Department of Pharmacy:
Adverse Drug Events Data Analysis
& Risk Reduction Strategies
October 22, 2012

Presented by:
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Assistant Director of Pharmacy,
Medication Safety
Adverse Drug Events Data Analysis & Risk Reduction Strategies

• Background
• Mechanisms to Identify ADE and ADR
• Examples of Risk Reduction Strategies
  – Hydromorphone
    • Analyzing data to find the problem
    • Creating a safer system
  – Argatroban
    • Infrequently used drugs outside of “the system”
    • Creating safety net for infrequently used medication
  – Insulin
    • Labeling to reduce confusion
Turning a Personal Tragedy Into a Passion for Avoiding Medication Errors

- Infant seen by newly licensed Pediatrician
- Treated for high fever with antibiotic
- Did not speak for years
- Started intensive speech therapy aged 3-4

PIVOTAL MOMENT
- Age 6: Hearing tests revealed severe bilateral sensorineural hearing loss, probably due to erythromycin overdose

NOW
- Assistant Director of Pharmacy, Medication Safety, Kings County Hospital Center
Turning a Personal Tragedy into a Passion for Avoiding Medication Errors

- 2008
- National Patient Safety Agency
- Resulting in Professor David Cousins recommending new labeling system to avoid mis-selection of injectable medicines

- 2010
- FDA Workshop
- Developing guidelines on Naming, Labeling and packaging practices to minimize errors

- 2007
- Medication Safety Fellow at Kingsbrook Jewish Medical Center

“Life-long disability impetus fuels my passions for helping others to avoid such errors”

Currently, Assistant Director of Pharmacy, Medication Safety at Kings County Hospital Center
Background

• KCHC is a 630-bed, acute care academic hospital in Brooklyn, New York
• Electronic Health Records (EHR)
• Computer Physician Order Entry (CPOE) implemented across the inpatient units
  – System includes decision support and standardized order sets
    – guide use of formulary drugs and protocols
• Electronic Medication Administration (eMAR)
• Bar Coded Medication administration (BCMA)
  – 90% BCMA Compliance
Safe use of opioids in hospitals

While opioid use is generally safe for most patients, opioid analgesics may be associated with adverse effects, the most serious effect being respiratory depression, which is generally preceded by sedation. Other common adverse effects associated with opioid therapy include dizziness, nausea, vomiting, constipation, sedation, delirium, hallucinations, falls, hypotension, and aspiration pneumonia. Adverse events can occur with the use of any opioid; among these are fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, and sufentanil. While there are numerous problems associated with opioid use, including underprescribing, overprescribing, tolerance, dependence, and drug abuse, this Alert will focus on the safe use of opioids that are prescribed and administered within the inpatient hospital setting. The Joint Commission recognizes that the emergency department presents unique challenges that should also be addressed by the hospital, but may not be directly addressed in this Alert. This Alert will provide a number of actions that can be taken to avoid the unintended consequences of opioid use among hospital inpatients.
Harm caused by the drug (adverse drug reactions and overdoses) and harm from the use of the drug (including dose reductions and discontinuations of drug therapy).
“Deep Dive” Medication Chart Review

Adverse Drug Reactions Data Analysis (Jan-Dec 2011)

- **Reported by various ways:**
  - Adverse Drug Reaction (ADR) Hot-line
  - Behavioral Health Service via email
  - Fall Committee Monthly Reports of Patients Falls
  - Recent: December 2011 Code 99 Patients List
    - Review any earlier adverse drug reactions prior to date/time of fall

- **Assistant Director of Pharmacy, Medication Safety:**
  - Review each reported adverse drug reaction
  - Fall Committee Monthly Reports - Review each patient’s medication profile before and after documented date/time of fall

- **Generate analysis of medications that may cause ADRs**

- **Drill down to the significant timing and doses:**
  - Are the medications classified as high alert medications?
  - Was it a medication error?

