ADVERSE DRUG EVENTS: WHY THEY HAPPEN AND HOW TO PREVENT THEM

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Wisconsin, 2006
- 16 year old in labor
- + for beta strep/ordered for PCN
- Patient began seizing, unclear as to why
- Full code called
- Mother died; infant son survived
- Nurse charged with criminally negligent homicide
- What went wrong?????

What do We Really Know about Medication Errors?
- Headline news: 98 K deaths!!!!
- Actual Research:
  - HMPS, 1990
  - UCMPS, 1999
- Challenge: as little as 1-5% of errors reported

Adverse Drug Event
- ADE: injury due to medication
  - Preventable (error)
  - Not preventable (unintended consequence)
    - Rash, confusion, unknown allergy
  - Potential
- Error: preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer.

Medication Administration
Estimated 30-40 steps in med management

Opportunities for Error
Upstream versus Downstream

- Errors intercepted “upstream”: prescribing, order entry versus at the point of administration or “downstream”
- Once in the hands of the nurse, less likely to intercept an error

Background

- Errors in medication administration account for:
  - 2.1 million injuries annually
  - Cost more than 3.5 billion dollars to treat
  - Result in 100,000 deaths annually as a result of errors in prescription medications
  - At least one error will occur during pt’s stay (estimated)
  - Frequency estimated at 5 errors/100 medications
  - At least 25% are preventable

Institute of Medicine (IOM), 2007

Background

- More than 4 out of 5 Americans take at least 1 med daily
  - Prescribed, OTC, herbal, vitamin
  - 1/3 take 5 different meds

Recommendations, IOM 2007

- Strong MD-pt partnership [? Surgeons]
- Consumers: maintain records of med [??]
- Implement error prevention strategies: CPOE, EMR, bar-coding, smart pumps, clinical decision support systems [??]
- HRO, internal monitoring systems [??]

What Do We Know in 2013?

- 2011: FDA received ~180K reports of serious/fatal ADEs [> of 9.4% from 2010]
  - Voluntary reports from consumers, health professionals [21,000]
  - Manufacturers [159,000]

Bleeding  Hemorrhage  ARF  Stroke
Severe liver injury  Pancreatitis  Rhabdomyolysis
Severe cutaneous Rxs  Suicidal thoughts

ISMP Medication Safety Alert, June 2012(10), Issue 6

Drugs w/ Largest # ADE

<table>
<thead>
<tr>
<th>Drug</th>
<th>ADEs</th>
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<tbody>
<tr>
<td>Dabigatran (Pradaxa)</td>
<td>*bleeding, RF</td>
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<tr>
<td>Warfarin</td>
<td>Duloxetine (Cymbalta)</td>
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<tr>
<td>Levoflaxin</td>
<td>Ciprofloxacin</td>
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<td>Carboplatin</td>
<td>Trimethoprim</td>
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<tr>
<td>Lisinopril</td>
<td>Sulfamethoxole</td>
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<td>Cisplatin</td>
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Implications for Nurses

- Monitoring
  - S/E burden
  - Creatinine clearance-?
  - Liver function-?
- Patient teaching
- Med rec
- Indications for use
- Appropriate use of safe systems

ISMP Medication Safety Alert, June 2012(10), Issue 6
Patients Have the Right To:

- Be the source of control for all medical management decisions
- Accept/reject medical therapy
- Ask questions/be informed
- Expect providers to tell them when an error has occurred and its significance
- Ask provider to report ADE


Wisconsin, 2006

- July 5th, 2006- 16 year old in labor, + strep
- Nurse hung PCN [she thought]
- Expectant mother began sz'ing, gasping for air-died
- Per ME: died from rapid infusion of “lethal chemicals into her body”:
  - Epidural solution

Criminal Complaint

- State of Wisconsin vs Plaintiff
- Failure to provide adequate medical care resulting in great bodily harm
- Defendant's lawyer:
  - Guilty of failing to read a label
  - Prosecutor: Not that simple
  - Nurse violated several policies- “dangerous”

Criminal Complaint

- Failure to obtain order to remove “lethal chemicals” from locked storage system
- Disregard of hospital policy by failing to scan bar code
  - Documented as trained
  - Disregard bright clearly written warning on epidural bag
- Failure to follow approved rate for pediatric meds: rapid injection of lethal chemicals to save time
- Failure to perform 5 rights of med admin

What Went Wrong?

