------|--------|--------------|-----------------|-------------------|------------------------|---|----|------------|------------|-----------------------------|-------|
| # | Description | # | Description | | Severity (S) | Probability (P) | Hazard Score (HS) | S | P | HS | Controlled | Detectable | Single Point Weakness (SPW) | KFM ? |
| 1.0 | Gather supplies for mixing | | | | | | | | | | | | | |
| 1.1 | Select drug | | | | | | | | | | | | | |
| 1.2 | Select diluent | | | | | | | | | | | | | |
| 1.3 | Select elastomeric AIP | | | | | | | | | | | | | |
| 1.4 | Select supplies | | | | | | | | | | | | | |
| 2.0 | Send supplies into clean room | | | | | | | | | | | | | |
| 3.0 | Pharmacy check of supplies | | | | | | | | | | | | | |
| 4.0 | Bring supplies into biological safety cabinet | | | | | | | | | | | | | |
| 5.0 | Create chemo mix | | | | | | | | | | | | | |
| 6.0 | Pharmacy check of mix | | | | | | | | | | | | | |
| 7.0 | Pharmacy documentation and sign off | | | | | | | | | | | | | |
| 8.0 | Handoff chemo mix to nursing | | | | | | | | | | | | | |
| 9.0 | Receive chemo mix and pump from pharmacy | | | | | | | | | | | | | |
| ... | ... | | | | | | | | | | | | | |

The work team then met to systematically identify failure modes and effects for each task step and sub-step as shown in [Table 33](#).

Table 33. Portion of the spreadsheet showing failure modes and effects based on the process flow diagram

| Task # | | Failure Mode (FM) | | Effect | Scoring | | | Key Failure Mode (KFM) | | | | | | |
|--------|-------------------------------|-------------------|----------------------------------|---|--------------|-----------------|-------------------|------------------------|---|----|------------|------------|-----------------------------|-------|
| # | Description | # | Description | | Severity (S) | Probability (P) | Hazard Score (HS) | S | P | HS | Controlled | Detectable | Single Point Weakness (SPW) | KFM ? |
| 1.0 | Gather supplies for mixing | 1 | Incorrect supplies gathered | Mix prepared incorrectly | | | | | | | | | | |
| | | 2 | Incomplete supplies gathered | Mix not prepared | | | | | | | | | | |
| 1.1 | Select drug | 3 | Wrong drug selected | Patient receives wrong drug | | | | | | | | | | |
| 1.2 | Select diluent | 4 | Wrong diluent selected | Infusion rate too fast or slow | | | | | | | | | | |
| 1.3 | Select elastomeric AIP | 5 | Wrong elastomeric selected | Infusion rate too fast or slow | | | | | | | | | | |
| | | 6 | Elastomeric not selected | Mix not prepared | | | | | | | | | | |
| 1.4 | Select supplies | 7 | Wrong supplies selected | Mix prepared incorrectly | | | | | | | | | | |
| 2.0 | Send supplies into clean room | 8 | Supplies not sent to clean room | Mix not prepared | | | | | | | | | | |
| 3.0 | Pharmacy check of supplies | 9 | Pharmacy does not check supplies | Patient receives wrong drug and/or wrong rate | | | | | | | | | | |
| ... | ... | ... | | | | | | | | | | | | |

After coming up with a preliminary list of failure modes and effects, the work team developed rating scales for review at the next advisory team meeting. The severity and probability rating scales are shown in [Table 34](#) and [Table 35](#), respectively.

Table 34. Severity rating scale developed by work team for this ^{HF}FMEA

| Severity | | |
|----------|-------------|-------------------------------------|
| Rating | Description | Definition |
| 1 | Minor | Patient unlikely to be harmed |
| 2 | Moderate | Patient could be temporarily harmed |
| 3 | Severe | Patient could be permanently harmed |
| 4 | Critical | Patient could die |

Table 35. Probability rating scale developed by work team for this ^{HF}FMEA

| Probability | | |
|-------------|-------------|--|
| Rating | Description | Definition |
| 1 | Remote | Unlikely to occur (may happen once in 5-30 years) |
| 2 | Uncommon | Possible to occur (may happen once in 2-5 years) |
| 3 | Occasional | Probable to occur (may happen more than once in 1-2 years) |
| 4 | Frequent | Likely to occur (may happen several times within the year) |

