

Failure Modes & Effects Analysis: A U-500 Insulin Case Study

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 WMSHP Spring Seminar
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Objective

- Understand the role of a failure mode and effects analysis (FMEA) in developing U-500 insulin use criteria



What is a FMEA?

- Failure Mode and Effects Analysis
- Systematic analysis of a process that identifies:
 - Possible ways process may fail (failure modes)
 - Effects or results of failures
 - Possible causes of failures
- Proactive technique
 - Identify & address problems before they occur

www.ashp.org/DocLibrary/Policy/QII/FMEA.aspx

Ongoing Quality Improvement Process

What should a FMEA be used to analyze?

- High-risk medications
- High-risk, error-prone procedures
- Changes in the medication use system
- Follow-up on reported incidents
 - At your facility
 - Reported in the medical literature
 - Reported by regulatory agencies

www.ashp.org/DocLibrary/Policy/QII/FMEA.aspx

Steps to Conducting a FMEA

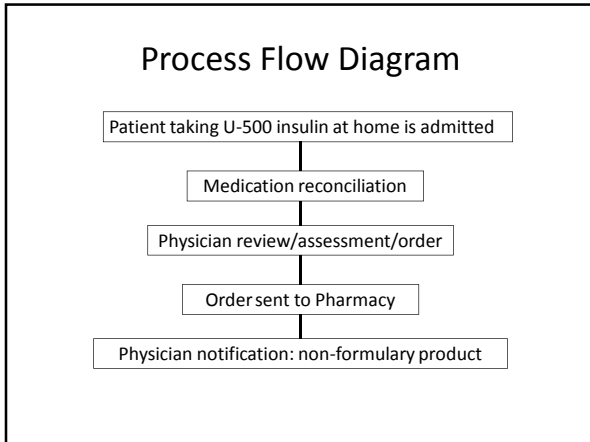
- Assemble multidisciplinary team
- Diagram process
- Evaluate each step in the process flow diagram to determine what could go wrong
- Identify the effects of the failures
- Rank & prioritize the failure modes
- Recommend changes to mitigate failure
- Reassess

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Assembling a Team

- Include representatives from all disciplines involved in the process
- Borgess U-500 FMEA Team Composition
 - Pharmacists
 - Diabetes Nurse Specialist
 - Diabetes Clinic Nurse Practitioner
 - Hospital Internists
 - Quality Director
 - Staff Nurses





Evaluate Each Step in Process

Step	Failure Mode	Failure Causes	Failure Effects
2	<ul style="list-style-type: none"> •Wrong information transcribed •Patient gives wrong information •U-500 not recorded on Meds Rec form 	<ul style="list-style-type: none"> •Knowledge deficit •Patient uncertain of dose or uses different type of syringe •Patient does not mention using U-500 insulin •Meds Rec policy not followed 	<ul style="list-style-type: none"> •Incorrect medication order •Medication is not properly monitored

- ### Ranking the Failure Modes
- Calculate Criticality Index (CI)
 - CI also known as Risk Priority Number (RPN)
 - $CI = O \times S \times D$
 - O: frequency of occurrence
 - S: severity
 - D: probability of detection
- www.ashp.org/DocLibrary/Policy/QII/FMEA.aspx

Occurrence Ranking Scale

How likely is it that this failure mode will occur?

Rating	Category	Criteria
1	Remote	Possible, no known occurrence
2	Low	Rarely occurs (yearly)
3	Moderate	Infrequently occurs (monthly)
4	High	Frequently occurs (weekly)
5	Very High	Almost always occurs (daily)

www.ashp.org/DocLibrary/Policy/QII/FMEA.aspx

Severity Ranking Scale

If failure occurs, how likely is it that harm will occur?

Rating	Category	Criteria
1	No harm	No harm to patient
2	Minor	Temporary harm; monitoring or minor intervention
3	Moderate	Temporary harm; initial or prolonged hospitalization
4	Major	Permanent harm
5	Severe	Terminal injury or death

www.ashp.org/DocLibrary/Policy/QII/FMEA.aspx

Detection Ranking Scale

If failure occurs, how likely is it that it will be detected?

