

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.

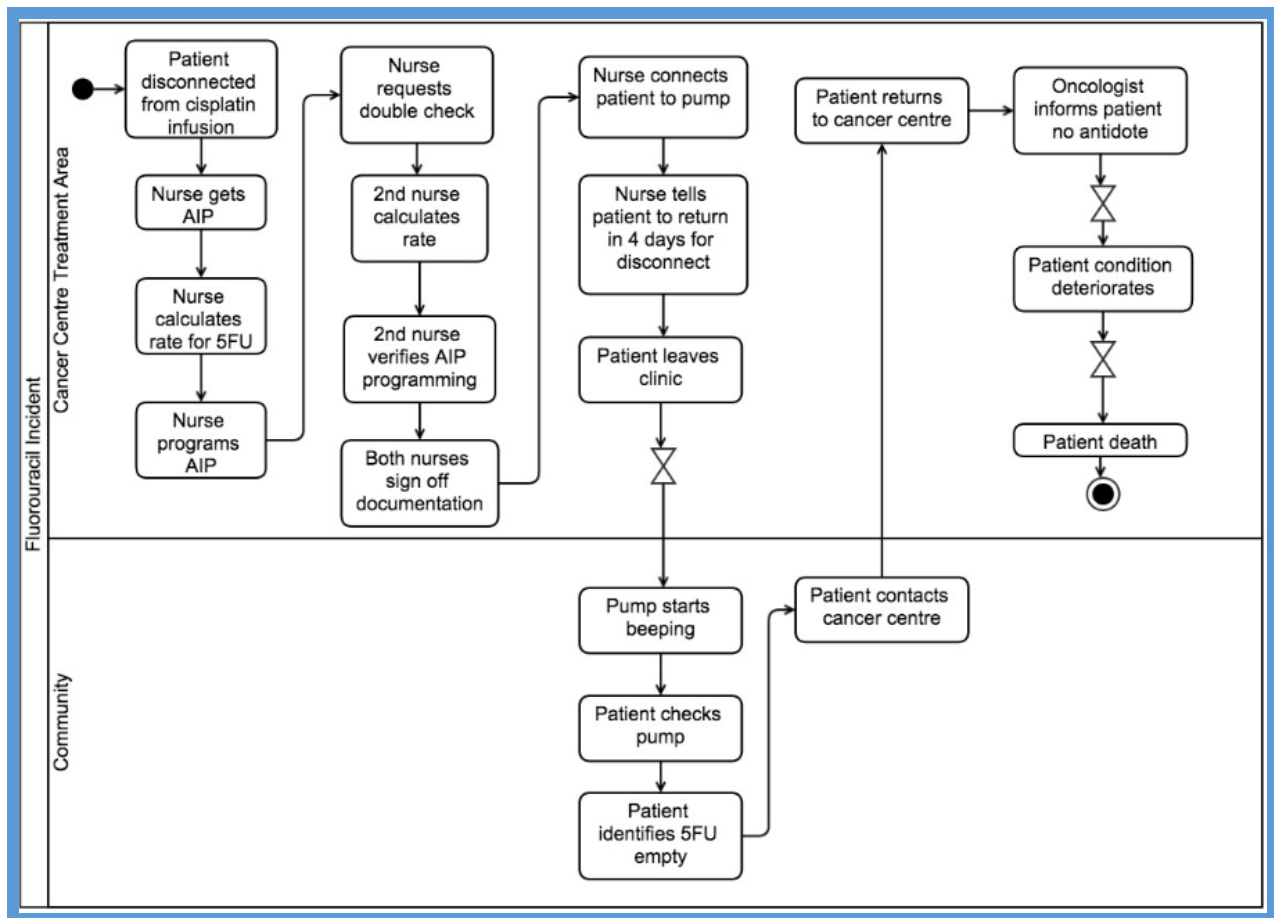


Figure 43. Process flow diagram based on the teams' initial understanding of the incident

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.