Team Meeting # 3:

Attendees: work and advisory teams

Purpose: review and expand upon potential failure modes and effects

Date: June 15, 2007

Time: 8:00-16:00

Meeting Notes:

- Reviewed agenda including scheduled breaks and lunch.
- Confirmed team members received a copy of the spreadsheet containing failure modes and effects for the approved process flow diagram.
- Facilitator led the group through the process steps and associated failure modes and effects row-by-row and asked for input from the group. The facilitator reminded the group that with this type of analysis, even if a failure mode seems unlikely or has not happened previously, it could happen and should be included on the spreadsheet.
- Group discussions about many of the listed failure modes, with several new failure modes being added by the team. The scribe documented this discussion in real-time so the team could see edits that will be made to the spreadsheet. Team members brought forth several causes, but this was not the focus of this meeting. So the scribe captured these in a separate file for later review.
- Some changes to the approved process flow diagram were suggested; these will be made by the work team following the meeting.
- Once the failure modes and effects were reviewed, the facilitator share the severity and probability scoring matrices with the group for discussion. The group agreed the scoring matrices did not need further modifications.
- Next steps: work team to update the process flow diagram and failure modes and effects spreadsheets and send both documents to the advisory team for review.

Section 13.2.5. Rate Failure Mode Effects and Determine Key Failure Modes

Using the severity and probability scoring matrices agreed upon by the advisory team, the work team rated each failure mode and effect ([Table 36](#)). Whenever there were disagreements about how an item should be scored, they were discussed until a consensus was reached.

Table 36. Portion of the spreadsheet showing scores assigned for severity and probability

| Task # | | Failure Mode (FM) | | Effect | Scoring | | Key Failure Mode (KFM) | | | | | | |
|--------|-------------------------------|-------------------|----------------------------------|---|--------------|-----------------|------------------------|-----|-----|------------|------------|-----------------------------|-------|
| # | Description | # | Description | | Severity (S) | Probability (P) | Hazard Score (HS) | S/S | S/H | Controlled | Detectable | Single Point Weakness (SPW) | KFM ? |
| 1.0 | Gather supplies for mixing | 1 | Incorrect supplies gathered | Mix prepared incorrectly | 3 | 3 | | | | | | | |
| | | 2 | Incomplete supplies gathered | Mix not prepared | 2 | 2 | | | | | | | |
| 1.1 | Select drug | 3 | Wrong drug selected | Patient receives wrong drug | 4 | 3 | | | | | | | |
| 1.2 | Select diluent | 4 | Wrong diluent selected | Infusion rate too fast or slow | 4 | 3 | | | | | | | |
| 1.3 | Select elastomeric AIP | 5 | Wrong elastomeric selected | Infusion rate too fast or slow | 4 | 4 | | | | | | | |
| | | 6 | Elastomeric not selected | Mix not prepared | 3 | 2 | | | | | | | |
| 1.4 | Select supplies | 7 | Wrong supplies selected | Mix prepared incorrectly | 3 | 3 | | | | | | | |
| 2.0 | Send supplies into clean room | 8 | Supplies not sent to clean room | Mix not prepared | 2 | 2 | | | | | | | |
| 3.0 | Pharmacy check of supplies | 9 | Pharmacy does not check supplies | Patient receives wrong drug and/or wrong rate | 4 | 3 | | | | | | | |
| ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... |

Team Meeting # 4:

Attendees: work and advisory teams

Purpose: reach consensus about severity and probability ratings for failure modes and effects

Date: June 26, 2007

Time: 14:00-17:00

Meeting Notes:

-Asked team members to help themselves to coffee and muffins

-Confirmed team members received a copy of the ^{HF}FMEA spreadsheet containing severity and probability scores and copies of the severity and probability scoring matrices

-Facilitator reminded the team to think about human limitations including cognitive bias, and limitations in memory and attention when scoring severity and probability of each failure mode. The facilitator made the point that staff have the best of intentions when they come to work, but they can't be expected to be superhuman.

-Facilitator worked through each failure mode, starting by sharing the work teams' scoring assignments and then invited discussion from the advisory team.

-Advisory team members agreed with many of the pre-assigned scores, however, some changes were requested and discussed by the group, with the scribe editing scores in real time.

