Patient Controlled Analgesia (PCA) Pump Programming Analysis

Materiel Services
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Submitted by:
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II. Executive Summary

The September-October 1997 issue of the Emergency Care Research Institute (ECRI) Problem Reporting System contained a review of Abbott PCA Plus II Pumps. This is the type of Patient Controlled Analgesia (PCA) pump used throughout the University of Michigan Hospitals. The report discussed potential hazards concerning the misprogramming of these pumps. This information, in conjunction with historical data contained in incident reports at University of Michigan Hospitals, indicated that an investigation of the problem was necessary. The objective in this case was not simply to try to reduce the number of errors, but to try to eliminate them completely. The error rate for patients who are using PCA therapy is currently close to 0.1% per year. The number of machine days that PCA pumps were used within the studied time period was 61,560, with the number of reported errors at 64 for the same time period. Even though the problem is relatively small in number, errors carry potentially tragic, and therefore, expensive consequences.

The goal of this project was to determine the causes of four types of errors: human, programming, manufacturing and miscellaneous, that occurred during the use of PCA pumps in the University of Michigan Hospital System. In addition, recommendations for changes to the existing system to reduce error rates were desired. Sixty-four incidents occurred within the past two years related in some manner to PCA use. The incidents were categorized into different error types, and from these, hypotheses were formulated about probable causes for each type. The hypotheses were statistically tested to detect any significant factors in the error causes via control charts. No significant factors were identified. The data analyzed represented the entire reported population of errors, not a random sample. It is possible that some errors were not reported.

Interviews were held with twelve nurses on units with high PCA use among their patient populations. These interviews were intended to gather information about which aspects of pump use posed the most problems. The interviews were also used to assess the nurses’ opinions of the pumps and the training/education for these nurses. Recommendations were made by the Program & Operations Analysis department to reduce the number of human errors and programming errors. The decision to focus on these error types was made for two reasons. First, these errors represented the majority of errors, comprising close to 83% of all errors. Therefore, reducing human and programming errors would reduce overall error rates the most. Second, the number of errors outside of this type were so few that recommendations would not be focused enough to significantly improve the process, based on the existing data.

There are two main bodies who should take action on these recommendations, the hospital system and the manufacturer.

Consistent manufacturer coding of pre-filled narcotic syringes is the only recommendation out of the direct control of the hospital system. The syringes are currently color coded, but only one type has a coding color band around the circumference of the syringe that can be viewed regardless of the syringe’s orientation in the machine. Extending the color-coding to the circumference of the syringe for all drugs allows nurses to visually check the drug type without opening the machine. However, in
order to be fully effective, this recommendation must be accompanied by changes in the educational/training program.

Recommendations the hospital system can take action on include an annual, standardized check of PCA programming competency for all nurses. A competency has been developed by Pain Services, which is currently used by Central Staffing Resources. Of the units interviewed, few unit nurses using the machines have had their PCA use competency checked since their initial orientation to the pumps.

Another suggestion, the University can also modify the educational/training program. Four additional factors should be included.

Knowledge of color-codes for different drugs should be added to the educational program. It was found that many nurses were unable to identify the existing color codes used on the pre-filled syringes. Codes cannot take the place of reading the drug concentrations, but would add the additional dimension of positive drug type identification by visual inspection.

Programming steps for the narcotic Dilaudid need to be stressed during the training program because this drug is mixed by the pharmacy and there is no pre-set concentration/drug choice in the PCA pump menu. Nurses must take additional programming menu steps to program the pump correctly when administering this medication. This was supported by the number of nurses who admitted difficulties with programming Dilaudid in the interviews. Furthermore, the percent of programming errors found related to Dilaudid (36%) was twice the actual use of Dilaudid (18%) for patient pain relief.

Also during the training program, nurses need to be taught to place syringes in the machine so the drug label is facing outward making it readable without unlocking the door on the PCA pump.

Finally, one area which has not directly been related to errors, but that could pose a problem in the future is the removal of syringes from their boxes while in the Omnicell storage cabinet. This creates a greater risk for tampering and confusion of the syringes. Under no circumstances should the syringes be removed from their boxes until the nurse is ready to administer the medication to the patient.