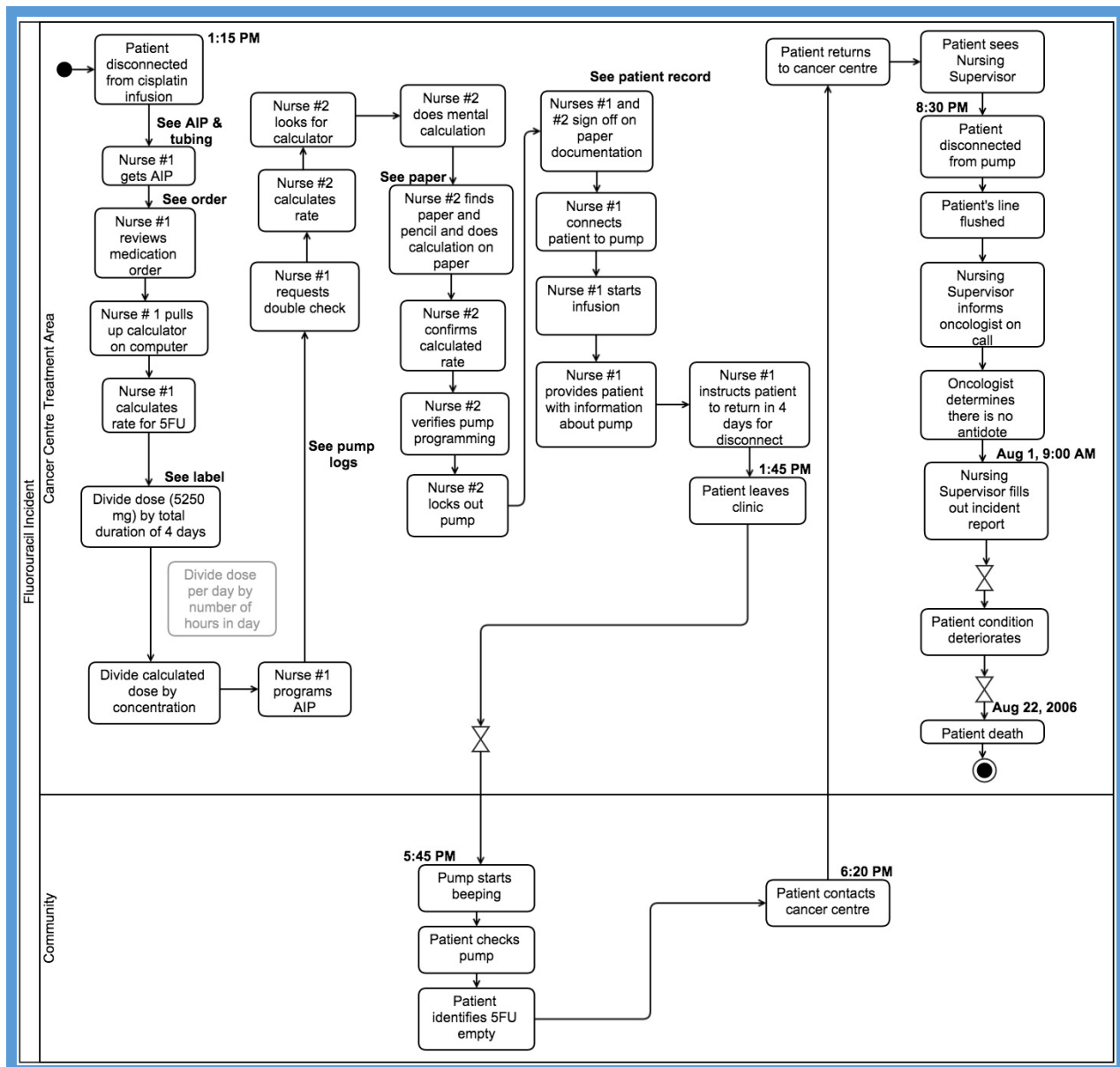


Figure 44. Updated process flow diagram based on data collected through interviews, observations, usability testing, and information searches.

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.