-Advisory team reviewed the scores for failure modes and effects and discussed cut-off thresholds for severity and hazard scores; decided on a severity threshold of 3 or higher and a hazard score threshold of 8 or higher.

Once the advisory team had agreed upon severity and probability scores, the work team met again and applied the Three Tests ([Section 9.5.6.1](#)) to determine whether each failure mode was a key failure mode ([Table 37](#)).

Table 37. Portion of the spreadsheet showing determination of key failure modes

| Task # | | Failure Mode (FM) | | Effect | Scoring | | | Key Failure Mode (KFM) | | | | | |
|--------|-------------------------------|-------------------|----------------------------------|---|--------------|-----------------|-------------------|------------------------|------------------|------------|------------|-----------------------------|-------|
| # | Description | # | Description | | Severity (S) | Probability (P) | Hazard Score (HS) | Can be prevented? | Can be detected? | Controlled | Detectable | Single Point Weakness (SPW) | KFM ? |
| 1.0 | Gather supplies for mixing | 1 | Incorrect supplies gathered | Mix prepared incorrectly | 3 | 3 | 9 | Y | Y | | | | Y |
| | | 2 | Incomplete supplies gathered | Mix not prepared | 2 | 2 | 4 | N | N | N | Y | | N |
| 1.1 | Select drug | 3 | Wrong drug selected | Patient receives wrong drug | 4 | 3 | 12 | Y | Y | | | | Y |
| 1.2 | Select diluent | 4 | Wrong diluent selected | Infusion rate too fast or slow | 4 | 3 | 12 | Y | Y | | | | Y |
| 1.3 | Select elastomeric AIP | 5 | Wrong elastomeric selected | Infusion rate too fast or slow | 4 | 4 | 16 | Y | Y | | | | Y |
| | | 6 | Elastomeric not selected | Mix not prepared | 3 | 2 | 6 | Y | N | | | | Y |
| 1.4 | Select supplies | 7 | Wrong supplies selected | Mix prepared incorrectly | 3 | 3 | 9 | Y | Y | | | | Y |
| 2.0 | Send supplies into clean room | 8 | Supplies not sent to clean room | Mix not prepared | 2 | 2 | 4 | N | N | N | Y | | N |
| 3.0 | Pharmacy check of supplies | 9 | Pharmacy does not check supplies | Patient receives wrong drug and/or wrong rate | 4 | 3 | 12 | Y | Y | | | | Y |
| ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... |

The work team created a new spreadsheet that included only those failure modes considered to be key failure modes. These failure modes carried with them a risk that was higher than the risk threshold that was predefined by the advisory team. These became the failure modes that required further consideration in the event the healthcare organization decided to move forward with implementing elastomeric pumps.

Section 13.2.6. Identify Causes

For those failure modes determined to be key failure modes, the work team met to discuss possible root causes and contributing factors. Causes that were brought up during past advisory team meetings, and kept track of by the work team member in the scribe role, were re-examined to determine whether they might be contributing factors to any of the key failure modes. A selection of key failure modes and possible causes are included in [Table 38](#).

Table 38. Portion of the updated ^{HF}FMEA spreadsheet showing possible causes of key failure modes

| Task # | | Failure Mode (FM) | | Effect | Causes | Mitigating Strategies |
|--------|----------------------------|-------------------|-----------------------------|--------------------------------|--|-----------------------|
| # | Description | # | Description | | | |
| 1.0 | Gather supplies for mixing | 1 | Incorrect supplies gathered | Mix prepared incorrectly | No pick list for supplies | |
| | | | | | Batch gathering of supplies can lead to mix-ups | |
| 1.1 | Select drug | 3 | Wrong drug selected | Patient receives wrong drug | Look alike sound alike drugs | |
| | | | | | Drug storage and organization | |
| | | | | | Batch gathering of supplies can lead to mix-ups | |
| 1.2 | Select diluent | 4 | Wrong diluent selected | Infusion rate too fast or slow | Storage makes it possible for wrong diluent to be selected | |
| 1.3 | Select elastomeric AIP | 5 | Wrong elastomeric selected | Infusion rate too fast or slow | Elastomeric pumps all look similar | |
| | | | | | Rate information is not obvious on pump | |
| | | | | | Several models to choose from | |
| | | | | | Lack of awareness about different pumps having different rates | |
| ... | ... | ... | ... | ... | | |

As part of the ^{HF}FMEA, the work team was careful to think beyond factors like compliance with established protocols and procedures, and other more human-centric causes. Instead, the work team focused on system-level causes and contributing factors, knowing that only when the system factors were addressed would meaningful improvements to patient and staff safety be achieved.