A third area for University action is the modification of labels used on PCA narcotics mixed by the pharmacy. First, these labels should be applied to the syringes so they can be easily read while in the machine. Labels should be oriented on the syringes so they can be read in a sideways rather than upside down position when the syringes are correctly placed in the machine. Larger type on the label (minimum 10pt) designating the drug and it’s concentration would also make it easier for nurses to quickly ascertain whether or not the patient is receiving the correct drug and concentration during their shift checks. The labels should be oriented so that they are in the same location as the pre-printed labels for Abbott mixed narcotics and do not cover the volume marks pre-printed on the syringes.
III. Introduction and Background

In 1990, the University of Michigan Hospital System began using Patient Controlled Analgesia (PCA) pumps for pain management purposes. Approximately 375 patients per month benefit from the use of these pumps. Benefits include a timely relief of pain and fewer post operative complications.

Physicians order PCA pumps for pain management; nurses are responsible for initiating the therapy. This usually occurs in one of two places: on the patient's unit or following surgery in the recovery room. The three primary narcotics used are Morphine, Demerol, and Dilaudid. Morphine and Demerol syringes come prepackaged from Abbott Laboratories in color-coded, sealed boxes and are delivered in pre-mixed concentrations ranging from 1mg/mL to 10mg/mL. Individual syringes are color-coded and have drug information printed on the outside casing. In addition, Morphine 5mg/mL has an orange-red band circling the syringe with the concentration printed on the band. Dilaudid comes in .2mg/mL and 1mg/mL concentrations. It is compounded in the pharmacy on an individual case-by-case basis with a white pharmacy label attached to the syringe. Individual Dilaudid syringes are not color-coded, but do have drug information printed on a label affixed to the outside of each syringe.

The existing educational program for the nurses consists of on the job training by another nurse for regularly scheduled unit nurses, and more formal training for nurses who 'float', or staff on a variety of units. Central Staffing Resource nurses use competency check-off lists annually. Formal policies do not exist in the units that were interviewed. Nurses must program the pumps for the amount of the drug, the concentration of the drug and the allowable dose frequency. The pump computes the volume of solution per dose. Patients self-administer the medication using a control pendant attached to the pump. Each time the patient experiences pain he/she feels is unacceptable, he/she can press the button on the pendant to receive another dose of medication. The pump determines whether or not enough time has elapsed to allow the patient to receive another dose, and ensures that the patient has not exceeded the maximum narcotic allotment for a four-hour time span. Nurses are responsible for patient education prior to PCA use.

The September-October 1997 issue of the Emergency Care Research Institute (ECRI) Problem Reporting System contained a review of Abbott PCA Plus II Pumps. It discussed potential hazards concerning the misprogramming of these pumps. This information, in conjunction with historical data contained in incident reports at University of Michigan Hospitals, indicated an investigation of the problem was necessary. The error rate for patients who are using PCA therapy is currently less than 1% per year. Even though the problem is relatively small in numbers, errors carry potentially tragic, and therefore, expensive consequences such as death or permanent disability.

The purpose of this investigation was to determine possible causes of the errors in the PCA pumps. Goals included finding and classifying the past problems, recommending improvements to the existing educational training, and if applicable, making recommendations to the manufacturer.
IV. Approach and Methodology

The scope of this project included all departments using PCA pumps for pain therapy. The study focused only on inpatients in the University, Women’s, and Mott Children’s Hospitals. Patients in Taubman and the Cancer/Geriatrics were not included in the investigation because they are outpatient facilities.

The key issue was the potential for patient dose errors due to misprogramming. The approach used to categorize the incident reports involved going to Risk Management and sorting non-injury data. The incident reports obtained were from January 1996 through December 1997. No injury cases have been reported within the past two years, therefore, injury reports were not sorted. Any report pertaining to PCA pump use was selected and categorized. The categories included: type of drug, type of error, location of error, month, type of drug per error, and time of day split into eight three-hour shifts. In this paper, an incident is defined as an event not normally occurring during patient care. This covers a broad range of events, from leaving a PCA and its narcotics out of the direct control of a patient, to administering the incorrect drug to a patient. Although these instances are both incidents, they have very different causes and consequences.

A literature search was performed to determine if other hospitals have had similar problems with the use of PCA pumps. This involved searching for any article regarding PCA pumps. In addition to the Abbott PCA pump, articles about other brands of PCA pumps were researched to determine what kind of problems were experienced in comparable products.

