Fentanyl Patch Disposal – A Sticky Situation
ICHP 2011 Annual Meeting

Linda Fred, Director of Pharmacy
Carle Foundation Hospital and Carle Physician Group

Learning Objectives & Disclosures

- Describe the proper disposal of used fentanyl transdermal patches.
- Describe appropriate documentation of used fentanyl patch residual waste.

Presenter has no conflicts of interest to disclose

How are you currently wasting fentanyl patches?

1. Cut up the patch and place in a sharps container
2. Cut up the patch and flush
3. Cut up the patch and waste in regular trash

Absence of documentation of waste

- Fentanyl patch waste was done by cutting up the patches and flushing them
- Patches that were discontinued prior to the 72 hour mark were wasted in this manner and documented in Omnicell
- Patches that were in place for the full 72 hours were wasted in the same manner but the waste was not documented in Omnicell

MM.03.01.01

- MM.03.01.01: The hospital safely stores medications.
  - EP3: The hospital stores all medications, including controlled (scheduled) medications, in a secured area to prevent diversion, and locked when necessary, in accordance with law and regulation.

FDA comments on patch destruction?

"When a drug contains instructions to flush it down the toilet … it's because FDA, working with the manufacturer, has determined this method to be the most appropriate route of disposal that presents the least risk to safety."

Capt. Jim Hunter, RPh, MPH, Senior Program Manager on FDA's Controlled Substance Staff

Environmental Concerns about Flushing

"… the main way drug residues enter water systems is by people taking medications and then naturally passing them through their bodies. Most drugs are not completely absorbed or metabolized by the body, and enter the environment after passing through waste water treatment plants."

" For those drugs for which environmental assessments have been required, there has been no indication of environmental effects due to flushing"

- Raanan Bloom. PhD, Environmental Assessment Expert in FDA's Center for Drug Evaluation and Research

National Take Back Initiative

- Date of the next National Prescription Drug Take Back Day:

  October 29, 2011
  10:00 am – 2:00 pm

- Visit the DEA web site for information for law enforcement agencies who wish to host a collection site.

How do you document patch waste

1. Paper documentation
2. Automated Dispensing Equipment
3. Electronic Medical Record
4. All of the above

Documentation of waste

- The method of documentation doesn't matter – as long as it is done
- Omnicell waste:
  - Configure your system to have a waste reason of "residual"
  - Can be used for other types of "overfill" and residual waste besides patches
  - This allows for documentation without decrementing the inventory

Learning assessment question

- How should used fentanyl patches be disposed of?
  - Cut up and placed in a sharps container
  - Cut up and placed in a pharmaceutical waste (black) container
  - Cut up and flushed
  - Any of the above is acceptable

Learning assessment question

- How should fentanyl patch waste be documented
  - Paper documentation
  - ADE documentation
  - EMR documentation
  - Method of documentation doesn't matter as long as it is done

Resources

1. The Joint Commission. (2011). Comprehensive Accreditation Manual for Hospitals E-dition. Medication Management Standard, MM.03.01.01, EP3.
2. US Department of Health and Human Services. FDA Consumer Updates. How to Dispose of Unused Medicines. Available at: http://www.fda.gov/forconsumers/consumerupdates/ucm101653.htm.
3. US Department of Justice – Drug Enforcement Administration. Got Drugs? – National Take Back Initiative. Available at: http://www.deadiversion.usdoj.gov/drug_disposal/takeback/index.html

TJC Pearls Session:
Insulin Management—A Sweet Deal

Jim Jansen, M.S., R.Ph.
Director of Pharmacy
OSF Saint Anthony Medical Center

The speaker has no conflicts to disclose.

Objectives

- Identify adverse events and medication errors associated with the use of insulin in hospitalized patients
- Describe strategies to manage insulin dosage forms in a bar code medication administration system

Insulin Medication Errors

Predominant Medication Error Event Types Associated with the Use of Insulin [N = 2057, 76.6%]; January, 2008 to June 6, 2009

Error Type	Number	% of Total Reports [N =2685]*
Dose Omission	662	24.7%
Wrong Drug	374	13.9%
Wrong dose/overdosage	348	13%
Other (specify)	309	11.5%
Extra dose	227	8.5%
Wrong dose/underdosage	137	5.1%

**Sum of percentages exceeds 76.6% due to rounding.*

78.7% [N = 2113] of the errors reached the patient; 1.8% [N = 49] of the errors resulted in patient harm

Pennsylvania Patient Safety Advisory 2010; 7(1):9-17.

