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* ([HF]PIP) 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 ^{HF}PIP 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 HFPIP (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 HFPIP 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 direct 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 HFPIP 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 HFPIP team reviewed a previous HFRCA (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).

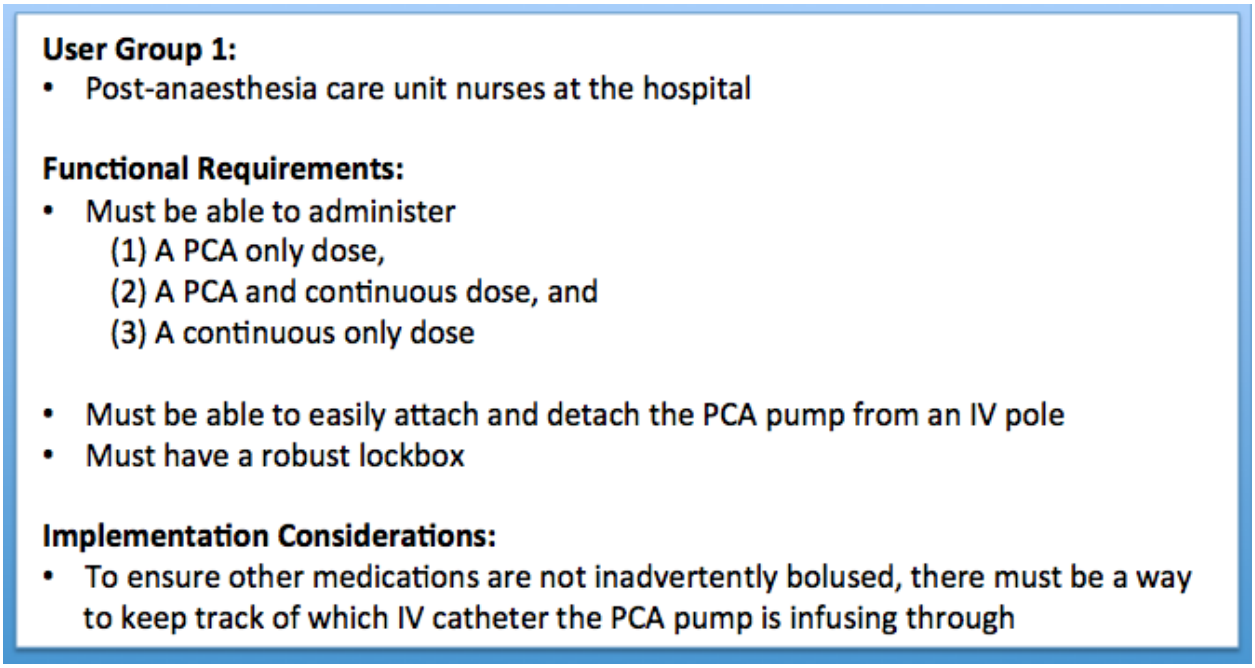


Figure 35. Selection of user needs and wants divided into functional requirements and implementation considerations.

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 HFPIP 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 HFPIP (Figure 36).

"Each product that is shortlisted for evaluation will undergo human factors testing, which will include a heuristic evaluation[1] and usability testing[2].

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.

[1]**Heuristic 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.

[2]**Usability 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 HFPIP 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 HFPIP, 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 HFPIP, while the PCA pump from the vendor that did not meet the requirements did not progress any further as part of the HFPIP.

As outlined in the RFP, the HFPIP 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

Pump A		
Issue	*Heuristic Violated*	*Recommended Changes or Actions*
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.

Pump B		
Issue	*Heuristic Violated*	*Recommended Changes or Actions*
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.
Pump C		
Issue	*Heuristic Violated*	*Recommended Changes or Actions*
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).