Team Meeting # 5:

Attendees: work and advisory teams

Purpose: finalize root causes for each key failure mode

Date: July 20, 2007

Time: 9:00-12:00

Meeting Notes:

-Asked team members to help themselves to coffee and muffins

-Confirmed team members received a copy of the ^{HF}FMEA spreadsheet containing causes

-Facilitator reminded the group not to focus on human-centric causes and a failure to follow procedures as root causes. Instead, group should be thinking about system level causes contributing to potential failure modes.

-Facilitator walked the group through each key failure mode and the potential causes that had been identified by the work team. The group discussed these and other potential causes for each key failure mode. The scribe captured the discussion in real time so all advisory team members could follow along.

-A number of system level causes that could contribute to several key failure modes were identified during the discussion. These types of contributing factors may be good to focus on when it comes to developing mitigating strategies as fixing even just one of these contributing factors would have the potential to mitigate several key failure modes.

Next Steps: The work team will meet to update and refine the list of causes based on this meeting. The updated spreadsheet will be circulated to the advisory team within the next three weeks for review and feedback.

Section 13.2.7. Develop and Implement Mitigating Strategies

Based on the causes identified by the advisory team, the work team met and brainstormed a number of possible mitigating strategies to address system issues at the root of each key failure mode. The work team referred to the Hierarchy of Effectiveness ([Chapter 3](#)) while developing potential mitigating strategies to ensure solutions addressed system-level, rather than person-level factors.

If the healthcare organization decided to implement elastomeric pumps, in parallel they would also want to consider implementing a number of the identified mitigating strategies to proactively prevent any potential errors as identified through the analysis, from occurring.

Team Meeting # 6:

Attendees: work and advisory teams

Purpose: develop mitigating strategies to address root causes for each key failure mode

Date: August 17, 2007

Time: 13:00-16:00

Meeting Notes:

- Asked team members to help themselves to coffee and muffins
- Confirmed team members received a copy of the ^{HFF}FMEA spreadsheet containing finalized causes, and preliminary ideas for mitigating strategies.
- Facilitator circulated copies of the Hierarchy of Effectiveness ([Chapter 11](#)) to each advisory team member and described the model to help ensure recommendations generated were more systems focused rather than person focused.
- Ideas for how to mitigate root causes for each failure mode were discussed by the team and the Hierarchy of Effectiveness was referred to throughout the discussion.
- Advisory team discussed possible criteria that could be used to highlight those mitigating strategies likely to be the most feasible. Considered several different aspects such as (1) how effective (Hierarchy of Effectiveness), (2) required resources, (3) available resources. The team agreed that it would be preferred to implement fewer high-impact mitigating strategies, than many lower-impact mitigating strategies.
- Advisory team looked for and identified possible areas of overlap where implementing a single recommendation would address more than one cause.
- Scribe recorded discussion in real time so team members could see and follow along.
- Next Steps: work team to circulate cleaned version of ^{HFF}FMEA spreadsheet containing ideas about mitigating strategies

Based on the preliminary ideas for mitigating strategies, and discussion during Team Meeting #6, the work team updated the ^{HFF}FMEA spreadsheet ([Table 39](#)), and circulated it to the advisory team for review and feedback.

Table 39. Part of the updated ^{HF}FMEA spreadsheet showing ideas for possible mitigating strategies