Insulin, Hospitals, and Harm

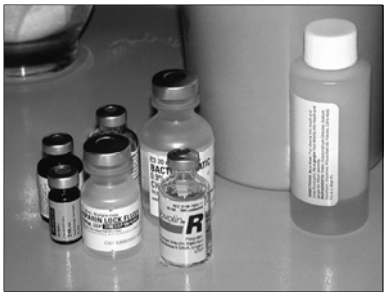
A review of patient safety incidents reported to the National Patient Safety Agency

Error Type	Number	% of Total Reports [N =16600]*
Wrong dose, strength, or frequency	4256	26%
Omitted and delayed doses	3390	20%
Wrong insulin product	2390	14%
Other	6564	39%

*Insulin reports between November, 2003 and November, 2009; 24% reported patient harm; 18 incidents of fatal and severe outcomes; 1042 incidents of moderate harm.

Clinical Medicine 2011; 11(1):28-30.

Unexpected Hypoglycemia in a Critically Ill Patient



Heparin and insulin vials as they appeared on the patient's bedside cart in the intensive care unit.

Annals of Internal Medicine 2002; 137:110-116.

Unexpected Hypoglycemia in a Critically Ill Patient

*The patient's arterial line had often become occluded, requiring frequent heparin flushes. The institution conducted a root cause analysis, reconstructing the patient's care leading up to the event. Strong circumstantial evidence suggested that the intended 1- to 2-mL heparin flush at 6:45 a.m. was **insulin** and not **heparin**; thus, the patient received **100 to 200 Units of regular insulin** on at least one occasion.*

In the chapter on high-alert medications in Cohen's seminal book on medication errors, the first bullet for insulin reads:

Intravenous insulin is lethal if it is given in substantially excessive amounts or in place of other medications. Insulin and heparin are often mistaken for one another because both are administered in units and both may be stored in proximity to each other.

Annals of Internal Medicine 2002; 137:110-116.

Inadvertent Administration of Insulin to a Non-diabetic Patient

*The most likely explanation appeared to be **substitution of insulin for a scheduled subcutaneous dose of heparin** on the evening before the patient was found unresponsive.*

*The root cause analysis team identified three opportunities **where insulin may have been inadvertently administered**:*

- *administration of rapid-acting insulin intended for a different patient during the night*
- *substitution of insulin for a dose of heparin the evening before the patient was found unresponsive*
- *administration of NPH insulin intended for a different patient the evening before*

Alberta RN 2010; 66(5):24-25.

Defective Pens

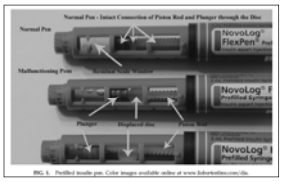


Figure 1. Flexpen used by the patient during the period of metabolic control impairment. Arrow points to the disengaged barb at the tip of the piston rotor.

Diabetes Technology & Therapeutics 2010; 12(3): 241-243
Journal of the American Board of Family Medicine 2008; 21(6): 575-576