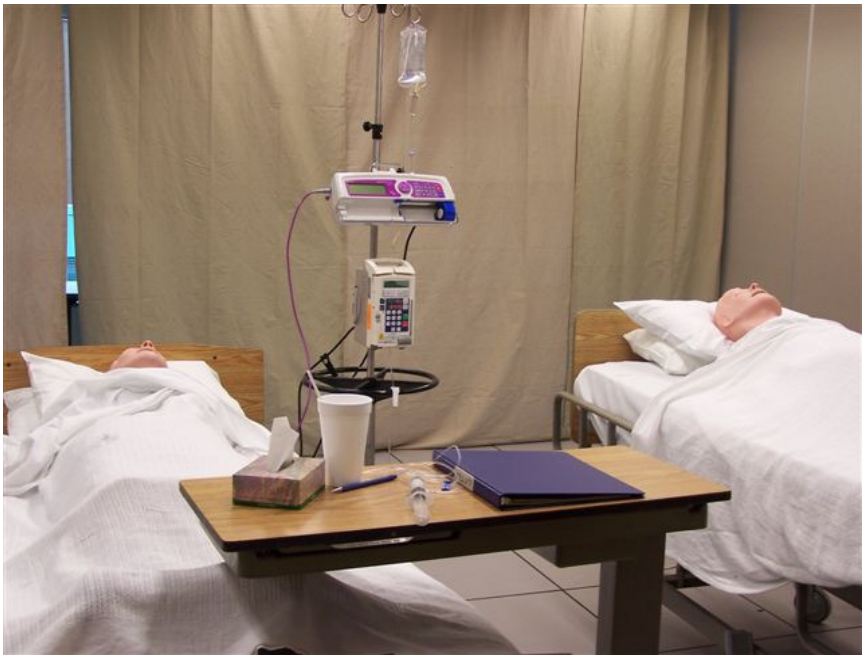


Figure 37. Usability testing environment for PCA usability testing

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 HFPIP 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.

[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."

Any questions?"

[Participant] *"No...not that I can think of..."* [or answer whatever question they have]

[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.

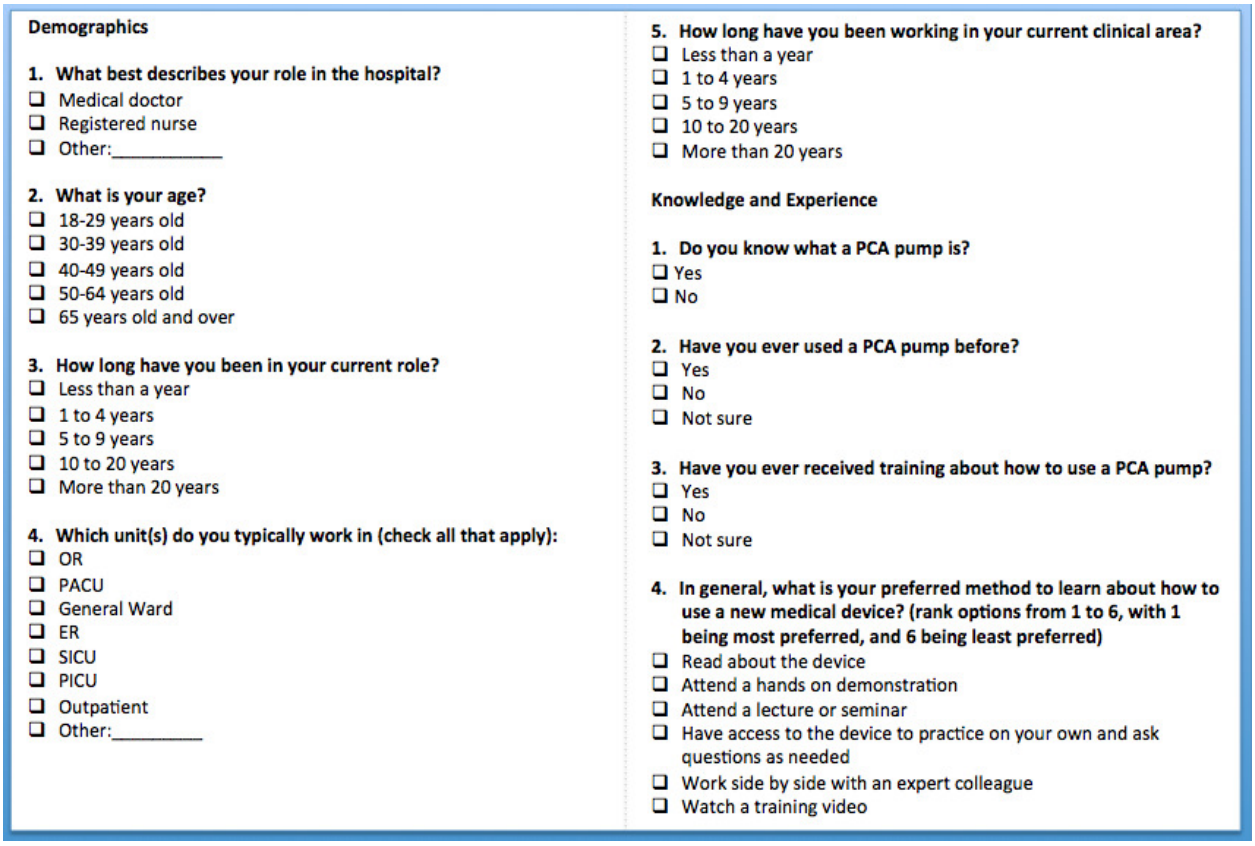
I'm just going to be over there with Ms. Wu so holler if you need anything, but hopefully you'll be okay on your own.

