Objectives

1. Review the top ten medications involved in adverse drug events.
2. Discuss the top ten mistakes made that lead to adverse drug events.
3. Describe current recommendations for the prevention of adverse drug events.

ADE: Adverse Drug Event

A Case Example: Mr. B is a 68-year-old man with colon cancer. He has a past history of CHF and AFib. His regular meds include furosemide 40 mg daily, dofetilide (Tikosyn) 250 mg every 12 hours, and warfarin 5 mg daily. He recently received treatment for his cancer with 5-fluorouracil. A week after his last treatment, he developed significant diarrhea. He continued all of his meds as prescribed and now presents with palpitations and unusual bruises on his arms and legs. On admission, his INR is 7.5, his potassium is 2.5 mEq/L, his QTi is 686 msec and he has developed ventricular polymorphism.

Categories of ADE

- Adverse Reactions
- Therapeutic Failures
- Withdrawal Events
- Drug Overdoses
- Medication Errors

ADE: Adverse Drug Event

Mr. B’s conditions are all drug-induced

1. Diarrhea is an adverse effect of 5-FU
2. Diarrhea causes hypokalemia
3. Furosemide causes hypokalemia
4. Hypokalemia can cause QT prolongation especially when coupled with dofetilide
5. Increased INR levels occur when warfarin is coupled with 5-FU

Medication Errors

“Any 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..."
Medication Errors

- Most common type of ADE
- Can occur at any point in the medication process
  - Prescribing phase: 49% to 56%
  - Administration phase: 26% to 34%
  - Dispensing phase: 14%
  - Transcribing phase: 11%

Medication Errors

- Errors of Commission: 
  Doing Something Wrong
    - Breach Of One Of The 5 Rights
      Wrong Drug, Dose, Time, Patient, Route
    - Look Alike-Sound Alike Mistakes
    - Misinterpretation of Handwriting
    - Inappropriate Drug Or Dose Ordered

Beers Criteria

- alprazolam (Xanax), indomethacin (Indocin), amiodarone (Cordaron), amitriptyline (Elavil), ketorolac (Toradol), lorazepam (Ativan), barbiturates, meperidine (Demerol), bисcodyl (Dulcolax), meperbamate (Equanil), chlorzoxazone (Librium), methyldopa (Aldomet), chlorpromazine (Chlor-Trintpec), chlorpropamide (Diabinese), cimetidine (Tagamet), naproxen (Naprosyn, Aleve), nifedipine (Procardia), cyclobenzaprine (Flexeril), oxybutynin (Ditropan) diazepam (Valium), pentazocine (Talwin), digoxin (Lanoxin), diphendhydramine (Benadryl), promethazine (Phenergan), dipyradomole (Persantine), disopramide (Norpace), propoxyphene (Darvon), doxepin (Sinequan), estrogens, ethacrynic acid (Edecrin), temazepam (Restoril), chlorzoxazone (Mebaril), ferrous sulfate (Iron), ticlopidine (Ticlid), flouxetine (Prozac), triazolam (Halcion), trimethobenzemide (Tigan) hydroxyzine (Vistaril)...

Elderly

- Account for 25-40% of all prescriptions
- Average...28.5 prescriptions/year in 2000
- Estimated to reach 38.5 by 2010

57% of Elderly Had AT LEAST One Appropriate Med Omitted
Medication Errors
“Preventable ADE”

- Cost $3.5 Billion Per Year
- Injure 1.5 Million Per Year

Patient Safety

"The very first requirement in a hospital is that it should do the sick no harm."

Florence Nightingale,
Notes on Hospitals, 1859.