- Nurse w/ 15 yrs experience
  - Highly regarded by her peers
- Role of fatigue- RN had worked 16 hours previous day; slept at hospital to make 7 AM shift
- Both the epidural and the PCN were in the room at the same time, both waiting to be administered.
- Role of distraction- young pt, anxious and crying

What Went Wrong?

- Safety systems in place
  - BCMA- ensures the 5 rights
  - Challenges-not able to scan clear bags of fluid
- Automated med dispensing system
  - Unclear as to processes in place
  - Custom had been to have epidural sol'n waiting for MD
  - PCN had been removed correctly by a colleague
At Trial…

“It should have been my life, not her's. Deep anguish and remorse are the sentences I will serve for all time. I would give my life to bring her back.”

Sentence: 2 misdemeanor charges; 3 years probation; license suspended
Hospital settles for 1.9 mil to Gregory

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Epidural Monitoring

- Pt s/p TKA, GA + epidural
- Chronic pain
- Obese
- ? OSA
- Transferred to inpt unit
  - POD # 1 eve- OOB x 3 hours
  - Returned to bed, >>> pain
  - s/b anesthetia
  - Bolused w/ lido
  - Frequent VS by inpt nsg staff
  - Codes
  - Transferred to ICU

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What Went Wrong?

- Unable to do meaningful neuro assessment in unstable pt
- Unable to reduce prop d/t agitation
- Neuro exam post extubation- pt unable to move LE but thought d/t lingering sedation
- Neg w/u for PE and MI
- Lack of focused attention on risk of epidural hematoma
- ? knowledge deficit

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Epidural Catheter

- Post-op pt recovered in ICU [weekend eve]
- Epidural catheter leaking - capped
- Pt. transferred to inpt unit
- Pt c/o pain, epidural orders still available
- Nurses started epidural infusion
  - Regular IV tubing
  - Pt hypokalemic- ordered for 20 mEq
- Attached to Y-port of tubing on epidural

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What Went Wrong?

- Inadvertent continuation of standing order
- Epidural P and P did not mention need for special tubing
  - Floor nurses had never set one up before
  - Special epidural tubing not stocked on unit
- Independent double check
  - New policy, process
  - Nurses unaware that it involved checking tubing connections
Safe Transfer of Care

- Pt in PACU s/p major urinary reconstructive surgery
- Epidural catheter replaced d/t lack of efficacy, bolused
- Required on-going neo gtt to maintain BP
- Decision to transfer to ICU overnight
- Attached to monitor in ICU:
  - RR 3-4
  - SBP 40’s
  - O₂ sats: <80
  - unresponsive

- Intubated upon arrival, code called
- Fluids, neo IVP
- Vitals stabilize, pt extubated POD #1
- Acting strange, restless and agitated
- No short term memory
- ??? Hypoxic brain injury
- Pt died 6 months later

Case Review

- Pt unaccompanied by PACU RN
- Not monitored
- Epidural bolus after reinsertion, pt transferred shortly thereafter
- Presumed hypotension, resp depression d/t epidural bolus
- Case settled based in part on ASPAN Standards recommendation for safe transfer of care

Recommendations for Safe Administration of Epidurals

- Safe systems
  - BCMA
  - Smart pumps
  - AMDD
  - Standardized order sets
  - Bright labeling to alert “epidural”

Recommendations for Safe Administration of Epidurals

- Nursing practices
  - High alert med: IDC
  - 5 rights
  - Tubing connections
  - Dedicated pump/pole
- Nursing practices: care of
  - Education
  - What can go wrong...