| Task # | | Failure Mode (FM) | | Effect | Causes | Mitigating Strategies |
|--------|----------------------------|-------------------|-----------------------------|--------------------------------|--|--|
| # | Description | # | Description | | | |
| 1.0 | Gather supplies for mixing | 1 | Incorrect supplies gathered | Mix prepared incorrectly | No pick list for supplies | Use IT system to generate electronic list based on protocol |
| | | | | | Batch gathering of supplies can lead to mix-ups | Change process so supplies for one patient's mix are picked before moving on to the next patient's mix |
| 1.1 | Select drug | 3 | Wrong drug selected | Patient receives wrong drug | Look alike sound alike drugs | Implement TALLman lettering |
| | | | | | Drug storage and organization | Store look alike sound alike drugs apart from one another |
| | | | | | Batch gathering of supplies can lead to mix-ups | Change process so supplies for one patient's mix are picked before moving on to the next patient's mix |
| 1.2 | Select diluent | 4 | Wrong diluent selected | Infusion rate too fast or slow | Storage makes it possible for wrong diluent to be selected | Store NS and D5W in different zones of the anteroom |
| 1.3 | Select elastomeric AIP | 5 | Wrong elastomeric selected | Infusion rate too fast or slow | Elastomeric pumps all look similar | Store pumps so different coloured tops are visible |
| | | | | | Rate information is not obvious on pump | Add labels to storage shelf so rate information is easier to see when picking |
| | | | | | | Contact manufacturer to see whether rate information can be made more salient |
| | | | | | Several models to choose from | Consider dose banding so only a few models are required |
| ... | ... | ... | ... | ... | ... | ... |

Team Meeting # 7:

Attendees: work and advisory teams

Purpose: prioritize mitigating strategies, create implementation plans, conclude ^{HF}FMEA

Date: August 31, 2007

Time: 8:00-12:00

Meeting Notes:

-Asked team members to help themselves to coffee and muffins

-Confirmed team members received a copy of the updated ^{HF}FMEA spreadsheet containing mitigating strategies

-Facilitator reminded the advisory team to refer to the Hierarchy of Effectiveness during the discussion, and reviewed the criteria discussed during the previous meeting for highlighting those mitigating strategies likely to be the most feasible.

-Facilitator presented the work groups' thoughts about which mitigating strategies would be most feasible and have the highest impact based on criteria chosen.

-Discussion took place among advisory group members about the pros and cons of eventually trying to implement the proposed mitigating strategies, and the discussion was opened up to consider whether other strategies should also be considered in more detail.

-The advisory team prioritized mitigating strategies considering the criteria chosen to determine (1) how effective, (2) the resources likely to be required, and (3) the resources likely to be available.

-Based on the long list of possible mitigating strategies, the advisory team chose the top 10 priority strategies and developed an implementation plan for each ([Section 9.6](#), What to Do With a Completed ^{HF}FMEA). In the event the healthcare organization decides to move to elastomeric pumps, each implementation plan will be assigned to a staff member who will see the plan through so the associated key failure modes can be mitigated before causing harm.

-The team leader concluded the meeting by thanking everyone for their participation as part of the ^{HF}FMEA advisory team. Although implementation work would continue if the organization decided to go ahead with elastomeric pumps, this was the last official meeting of the ^{HF}FMEA team.

Following the final ^{HF}FMEA meeting, the work group met to create a summary document outlining (1) the ^{HF}FMEA process followed, (2) team members on both the work and advisory groups, (3) key decisions made, (4) lessons learned, (5) implementation

strategies developed, and (6) an appendix containing the key failure modes, their causes and effects. Before providing the report to upper management, it was shared with the advisory team for feedback.

The report was shared with management at the healthcare organization in a timely manner so that information about key failure modes and potential means of mitigating risks associated with implementing elastomeric pumps could be integrated with the healthcare organizations' decision-making process. This resource provided insight to potential risks associated with implementing elastomeric pumps, which could then be compared with the inherent risks associated with keeping the electronic ambulatory infusion pumps uncovered as part of the ^{HF}RCA. In this way, management was able to make a more informed decision by weighing the residual risk associated with keeping the existing electronic pumps versus implementing the new elastomeric pumps.

Human Factors Resources

HumanEra

This book is based on the collective experience of the team members of HumanEra. HumanEra is a healthcare human factors research team based out of the Centre for Global eHealth Innovation in Toronto, Canada with over a decade of experience conducting applied research and implementation projects to improve healthcare system safety. To contact or learn more about HumanEra visit our website at www.HumanEra.ca.

Human Factors Books

There is no shortage of books and texts on the subject of human factors, its methods, and specific applications across individual domains, but the following two books provide an excellent primer on the topic and are filled with relevant examples.

1. Kim J. Vicente. **The human factor: Revolutionizing the way we live with technology**: Vintage Canada; 2004.
2. Steven M. Casey. **Set phasers on stun: And other true tales of design, technology, and human error**: Aegean Publishing Co.; 1998.