Insulin Products

Category	generic name [Trade name]	Manufacturer	How Supplied
Rapid-Acting	*lispro [Humalog]*	Lilly	*3 mL vial*, 10 mL vial, 3 mL pen*, 3 mL cartridge
Rapid-Acting	aspart [Novolog]	NovoNordisk	10 mL vial, 3 mL pen, 3 mL cartridge
Rapid-Acting	glulisine [Apidra]	Sanofi Aventis	10 mL vial, 3 mL pen, 3 mL cartridge
Short-Acting	*regular [Humulin U-100]*	Lilly	*10 mL vial*, 3 mL pen, 3 mL cartridge
Short-Acting	regular [Humulin U-500]	Lilly	20 mL vial
Short-Acting	regular [Novolin U-100]	NovoNordisk	10 mL vial, 3 mL pen, 3 mL cartridge
Intermediate-Acting	*NPH [Humulin N]*	Lilly	*3 mL vial*, 10 mL vial, 3 mL pen
Intermediate-Acting	NPH [Novolin N]	NovoNordisk	10 mL vial, 3 mL pen, 3 mL cartridge
Intermediate- to Long-Acting	*detemir [Levemir]*	NovoNordisk	*10 mL vial*, 3 mL pen
Long-Acting	*glargine [Lantus]*	Sanofi Aventis	*10 mL vial*, 3 mL pen, 3 mL cartridge
Combination	aspart protamine suspension/aspart [Novolog Mix 70/30]	NovoNordisk	10 mL vial, 3mL pen
Combination	*lispro protamine suspension/lispro [Humalog Mix 75/25]*	Lilly	*10 mL vial*, 3 mL pen
Combination	lispro protamine suspension/lispro [Humalog Mix 50/50]	Lilly	10 mL vial, 3 mL pen
Combination	NPH/regular [Humulin 70/30]	Lilly	10 mL vial, 3 mL pen
Combination	NPH/regular [Humulin 50/50]	Lilly	10 mL vial
Combination	NPH/regular [Novolin 70/30]	NovoNordisk	10 mL vial, 3 mL pen, 3 mL cartridge

OSF SAMC Insulins
*Pre-filled disposable pens

How many different insulin packages are stocked at your hospital?

1. < 5
2. 6-10
3. 11-15
4. >15

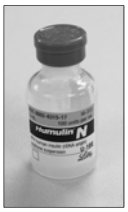
What types of single-entity insulins are stocked in your hospital?

1. regular U-100
2. lispro [Humalog]
3. glulisine [Apidra]
4. aspart [Novolog]
5. NPH
6. detemir [Levemir]
7. glargine [Lantus]
8. regular U-500

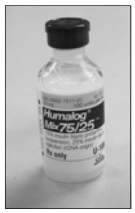
OSF SAMC Insulin Products

- No U-500 Insulin
- No interchange for Levemir and Lantus
- No Pens
- LASA drug pairs minimized
- CPOE and BCMA within the EMR
- Nursing prepares rapid-acting insulins [HumaLOG and REGULAR]
- Pharmacy prepares all other insulins in patient-specific pre-filled syringes

Pharmacy-Prepared Insulin Syringes



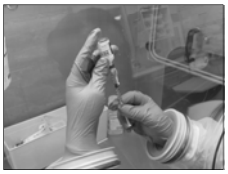




- Patient specific bar code labels batch-printed in Anteroom
- Bar code references the patient's order [e.g., Lantus 18 Units]
- 24 hour expiration date assigned; technician and pharmacist initial label
- Syringes hand-delivered to units in tamper-evident packages

Patient-Specific Insulin Dose Preparation





Patient-Specific Insulin Dose Labeling

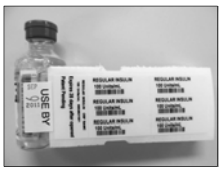


Patient-Specific Insulin Dose Checking/Packaging



Rapid-Acting Insulin Process

HumaLOG and REGULAR [~~Humulin~~]

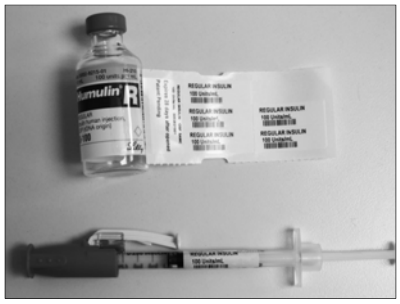


Rapid-Acting Insulin Process

- regular insulin [Humulin] 10 mL vial
- lispro insulin [Humalog] 3 mL vial
- Supplied to all inpatient units; stored in refrigerator; individually labeled plastic boxes
- 28 day expiration dates pre-assigned in pharmacy
- Insulin boxes exchanged every 28 days with a duplicate set in pharmacy; unopened vials re-dated; remainder tracked
- Vials issued with multiple bar code peel-off labels attached
- Labels read REGULAR INSULIN and HumaLOG
- All vials logged in notebook with technician and pharmacist sign-off

Rapid-Acting Insulin Process

Regular Insulin Syringe



To administer a dose of glargine insulin [Lantus] to a patient, what bar code is scanned at the bedside in your hospital?