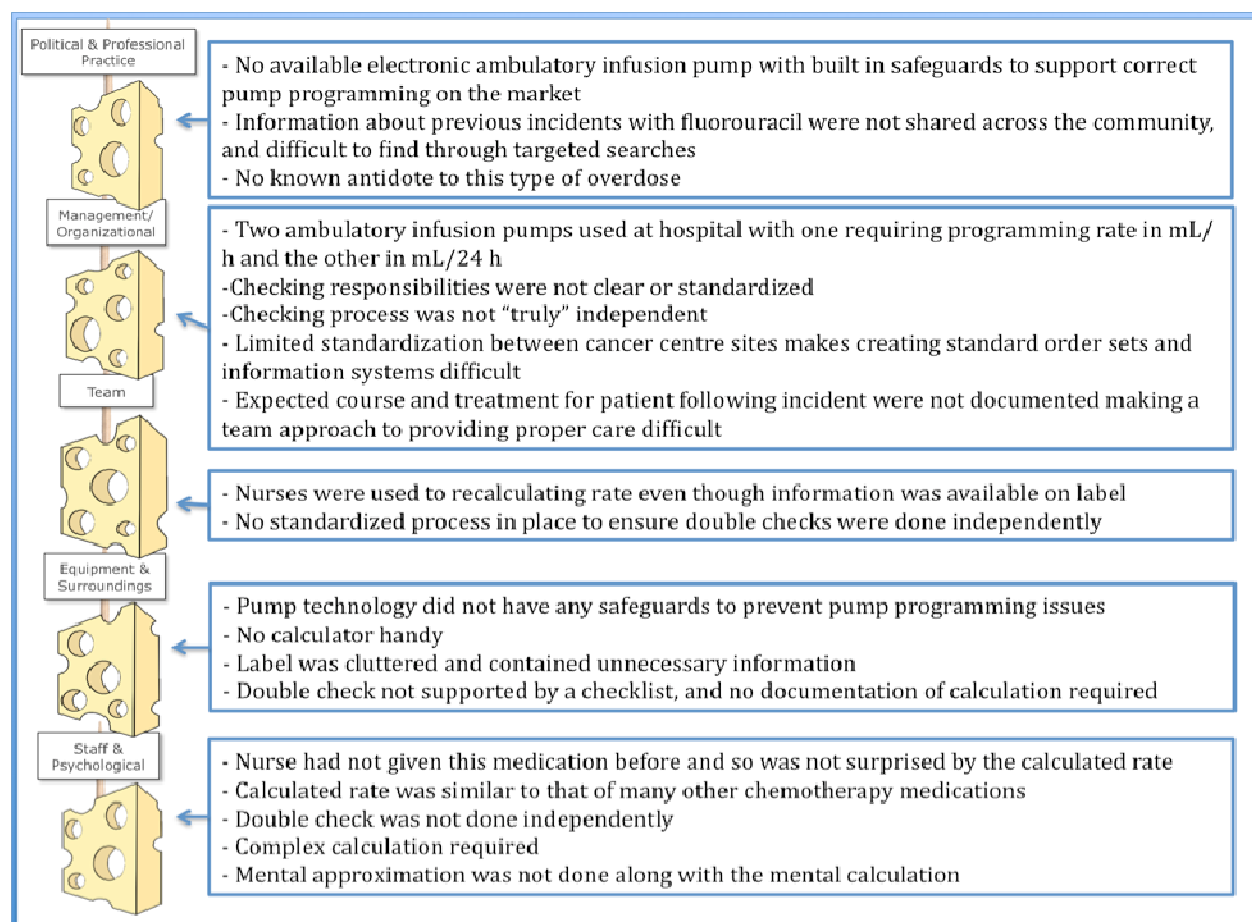


Figure 45. Using Reason's Swiss Cheese Model and Vicente's Human-tech ladder to identify contributing factors to a sentinel event.

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.

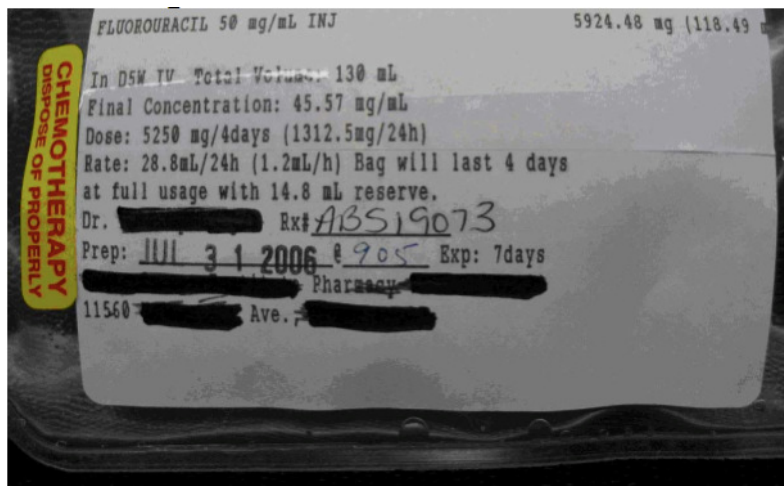


Figure 46. Medication label for fluorouracil infusion containing two different rates

- 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](#)).