Medication Errors Data Analysis

- **Evaluate medication errors – Jan-Dec 2011 data entries**

- **Reporting Process:**
  - Prescribing, Dispensing, Administration, Documentation, Computer

- **Medication Safety**
  - Tracking and trending

- **Drill down to the significant problems in medication errors**

- **Identify the most common issues**
  - Determine what is the internal data telling us?
  - Risk reduction strategies to reduce the identified problems in medication-use process

Updates: Congestive Heart Failure (CHF) Readmission Task Force and Medication Reconciliation
Medication Safety Issues:
HYDROMORPHON
Multidisciplinary teamwork
HYDROMorphine
A High Alert Drug

• Assemble a multi-disciplinary team
• Share and learn meetings as a safety initiative
• Focus on patterns of HYDROMorphine usage
• Understand potency of HYDROMorphine
  – 1mg IV HYDROMorphine = 7mg IV morphine
• Review to remove route “IM” (intramuscular)
• Review practices for assessment
  – Guidelines for monitoring and documentation (vital signs & sedation scale)
HYDROMorphone Issues

• KCHC Internal Database Findings
  – Adverse Drug Reactions
    • Naloxone administration as rescue drug
  – Medication Errors

• Nationwide and global error reports
  – 2008 MEDMARX top list of drugs involved in harmful errors
  – Canadian Study: 251 deaths in past decade due to oral and IV overdoses

KCHC Initiative Project: HYDROMorphe Safety: 4-4-12

• Analysis Data: June through December 2011 HYDROMorphe administration reports - INITIAL FINDINGS
• 292 CP, ED patients & inpatients prescribed for 7 months 2011 using “Dosage” Field
• There was a total of 9, 832 events – (IVP, Subcutaneous, IM, Oral)

Data Analysis KCHC HYDROMorphe

• Prescribed Routes Frequencies Percentage:
  • “IM” —— 97.96%
  • “IVP” —— 0.48%
  • “Subcut” — 0.56%
  • “PO” ——— 0.93%

  98% “IM”

• Frequency of Administered “IM” Dosage of all Patients:

<table>
<thead>
<tr>
<th>Dose (mg)</th>
<th>Frequency (9, 832 Events)</th>
<th>Percentage %</th>
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<tbody>
<tr>
<td>0.5</td>
<td>1</td>
<td>0.01</td>
</tr>
<tr>
<td>1</td>
<td>406</td>
<td>4.22</td>
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<tr>
<td>1.5</td>
<td>2</td>
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<tr>
<td>2</td>
<td>1453</td>
<td>14.97</td>
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<tr>
<td>3</td>
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<td>4</td>
<td>2872</td>
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<td>0.03</td>
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<tr>
<td>8</td>
<td>195</td>
<td>2.02</td>
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</tbody>
</table>

Findings-Clinical Assessments

Issues with “IM” route of injectable HYDROMorphe:

1) “IM. use may resulted in variable absorption and a lag time to peak effect”

2) “The American Pain Society discourages intramuscular (IM) administration of pain medications. IM administration is painful, yields wide fluctuation in absorption, has up to a 60-minute lag time for analgesic effect, rapid fall off, and may cause sterile abscesses and fibrosis of muscle and soft tissue.”
   (Reference: American Pain Society, Postural Approach to the Treatment of Post-Care Condition, 2006)

3) “...IM injections, in general, are dependant on certain variables, such as blood flow to the muscle and the muscle group into which the medication is injected.