THE TOXIC 10

1. Insulin 4%
2. Morphine 2.3%
3. Potassium Chloride 2.2%
4. Albuterol 1.8%
5. Heparin 1.7%
6. Vancomycin 1.6%
7. Cefazolin 1.6%
8. Acetaminophen 1.6%
9. Warfarin 1.4%
10. Furosemide 1.4%

Insulin…#1

- 33% of Medication-Related Deaths Related To Insulin!
- Errors include:
  - Mixing up products with similar packaging (look-alike products)
  - Confusing generic listings on computer databases
  - Similarity in names (Humalog & Humulin);
  - Confusing the abbreviation "u" for units with the number 0

Insulin Use Safety Recs

Prescribing
1. EBP Order Sets: for ALL situations (DKA, HHS, hyperkalemia, CV surgery, transition from IV to SQ, nutrition changes, hypoglycemia...)
2. Free Text Orders: Eliminate
3. Sliding Scale: Eliminate as a primary strategy
Dispensing/Storage
4. U100 ONLY: Syringes & pens; Segregate
5. Insulin Infusions: Standardize concentration
Administering
6. Pharmacy: Prepares ALL bolus & infusion insulin
7. Pens: Single patient use

Monitoring
8. Mealtime: Accuchecks, insulin, food coordinated!
Evaluating
9. Monitoring: Rates of hypo-hyperglycemia
Planning
10. Competency: Training and checks for ALL!
Insulin Or Heparin
- Insulin In TPN Bag Instead Of Heparin: NICU Infant BS 17
- Vascular Catheter Flush With Insulin Instead Of Heparin: 2 Deaths
- Nurse Wrote “Resume Heparin Drip” Instead Of Insulin Drip
- Pharmacist Entered Insulin 500 Units Instead Of Heparin 500 Units

Morphine…#2
- Likely all opioids
- Drug confusion
  - Liquid Morphine (ml versus mg)
    - 5 ml (20 mg per ml = 100 mg)
    - 5 mg (0.25 ml)
  - Morphine versus Hydromorphone
  - Avinza (morphine ER caps) versus Evista
  - Hydrocodone versus Oxycodeine
  - Oxycodone versus MS Contin
  - Oxycodone versus Oxycodone ER
  - Oxycodone versus Codeine

Heparin…#5
- China Additive Anaphylaxis
- Indianapolis Babies

Antibiotics…#6 & #7
- 23 Million Prescriptions Written Annually For:
  - Colds
  - Upper Respiratory Infections
  - Bronchitis

Acetaminophen…#8
- In many OTC medications
- In several prescription analgesics
  - i.e. hydrocodone 10/650…650 of acetaminophen
- Errors made mostly by teens and young adults
- 40% of acute liver failure cases due to acetaminophen

**Antibiotics Don’t Kill Viruses**
THE TOXIC 10

1. Dose Error 31%
2. Frequency 17%
3. Route Error 10%
4. Missed Dose 7%
5. Wrong Technique 6%
6. Illegible Order 6%
7. Duplicate Therapy 5%
8. Known Allergy 4%
9. Wrong Drug/Patient 4%
10. Drug-Drug Interaction 4%

Bedside Nurses & ADE

- Last Link In The Chain
- Expect To Follow 5 Rights
- Expected To Avoid Personal Errors AND
- Expected To Intercept Everyone Else’s Errors

Bedside Nurses & ADE

- Traditional View…Nurse Error Due To:
  - Forgetfulness
  - Carelessness
  - Inattention
  - Incompetence
  - Negligence

- 47% prescribing mistakes...
  Nurses intercept 48% of these errors
- 11% transcription mistakes...
  Nurses intercept 23% of these errors
- 14% dispensing mistakes...
  Nurses intercept 37% of these errors
- 28% administration mistakes...
  Once given, unable to intercept!