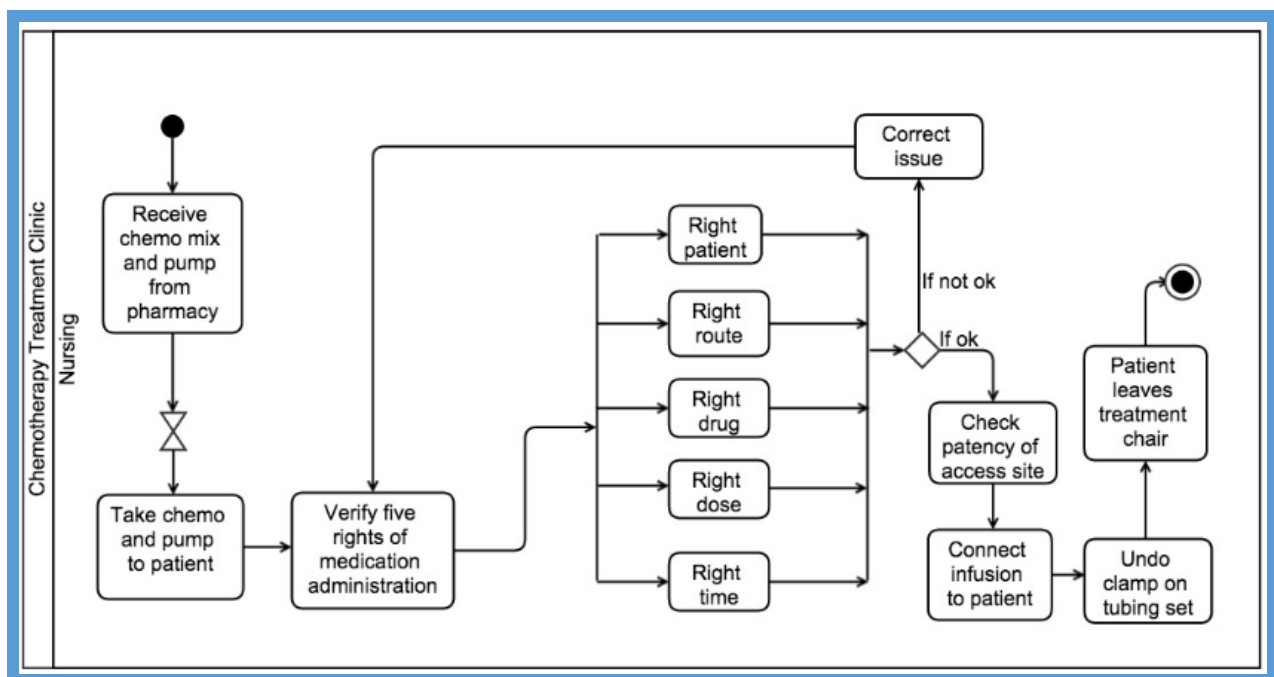


Figure 48. Initial process flow diagram for administering chemotherapy to an adult patient with an elastomeric ambulatory infusion pump

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.