Human Factors Organizations/Events

- The Human Factors and Ergonomics Society (HFES); www.hfes.org.

This American organization hosts an annual conference (produces published proceedings) and publishes the journals *Human Factors*, *Ergonomics in Design* and the *Journal of Cognitive Engineering and Decision Making*. HFES has a Healthcare Technical Group (<http://hctg.wordpress.com>) and organizes an annual Symposium on Human Factors and Ergonomics in Healthcare. HFES also has a European Chapter.

- SIGCHI; www.sigchi.org.

This international organization hosts an annual conference (produces published proceedings and publishes the journal *TOCHI (ACM Transactions on Computer-Human Interaction)*).

- The Institute of Ergonomics and Human Factors; <http://iehf.org>.

This UK-based organization hosts an annual conference, accredits professionals, and has a Healthcare special interest group.

- The International Conference on Applied Human Factors and Ergonomics and the Affiliated Conferences; www.ahfe2014.org.

Held concurrently as part of this event is an International Conference on Human Factors and Ergonomics in Healthcare. AHFE publishes post-conference edited books with accepted and peer reviewed papers.

Healthcare Human Factors Guidance Documents

1. The FDA has developed a draft guidance document to assist industry in conducting appropriate human factors testing and identifying device features that manufacturers should optimize throughout the total product life cycle. Available at:

<http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm259748.htm>

2. The World Health Organization has produced a document that reviews ten topic areas related to organizational and human factors influencing patient safety. Available at:

http://www.who.int/patientsafety/research/methods_measures/human_factors/human_factors_review.pdf?ua=1

3. The clinical human factors group (www.chfg.org) has influenced the first volume and produced the second volume of a document titled Implementing Human Factors in healthcare.

Volume 1 (published by Patient Safety First) available at:

<http://www.patientsafetyfirst.nhs.uk/ashx/Asset.ashx?path=/Intervention-support/Human%20Factors%20How-to%20Guide%20v1.2.pdf>

Volume 2 available at:

[Http://www.chfg.org/wp-content/uploads/2013/05/Implementing-human-factors-in-healthcare-How-to-guide-volume-2-FINAL-2013_05_16.pdf](http://www.chfg.org/wp-content/uploads/2013/05/Implementing-human-factors-in-healthcare-How-to-guide-volume-2-FINAL-2013_05_16.pdf)

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Appendix A: Confidentiality and Anonymity

Most of the human factors methods presented in this book require the time and participation of the end-users of the technology. It is important that information gathered using these methods be treated as confidential and anonymous, to protect the reputation and credibility of participants, and respondents are usually more honest under these conditions. Those responsible for carrying out human factors methods should get agreement from clinical managers, and all members of the team or committee involved in reviewing the human factors data, that all data gathered will be kept confidential and will not be used in any way to evaluate clinical competence or expose them to professional risk. No disciplinary action should ever result from participation in human factors testing.

Best practice is to not collect or record any unnecessary participant information that is identifying (e.g., names of participants). Participant numbers can be assigned for comparison and reference purposes. Additionally, to help communicate your commitment to confidentiality and/or anonymity, it is important to get informed consent. This purpose of informed consent is to ensure that participants understand [95]:

- the aims and methods of the study/project;
- that their participation is voluntary, and they can withdraw at any time without any consequences (and how their data will be handled);
- any risks and benefits of their participation;
- that their data will be anonymized and kept confidential;
- how the results of the study/project will be used and shared (e.g., to make a procurement decision);

A sample consent form is provided at the end of this section for you to use as a template.

The process of obtaining informed consent usually involves ensuring the participant understands the points listed above by reading through a consent document that explains each of the points and allowing the participant as much time as they need to review the document and ask questions before deciding whether or not to participate. If they choose to participate, they must sign the consent document.

If you are conducting an internal project that involves participants and it is not part of a research study and there are no plans to disseminate the findings outside of the organization, it is likely sufficient to use a consent form that covers the points described above without requiring research ethics approval. However, it is recommended that you

investigate whether ethics approval is required for the work you are undertaking prior to collecting any data to ensure the data can be used for its intended purpose, and without any restrictions, as a result of not obtaining research ethics approval. Generally speaking, research ethics approval is required if:

- the data being collected is part of a research study.
- there is a possibility that the data will be used for research at a later date.

