Reducing Medication Errors

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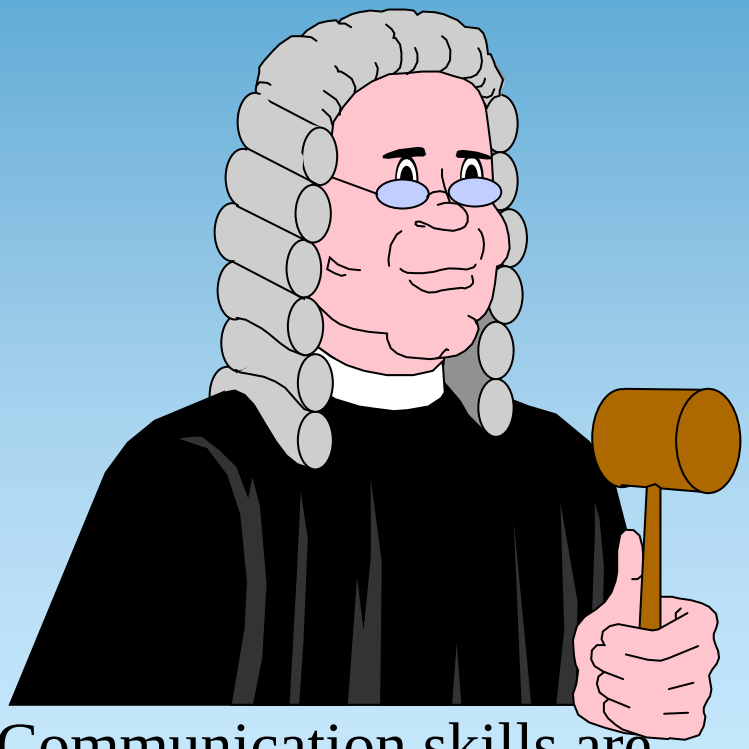
Why Do Pts Sue Their Doctors? Problematic Relationships: 71%*



Communication skills are as important as clinical skills in avoiding law suits!

- Deserted PT - 32%
- Devalued PT and/or Family Views - 29%
- Delivered Information Poorly - 26%
- **Failed to Understand Patient or Family Perspective** - 13%

*Beckman et al, Arch Int Med 1994;154:1365

What is a Medication Error?

"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, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."

www.nccmerp.org

Common Medication Errors

- **Wrong Drug**
- **Wrong Dose**
- Wrong Route (of administration)
- Wrong Patient
- Wrong Time (or omission)
- Ambiguous/Illegible Rx->Transcription Error
- Inadequate Monitoring (e.g., lack of proper follow-up)
- JC Pt Safety Goal: Must reconcile medications across a continuum of care

What Information About a Drug Should you Provide a Patient?*

- Nature of the proposed treatment or procedure
- Reasonably Foreseeable material risks
- Appropriate alternative treatments or procedures
- Foreseeable risks if patient becomes pregnant
- Special instructions re: food, drink, lifestyles, eg, no Chianti with MAOIs
- **Tell patients to call if:** rash, dark urine, or anything unexpected occurs;
- Pt should repeat critical info; Ask pt for questions

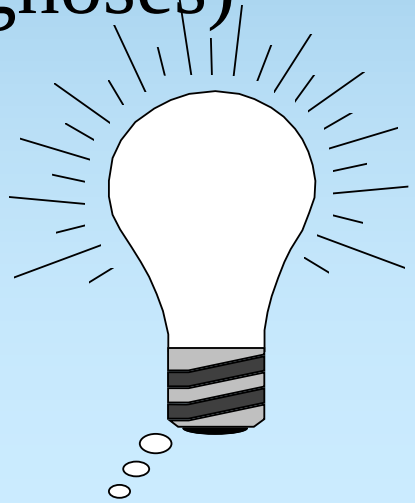
*Benjamin, DM. Reducing Medication Errors and Increasing Patient Safety:Case Studies in Clin Pharm, J Clin Pharmacol 2003;43:768-783

Top Five Claims Against Physicians (Mass Pro-Mutual Ins Co., 2003) (They're still the same!)

- Failure to Diagnose
- Misinterpretation of Laboratory Test or Study
- Failure to Conduct a Proper History & Physical
- Failure/Delay in Obtaining a Timely Referral or Consult
- Failure/Delay in Admitting a Patient to the Hospital

Quality Improvement: A Refocus on Errors - What Got Everything Started?