Rating	Category	Criteria
1	Very High	Almost always be detected (95 – 100%)
2	High	Frequently detected before reaching patient (75-94%)
3	Moderate	Infrequently detected before reaching patient (40 – 74%)
4	Low	Rarely detected before reaching patient (6 – 39%)
5	Remote	Detection not possible at any point in the system (0 – 5%)

www.ashp.org/DocLibrary/Policy/QII/FMEA.aspx

Criticality Index Example

- Failure Mode: Wrong information transcribed
- Occurrence = ____
- Severity = ____
- Detectability = ____
- CI = ____ x ____ x ____ = ____
- Rank list of all failure modes
 - Rank from highest to lowest CI



Borgess' Recommended Changes

- Add U-500 insulin to formulary
- Create preprinted order form, which clinicians must use to order U-500
- Only certain clinicians permitted to prescribe
- RPh to verify home regimen with prescriber
- Pharmacy to draw up all doses of U-500 in TB syringe
- Pharmacy to segregate U-500 from other insulin products


Borgess' Recommended Changes

- Independent RPh double check
- Doses listed on eMAR in both mLs and units
- Hypoglycemia warning added to eMAR & label comments
- High risk labels to be placed on each syringe dispensed
- All hospital-employed RPh, CPhTs, RNs, and MD/DOs must complete U-500 competency

Useful Websites

- www.ashp.org/DocLibrary/Policy/QII/FMEA.aspx
- www.ismp.org/tools/FMEA.asp
- www.ismp-canada.org/fmea.htm
- www.patientsafety.gov/SafetyTopics.html





 SAINT MARY'S
 HEALTH CARE

Expect Something More

Insulin U-500 Safety

Kymberlee Moline, PharmD, MSA
 Clinical Pharmacist – Medication Safety
 Saint Mary's Health Care


*WMSHP Spring Seminar
 May 17, 2011*


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Safety Considerations


- 5 times the potency of U100
- Use of U100 syringe
- Communicating the dose (lines v. units)
- Infrequent use
- Product selection
- Double checks


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U-500 On Formulary (March 2007)

- TB Syringe prepared by pharmacy
- Alert label added to syringe
- Alert added to MAR:
 - Requires Double Check
 - 1 line on U-100 syringe = 5 units insulin


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ALERT

Humulin R **Concentrated U-500** Insulin

HIGH ALERT MEDICATION REQUIRES DOUBLE CHECK

500 units/mL – **5 times the potency of regular insulin**

NOT for IV use

For in hospital use: Only use for basal doses of insulin (NOT for use with sliding scale)


NOTE: 1 line on U -100 syringe = 5 units insulin


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Safety Assessment (November 2007)

- Order entry screen- product selection
- Pharmacist verification and preparation
- Storage
- Alerts
- Dispensing patient specific syringe
 - How to handle quick turn around for adjustment doses?


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Non-Formulary With Interchange

- Insulin glargine plus insulin aspart
- Prescriber provides total daily home dose
 - Usual daily dose including adjustments
 - Lower end of range
- Pharmacy converts
 - Lantus = ½ total daily dose (TDD)
 - Novolog = remaining TDD divided by 3

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Implementing the Interchange

- Prescribing: Order set
- Dispensing: Dosing tool
- Administering: Instructions on MAR
- Interchange message for discharge reconciliation (Lantus and Novolog):
 - "Not intended for use at discharge. Patient is on U-500 at home"

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Careset - Insulin U-500 (gk)

Component Order Details

Advisory: U-500 Insulin is Restricted

It will be interchanged by pharmacy to insulin glargine (Lantus) and insulin aspart (Novolog) unless used in a continuous subcutaneous infusion pump. (To order U-500 for use in continuous subcutaneous infusion pump, use insulin continuous subcutaneous infusion pump order set).

Prescriber instructions:

Determine total daily dose of U-500
Include the usual amounts required to adjust for blood sugar and carbohydrates.
For patients who report a wide variation in dosages, use the lower end of the range.
Caution: some patients may express their dose in "lines" on an insulin 1 line is equal to 5 units of insulin.