1. A patient-specific vial
2. A patient-specific pen
3. A patient syringe label
4. A floor stock vial
5. No bar code scanning on administration

Pharmacists' role in ensuring safe and effective hospital use of insulin

- Pharmacists should prepare and dispense prefilled syringes for once-daily doses of long-acting insulin but only when they can be given within the labeled time frame
- All insulin preparations should be independently double-checked against original orders prior to dispensing
- Applying "tall man" lettering to dissimilar portions of name can be helpful
- Do not dispense insulin in its original carton; discard the carton upon dispensing

Am J Health-Syst Pharm 2010; 67(Suppl 8):S17-S21.

References

1. Anonymous. Medication errors with the dosing of insulin: problems across the continuum. *Pennsylvania Patient Safety Advisory* 2010; 7(1):9-17.
2. Cousins, D., Rosario, C., Scarpello, J. Insulin, hospitals and harm: a review of patient safety incidents reported to the National Patient Safety Agency. *Clinical Medicine* 2011; 11(1):28-30.
3. Bates, D. Unexpected hypoglycemia in a critically ill patient. *Annals of Internal Medicine* 2002; 137:110-116.
4. Anonymous. Inadvertent administration of insulin to a nondiabetic patient. *Alberta RN* 2010; 66(5):24-25.
5. Lakshmanadoss, U., Ayyappan, S., Jain, A., Konezny, M., Rajamani, K. The Broken Pen Penalty. *Diabetes Technology & Therapeutics* 2010; 12(3):241-243.
6. Boronat, M., Garcia-Delgado, Y., Perez-Martin, N., Novoa, F.J. *Journal of the American Board of Family Medicine* 2008; 21:575-576.
7. Cohen, M.R. Pharmacists' role in ensuring safe and effective hospital use of insulin. *Am J Health-Syst Pharm* 2010; 67 (Suppl8):S17-S21.

ICHP 2011 Annual Meeting
TJC Pearls
Jim Jansen, MS, RPh
121-000-11-032-L04-P & T

Post Test:

1. Which of these practices is not recommended in the management of insulin in hospitalized patients:

a) Pharmacists should prepare and dispense prefilled syringes for once-daily doses of long-acting insulin but only when they can be given within the labeled time frame
b) All insulin preparations should be independently double-checked against original orders prior to dispensing
c) Applying "tall man" lettering to dissimilar portions of name can be helpful
d) Dispense insulin in its original carton to inpatient nursing units

2. The incidence of patient harm associated with insulin adverse events and medication errors was found to be 24% in reporting to what agency?

a) FDA
b) ISMP
c) NPSA
d) IOM

3. Insulin is often confused for which drug because they are both measured in Units?

a) Heparin
b) Oxytocin
c) Vasopressin
d) Corticotropin

4. Which of these insulins is least likely to be on a hospital's formulary?

a) Apidra
b) Levemir
c) Lantus
d) U-500 Regular

OR MEDICATION SECURITY – WE'RE IN LOCKDOWN

Andrew Donnelly, PharmD, MBA, FASHP
Director of Pharmacy
University of Illinois Medical Center at Chicago
Clinical Professor of Pharmacy Practice,
University of Illinois at Chicago College of Pharmacy

The speaker has no conflicts to disclose.

TJC Visit
UIMC

- Surveyed February 2011
- Lead surveyor spent significant time in perioperative setting
- Medical center's interpretation of standards and NPSGs differed from surveyors' interpretation
- Submitted clarifying evidence once preliminary report received
  - TJC reversed significant number of direct impact and indirect impact RFIs of those contested

NPSG.03.04.01

- Requires labeling of all medications, medication containers, and other solutions on and off the sterile field in perioperative and other procedural settings
- EP2 – in perioperative and other procedural settings both on and off the sterile field, labeling occurs when any medication or solution is transferred from the original packaging to another container
- EP4 – verify all medication or solution labels verbally and visually. Verification is done by two individuals qualified to participate in the procedure whenever the person preparing the medication is not the person who will be administering it.