Over 80 % Dosage 4 mg or Higher
## Risk Reduction Strategies

1) “IM” route removed from QuadraMed pre-built order
2) “IM Route Alert”
3) HYDROMorphonone 1 mg = Morphine 7 mg
4) Morphine Equivalents posted for each dose choice

### Procedure Table

<table>
<thead>
<tr>
<th>Procedure Table</th>
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</thead>
<tbody>
<tr>
<td>Procedure Table</td>
</tr>
<tr>
<td>Facility: Kings County Hospital Center</td>
</tr>
<tr>
<td>Procedure: HYDROMorphonone HCL (9762)</td>
</tr>
<tr>
<td>Typical Order Information</td>
</tr>
<tr>
<td>#</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td>5</td>
</tr>
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**Subcutaneous**

<table>
<thead>
<tr>
<th>Dose</th>
<th>Equivalent</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 mg SubQ STAT</td>
<td>equal to about 14 mg of Morphine</td>
</tr>
<tr>
<td>4 mg SubQ STAT</td>
<td>equal to about 28 mg of Morphine</td>
</tr>
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</table>

**Injection**

<table>
<thead>
<tr>
<th>Dose</th>
<th>Equivalent</th>
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<tbody>
<tr>
<td>1 mg SubQ q 4h prn moderate pain</td>
<td>equal to about 7 mg of Morphine</td>
</tr>
<tr>
<td>2 mg SubQ q 4h prn severe pain</td>
<td>equal to about 14 mg of Morphine</td>
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**IV Push**

<table>
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<th>Dose</th>
<th>Equivalent</th>
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<tbody>
<tr>
<td>1 mg IVP now over 2-3 min</td>
<td>equal to about 7 mg of Morphine</td>
</tr>
</tbody>
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**Oral**

<table>
<thead>
<tr>
<th>Dose</th>
<th>Equivalent</th>
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</thead>
<tbody>
<tr>
<td>2 mg po q 4h prn moderate pain</td>
<td>equal to about 14 mg of Morphine</td>
</tr>
<tr>
<td>2 mg po q 6h prn moderate pain</td>
<td>equal to about 14 mg of Morphine</td>
</tr>
<tr>
<td>4 mg po q 4h prn severe pain</td>
<td>equal to about 28 mg of Morphine</td>
</tr>
<tr>
<td>4 mg po q 6h prn severe pain</td>
<td>equal to about 28 mg of Morphine</td>
</tr>
</tbody>
</table>
Risk Reduction Strategy: Educational Screen Saver

HYDROmorphe on EHR Desktop

Home Run
HYDROmorphe
1 mg

≈

Touchdown
Morphine
7 mg

Listed in the Top 10 Drugs Causing Patient Harm in ....
- MEDMARX database

Screen Saver on EHR Desktop
Argatroban RCA: System Enhancement
Snapshot: Argatroban Error That Reached the Patient

CPOE Non-Formulary Order

Pre-Printed Argatroban Label With Typed in CPOE order rate
Argatroban IV Therapy Process: Medication Error RCA

- Describe the medication error involving argatroban IV from prescribing and administration
- Pharmacist reviewed and prepared correctly Argatroban IV
- Develop initiatives to prevent future repetition of same argatroban IV medication error
  - Ensure the safety of high-risk intravenous argatroban IV therapy

1. Order Argatroban NF Drug CPOE:
   1) NF Section
   2) IV Fluid Order

2. MD prescribed:
   a. Dose: 38 mcg/min (stat) @ 12/28/10 18:50
   b. Instruction field: "mix Argatroban 250 mg in 250 ml NS, infuse @ 38 mcg/min, adjust according to PTT"
   c. Problem field “Pneumonia due to other specified bacteria”

3. ICU RN reviewed order on 12/28/10 20:09
   a. WHAT TIME DID THE ICU RN CALL TO PHARMACY FOR ARGATROBAN DRIP?

   ICU RN: checked aPTT around 11pm

4. RPh double checked:
   a. the order, pt's profile, wt
   b. calculate manually the correct rate in mL/hr from mcg/min order
   c. entered in QuadraMed medication IV order
   d. Prepared argatroban drip
   e. Sent up by 11 pm to ICU

5. ICU RN entered in ALARIS Pump around 11pm: 38 mL/hr
   - RN thought of mL/hr when looked at Argatran IV drip label: “RATE=38 MC/MIN=2.28ML/HR”