However, even quality improvement initiatives can present ethical risks and should be managed by a formal research ethics process. To help determine whether this is indeed the case, you can use the online ARECCI Ethics Screening Tool found at <http://www.aihealthsolutions.ca/arecci/screening/30863/6d62b234cf1570caeb290708caf72dd3>, or inquire directly to your organization's research ethics committee.

A detailed discussion of the research ethics approval process in healthcare as it relates specifically to conducting human factors studies is covered in the book *Fieldwork for Healthcare: Guidance for investigation human factors in computing systems*[95]. A free chapter of the book, containing the sections related to research ethics approval and informed consent is available at:

http://www.morganclaypool.com/doi/suppl/10.2200/S00606ED1V02Y201410ARH007/suppl_file/Furniss_Ch1.pdf.

Sample Consent Form

CONSENT TO PARTICIPATE IN A USABILITY STUDY

Introduction

You are being asked to take part in a usability study. Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this study is voluntary.

Purpose

The purpose of this project is to [insert purpose here]. Your participation helps us to determine [insert benefit here such as "identify which product is the safest for your unit"].

Procedures

If you agree to participate in the study your demographic information (e.g., age, sex, years nursing experience) will be collected and you will be asked to complete a series of clinical tasks in a *simulated* clinical environment. In other words, you will be in a room with clinical equipment and scenarios but no real patients or patient care. You will be taught how to use the devices not in routine use on your unit prior to starting the simulations. After training you will be oriented to the simulated environment, and asked to perform various tasks to a simulated patient (mannequin and/or actor). After each scenario, we will ask you for your feedback based on our observations to further understand the risks and benefits of the devices being tested. The session will last no more than 3 hours, and will be videotaped for later analysis. Your performance/competency is NOT being evaluated in a way that will impact your employment, but rather the results of this study will be used to better understand issues relating to the devices we are evaluating.

Risks

There are no anticipated or known medical risks associated with this study. You may experience discomfort in sharing your opinions with the researchers. You only have to share as much about your opinions as you wish. Your participation will have NO impact on your employment.

Benefits

You may or may not receive direct benefit from participating in this study. Information from this study may help to increase your knowledge about [insert the type of device here].

Voluntary Participation

Your participation in this study is voluntary. You can choose not to participate or you may withdraw at any time. Whether you choose to participate or not has no impact on your employment. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved

institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

Confidentiality

All information obtained during the study will be held in strict confidence. You will be identified with a subject number only. No names or identifying information will be used in any reports, publication or presentations that may come from this study. No information identifying you will be transferred outside the investigators of this study. If the videos from the research are shown outside the research team, your face will be blurred and all identifying information will be made anonymous. However, despite best efforts, there is a very small possibility that you may still be identified. Data from the study (e.g., videotapes, paper records) will be kept for a minimum of two years, and a maximum of seven years, after the completion of the study. Any personal identifiable information will be stored and protected on secured servers or kept in a locked filing cabinet and then destroyed by shredding of paper or erasing of digital information.

Reimbursement

You will not receive any financial reimbursement for your participation.

Questions

If you have any questions, concerns or would like to speak to the study team for any reason, please contact [insert contact name and information of person responsible for the study].

Consent

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to take part in this study.

| | | |
|---|-------------------------|------|
| Study participant's name (please print) | Participant's Signature | Date |
|---|-------------------------|------|

(You will be given a signed copy of this consent form)

My signature means that I have explained the study to the participant named above. I have answered all questions.

| | | |
|----------------------------------|-----------|------|
| Name of person obtaining consent | Signature | Date |
|----------------------------------|-----------|------|

About the Authors



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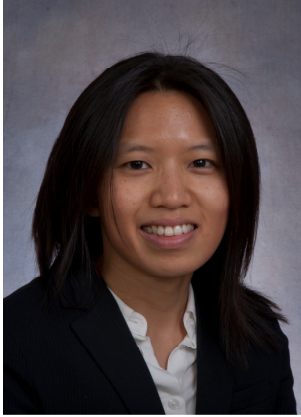
Melissa is a clinical engineer and human factors specialist. She received her Master of Health Science degree in Clinical Engineering from the University of Toronto. Her work has focused on applying human factors methods to a wide range of healthcare environments, including home care and oncology. She is passionate about improving patient safety across our health system and teaching others to apply this way of thinking in their daily work.



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