Recommendations for Safe Administration of Epidurals

- Monitoring and documentation
  - Pain
  - LE movement, sensation
  - Dermatome levels
  - Insertion level [depth documentation]
  - Site assessment
  - V5
  - S/E burden
  - Appropriateness of dose, use, monitoring devices
Case Study: Bill

- 71 yo male, L TKA
- ASA 3, BMI 31.3, PMHx:
  - Afib: coumadin, recent TIA
  - HTN
  - Cardiomyopathy, CHF
  - OSA
- Plan GA and regional

- Pre-op: tylenol, oxycontin, lyrica, versed, fent
- L femoral nerve block placed in pre-op
  - 40 cc 0.5% ropivicaine
- Pt unresponsive, tonic/clonic seizing
- EKG changes
  - V-tach 120-130
- Intralipid infusion initiated
- Versed, prop, sux: intubated

Case Study: Bill

- PACU: Vent, 100%, sats 100, HR 118 afib, BP 110/67 on neo
- Extubated 30 mins later, MAE, c/o pain and some weakness bil UE
- Eval. by neuro, cardiology, medicine
  - Transferred to tele floor later that day
  - Did well- only c/o UE pain, weakness

- Intravascular administration of local anesthetic = cardiovascular collapse
- Sxs:
  - Ringing in ears, metallic taste
  - Motor twitching, seizures
  - Ventricular ectopy, VT/VF, astole
- Lipids: binds with lipid soluble local anesthetic to reduce plasma level
- Recommendations:
  - Staff education
  - Lipid rescue available in high risk areas

PCA by Proxy #1

- 72 yo woman s/p cancer surgery
- Obese, COPD
- PCA prescribed and set up in PACU
- Restless and agitated in PACU; unable to verbalize pain
- RNs pushed PCA button for 48 hours

PCA by Proxy

- Pt arrested-
- Hypoxic brain injury-died several months later w/o ever regaining consciousness
- What went wrong?
PCA Pump vs Call Light
- Father of pt in sickle-cell crisis
- Pushed button on PCA, thinking it was call light
- Overdose of morphine
- Respiratory crisis
- 18 yo now on ventilator
- At trial, MD testified that PCA was programmed to make it impossible for pt to get OD which could lead to resp depression

PCA by Proxy # 3
- Pt’s nurse knew that only the pt should push the PCA button
- RN told pt’s daughter to push button while mother slept; pt s/p bil TKR
- 0700: difficulty breathing
- Cardiac arrest, anoxic brain injury
- Settlement: $8,000,000 for life-long care

PCA Safety Strategies
- Establish selection criteria
- Standardized order sets
- Carefully monitor pts
- Require 2 clinicians to independently double check settings
- Educate pts and families
  - NO PROXY USE
- Educate staff

Postoperative Patient
- Adult male post-op, significant c/o pain
- Received morphine, versed, hydromorphone
  - In report: “still has pain”
- Transferred to inpatient unit
- VS: RR< HR>, more comfortable
- Nurse checked pt 3 times/next hour
- Bedside alarm: pt unresponsive, coded
- Resuscitated and survived
- Review: pt had received > 100 mg morphine in PACU

Post Anesthesia Orders
- Pt s/p abd surgery, gea
- Ordered for IV dilaudid while in PACU
- Post surgical orders: dilaudid PCA
- CPOE/EMR system did not d/c PACU orders on transfer
  - Inpt RN saw IVP dilaudid available for pt who was c/o pain
  - Administered IVP dilaudid as well as PCA
  - Pt unmonitored, resp arrested

IV Fentanyl
- 17 yo s/p tonsillectomy
- GEA, rocuronium, fent up front
- Restless on arrival to PACU- fentanyl given by CRNA
- RN does admission VS
  - Leaves for coffee
- 2nd RN “asked to cover”
- Checks on pt- not breathing- alerted staff
IV Fentanyl

- Anesthesia present, pt reintubated ~ 50 minutes after arrival to PACU
- Transferred to acute care facility
- Pronounced brain dead 2 weeks later
- Life support w/drawn

What Went Wrong?

- Lack of vigilance
  - Pt required on-going 1:1 PACU nursing care
- Lack of knowledge of rapid onset of med
- Equipment - alarm on silence - default mode
  - New monitors
  - No resp. wave form or RR on monitor
  - ? no documented training
  - 2nd RN unaware of alarms "off"

Challenges w/ Opiates in the PACU

- Large doses of narcotics
- Focus on pain score vs evaluation of sedation as well as pain
- Little or no use of adjuvants
- Syringe push method; no safeguards except for the "user"
  - Versus "smart pump" technology
- ? Pharmacy oversight of dosage?