[Participant]: Sure

[Nurse Actor]: Great, thanks! I'll be back in a little bit.

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.



Demographics

1. What best describes your role in the hospital?
- ❑ Medical doctor
- ❑ Registered nurse
- ❑ Other:_____

2. What is your age?
- ❑ 18-29 years old
- ❑ 30-39 years old
- ❑ 40-49 years old
- ❑ 50-64 years old
- ❑ 65 years old and over

3. How long have you been in your current role?
- ❑ Less than a year
- ❑ 1 to 4 years
- ❑ 5 to 9 years
- ❑ 10 to 20 years
- ❑ More than 20 years

4. Which unit(s) do you typically work in (check all that apply):
- ❑ OR
- ❑ PACU
- ❑ General Ward
- ❑ ER
- ❑ SICU
- ❑ PICU
- ❑ Outpatient
- ❑ Other:_____

5. How long have you been working in your current clinical area?
- ❑ Less than a year
- ❑ 1 to 4 years
- ❑ 5 to 9 years
- ❑ 10 to 20 years
- ❑ More than 20 years

Knowledge and Experience

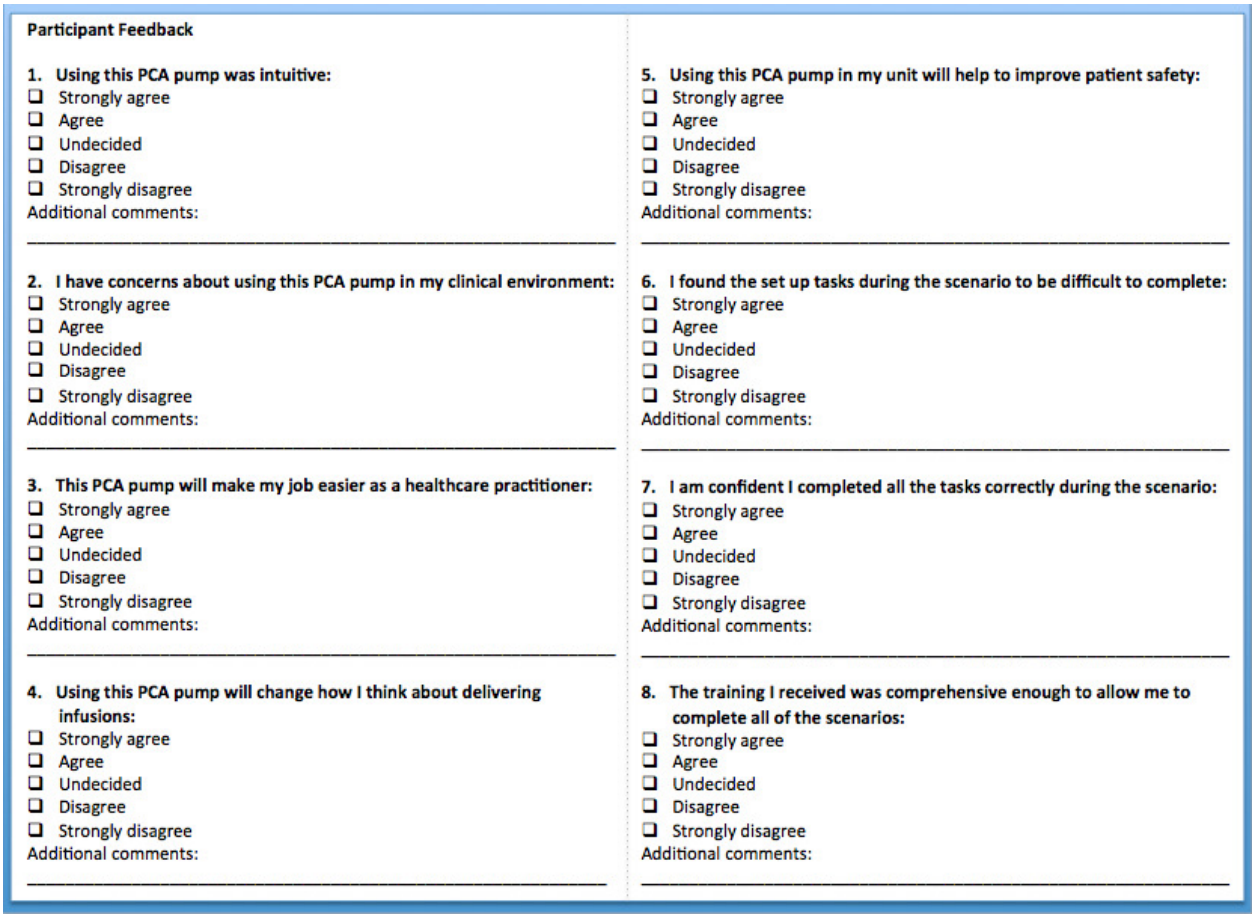
1. Do you know what a PCA pump is?
- ❑ Yes
- ❑ No