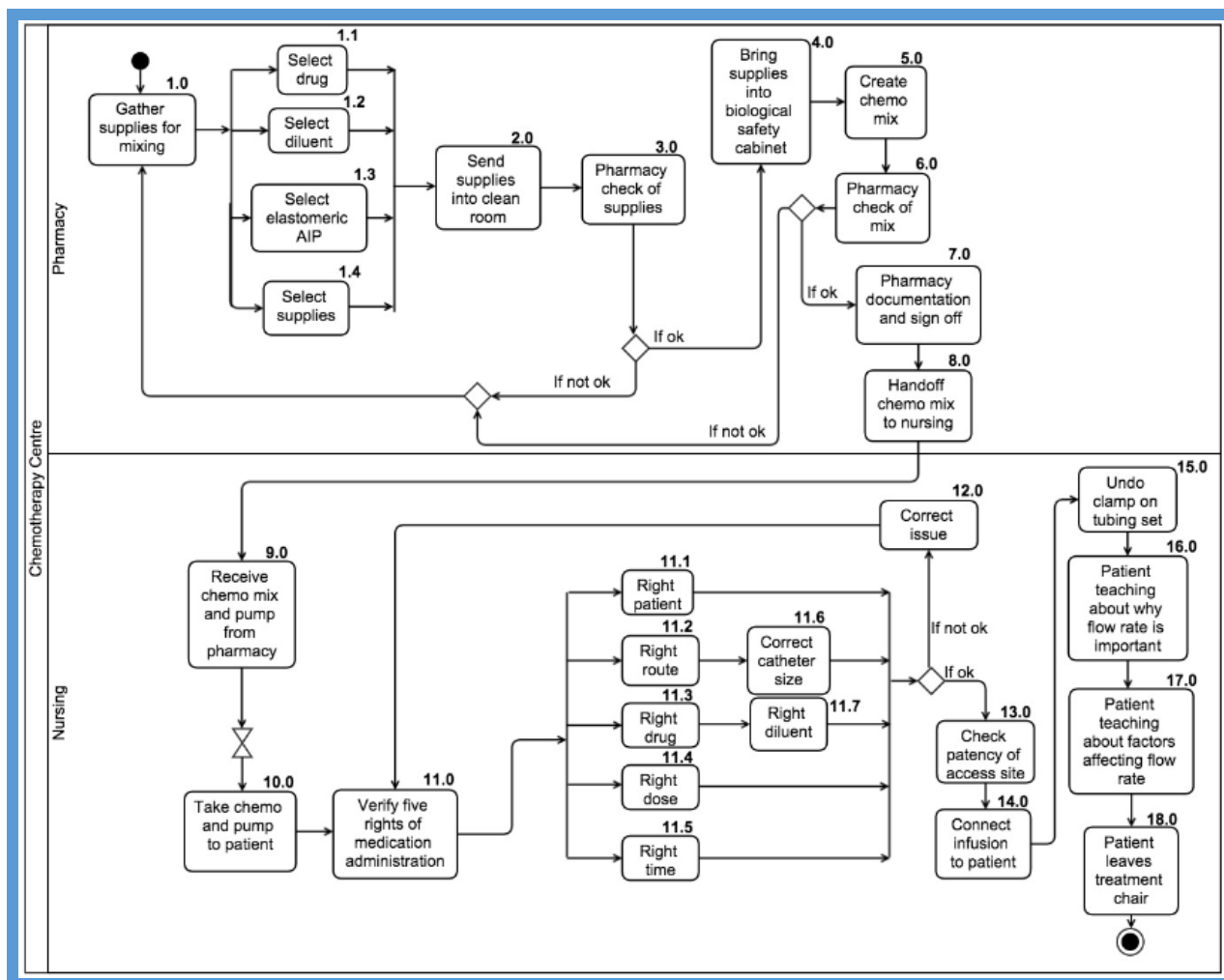


Figure 49. Updated process flow diagram based on information learned through observations and interviews in the field

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 ^{HF}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 ^{HF}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 ^{HF}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)

References

1. **To Err Is Human: Building a Safer Health System:** The National Academies Press; 2000.
2. Baker GR, Norton PG, Flintoft V, Blais R, Brown A, Cox J, Etchells E, Ghali WA, Hébert P, Majumdar SR *et al*: **The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada.** *Canadian Medical Association Journal* 2004, **170**(11):1678-1686.
3. Sari ABA, Sheldon TA, Cracknell A, Turnbull A, Dobson Y, Grant C, Gray W, Richardson A: **Extent, nature and consequences of adverse events: results of a retrospective casenote review in a large NHS hospital.** *Quality & Safety in Health Care* 2007, **16**(6):434-439.
4. Davis P, Lay-Yee R, Briant R, Ali W, Scott A, Schug S: **Adverse events in New Zealand public hospitals I: occurrence and impact.** *The New Zealand medical journal* 2002, **115**(1167):U271.
5. Wilson RM, Harrison BT, Gibberd RW, Hamilton JD: **An analysis of the causes of adverse events from the Quality in Australian Health Care Study.** *The Medical Journal of Australia* 1999, **170**(9):411-415.
6. James JT: **A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care.** *Journal of Patient Safety* 2013, **9**(3):122-128.
7. FDA: **Draft Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Optimize Medical Device Design.** In.; 2011.
8. **American College of Clinical Engineering (ACCE)**
[<http://www.accenet.org/default.asp?page=about§ion=definition>]
9. Vicente K: **The human factor: Revolutionizing the way we live with technology:** Vintage Canada; 2004.
10. Norman DA: **The Design of Everyday Things:** Basic Books; 2002.
11. United States. Army Air Forces. Headquarters AMCED: **Analysis of Factors Contributing to 460 "pilot-error" Experiences in Operating Aircraft Controls:** Army Air Forces Headquarters, Air Material Command, Engineering Division; 1947.
12. Wiener EL, Nagel DC: **Human factors in aviation:** Access Online via Elsevier; 1988.
13. Misumi J, Miller R, Wilpert B: **Nuclear safety: A human factors perspective:** CRC Press; 1998.
14. Stanton NA: **Human factors in nuclear safety:** Taylor & Francis; 1996.
15. Carayon P: **Human factors in patient safety as an innovation.** *Applied ergonomics* 2010, **41**(5):657-665.
16. Cooper JB, Newbower RS, Long CD, McPeck B: **Preventable Anesthesia Mishaps: A Study of Human Factors.** *Anesthesiology* 1978, **49**(6):399-406.
17. Leape LL: **Error in medicine.** *JAMA-Journal of the American Medical Association-US Edition* 1994, **272**(23):1851-1856.
18. Leape LL, Brennan TA, Laird N, Lawthers AG, Localio AR, Barnes BA, Hebert L, Newhouse JP, Weiler PC, Hiatt H: **The nature of adverse events in hospitalized patients: results of the Harvard Medical Practice Study II.** *New England Journal of Medicine* 1991, **324**(6):377-384.