Student Nurses

Duality Assignments

- Morning Insulin Dose Missed Because Student Arrived Late
- Student Left Floor For A Conference And Didn’t Chart Heparin…Preceptor Gave Another Dose
- Preceptor Gave Patient Methodone & Charted It On MAR…Student Gave It Again Because She Was Using Her Worksheet Instead Of The MAR
- Patient Did Not Receive IV Antibiotic 3 Days Because Preceptor Did Not Know Student Could Not Give IV Meds

Student Nurses

Lack Of Knowledge/Experience

- Did Not Administer A Respiratory Med Because He Thought The RT Would Do It
- Administered An Extra Dose Of Morphine Not Realizing It Was Given (& Recorded) On The PACU Record
- Did Not Know The Meaning Of A Yellowed-Out Section On The MAR & Gave A Discontinued Dose Of KCL
- Gave Lovenox Ordered Held For INR > 2…INR 2.5
- Gave A Full Tablet (4 mg) Of Dexamethasone As Dispensed When Half Tablet (2 mg) Was Ordered
Student Nurses
*Lack Of Knowledge/Experience*

- Administered Oral/Liquid Vancomycin IV
- Gave Patient In Bed 1 Medications Intended For A Patient In Bed 2
- Phone Order: “Slow-Mag 64 mg 3 tabs today”
  - Written in Text Message shorthand:
    Slomag 64 mg 3 tabs 2day

Okay!
So What Do We Do About ADE?

Safety Elements

1. Patient Information:
   - Age
   - Weight
   - Allergies
   - Diagnoses
   - Pregnancy Status
   - Liver & Kidney Function
   - Accurate Drug List

2. Drug Information:
   - Accurate
   - Up-To-Date
   - Easily Accessible
     - Internet
     - PDA
     - Formulary
     - Protocols
Safety Elements

3. Communication of Drug Information:

- Poor Communication Of Medical Information At Transition Points Is Responsible For As Many As 50% Of All Medication Errors And Up To 20% Of In-Hospital ADE

Better Utilize PharmD

- Multi-Disciplinary Rounds
  - Core Measure Meds
  - Prophylaxis Meds (Heparin, Pcpd...)
  - Safe Dosing For Renal/Liver Function
  - Best Empiric Antibiotic Selection
  - Pain & Sedation Management
  - Polypharmacy Evaluation
- Rapid Response Team
- Code Team
- Drug Clinics (HF, DM, warfarin)

Safe Hand-Offs

- Face-To-Face
- Interactive Questioning
- Limited Interruptions
- Order Review & Read Back
- Medication Review
- Bedside Overview Of Drips/Rates

Safety Elements

3. Communication of Drug Information:

- Multidisciplinary Culture
- Teamwork Mentality
Case Example

- Admission: Fever, Vomiting, Diarrhea & Dehydration
- History: Liver Failure, Thrombocytopenia, Coagulopathy
- Hospitalist: Routine Admission Orders
  - Acetaminophen Ordered For Fever
  - Enoxaparin Ordered For DVT Prophylaxis
  - Home Meds Continued Including Furosemide & Spironolactone

Safety Elements

3. Communication of Drug Information:
   - Multidisciplinary Culture
   - Teamwork Mentality
   - Patient/Family Participation
   - Rectify Issues Of: Poor Handwriting, Name Confusion, Misuse Of Zeros & Decimals, Inappropriate Abbreviations…

4. Drug Labeling/Packaging/Nomenclature:
   - Limit “Look-Alike” & “Sound-Alike” Drug Names
   - Vary Drug Packaging For Better Differentiation
   - Utilize Unit Dose Systems
   - Employ TallMan Lettering & Color For Differentiation: DOBUTamine vs DOPamine

Safety Elements

5. Drug Storage/Stock/Standardization:
   - Standardize Drug Concentrations
   - Standardize Administration Times
   - Restrict Access To High Alert Drugs

Errors with high risk drugs may or may not be more common, but, the consequences of their errors may be devastating!
Targeting 4

- Insulins
- Narcotics/Opiates
- Sedatives
- Anticoagulants

How-to Guide: www.ihi.org/ihi/programs/campaign

High Alert Meds

- Insulin
  - Establish a 2-nurse, 2-step check system
  - INDEPENDENT DOUBLE CHECKS

  2 RN's independently verify right med, time, route & individually calculate RIGHT DOSE!

Nursing Survey

- 16% Of Nurses Reported They NEVER Use An Independent Double Check!
- 27% Reported They “Sometimes” Use An Independent Double Check
- Reason:
  - Too Many Drugs On High Alert List
  - Too Short Staffed

High Alert Meds

- Narcotics & Sedatives
  - Limit floor stock
  - Educate regarding hydromorphone and morphine mix-ups
  - PCA double-checks (drug, dose, setting)
  - Standing Orders For Reversal Agents
  - Consult Pain Specialists As Needed
  - Vital Signs, SpO2 & Pain Score Monitoring
  - Falls Precautions (patient teaching, scheduled toileting, good lighting...)