Fentanyl Patch #1

- Child complained of neck pain
- Foster mom gave motrin
- ALSO placed a leftover fentanyl patch on child's ear
- Following day, child found unconscious
- Pronounced dead on arrival
- Foster mother charged with criminal gross negligence

Fentanyl Patch #2

- Pt on morphine postop
- D/c to home POD #1
- Nurse applied fentanyl patch to pt's skin prior to d/c; gave him 3 patches to take at home
- Pt also had script for oxycodone
- Pt died 12 hours after discharge
- Coroner: d/t fentanyl patch
- Pt was opiate naïve, OSA, bronchopneumonia

Fentanyl Patch #3

- Family visiting grandmother at LTC facility
- 2 year old playing on the floor w/ toys
- Died 2 days later
  - W/u = piece of tape in throat
  - Toxicology = fentanyl
  - Tape = fentanyl patch
- LTC facility investigated
  - Used fentanyl patches on tables, floor, wastebasket, stuck to railings
Fentanyl Patch

- 2012 FDA: 26 children exposed to fentanyl patches
  - 16 cases < 2 years old
  - 10 died, 12 hospitalized

Safety Strategies

- Fentanyl patch is NOT appropriate for an opiate naïve pt
- Appropriate only for opiate tolerant, chronic pain
- Pt education must be provided prior to d/c
- To include proper disposal of patch
- Clear prescriber/dispensing guidelines needed
- Prescribed at lowest dose needed for pain relief
- Only take as directed
- NEVER share with others

Post-Surgical Nursing: Departure for Standard of Care

- Pt s/p breast reconstruction post breast ca
- OR: 10 mg morphine
- PACU: add’l morphine + PCA: 9 mg total
- Tx to telemetry
  - Not placed on telemetry
  - Nurse did not check pt
- Resp arrest/hypoxemia/permanent brain injury
- Court awarded pt’s husband $1.6 million

TJC: Sentinel Event Alert Safe Use of Opioids in Hospitals

- Opiates: drug most frequently assoc. w/ ADE
  - Respiratory depression preceded by
  - Sedation
  - Dizziness
  - N/v
  - Constipation
  - Delirium
  - Falls
  - Aspiration pneumonia
  - Death

Reported ADEs (2004-2011)

- 47% wrong dose errors
- 29% improper monitoring
- 11% other: excessive dosing, med interactions, adverse drug reactions

* represents small proportion of actual events

Opiate Associated ADEs

- Potential causes
  - Drug-drug interactions
  - Lack of knowledge about potency differences
  - Improper administration and prescribing of mult. opioids & modalities
  - Inadequate monitoring

Legal Eye Newsletter, August 2010

ADEs w/ Opioids
- ASA closed claims database= 7000 cases
- 144 assoc w/ acute pain management
- 15 cases assoc w/ PCA
- 16 assoc w/ central neuraxial narcotics
- Resp event onset in 1st 24 hours
- 50% PCA
- 62% neurxial
- 60% died/13% permanent brain damage/25% no permanent injuries

Safe Use of Opioids
- ID pts at risk
  - OSA
  - Morbid obesity
  - Older adult
  - Opiate naïve
  - Post abd or thoracic surgery
  - Longer recovery time post GA
  - Receiving other sedating meds

Safe Use of Opioids
- Assess sedation levels
- Consult w/ pharmacist, pain expert for equianalgesic dosing calcs
- Multimodal
- Hand-offs
- Avoid dosing based on arbitrary pain rating
- Continuous monitoring??????