Enter the total daily units of insulin in the comments of order below

Pharmacy Communication Order (Pharmacy to Dose Insulin U 500)

Glucose PDCT orders

Glucose PDCT for Docking Process

Glucose PDCT for Docking Process

Blood - Capillary, Routine, ac TID

Interchange guideline reference:
To determine the Lantus dose: Divide the total daily dose by 2. Order daily at bedtime.
To determine the Novolog dose: Subtract the Lantus units from the total and divide by 3. Order three times daily before meals.
Note: Do not continue Lantus and Novolog at discharge; instruct patient to restart insulin u-500.

Prescriber enter UNITS of U-500 here

Pharmacy to convert U-500 insulin to insulin glargine and insulin aspart.

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Microsoft Excel - Insulin U-500 protocol Reconciled

	A	B	C	D	E	F
1						
2						
3						
4						
5						
6						
7						
8	Insulin U-500 Protocol (Policy 12-316)	Pharmacy Actions:	Units	Frequency	Comments	
9	1. U-500 is non-formulary.	1. Enter units from pharmacist's order.	Insulin dose	180		
10	2. Patients who are admitted to SMHC with U-500 insulin as a home medication will be interchanged to insulin glargine (Lantus) and insulin aspart (Novolog).	2. Place order for this dose given daily at bedtime. Include the comment: "Not intended for use at discharge. Patient is on U-500 at home."	Calculated Lantus Dose	90	HS	Not intended for use at discharge (Patient is on U-500 at home)
11	3. The ordering physician will provide the pharmacy with the total units of U-500 insulin that the patient has been administering daily at home.	3. Place order for this dose given AC TID. Include the comment: "Not intended for use at discharge. Patient is on U-500 at home."	Calculated Mealtime Novolog dose	30	AC TID	Not intended for use at discharge (Patient is on U-500 at home)
12	a. Include the usual amounts required to adjust for blood sugar and carbohydrates. b. For patients who report a wide variation in dosages, use the lower end of the range. c. Caution: some patients may express their dose in "lines" on an insulin syringe. Note that 1 line is equal to					

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hydrochlorothiazide (Hydrochlorothiazide 50 mg Tab (Hydrodiuril GEq))
50 mg = 1 Tab, PO, Tab, Daily, Routine, 12/31/10 9:00:00 ...

insulin aspart (Insulin Aspart 100 Units/mL Vial 10 mL (Novolog GEq))
68.3 Unit = 0.68 mL, Subcut, Inject, w/meals TID, 12/31/10 0:00:00 EST

insulin aspart (Insulin Aspart 100 Units/mL Vial 10 mL (Novolog GEq))
205 Unit = 2.05 mL, Subcut, Inject, Bedtime, 12/30/10 21:00:00 EST
Order Comment: Prescriber enter UNITS of U-500 here (total 410 unit per day of U-500)
Pharmacy to convert U-500 insulin to insulin glargine and insulin aspart.

insulin glargine (Insulin Glargine 100 Units/mL Vial 10 mL (Lantus GEq))
205 Unit = 2.05 mL, Subcut, Inject, TID, 12/31/10

insulin regular (Insulin H (HIGH Conc Humulin R Subcut, Inject, TID, 12/31/10

patient takes: 30 lines at 10 am, 20 lines at 2pm, 16 lines at 6 pm and 16 lines at 11 PM
Rx conversion: 1 line = 5 units Insulin
150 unit (30 lines) + 100 unit (20 lines) = 80 unit (16 lines) + 80 unit (16 lines)
TOTAL = 410 units per day
Divided in 1/2 of dose as Lantus at bedtime= 205 units
Other 1/2 of dose divided in Aspart tid w/meals= 68.3 units tid w/meals
Instruct pt to restart U-500 insulin at discharge- do not discharge on Lantus and Aspart insulin

Event/Task Summary Order Info

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Follow Up

- Revised formulary status
 - U-500 approved for pump
- A look at usage over 2 years
 - 8 patients / 19 admissions
 - 4 patients interchanged
 - 4 patients "Patient's home med"

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Next Steps


- Order set revision
 - Glycemic team consult
- "Home med" orders
 - Glycemic team will follow
- RN education
- Consider dividing Lantus dose into 2 doses?