- The Institute of Medicine issued: To Err is Human which reported that 44,000 - 98,000 patients died each year as a result of "Medical Error" (*e.g.*, medication errors, surgical errors, missed diagnoses)
- At an estimated cost to the US economy of $17-$29 billion



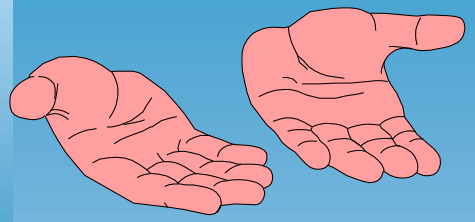
Major Findings of the IOM Study

- Based on two reports from three states: New York (1984), Utah and Colorado (1992)
- NY study sampled 30,000 charts from 51 state hospitals and found:
- 3.7% of pts suffered injury severe enough to disable them or prolong hospitalization
- 58% of these injuries were due to error; 13.6% were fatal

Major Findings of the IOM Study-2

- The 98,000 number was extrapolated from the NY study, based on the number of hospitalizations for 1997
- Based on reports from Utah and Colorado (1992), 15,000 charts were sampled
- 44,000 deaths was extrapolated from these data
- The IOM report has been criticized by one of the investigators, Troyen Brennan, MD, JD, MPH of the Harvard School of Public Health

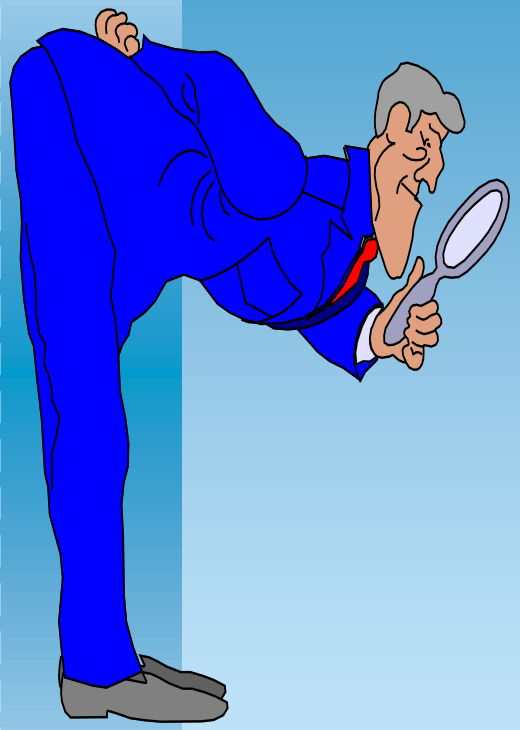
Develop a Philosophy of Patient Safety



- Recognize the patient's needs
- Be alert for better ways to do things
- Record & track medication/medical error and investigate all instances & "near misses"
- Re-engineer faulty medication delivery systems to reduce the risk of errors (RCAs)
- Focus on the system, not the person

Patient Safety and Quality Improvement Act of 2005

(S. 544 - Public Law N 109-41- Passed July 29, 2005)



- **Report errors anonymously to Patient Safety Organizations (PSOs)**
- **Obtain legal privilege for reports**
- Analyze non-identifiable pt. safety data
- Develop national standards promoting interoperability and health care information technology systems
- Develop Med Info Technology Advisory Board to determine: best practices in IT, lexicon for computer technology; RFID, Bar Coding using NDC number.

Risk Management Strategies For Preventing Law Suits

- Be Professional and Courteous
- Keep Good Records and Never alter a patient's chart in the event of, or fear of litigation - your credibility becomes 0
- Provide an Adequate Informed Consent & Instructions to call at the first sign or symptom of a serious ADR
- Project Realistic Outcomes & Expectations, *e.g.*, don't say "It won't hurt", say "We will manage the pain and keep you comfortable."