The next step of the project involved flowcharting the programming process of the Abbott PCA Plus II pump in detail. Four main steps exist in the programming process. The first step, initiation, is when the pump is purged and the decision whether to retain the old prescription setting is made. The second step is to set the mode to one of three settings: continuous, PCA, or PCA + continuous. The third step is drug selection, and the final step is verification of the previous settings. After each pump-programming step, a new liquid crystal display (LCD) screen appears and prompts the nurse to decide which step to take next. (Appendix A)

Once the incident reports were categorized, a review of the patient classification data was completed. This involved obtaining the staff to patient ratios for the unit, date, and time of day when the incidents occurred. In addition, the acuity at the time of the incident was identified. Most of the acuity indices were identified for each unit by the date and the time of day, but this information was not available for all of the incident reports. Thus, the acuity indices were also analyzed by using only the average acuity for each unit and date, excluding the time of day.

In addition to the patient classification data, it was determined that more information concerning the volume of equipment use was needed. Using the Patient Equipment database, the number of days any patient used a machine was collected for each unit. This provided the pump use by unit in machine-days. This was necessary because the number of errors found from the incident reports in a certain unit does not provide useful information unless the number of times per week or month they are used is known. Both of these numbers together are useful, as they provide a use rate for the pumps by unit.
The rate can then be used to compare errors across units. Similarly, information on the percentage that each drug is used for patient controlled analgesia was needed. Comparing this percentage to the percentage each drug contributed to programming errors indicated whether or not one type of drug displayed more problems or incidents than expected by use rate. If an error rate is significantly higher than its use rate, then the drug type may be a factor in the error.

After collecting all necessary data, it was statistically analyzed and graphed using three-sigma control charts for each category to identify special-cause variation. The graphs were then analyzed to determine which areas were in control, meaning which categories had numbers of errors that fell between statistically predicted values. Areas that were out of control were then investigated further using rate information when possible. Areas not out of control were investigated through the nursing interviews. Some factors were not stratified enough to find relevant control limits. These factors were analyzed using deviation from nominal control charts and comparative pie graphs.

Interviews were conducted with nurses in order to get information and feedback regarding their opinions of the pumps and the processes related to pump use. The interviews were not held until all the incident reports were analyzed. By doing this, the questions were focused to the areas in the hospital exhibiting the most problems. Also, the questions focused on the types of problems evident from incident analysis, and ways these problems could be resolved. (Appendix B)

The existing educational program was then evaluated. The information gathered in the literature search, incident reports, patient classification data, and interviews contributed valuable ideas that led to educational program recommendations. Nurses were asked specific questions during the interviews regarding the scope, depth, and adequacy of training, as well as questions related to their knowledge of the incidents and precipitating factors found in the incident reports.

Key phases of the project are outlined below:

I. Literature Search
   A. Related/Similar Incidents
   B. Comparable Products
II. Flowchart process in detail
III. Categorization of Incident Reports
   A. Drug Type
   B. Location
   C. Type of error
   D. Use Rates – Machines and Drugs
   E. Average per Month
   F. Time of Day
IV. Review of Patient Classification Data
   A. Staff to Patient Ratio
   B. Acuity Indices
V. Interviewing
   A. Nurses
VI. Evaluating Existing Educational Program
V. Current Situation

Abbott PCA pumps are used on inpatients in the University, Women’s, and Mott Children’s Hospital. As mentioned before, the error rate, defined as errors per machine-day, is less than 1% per year for patients who are using PCA therapy. The error rate was found by taking the total number of incidents and dividing it by the total number of machine days the pumps are used. In our study the error rate = 64 incidents/61560 machine days = 0.10%. The object of this investigation was to reduce these errors as much as possible. For the past two years, there were on average three errors reported per month. The existing educational program for the nurses consists of on the job training by another nurse for regularly scheduled unit nurses, and more formal training and competency checks for nurses who ‘float’, or staff, on a variety of units. There are no hospital-wide programs in place to test the competency of a nurse assigned to a unit. There are however, yearly competency tests for Central Staffing Resource Nurses.

VI. Hypotheses Considered

Four types of errors: human, programming, manufacturing, and miscellaneous were considered in the determination of PCA error cause. When determining error categories, “Wrong Concentration” and “Wrong Drug” errors were considered human errors. These were defined as events where the programming of the pump matched the prescribed use, but the incorrect syringe, either in drug type or concentration, was inserted into the machine. Programming errors constituted an entire category and included all incidents where the machine contained a correct syringe according to the prescription, but was programmed incorrectly with respect to concentration or method of delivery (PCA, continuous, or PCA + continuous). Manufacturer errors were considered those caused by machine malfunction. Miscellaneous errors consisted of errors not falling into any of these categories. Examples include such instances as pharmacy mixing errors, PCA tubing being used with blood products or other drugs, and narcotics being left in the machine but not connected to a patient.