NPSG.03.04.01
EP2

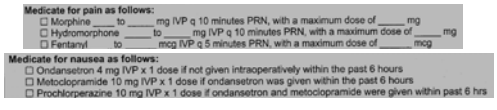
- TJC surveyor finding – two prelabeled syringes found in GI lab
- TJC recently deleted the FAQ prohibiting prelabeling of syringes
  - TJC still requires all filled syringes to be labeled (unless immediately administered)
  - Beyond scope to identify all the safe and unsafe methods in which a syringe is filled and labeled
- TJC surveyor newsletter – "if you observe such a practice, simply confirm that the organization has made a deliberate decision that this is an appropriate process for their given circumstances"
- Decision should be documented in hospital policy
- Still have RFI; elimination of FAQ after survey

NPSG.03.04.01
EP4

- TJC surveyor interpretation – actual preparation of all medications must be witnessed by a second person if the person preparing is not the person administering, with both persons initialing the label
- UIMC interpretation – EP applies only during a handoff process, with both individuals looking at the label and verbalizing the contents as well
- *Joint Commission Perspectives* (December 2010, Volume 10, Issue 12, page 8) – "Verbal communication of what is being handed from one person to the next is another way to help ensure that the patient is receiving the correct medication. As the syringe is being passed from one person to the next, it should not only be labeled, but the person passing the medication should state what is in the syringe."
- RFI reversed

MM.04.01.01
EP13

- EP13 – The hospital implements its policies for medication orders
- Observations
  - Preprinted "Post Anesthesia Order and Discharge Sheet" contained three pain medication choices and three antiemetic medication choices; the anesthesiologist had checked the boxes for two of the pain medications and all the antiemetic medications
  - Preprinted "Post Anesthesia Order and Discharge Sheet" had fentanyl written in a dose of 25 to 50mcg IVP q 5 minutes PRN pain


Medicate for pain as follows:
☐ Morphine ____ to _____ mg IVP q 10 minutes PRN, with a maximum dose of _____ mg
☐ Hydromorphone _____ to _____ mg IVP q 10 minutes PRN, with a maximum dose of _____ mg
☐ Fentanyl to _____ mcg IVP q 5 minutes PRN, with a maximum dose of _____ mcg

Medicate for nausea as follows:
☐ Ondansetron 4 mg IVP x 1 dose if not given intraoperatively within the past 6 hours
☐ Metoclopramide 10 mg IVP x 1 dose if ondansetron was given within the past 6 hours
☐ Prochlorperazine 10 mg IVP x 1 dose if ondansetron and metoclopramide were given within past 6 hrs

MM.04.01.01
EP13

- Surveyor findings
  - Hospital's policy does not allow range orders
  - Physician approved protocols not in place to direct choice of pain medication and antiemetic
- UIMC actions
  - Reinforce that range orders are not allowed; empower nurses in PACU not to accept "Post Anesthesia Order and Discharge Sheet" with range orders
  - Revised "Post Anesthesia Order and Discharge Sheet" to include directions for antiemetic use
  - Implemented handoff process where anesthesiologist reviews analgesic orders with PACU nurse

MM.03.01.01
EP5

- EP5 – The hospital implements its policy addressing the control of medications between receipt by an individual health care provider and its administration
- Observation: anesthesiologist observed carrying two prefilled syringes in front pocket of scrubs in preparation for next case
- TJC surveyor interpretation – UIMC not following its policy which states that anesthesiologists' medications be stored and secured in the anesthesia medication cart
- UIMC policy states "Controlled substances are kept locked at all times. The sole exception is for controlled substances under the direct control of the anesthesiologist or other clinician involved in the administration of the drug."
- RFI reversed