19. Hollands JG, Wickens CD: **Engineering psychology and human performance**: Prentice Hall New Jersey; 1999.
20. Weissman JS, Rothschild JM, Bendavid E, Sprivulis P, Cook EF, Evans RS, Kaganova Y, Bender M, David-Kasdan J, Haug P *et al*: **Hospital workload and adverse events**. *Med Care* 2007, **45**(5):448-455.
21. Harrison MI, Koppel R, Bar-Lev S: **Unintended consequences of information technologies in health care**—an interactive sociotechnical analysis. *Journal of the American Medical Informatics Association* 2007, **14**(5):542-549.
22. Jennings BM: **Work Stress and Burnout Among Nurses: Role of the Work Environment and Working Conditions**. 2008.
23. Flewwelling CJ: **No Fault Found Reporting and its Relation to Human Factors Related Design Faults of Medical Devices**. 2012.
24. Smith EE, Kosslyn SM: **Cognitive Psychology: Mind and Brain**: Pearson/Prentice Hall; 2007.
25. Mack A, Rock I: **Inattentional Blindness**: MIT Press; 1998.
26. Alert IMS: **Medication error prevention “tool box”**. Retrieved June 1999, **30**:2004.
27. McCarney R, Warner J, Iliffe S, van Haselen R, Griffin M, Fisher P: **The Hawthorne Effect: a randomised, controlled trial**. *BMC Med Res Methodol* 2007, **7**:30.
28. Bailey RW: **Performance vs. preference**. In: *Proceedings of the Human Factors and Ergonomics Society Annual Meeting: 1993*. SAGE Publications: 282-286.
29. Crabtree BF, Miller WL: **Doing Qualitative Research**: SAGE Publications; 1999.
30. Glaser B: **The Constant Comparative Method of Qualitative Analysis**. *Social Problems* 1965, **12**(4):436-445.
31. Kirwan BE, Ainsworth LK: **A guide to task analysis**. 1992.
32. Nielsen J: **Usability inspection methods**. In: *Conference Companion on Human Factors in Computing Systems; Boston, Massachusetts, USA*. ACM 1994.
33. Shneiderman SB, Plaisant C: **Designing the user interface 4 th edition**. In.: Pearson Addison Wesley, USA; 2005.
34. Zhang J, Johnson TR, Patel VL, Paige DL, Kubose T: **Using usability heuristics to evaluate patient safety of medical devices**. *Journal of Biomedical Informatics* 2003, **36**:23-30.
35. Nielsen J, Molich R: **Heuristic evaluation of user interfaces**. In: *Proceedings ACM CHI'90 Conf: 1990; Seattle, WA, 1-5 April*. ACM: 249-256.
36. Food, Administration D: **Draft Guidance for Industry and Food and Drug Administration Staff. Applying Human Factors and Usability Engineering to Optimize Medical Device Design**. *US Food and Drug Administration, Silver Spring, MD* 2011.
37. DeRosier J, Stalhandske E, Bagian JP, Nudell T: **Using health care Failure Mode and Effect Analysis: the VA National Center for Patient Safety's prospective risk analysis system**. *Jt Comm J Qual Improv* 2002, **28**(5):248-267, 209.
38. **Failure Mode And Effects Analysis (FMEA): A Tool to Help Guide Error Prevention Efforts** [<https://www.ismp.org/tools/FMEA.asp>]
39. **ISMP Canada Failure Mode and Effects Analysis** [<http://www.ismp-canada.org/fmea.htm>]
40. **Institute for Healthcare Improvement: Failure Mode and Effects Analysis (FMEA) Tool** [<http://app.ihl.org/Workspace/tools/fmea/>]