   ERROR DISCOVERED 3AM 12/29/10

5MD and RN communicated with each other on error drip rate.
6MD called RPh at 3AM to recalculate
8MD again prescribed Argatroban at 03:32 STAT

7. RPh around 3AM:
   a) calculated from 38 mcg/min into mL/hr for MD
   b) Recommended MD to order aPTT after told of overdose and NOT TO ORDER UNTIL RECEIVED APTT

8. LAB CALLED at 04:16
   CRITICAL RESULTS

9. MD D/C active Argratoban order around 08:10

10. MD prescribed:
    a. Dose: 38 mcg/min (stat) @ 12/28/10 18:50
    b. Instruction field: "mix Argatroban 250 mg in 250 ml NS, infuse @ 38 mcg/min, adjust according to PTT"
    c. Problem field “Pneumonia due to other specified bacteria”

11. RPh calculated manually the correct rate in mL/hr from mcg/min order
12. Entered in QuadraMed medication IV order
13. Prepared argatroban drip
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15. ICU RN reviewed order on 12/28/10 20:09
    a. WHAT TIME DID THE ICU RN CALL TO PHARMACY FOR ARGATROBAN DRIP?

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16. ERROR DISCOVERED 3AM 12/29/10

17. 5MD and RN communicated with each other on error drip rate.
18. 6MD called RPh at 3AM to recalculate
19. 8MD again prescribed Argatroban at 03:32 STAT

20. LAB CALLED at 04:16
    CRITICAL RESULTS

21. MD D/C active Argratoban order around 08:10

IV Fluid Order Procedure
Non-Formulary procedure built as typical order
Argatroban procedure flagged as “High Alert Medication”
Order concentration: standard IV dilution concentrations
Typical rate orders with weight-based dosing
Non-Formulary vs Formulary Database Build

- Order set NOT embedded in Anticoagulation Pathway (Non-Formulary)
- Requires Chief of Service approval for non-formulary medication
- Created customized Duplicate Warning Advisory Alert

**Duplicate Warnings Advisory Alert**

**Required comment**
Pharmacist accepts order and selects product - shows “High Alert Medication”

24 hour Automatic Stop Order

Pharmacy IV label produced after order activation
Non-Formulary Database Build

- Nursing eMAR shows “High Alert Medication”
- Required dual nursing verification for med administration
Patient’s Profile: Non-Formulary Argatroban

WARNING: “HIGH ALERT MED”
KCHC Pharmacy Department
Risk Reduction Strategies

• QuadraMed Pre-Built Non-Formulary Order
  – “HIGH ALERT MEDICATION
  – “DUPLICATE WARNING ADVISORY ALERT”

• IV Label emphasizing mL/hr first then mcg/min

• Smart Pump Library updated with Argatroban dosing limits
Dear Hospital Administrator,

The New York State Department of Health Patient Safety Center is kicking off a new initiative to provide facilities with important feedback from the New York Patient Occurrence and Tracking System (NYPORTS). This letter concerns several recently reported medication errors involving Argatroban. Argatroban is an anticoagulant often used for patients with heparin-induced thrombocytopenia. It is a high alert medication, indicating heightened risk of causing significant patient harm when it is used in error. Several commonalities have been identified in the root cause analysis reports received from facilities over the past several years.

- Argatroban was not included in clinical decision support systems and drug libraries, including smart pump drug library and pharmacy drug verification systems. This prevented the systems from providing alerts following errors in dosing or in pump programming.
- Argatroban was not on the high alert medication lists. This meant the dose could be dispensed and administered without the double checks in place for other high alert medications.
- The relative infrequency of Argatroban use contributed to inexperience of medical, nursing and pharmacy staff in safe dosing and administration. In particular, hepatic and renal impairment should be considered when choosing the most appropriate direct thrombin inhibitor and in determining the dosing schedule.