High Alert Meds

- Insulin
  - Establish a 2-nurse, 2-step check system
  - Do not store insulin and heparin together
  - Spell out the word "units" instead of "U"
  - Standardize IV Concentrations & Sliding Scale Protocol

End-Tidal CO2

- American Society of Anesthesiologist
- July 2011
- Standard 3.2.4

"During moderate or deep sedation the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs and monitoring for the presence of exhaled carbon dioxide unless precluded or invalidated by the nature of the patient, procedure, or equipment."
End-Tidal CO2

- PATIENTS WITH OPIOID USE VIA PCA OR CONTINUOUS INFUSION, WITH:
  - Diagnosis of sleep apnea (NA with CPAP/BiPAP)
  - COPD with acute respiratory problems
  - Neuromuscular conditions affecting breathing or breathing drive
  - BMI of ≥ 40
  - Anatomical abnormalities that compromise the respiratory system (kyphosis, dwarfism...)
  - Children

High Alert Meds

- Anticoagulants
  - Use Only Single-dose Containers & Limit Drug Concentrations
  - Separate Heparin and Insulin Stock
  - Use Preprinted Order Forms/Protocols With Start, Hold & Stop Procedures
  - Account For Thrombolytics & GP Inhibitors
  - Ensure 6-12 Hrs Between Heparin & LMWH
  - Point Of Care Testing Or Results In < 2 Hrs
  - Have Reversal Agents Readily Available
  - Consider Anticoagulant Services/Clinics

Safety Elements

6. Drug Device Acquisition/Use/Monitoring:
- Planned Safety Assessments
- Independent Double Checks
- Proper Orientation To Device
- Established Line Priming & Use

A.D.C.

- Automatic Distribution Cabinet
- Used By 75-95% Of Hospitals
- Problems:
  - No PharmD Stock Check (75%)
  - No PharmD Verification Before Removal (64%)
  - No Double Check For Override Removals (29%)
  - Multiple Open Compartments (50%)
  - Multiple Patient Drugs Removed (31%)
  - Multiple Concentrations (35%)
  - Located In High Distraction Areas (48%)

Bar Coding

- To be sure the right drug in the right dose and the right route is given to the right patient at the right time
- Only 25% Using As Of ’07

IV Pumps

- Traditional Pumps: Depend On Error-Free Programming & Human Intelligence
- Smart Pumps: “Test Of Reasonableness”
  - Select Area: ICU, NICU
  - Drug & Concentration From A Pick List
  - Compares Selections To Internal Drug Library Customized By Hospital
  - High Rate & Dose Alerts
Safety Elements

7. Environmental Factors:
   - Improve Work Station Lighting
   - Reduce Noise & Clutter
   - Assign Appropriate Work Loads
   - Maintain Adequate Staffing
   - Limit Interruptions & Distractions

Safety Elements

8. Competency And Staff Education:
   - Include Core Info In New RN Orientation
   - Review New Formulary Additions
   - Regular Reinforcement Of Information Related To High Alert Medications
   - Briefing On Internal & External ADE’s
   - Encouragement Of “Near-Miss” Reporting
   - Drug Calculation Reviews
   - Protocols & Policy / Procedure Reviews

Safety Elements

9. Patient Education:
   - Review Brand & Generic Names
   - Explain Drug Use, Dose, Frequency
   - Review Side Effects & What To Do If They Occur
   - Explain When Results Might Be Expected
   - Review Drug/Food Interactions
   - Encourage Questions
   - Assist Patients In Understanding Their Role In Preventing ADE