From these definitions, several hypotheses were investigated for the human and programming categories. Manufacturer errors were not investigated because they were not included in the scope of this project. A list of possible factors for each category are described below:

**Human Errors**

- Lack of time - understaffing of nurses on units
- Inability to view syringe label while in pump
- Clarity/Legibility of syringe labels
- Inattention
**Programming Errors**

- Inability to view syringe while in pump
- Educational deficiencies
- Difficulty of programming steps
- Inattention to prescription review

**VII. Findings and Conclusions**

After completing the key phases of the project, conclusions were drawn from many sources. First, the literature search provided useful information about the types of problems other hospitals have experienced with the PCA pumps. One problem found was family members of a patient would activate the pendant to deliver drugs to the patient. If the patient did not need medication adverse effects could develop, (Pasero, 22-3). Another problem was inadequate nurse education and/or teaching programs in other hospitals (Fulton, 383-95). According to the literature review, there should be periodic testing of nurses’ competency on the pumps. Also, management support of nursing difficulties is important in making the staff more comfortable with newly introduced pumps. This allows nurses to feel comfortable with the pump before having to perform this new task, (Fulton, 383-95). Respiratory depression is caused by overdose by PCA pumps. This has the potential for disastrous consequences. “Increasing awareness and education... (for both patients and administrators)... about precipitating factors can further reduce the incidence of PCA respiratory depression. When RR (respiration rate) and sedation level are monitored hourly, PCA is a safe method of administering postoperative analgesic”, (Looi-Lyons et. Al., 151-5). This suggests PCA pumps are a very good way to control patient’s pain, as long as they are used correctly every time.

The flow chart of the programming process visually displays each step a nurse would have to take when programming a pump. (Appendix A) It was concluded the process was straightforward and easy to follow. The nurses interviewed supported this conclusion. When asked to rank on a scale of 1-10 the difficulty of programming a pump (1 being easy and 10 being difficult), eight of the twelve nurses responded with a score of “1”, three reported a score of “2”, and one nurse responded with a “3”.

The incident reports contributed the majority of information. The non-injury reports from January 1996 through December 1997 were analyzed to find out what types of errors were occurring. It was found the majority of the incidents were due to programming and wrong concentration/drug errors, with unit 5A having the most incidents reported, at 23%. When a control chart was made with the number of incidents per unit, 5A was found to be ‘out of control’. An ‘out of control’ condition indicates that special cause variation exists within the population. The number of incidents that occurred on the other units did not suggest out of control tendencies. (See Appendix C for the control charts) While the number of incidents on a particular unit is important when identifying problem areas, it is also necessary to identify the equipment use rate per unit. This information demonstrated which units had higher error incidence by comparing the number of incidents on each unit to the number of times the pumps were used per unit over the last two years. When these data were obtained, 5A was slightly below average in terms of use rate, while units 4D and 8A had the highest error rates at 0.91% and
0.86%, respectively. These percentages were found by taking the total number of incidents reported on the unit divided by the total number of machine-days pumps were used on the unit. The average error rate was 0.258%, and the process was considered out of control at an error rate of 1.028%. Therefore, according to use rates, none of the units were out of the control limits.

The same comparison was completed for the frequency each drug was used. It was found that Dilaudid was used 18% of the time, but the number of programming errors associated with Dilaudid was 36%, twice that amount. This demonstrated that Dilaudid, a drug used less than the other drugs, contributed a greater percentage of the programming errors than was statistically expected. Consequently, more attention needs to be given to Dilaudid use. (Appendix C)

We also categorized the incidents by time of day, in three-hour intervals and average incidents per month. This information, however, when analyzed through control charts, fell within respective control limits and therefore was in statistical control. Although the control charts indicated that there was no special cause (Beta) variation, normal (Alpha) variation could still have been related to one or more factors. The interviews did not reveal any information that would support the theory that these factors were related to drug errors.