41. **2014 Hospital Accreditation Standards.** Oakbrook Terrace, Illinois: Joint Commission; 2013.
42. **Required Organizational Practices 2012.** In., vol. 2013. Ottawa: Accreditation Canada; 2012.
43. Safety VNCfP: **The basics of Healthcare Failure Mode and Effect Analysis.** In., vol. 2013: Veterans Affairs National Center for Patient Safety; 2001.
44. Commission J: **Sentinel Events.** *Comprehensive Accreditation Manual for Office-Based Surgery Practices* 2011:SE-1 to SE-18.
45. Smetzer J, Baker C, Byrne FD, Cohen MR: **Shaping systems for better behavioral choices: lessons learned from a fatal medication error.** *Joint Commission Journal on Quality and Patient Safety* 2010, **36**(4):152.
46. Cohen MR: **An Injustice Has Been Done: Jail Time for an Error.** *Patient Safety and Quality Healthcare* 2009(September/October 2009):6-7.
47. Wu AW: **Medical error: the second victim.** *BMJ* 2000, **320**(7237):726-727.
48. Anderson P, Townsend T: **Medication errors: Don't let them happen to you.** *American Nurse Today* 2010, **5**(3):23-27.
49. Clancy CM: **Alleviating "second victim" syndrome: how we should handle patient harm.** *J Nurs Care Qual* 2012, **27**(1):1-5.
50. **Framework for Conducting a Root Cause Analysis and Action Plan | Joint Commission**
[http://www.jointcommission.org/Framework_for_Conducting_a_Root_Cause_Analysis_and_Action_Plan/]
51. **Root Cause Analysis - VA National Center for Patient Safety**
[<http://www.patientsafety.va.gov/media/rca.asp>]
52. **ISMP Canada - Root Cause Analysis** [https://www.ismp-canada.org/rca.htm]
53. **Canadian Incident Analysis Framework**
[<http://www.patientsafetyinstitute.ca/English/toolsResources/IncidentAnalysis/Documents/Canadian%20Incident%20Analysis%20Framework.PDF>]
54. **Patient Safety - Root Cause Analysis toolkit | conditions of use**
[<http://www.nrls.npsa.nhs.uk/resources/rca-conditions/>]
55. Meadows S, Baker K, Butler J: **The Incident Decision Tree: Guidelines for Action Following Patient Safety Incidents,** vol. *Advances in Patient Safety: From Research to Implementation (Volume 4: Programs, Tools, and Products).* Rockville MD; 2005.
56. Miller R, Griffith S, Vogelsmeier A: **A statewide approach to a just culture for patient safety: The Missouri story.** *Journal of Nursing Regulation* 2010, **1**(1):52-57.
57. Marx DA: **Patient safety and the "just culture": a primer for health care executives.** Trustees of Columbia University; 2001.
58. Doran GT: **There's a SMART way to write management's goals and objectives.** *Management review* 1981, **70**(11):35-36.
59. ECRI: **Burns and Fires from Electrosurgical Active Electrodes.** *Health Devices* 1993, **22**(8-9):2.
60. ECRI: **ESU Burns from Poor Return Electrode Site Preparation.** *Health Devices* 1987, **16**(1):2.

61. Donato M: **Family Still Coming To Grips With Electrocution Of Baby.** In: *Chicago Tribune*. 1993.
62. **Newborn Is Electrocuted.** In: *New York Times*. 1993.
63. Campbell EM, Sittig DF, Ash JS, Guappone KP, Dykstra RH: **Types of unintended consequences related to computerized provider order entry.** *J Am Med Inform Assoc* 2006, **13**(5):547-556.
64. Saathoff A: **Human factors considerations relevant to CPOE implementations.** *J Healthc Inf Manag* 2005, **19**(3):71-78.
65. Connolly C: **Cedars-Sinai Doctors Cling to Pen and Paper.** In: *The Washington Post*. 2005.
66. FDA: **Preventing Tubing and Luer Misconnections > Examples of Tubing and Luer Misconnections.** In. Edited by Health C-CfDaR. Rockville; 2015.
67. FDA: **Guidance for Industry and Food and Drug Administration Staff - Total Product Life Cycle: Infusion Pump - Premarket Notification [510(k)] Submissions - Draft Guidance.** In. Edited by Health C-CfDaR. Rockville; 2010.
68. Johnson TR, Zhang J, Patel VL, Keselman A, Tang X, Brixey JJ, Paige D, Turley JP: **The role of patient safety in the device purchasing process.** In.: DTIC Document; 2005.
69. Cassano AL: **Applying human factors to the procurement of electrosurgical medical devices: a case study.** In: *Proceedings of the Human Factors and Ergonomics Society Annual Meeting: 2003*. SAGE Publications: 1815-1819.
70. Cassano-Piché A, Cafazzo JA, Chagpar A, Easty AC: **Choosing Safer Medical Technologies: How Human Factors Methods Can Help in the Procurement Process.** *Biomedical Instrumentation & Technology* 2010, **44**(s1):49-56.
71. Ginsburg G: **Human factors engineering: A tool for medical device evaluation in hospital procurement decision-making.** *Journal of Biomedical Informatics* 2005, **38**(3):213-219.
72. Namshirin P, Ibey A, Lamsdale A: **Applying a multidisciplinary approach to the selection, evaluation, and acquisition of smart infusion pumps.** *Journal of Medical and Biological Engineering* 2011, **31**(2):93-98.
73. Instrumentation AftAoM: **ANSI/AAMI HE75: 2009: Human factors engineering: Design of medical devices.** AAMI, Arlington 2009.
74. Israelski E: **Overview of International Medical Device Human Factors Standards.** In: *Symposium on Human Factors and Ergonomics in Health Care: Bridging the Gap: 12-17 March 2012* 2012. 2015.
75. Holden RJ, Karsh B-T: **The Technology Acceptance Model: Its past and its future in health care.** *Journal of Biomedical Informatics* 2010, **43**(1):159-172.
76. Lapointe L, Rivard S: **A multilevel model of resistance to information technology implementation.** *Mis Quarterly* 2005:461-491.
77. Markus ML: **Power, politics, and MIS implementation.** *Communications of the ACM* 1983, **26**(6):430-444.
78. Zuboff S: **In the age of the smart machine: the future of work and power:** Heinemann Professional; 1988.
79. Lorenzi NM, Riley RT: **Managing change: an overview.** *J Am Med Inform Assoc* 2000, **7**(2):116-124.