Anesthesia Patient Safety Foundation
- Continuous monitoring of oxygenation (pulse ox)
- Reduced efficacy w/ supplemental O2
- Capnography: estimate end-tidal CO2 & assess breathing
- Use when supplemental O2 indicated
- Monitoring system linked to reliable response system
- Reduce risk
  - ID those at risk
  - Order appropriately
  - Monitoring as clinically indicated

Medication Reconciliation #1
- 64 yo female in ED w/ szs
- Med history: metoprolol BID
- RN entered into computerized med rec form as methadone
- Pt transferred to inpt unit
- Admission orders written on floor based on med list obtained in ED
- Pharmacy questioned order, contacted MD: cont med as ordered

Medication Reconciliation #1
- Pt received 2 doses methadone 100 mg
- Arrested
- During code, med list reviewed- narcan administered, pt recovered
**Medication Reconciliation #2**

- Ambulatory surgery
- 80 yo pt s/p cysto, bladder bx
- Hx of a-fib, on coumadin
- Coumadin stopped 5 days before OR
- Pt unclear as to when to resume
- Suffers stroke 5 days postop

**Safety Strategies for Medication Reconciliation**

- Obtaining accurate list
- Partner w/ the pt
- Ensure pharmacy review of home med list as well as orders
- Review w/ pt/family med, indication for use, SE prior to administration
- If known opiate naïve, question
- D/c teaching-

**Automated Medication Dispensing Device**

- PACU pt c/o nausea
- RN went to the AMDD for antiemetic
- Vial of phenylephrine removed & administered to pt
- Patient required a prolonged stay in the PACU to manage >HR, BP and HA

**Indianapolis, 2006**

- September, 2006
- Neonatal ICU
- Heparin routinely used for umbilical lines
- Six infants received heparin, 10,000 units/ml
- 3 infants died

**What Went Wrong?**

- Human error- wrong medication stocked
- Human error- nurses never checked the label on the heparin
- Entered the correct patient name, profile approved heparin, drawer opened that contained heparin-**nurse never verified**
- Labeling- similar color and size vials

**Ventriculostomy Catheter**

- Pt w/ intracranial ventriculostomy catheter
- Ordered for dopa, mag, amiodarone, K
- RN attached IV tubing to ventriculostomy drainage catheter
- Error discovered by another RN after 296 ml infused- pt died
- Court agreed w/ expert that intracranial fluid overload was cause of death

Legal Eye Newsletter, April, 2007
Safety Strategies
- Clear labeling of tubes, lines
- Ensure tubing connection as part of the “rights” of medication administration, IDC
- Color coding of tubes, lines

Denver, 1996
- One day-old infant
- ?? Syphilis
- Penicillin G benzathine
- Telephone order
- Spanish speaking family
- Nurses unsure of med-limited resources
- Dose too large for IM
- Infant dies

What Went Wrong?
- Limited resources
- Pharmacist misread “u” as a zero
- Consulting physician outside hospital
- Language barrier
- **Nurses realized that the dose sent to them was too large for IM- never questioned further
- On case review, it was determined that over 50 problems in the system contributed to this patient death.

How Do We Teach our Patients?
- Speaks English, must read English
- Busy, focus on d/c process
- D/C teaching
  - Primary language
  - Encourage pt to discuss script w/ pharmacy
  - Be clear on indication for use
  - F/U- question med management

Strategies Used by Critical Care Nurses
- Exploratory study- focus groups
- N= 20, 5 critical care units
- Factors associated w/ errors
  - High acuity
  - Nurse-pt ratio
  - Increased work demand/decreased resources
  - Intimidation
  - Poor communication

Strategies Used by Critical Care Nurses
- Identify errors:
  - Knowing the pt
  - Knowing the players
  - Knowing the plan of care
  - Surveillance
  - Knowing policy/procedure
  - Double checks
  - Using systematic processes
  - Questioning
Closing Thoughts

- A medication error can change the life of many people in an instant:
  - Nurse, patient, family, organization
  - Only by reporting errors, can flaws in the system be changed
  - Our pts are one of the most vulnerable
  - A nurse's hands are the last ones to touch a medication before it reaches a patient
  - Other than the patient, the nurse is often the last one who can intercept a medication error

Strategies Used by Critical Care Nurses

- Interrupt errors
  - Offer assistance
  - Clarifying
  - Verbally interrupting
- Correct errors
  - Persevering
  - Being physically present
  - Involve another MD, RN
  - Review plan of care
  - Reference standards