Since Argatroban has no known reversal agent, it makes awareness and prevention the principal mechanisms for avoiding serious patient harm due to overdose. Based on our review of Argatroban events PSC recommends that each facility:

- Review, and revise as necessary, high alert medication lists, IV pump drug libraries, and other drug information systems, to assure inclusion of Argatroban and implementation of appropriate dosing and error prevention activities.
- Determine if sufficient safety systems are in place with regard to Argatroban, and other high alert medications, to provide evidenced based treatment upon detection of an overdose.
- Consider implementing additional safety measures and education efforts when a high alert medication is new to a facility/unit/diagnostic and/or therapeutic patient population.

The Department hopes that this type of communication is helpful to your pursuit of improving patient safety. If you have any questions, please contact the Patient Safety Center at (518) 408-1219 or patientsafety@health.state.ny.us.

Sincerely,

John Morley
Medical Director
Office of Health Systems Management

Colleen McLaughlin
Patient Safety Center
Across the pond: global sharing of a unique high alert medicine novel labeling system to reduce the risk of selection errors when dispensing insulin

Presented by:
Miriam Klein, B.S., Pharm.D., RPh.
Assistant Director of Pharmacy, Medication Safety
Kings County Hospital Center (KCHC)
Brooklyn, New York

Presented as part of Management Pearls 2011
Background: Proactive Insulin Storage Labels

- KCHC Pharmacy Department identified high alert injectable medication insulin storage issues
  - Problematic storage & dispensing many formulations of insulin vials looking alike
  - Medication storage bins clumsy, messy & chaotic in refrigerator
  - Labels not clearly printed nor standardized
- Channeled 6S theme into implementing safer hospital-wide medication storage: sort, straighten, standardize, shine, safe and sustain
  - Created “home grown” unique novel labeling system
- 2009 as “Best Practice” by The Joint Commission
- Won NYC HHC 2010 Patient Safety President’s Award
- Presented at 2010 Patient Safety Congress (UK)
Sharing Global:

- Harrogate & District NHS Foundation Pharmacy Department employed novel labeling system
  - Adopted from KCHC Pharmacy Department poster shown in May 2010 at Patient Safety Congress
- Numerous dispensing errors with insulin at Harrogate and District NHS Foundation Trust
  - Increased choices of insulin & their devices lead to confusion
  - Similar packaging, labeling and storage on same shelves
- Implemented eye catching labels attached to clear plastic unit trays
  - Labels mirrored the colours in the insulin packaging
  - Labels included words “high risk” in shape of a stop sign
    - To alert staff to double check the product selected
Results -

- Pharmacy staff educated on changes particularly difference between Humalog® and Humalog Mix 25®
  - Both causing the most errors

- Between 2009-October 2010 before implementation of safer labeling system, ten incidents relating to incorrect insulin/form of insulin were identified

- Since then, only one incident of incorrect insulin dispensed for a product that had not yet been properly labeled
Special Thanks

- Sarah Abbas, Lead Pharmacist, Medicines Information & Paediatrics
  Harrogate and District NHS Foundation Trust
- Andrew Alldred, Clinical Director Clinical Support and Cancer Services/Director of Pharmacy
  Harrogate and District NHS Foundation Trust
- Christopher Russo, Director of Pharmacy
  Kings County Hospital Center
Special Thanks

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- Leslie Williams, Assistant Coordinating Manager
- Henry Burns, System Project Leader
- Claire Patterson, Associate Executive Director
- Dr. Naresh Sharma, Patient Safety Officer
- Dr. Peter Peacock, Chief Medical Informatics Officer
- David Quinn, Data Analyst
- KCHC Multi-Disciplinary Team of prescribers, nurses and pharmacists
- KCHC Leadership
- Ryan A. Leonard, formerly of KCHC
- GNYHA Clinical Pharmacy Team-HYDROmorphe Research Articles
THE END