80. Smith MJ, Carayon P: **New technology, automation, and work organization: Stress problems and improved technology implementation strategies.** *International Journal of Human Factors in Manufacturing* 1995, **5**(1):99-116.
81. LÃ¡rum H, Ellingsen G, Faxvaag A: **Doctors' use of electronic medical records systems in hospitals: cross sectional survey.** *BMJ* 2001, **323**(7325):1344-1348.
82. Davis FD: **Perceived usefulness, perceived ease of use, and user acceptance of information technology.** *Mis Quarterly* 1989:319-340.
83. Davis FD, Bagozzi RP, Warshaw PR: **User acceptance of computer technology: a comparison of two theoretical models.** *Management Science* 1989, **35**(8):982-1003.
84. Vicente KJ, Kada-Bekhaled K, Hillel G, Cassano A, Orser BA: **Programming errors contribute to death from patient-controlled analgesia: case report and estimate of probability.** *Canadian Journal of Anesthesia* 2003, **50**(4):328-332.
85. Weinger MB, Pantiskas C, Wiklund ME, Carstensen P: **Incorporating human factors into the design of medical devices.** *Jama* 1998, **280**(17):1484.
86. **Abbott PCA Plus II patient-controlled analgesic pumps prone to misprogramming resulting in narcotic overinfusions.** *Health Devices* 1997, **26**(9-10):389-391.
87. **Evidence builds: lack of focus on human factors allows error-prone devices.** In: *ISMP Medication Safety Alert*. vol. 2013. Horsham, PA: Institute for Safe Medication Practices; 1999.
88. Lin L, Isla R, Doniz K, Harkness H, Vicente K, Doyle DJ: **Applying Human Factors to the Design of Medical Equipment: Patient-Controlled Analgesia.** *Journal of Clinical Monitoring and Computing* 1998, **14**(4):253-263.
89. Fairbanks Rollin J, Caplan S: **Poor Interface Design and Lack of Usability Testing Facilitate Medical Error.** *Joint Commission Journal on Quality and Patient Safety* 2004, **30**(10):579-584.
90. Gagnon R, Laberge J, Lamsdale A, Histon J, Hudson C, Davies J, Caird J: **A User-Centered Evaluation of three Intravenous Infusion Pumps.** *Proceedings of the Human Factors and Ergonomics Society Annual Meeting* 2004, **48**(15):1773-1777.
91. Kaye R, Crowley J: **Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management.** 2000.
92. Elliott M, Liu Y: **The nine rights of medication administration: an overview.** *British journal of nursing (Mark Allen Publishing)* 2010, **19**(5):300-305.
93. Ontario CoNo: **Practice Standard: Medication.** In.; 2015.
94. **Fluorouracil Incident Root Cause Analysis Report.** In., vol. 2014. Toronto: Institute for Safe Medication Practices Canada; 2007.
95. Furniss D, Randell R, O'Kane AA, Taneva S, Mentis H, Blandford A: **Fieldwork for healthcare: guidance for investigating human factors in computing systems.** *Synthesis Lectures on Assistive, Rehabilitative, and Health-Preserving Technologies* 2014, **3**(2):1-146.

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
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(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
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About the Authors



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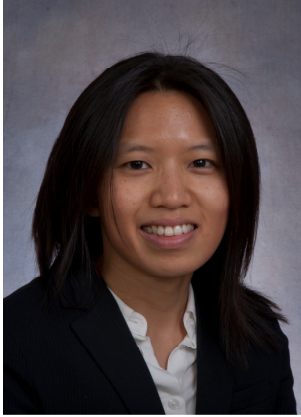
Melissa is a clinical engineer and human factors specialist. She received her Master of Health Science degree in Clinical Engineering from the University of Toronto. Her work has focused on applying human factors methods to a wide range of healthcare environments, including home care and oncology. She 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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