SPECTRUM HEALTH

Humulin R Regular U-500 (Concentrated) Insulin Human Injection

Dana Staat PharmD
Clinical Specialist-Internal Medicine
WMSHP Spring Seminar 2011




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Objective

- By the end of this presentation, you should be able to:
 - Discuss the medication safety concerns associated with U500 insulin



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Insulin U-500

Medication Safety concerns

- U-500 insulin is used infrequently, increasing the potential for error
- Storage concerns
 - U-500 vials look somewhat similar to U-100 insulin vials
 - U-500 vials are 20 mL vs 10 mL vials of U-100
 - U-500 boxes and vials are striped to indicate their difference from U-100
 - U-500 insulin should be stored in a separate location from other insulin
 - U-500 insulin should never be sent or stored on a nursing unit due to errors that have occurred during nurse administration

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SPECTRUM HEALTH



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SPECTRUM HEALTH

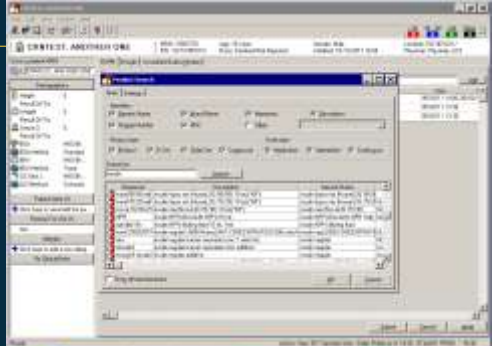
Medication Safety Concerns

Dosing concerns

- Numerous 5-fold dosage errors have been reported to ISMP
 - Prescribing errors
 - Plan: Restriction to Diabetes and Glycemia Management Service
 - Processing errors
 - Plan: Storage separate from other insulins
 - Plan: U-500 entry in PharmNet will be clearly indicated as different from other insulins

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Medication Safety Concerns

- Administration errors
 - Plan: U-500 will never be sent to the nursing unit
 - Dose will be drawn up in pharmacy
- Recommended to dispense U-500 insulin in tuberculin syringes instead of insulin syringes
 - Plan: Pharmacy will draw up dose and dispense in TB syringe
- If insulin syringes are used and 10 units are ordered and drawn up, patient will actually receive 50 units of insulin


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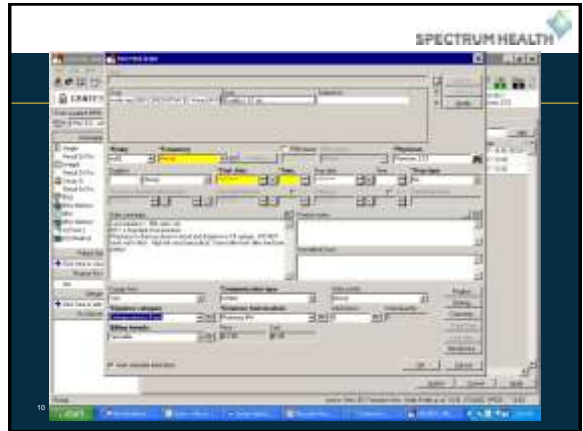
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Medication Safety Concerns

- How to enforce physician restriction:
 - U500 insulin cannot be ordered through CPOE
 - Requires a phone call by ordering physician to pharmacy
 - Pharmacy must enter through the pharmacy system (PharmNet)
- Nursing considerations
 - MAR comments
 - Independent double check

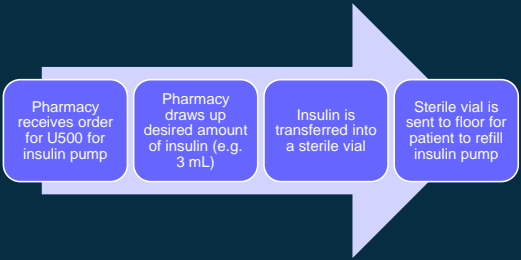


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SPECTRUM HEALTH

U500 for Insulin Pump Process



1. Pharmacy receives order for U500 for insulin pump
2. Pharmacy draws up desired amount of insulin (e.g. 3 mL)
3. Insulin is transferred into a sterile vial
4. Sterile vial is sent to floor for patient to refill insulin pump

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