After this preliminary information was obtained, it was necessary to find the staffing ratios and acuity indices for the specific times and locations in which the incidents occurred. From this, the majority of the staffing ratios were found to be at, or above, the required levels. Also, on average, the acuity indices were found to be within the acceptable levels for each unit at the time the incidents occurred. Therefore, from this data, these factors did not directly contribute to the incidents. (Appendix D)

The interviews of the nurses provided a great deal of useful information. A total of twelve nurses were interviewed from units 5A and 8B. The nurses had a variety of backgrounds, from 6 months to 23 years of experience. Two of the nurses were Central Staffing Resource nurses. All of the nurses said the pumps were very easy to program and on a scale of 1 to 10, with 1 being easy and 10 being difficult, eight of them rated it a “1”, three rated it a “2” and one nurse rated it a “3”. The nurse who rated it a “3” was a new nurse and had only been working for 6 months. The nurses informed us that they program the pumps about 1-3 times per week. When the pumps were first used in the hospital, Abbott gave presentations on how to use the pumps. Presently, an experienced nurse on each unit teaches new nurses how to program the pumps. Each nurse is made aware of the location of the unit’s reference booklet explaining how to use the pumps if they have a problem. All of the nurses noted that they never had to reference the booklet.

When asked what they thought was the most difficult aspect in programming the pumps, 27% of the nurses mentioned using Dilaudid, another 27% said that nothing was difficult about programming the pumps, 20% expressed checking the numbers on the pump to ensure accuracy, 13% said giving boluses and another 13% stated changing the syringes. Dilaudid was said to be the most difficult drug to use since it is difficult to read the drug concentrations and milliliter levels. Furthermore, when the syringe is in the pump, if the label is turned the wrong way the concentration of the drug cannot be read and thus the
nurse may assume the pump was programmed correctly. Giving boluses was found to be difficult only because it was not a common practice. While discussing the types of error the nurses had noticed in relation to the pumps, four of the twelve indicated the errors they had witnessed or heard of were directly related to nursing errors. Some excerpts from the interviews:

"(The errors)...were nursing related. There were no serious, meaning fatal, consequences. I have not noticed any errors related to the pump."
"(The errors)...were nurse related. The patient was close to coding."
"A new nurse forgot to re-program the pump."
"Not checking on patients when we are supposed to. Nurses also don’t decrease the rate of a dose when the patients pain does not need the higher dose."

The nurses provided a variety of recommendations for the pumps. The main recommendation made by most of the nurses was that the syringes be color-coded. However, the syringes are currently color-coded. This discrepancy indicated that the nurses were not actively aware of the color-coding presently in use. The color-coding occurs in two places, on the boxes, and on the syringes. The boxes which Morphine and Demerol are packaged in are color coded according to drug and concentration. The actual syringes are additionally color-coded to match their respective boxes. This coding is to help nurses distinguish at a glance what type of drug is in the machine. Also, since the label on Dilaudid was said to be very difficult to read, it should be color-coded or modified in order to make it easier to read. Another recommendation stated by three of the nurses made was to have a stronger battery. In addition, some of the nurses on 8B said the pumps were too heavy and the IV poles often tipped over when patients were transported to appointments.

The results concerning how often the incident reports were filed varied from nurse to nurse. Some said they reported incidents every time they occurred, whereas others said if it was not too important then the incident was not reported. Everyone did say that if an incident directly affected a patient then it was reported. (See Appendix B for a complete list of interview questions)

VIII. Recommendations

Based on the goals of this investigation of Abbott PCA Plus II pumps, recommendations were made in many areas. The most noticeable errors occurred in the programming and wrong concentration/drug categories, thus these areas were given the most attention. One recommendation is to revise the existing educational program. These revisions will determine if the nurses have had the proper education to operate the machines correctly. Therefore, the nurses should be evaluated in annual competency checks. (See Appendix E) This will stress the importance of knowing the correct programming procedures for PCA pump usage. This should especially stress programming with non-standard drugs, such as Dilaudid as this represents a significant portion of the programming errors. Furthermore, knowing the correct color-coding of the different syringes needs to be stressed more during nurses training. Based on the human factors theory of signal detection, the more distinguishing characteristics an item has the more probable it is the item will be correctly identified. This basic knowledge could be a key factor in
eliminating human errors by giving nurses additional visual stimuli with which to distinguish one syringe from another.