2. Have you ever used a PCA pump before?
- ❑ Yes
- ❑ No
- ❑ Not sure

3. Have you ever received training about how to use a PCA pump?
- ❑ Yes
- ❑ No
- ❑ Not sure

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)
- ❑ Read about the device
- ❑ Attend a hands on demonstration
- ❑ Attend a lecture or seminar
- ❑ Have access to the device to practice on your own and ask questions as needed
- ❑ Work side by side with an expert colleague
- ❑ Watch a training video

Figure 41. Sample of pre-questionnaire for PCA pump usability testing



Participant Feedback

1. **Using this PCA pump was intuitive:**
❑ Strongly agree
❑ Agree
❑ Undecided
❑ Disagree
❑ Strongly disagree
Additional comments:

2. **I have concerns about using this PCA pump in my clinical environment:**
❑ Strongly agree
❑ Agree
❑ Undecided
❑ Disagree
❑ Strongly disagree
Additional comments:

3. **This PCA pump will make my job easier as a healthcare practitioner:**
❑ Strongly agree
❑ Agree
❑ Undecided
❑ Disagree
❑ Strongly disagree
Additional comments:

4. **Using this PCA pump will change how I think about delivering infusions:**
❑ Strongly agree
❑ Agree
❑ Undecided
❑ Disagree
❑ Strongly disagree
Additional comments:

5. **Using this PCA pump in my unit will help to improve patient safety:**
❑ Strongly agree
❑ Agree
❑ Undecided
❑ Disagree
❑ Strongly disagree
Additional comments:

6. **I found the set up tasks during the scenario to be difficult to complete:**
❑ Strongly agree
❑ Agree
❑ Undecided
❑ Disagree
❑ Strongly disagree
Additional comments:

7. **I am confident I completed all the tasks correctly during the scenario:**
❑ Strongly agree
❑ Agree
❑ Undecided
❑ Disagree
❑ Strongly disagree
Additional comments:

8. **The training I received was comprehensive enough to allow me to complete all of the scenarios:**
❑ Strongly agree
❑ Agree
❑ Undecided
❑ Disagree
❑ Strongly disagree
Additional comments:

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 HFPIP 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 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.
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 HFPIP, neither an HFFMEA (Chapter 9) nor in-use trials (Section 11.6.2.4) were conducted. Since the healthcare organization's policy allowed it, the HFPIP 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 HFPIP 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 HFPIP 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 HFPIP 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 HFPIP 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 HFPIP 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 HFPIP 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.