ASA Concerns – MM Standards and NPSGs
TJC Response

- Prohibition of prelabeled syringes (NPSG.03.04.01, EP2)
  - FAQ that prohibited prelabeling removed – over interpretation, prelabeling not addressed in safety goal itself
- Labeling of spinal and epidural anesthetics and analgesics (MM.05.01.09, EP1; NPSG.03.04.01, EPs 1 and 5)
  - Requirement for labeling remains unchanged
- Label verification requirements when two individuals are involved (NPSG.03.04.01, EP4)
  - Requirement remains unchanged

ASA Concerns – MM Standards and NPSGs
TJC Response

- Control of medication between receipt by a health care provider and administration of the medication, including safe storage, handling, security, disposition, and return to storage (MM.03.01.01, EP4) – confirmation that anesthesia professionals are not prohibited from carrying medications on their person when indicated and/or necessary for patient safety and in accordance with institutional policy
  - Practice accepted as long as organization has written policies with policies followed
- Factors to consider
  - Medication not going to deteriorate during time stored on provider's person
  - How long medication may be stored by provider
  - Security issues
  - Disposition and return to stock

ASA Concerns – MM Standards and NPSGs
TJC Response

- Requirement that uncontrolled medications be kept in a secure area and controlled substances be locked and kept in a secure area (MM.03.01.01, EP3) – confirmation that uncontrolled medications can be kept on top of anesthesia cart before and in between cases and that controlled substances can be kept in locked drawer of anesthesia cart in a secure operating room
  - Requirement met if hospital policy followed regarding what is a secure area

QUESTIONS

Learning Assessment Questions

TJC Pearls Session
OR Medication Security – We're in Lockdown
Andy Donnelly

1. Which of the following statements related to NPSG.03.04.01 is true?
   a. syringes do not need to be labeled as long as the health care provider knows what is in them
   b. prelabeling of syringes is not allowed
   c. if prelabeling of syringes is done, the organization should have an appropriate process in place to do this
   d. there are never any circumstances where it is allowable not to label a syringe prior to the medication being administered to the patient

2. Which of the following will result in the institution receiving a recommendation for improvement (RFI) from The Joint Commission?
   a. Prelabeling of syringes with an appropriate process in place for how to do this
   b. Not labeling spinal and epidural anesthetics and analgesics if placed on the sterile field for administration at a later time
   c. Employing a hand-off process when a syringe is being passed from one person to another that includes the person passing the medication stating what is in the syringe
   d. The anesthesia provider carrying medication on his/her person when indicated and/or necessary for patient safety and in accordance with institutional policy

Contrast Media - The Whole Picture

Se Choi, PharmD
Director of Pharmacy

PROVENA
Saint Joseph Medical Center

No Conflict of Interest to declare

The Joint Commission

- Surveyors:
  - Beverly M. Gaddy, RN - (01/24 - 01/28/2011)
  - John V. Milazzo, MD - (01/24 - 01/28/2011)
  - Darryl S. Rich, PharmD (Administrator) - (01/24 - 01/28/2011)
  - Kurt P. Streit (Facilities)- (01/25 - 01/26/2011)
  - John C. Wallin, MS, RN (Training)- (01/24 - 01/28/2011)

Findings

- 10 Direct Standards
- 7 Indirect Standards

- What happened to RFI?
- Did we pass?

- Yes

Our Process

- Patient questionnaire completed by the radiology technician.
- Type of contrast information required sent to pharmacy with SCr, Weight, Height.
- Pharmacist calculates CrCl and sends information back to unit.
- Radiologist is contacted if CrCl is <30 ml/min and decision is made to use IV contrast or not.

Tracer By Administrator

- Examination of room prior to treatment.
- When the patient arrived, he observed the process from timeout, medication usage, labeling, documentation, ect.
- Order process for contrast.
- Pharmacy review of IV contrast.
- His findings: Our process was “good”

ICHP 2011 Annual Meeting
TJC Pearls
Se Choi, PharmD

Post Test::

1. Should Pharmacy review all radiologic contrast media?
    a. Yes
    b. No

2. Contrast media is safe and has no adverse reactions.
    a. True
    b. False