Another important aspect to reduce the human errors (wrong concentration/wrong drug) is for the nurses, when inserting a new syringe into the machine, to always make sure the label can be clearly read through the transparent door. This will enable the nurses to verify the concentration/drug programmed in the machine is actually what is in the syringe. (Not all nurses have easy access to the key that opens the door if they need to verify what is in the machine and the label is not clearly visible. Thus, sometimes this check is skipped.) A way to solve this problem is for the manufacturer to label each of the different concentrations/drugs it produces in the same manner it labels its 5mg/mL Morphine solution. The consequences that can evolve from the magnitude of this concentration of Morphine are very serious; therefore, the manufacturer currently labels this syringe with an orange-red ring encircling the bottom of the syringe. Thus, if a syringe placed in a pump turned so the main label is not visible, the orange-red ring clearly says “5mg/mL” around the circumference of the syringe for the nurse to see. Adding this ring to the Morphine 1mg/mL and Demerol syringes in the respective colors would make the labeling visible no matter what the orientation of the syringe in the pump. Another labeling change the hospital should institute is a set of guidelines regarding Dilaudid labeling. The labels should be oriented on the syringe so they are readable, and if possible, the font should be enlarged. A font size of 10 points or greater would help readability. A long-term recommendation is to investigate the possible use of color-coding on the Dilaudid syringes prepared by the pharmacy.

The OmniCell is a new drug storage system recently implemented in the hospital. Its purpose is to limit access to drugs, and to securely store medications and document drug use for patients. The main problem found with this dispensing system was that not all of the OmniCells had the same storage location for the syringes. This would not be a problem except that some of the syringes were taken out of their boxes before being placed in the OmniCell. Having the syringes out of their respective boxes could create a potential liability issue for the hospital. If the seal on the box has been broken before a nurse needs to use the syringe, there is the possibility the drug could have been tampered with. This could provide the potential for narcotic diversion, especially when the narcotics were placed in the open top shelf area where there is enough room for several drugs to be stored. When the syringes are placed in the OmniCell, it is imperative the syringes are left in their boxes regardless of their location in the cabinet. This serves dual purposes: to avoid confusion in selecting the correct concentration/drug, and to prevent the diversion of narcotics and related tampering.

IX. Action Plan

There are two main bodies who should take action on these recommendations, the hospital system and the manufacturer.

Recommendations for the Hospital:

Educational Program Revisions
**Goal:** Stress color coding, non-standard drug programming, proper placement of syringe in machine and keeping syringes in boxes until ready for use.
- Recommended time to completion: Six months
- Responsible Parties: Educational Coordinators, Pain Services, Educational Services for Nursing
- Method for implementation: Either unit-by-unit training or coordinate efforts with Abbott to increase educational seminars taking place

**Yearly Competency Checks**
**Goal:** Ensure that all nurses who are administering PCA therapy have had an annual competency check, and that they have additional knowledge related to the above educational goals
- Recommended Time to Completion: Six months
- Responsible Parties: Nurse Educator on Unit
- Method for Implementation: To be determined by Nurse Educator

**Pharmacy Labeling Changes**
**Goal:** Ensure that Dilaudid labels are correctly oriented and readable. Enlarge font of Drug name and concentration on syringe labels.
- Recommended time to completion: One month
- Responsible Parties: Pharmacy Administration, Employees
- Method for Implementation: Reminder memo for label orientation, Programming changes for font enlargement

**Recommendations for the Manufacturer:**

**Manufacturer Coding of Label**
**Goal:** Create a method for distinguishing syringes visually regardless of orientation in PCA pump.
- Recommended time to completion: One year
- Responsible Parties: Abbott Labeling Department
- Method for Implementation: Memorandum to Abbott suggesting changes
X. Bibliography


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Appendix A
Part 1: Initiation

To Make Changes
Press
Review Change

? Clear Dose HX

Yes

Change Any Settings/Mode?

Yes

Change RX Concentration

Yes

Change Mode?

No

Page 2
Drugs

Page 3
Mode

No

Change PCA Dose

No

Change Lockout?

No

Change 4 Hour Dose Limit?

Yes

4 Hour Limit Not Set
Press Enter

No

_____ mg (or Min)
Press Enter

To Confirm
Press HX
Lock Door
Part 2: Mode

Mode

PCA

Yes

No

PCA Continuous

Yes

No

PCA Dose

____ mg

Enter

Continuous

Yes

No

Cont. Rate

____ mg/hr

Enter

PCA Dose

____ mg

Enter

Lockout Interval

____ Min

Enter

Lockout Interval

____ min

Enter

4 Hour Dose Limit Set?

No

Yes

4 Hour Dose Limit

Set?

Yes

____ mg

Enter

PCA Settings

Confirm

Press HX

Lock Door

Cont. Settings

Confirm

Press HX

Lock Door

PCA Cont.