Adult Literacy

- 14% Read Below Basic Level To Function In American Society
- 22% Could Read & Understand Only Basic Material

National Assessment Of Adult Literacy 2003

Safety Elements

10. Quality Processes/Risk Management:
   - Encourage ADE Reporting
   - Develop Easy Reporting Processes

Reporting ADE

- Vital For Postmarket Surveillance
- Assists Regulators In Updating Safety Information
- Facilitates Removal of Dangerous Drugs From The Market
- Important In Developing National & Institutional Improvements In Medication Management
The FDA Estimates That Only 1% Of ADE’s Are Reported

Root Cause Analysis: RAC

*Basic Questions to Answer During a RCA*

1. What happened?
2. What do policies/procedures require?
3. What normally happens?
4. Why did it happen?
5. How was the organization managing the risk before the event?

Triggers

- **Reversal Agent/Antidote Administration:** Diphenhydramine, Vitamin K, Flumazenil, Naloxone, Kayexalate, Digibind, Antidiarrheals, Antiemetics,
- **Abnormal Lab Tests:** High aPTT, INR, Creatinine or Low WBC, Blood Sugar or Stool C Difficile
- **Elevated Drug Levels:** Digoxin, Lidocaine, Vancomycin, Gentamycin, Tobramycin, Theophylline,
- **Untoward Events:** Transfer To Higher Level Of Care, Hypotension, Lethargy, Falls, Skin Rash, N & V, Abrupt Drug Withdrawal

Safety Elements

10. **Quality Processes/Risk Management:**
   - Encourage ADE Reporting
   - Develop Easy Reporting Processes
   - Build In Checks & Balances
   - Force Functions & Foolproof Systems
   - Formalize ADE Analysis & Prevention Systems

Safety Elements

10. **Quality Processes/Risk Management:**
   - Encourage ADE Reporting
   - Develop Easy Reporting Processes
   - Build In Checks & Balances
   - Force Functions & Foolproof Systems
   - Formalize ADE Analysis & Prevention Systems
   - Mitigate Patient Harm
THE TOXIC 10
And The Patient & Family

WHAT DO VICTIMS WANT?

How It Feels To Be A Victim

- **The Error**: Causes Patients/Family to Feel Confusion, Uncertainty, Fear Anxiety and Loss of Trust.
- **The Response**: If the Injury Is Not Acknowledged or If Concerns Are Dismissed, Patient/Family Feel Devalued, Humiliated and Disrespected. Anxiety Turns to Anger and the Doctor/Nurse-Patient/Family Relationship Is Shattered.

Charles Vincent

Sorry Works

- **Step 1: Initial Disclosure**... Apologize with no fault admitted/assigned; provide for immediate patient/family needs; promise a thorough investigation; reestablish trust and exhibit empathy
- **Step 2: Investigation**... Learn the truth; establish if standard of care breached; Move quickly and keep in contact with patient/family
- **Step 3: Resolution**... Share investigation results; admit fault if needed; apologize; review plan for change; offer appropriate compensation; if no error, continue to empathize; hand over records to prove innocence

www.sorryworks.net

2nd Victim Facts

- Victims Suffer From PTSD
- Victims Need “Emotional First Aid”
- Victims Need to Hear 3 Things:
  - Their supervisor still has confidence in them
  - Their peers respect and support them, and
  - They are still a trusted & valued team member
Support of 2nd Victims

- Actions:
  - "Be there": active listening!
  - If you had a similar experience...share it!
  - Avoid gossip...it could have been you!
- Key phrases:
  - "I'll help you work through this."
  - "You are a good nurse working in a complex unit."
  - "I believe in you."
  - "I'm glad that we work together."
  - "You can be my nurse anytime."
  - "I can't imagine what it must have been like for you."
  - "I'm here if you want to talk."

References