Confirm

Press HX

Lock Door

Push

Reset/Start

Cont. Rate

____ mg/hr

Enter

4 Hour Dose Limit Set?

No

Yes
Part 4: Verification

Start

Check RAM OK
Timer ROM OK
CPU Test Complete
8888.8

Time:
Date:

Administer Loading Dose?
Yes
Confirm
No

HX and DX cleared
Clear HX and RX?
Yes

Purge the system?
Yes
Press and Hold Purge
No

Retain RX Conc & Settings No / Yes

Flow Seen? Complete?
Yes
Continued
No

Confirm
Appendix B
Nursing Interview Questions:

Years of nursing experience: \\
Years in this department: \\

1) What kind of experience do you have with PCA pumps? Have you ever used other similar types of pumps?

2) How many times per week, on average, do you program a PCA pump?

3) What form of training/educational program is currently present for PCA pumps in this department? Do you feel that the training is adequate?

4) What is your opinion regarding the programming of the pumps? Please rank it on a scale of 10 (10 very difficult – 1 easy)

5) What is the most difficult aspect of programming the pumps?

6) Do you have any recommendations or ways that you think that the PCA pumps could be improved?
7) What kind of errors have you noticed related to PCA pumps? What were the consequences of these errors?

8) In your opinion, what factors outside of the actual programming affect the difficulty associated with the use of the pumps?

9) Have you ever experienced difficulty finding the correct drug or concentration to administer to a patient? If so, what factors contributed to this?

10) How difficult is it to distinguish between the different types of syringes received from pharmacy?

11) Has your competency on PCA pumps ever been tested? If so, when and how often?

12) How would you define an incident?

13) In general, how often are incident reports filed when incidents actually occur?
Appendix C
Control Chart: Incidents per Error Type

Error Type

Occurrences
Upper Limit
Average

Number

Machine Failure
Miscellaneous
Programming
Pharmacy
Wrong Concentration/Drug
Number of Drug Incidents per Error Type

Drug

Number

Programming
Wrong Conc./Drug
Pharmacy
Manufacturer
Miscellaneous

Morphine
Dilaudid
Percentage that Drugs are used

- Morphine: 78%
- Dilaudid: 18%
- Demerol: 4%

Number of Programming Errors per Drug

- Morphine: 40%
- Dilaudid: 36%
- Unknown: 24%
Control Chart: Incidents per Unit
Incident Rate by Unit

Incident Rate (%) vs. Unit

- Incident Rate
- Upper Limit
- Average

Units: 4A, 4B, 4C, 4D, 5A, 5B, 5C, 5D, 5E, 5F, 5G, 6A, 6B, 6C, 7A, 7B, 7C, 8A, 8B, 8C, PICU, Trauma Burn
Control Chart: Incidents by Time of Day

- **0:00 - 2:59:** 3
- **3:00 - 5:59:** 5
- **6:00 - 8:59:** 15
- **9:00 - 11:59:** 25
- **12:00 - 14:59:** 10
- **15:00 - 17:59:** 10
- **18:00 - 20:59:** 5
- **21:00 - 23:59:** 2

**Upper Limit:** 30
**Average:** 10
Control Chart: Average Incidents per Month

Month: Jan, Feb, Mar, Apr, May, Jun, Jul, Aug, Sep, Oct, Nov, Dec

Number: 0, 1, 2, 3, 4, 5, 6, 7

Avg/month, Upper Limit, Average
Appendix D
Appendix E
Education Program Revisions

Core Competency for PCA Use Addendum:

1. Demonstrates knowledge of narcotic color-codes.
   - Morphine, Demerol, Dilaudid
2. Demonstrates mastery of non-standard drug programming steps.
   - Programming with Dilaudid or Fentanyl
3. Demonstrates knowledge of proper narcotic storage methods
   - Always in box until ready to administer to patient
4. Demonstrates proper method of syringe placement in machine
   - Label facing outward so that the drugs name and concentration are legible and visible.
### Critical Behaviors

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<th>Preceptor Initial/Date</th>
<th>Learning Resources</th>
<th>Evaluation</th>
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<td>1. Documentation on APS flowsheet includes: PCA settings, amount of drug received, side effects, pain score, sedation score, date, time, when machine was cleared, and any other comments.</td>
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#### 1. Assesses the patient’s pain and sedation level using appropriate tools (see Acute Pain Service flowsheet).

2. Evaluates the effectiveness of PCA therapy and takes action when appropriate.

3. Provides appropriate interventions for any side effects the patient may experience.

4. Recognizes respiratory depression and intervenes appropriately.
   - A. Stop PCA
   - B. Give Narcan 0.1mg IVP every 3-5 min. May be repeated three times for a total of 0.4mg, according to standard and orders.
   - C. Notify MD stat.

5. Demonstrates ability to set up, maintain, and discontinue PCA therapy.

6. Demonstrates ability to document drug dose, amount received, pain level, and sedation score.

#### Comments/Action Plan:

- View PCA video tape or attend PCA inservice.
- Review Acute Pain Service (APS) flowsheet (see attached).
- Review PCA handouts, set up pamphlet and cascade guide (see attached).
- Acute Pain Service personnel.
PATIENT CONTROLLED ANALGESIA (PCA)
Skills Check-off List

Patient Controlled Analgesia (PCA) is a mechanism providing pain relief to enable effective coughing, deep breathing, and early ambulation. These activities decrease the potential for post-op complications and prolonged hospitalizations.

**PCA SETUP**

1. Assemble Abbojet narcotic and purge air bubble.
2. Attach tubing and flush it.
3. Attach primary tubing to pigtail & flush.
4. Insert Abbojet into machine cradle. Pinch and lock into bottom jaws.
5. The machine will prompt you with questions:
   a. Clear previous history.
   b. Purge syringe now? (Yes or No, & Confirm)
   c. Choose drug and concentration (Confirm)
   d. Administer loading dose? (Yes or No)
   e. Select mode. (PCA, continuous, or PCA + continuous)
   f. Select PCA dose, lockout interval, continuous rate (optional), and 4 hr. limit (optional).
   g. Confirm settings, lock, door, press start (if using continuous or PCA + continuous mode).

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**CHANGING SYRINGE**

1. Assemble Abbojet narcotic and purge air bubble.
2. Disconnect used Abbojet and connect new.
3. Insert Abbojet into machine cradle. Pinch, push down, and lock into bottom jaws.
4. The machine will prompt you with questions; confirm settings.
5. Lock door. (If using continuous infusion, press start).
6. Document on flow sheet; new syringe and comments.

**CLEAR TOTAL DELIVERED**

1. Read amount infused.
2. Open door.
3. Press review change.
4. Press (Yes).
5. Close and lock door.
6. If on continuous, press start.
7. Document on flow sheet that the machine has been cleared.
8. Clear every 8 hour/shift.

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**PCA Checklist**

2/92
ALARMS
1. Low syringe --
   a. About 5ml of solution left in Abbojet.
   b. Press SILENCE to stop the alarm. This reminds you of your need for a new syringe.
2. Low battery --
   a. Battery symbol will flash.
   b. There are only 30 min. of battery life remaining.
   c. Plug PCA machine into standard hospital outlet.

DOCUMENTATION PCA FLOW SHEET
1. Response to and side effects of PCA.
2. Drug started, and mode.
3. Dose, frequency, and any changes.
4. Patient activities.
5. When machine is cleared.
6. When syringe is changed.

DOCUMENTATION OF PATIENT EDUCATION
1. Patient verbalizes that the therapy is safe and non-addictive.
2. Patient viewed channel #27 PCA educational program.
Appendix F
Memorandum

To: Abbot Laboratories
Labeling Division

From: University of Michigan Hospitals
Program & Operations Analysis Department

Date: April 22, 1998

Re: Color Coding of Pre-filled Narcotic Syringes used in Abbott PCA Plus II

This memo is regarding a study which the University of Michigan Hospitals undertook related to the September-October 1997 issue of the ECRI reporter regarding potential programming hazards with the Abbott PCA Plus II pump.

One hazard determined during the study can be rectified with your assistance. We have found that it is possible for staff to confuse the syringes that contain different medications or different concentrations of medications when the syringes are turned so the main label is facing inward while in the PCA pump. This makes it difficult to tell from visual inspection what drug and concentration is in the syringe without first unlocking the security door. Inability to read the drug and concentration of the syringe whose identifying label is placed in the Abbott machine backward occurs on a daily basis, though adverse patient incidents are rare at 0.1%. Wrong concentration or drug errors make up 44% of these errors. By modifying the existing label slightly, it may be able to prevent some of these occurrences.

On the current syringe labels, Morphine 5mg/ml has an orange colored band around the circumference of the syringe. This band also has the drug concentration printed in black letters. We feel that adding similar bands to all drugs and concentrations that are currently used in PCA therapy would help nurses distinguish the syringes more easily when the labels are facing inward. These bands should be in the same location as the current band found on Morphine 5 mg/ml, and should use the existing color codes found on the syringe’s main label. This change will reduce the probability of error based on the orientation of the syringe and may help errors to be noticed more quickly once they have been made.