Elements of a Negligence Claim

- Physician-Patient relationship established, or professional owed a duty of reasonable care to patient
- Physician's conduct was below the standard of care **(what a reasonable MD would have done under similar circumstances)**
- Patient was injured (damages)
- Negligence was a "Proximate Cause" of the patient's damages

Types of Adverse Drug Reactions (ADRs) Frequently Encountered

- **Overmedication - too much or too many**
- **Side Effect - an undesirable drug effect**
- **Secondary Effect - additional drug effects**
- Allergic Reactions - e.g., to antibiotics
- Idiosyncratic - rare
- Maternal-Fetal - *in utero* or during nursing
- Drug-Drug Interactions - ADME
- Alternative Medical Products & OTC drugs

Take a Complete Drug History Including Alternative Medical Products

- "Natural Products", *e.g.*, St. John's Wort is an MAOI & Reduces serum Digoxin levels
- Kava Kava causes liver damage
- Herbals, *e.g.*, Ephedrine-containing
- Food Supplements, *e.g.*, L-Tryptophan
- Androgenic Supplements - Heart Failure
- Vitamins & Minerals in Excessive Doses, e.g., >10,000 IU Vitamin A/day--> Toxicity
- OTC Drugs

Identifying High Risk Drugs

- **Low Therapeutic Index: digoxin, anti-coagulants**
- Inherent Undesirable Effect(s), *e.g.*, steroids, chemo
- Class of Drugs Which Share Toxicity: **NSAIDs, ACEIs**
- **Drug Allergies - antibiotics; cross-sensitivity**
- Narcotics - Patient Controlled Analgesia
- Newly Approved Drugs - Minimal Safety Data
- "Off-Label" Use of Drugs, *e.g.*, Fen-Phen
- Pharmacokinetic Drug Interactions, *e.g.*, SSRIs
- Advertised: Direct-to-Consumer, "Doctor, can I have some of that stuff I saw on TV?"

What Classes of Drugs are Involved in Common Medication Errors?

- Antibiotics: 19-30%
- Analgesics: 7-30%
- Cardiovascular: 8-18%
- Concentrated electrolytes: 1-10%
- Antineoplastic drugs: 7-8%
- Sedatives: 4-8%
- Anticoagulants: 1.3-3% (1000U Heparin)

Source: Agency for Healthcare Research and Quality (AHRQ) sponsored studies

Classes of Drugs Appearing Twice During 1996-98 in PHICO's Closed Claims Project*

- Antibiotics
- Anticoagulants
- Antirheumatics
- Tranquilizers
- Concentrated electrolytes
- Insulin
- Oral Antidiabetics
- Antihypertensives
- Opiates
- Fibrinolytics

*Benjamin, DM and Pendrak, RF. : Medication Errors: An Analysis Comparing PHICO's Closed Claims Data and PHICO's Event Reporting Trending System (PERTS). J Clin Pharmacol 2003;43:754-759.

Medication Errors Appearing in PHICO's 1998 Closed Claims*

- **Allergic/Adverse Reaction (25%)**
- Contraindicated drug administered (22%)
- IM Technique Issue (10%)
- Incorrect dose (10%)
- **Wrong Patient (3%)**
- Wrong route (3%)
- **Labeling/dispensing error (1%)**
- Not classified: eg, failure to monitor or prescribe

*Benjamin, DM and Pendrak, RF. : Medication Errors: An Analysis Comparing PHICO's Closed Claims Data and PHICO's Event Reporting Trending System (PERTS). J Clin Pharmacol 2003;43:754-759.

What to do About "High Risk" Drugs

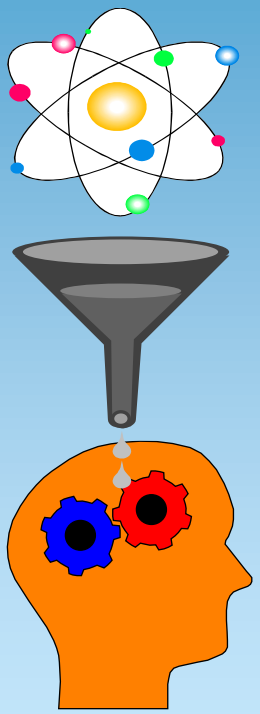
- Recognize and Identify them!
- Limit use to when needed; employ pre-written "Limit Dose" Protocols
- Review and update protocols for administration to insure proper dosing, lack of drug-drug interactions, & adequate monitoring
- Use appropriate laboratory tests (e.g., Pro-Times) or blood level monitoring to confirm proper therapeutic response and safety

Proximal Causes of Medication Errors:

Leape, LL et al, System Analysis of Adverse Drug Events, JAMA, 1995;274:35-43.

- **Lack of Knowledge About the Drug**
- Lack of Information About the Patient
- Rule Violations
- Slips and Memory Lapses
- Transcription Errors
- Faulty Drug Identification
- Dosing Errors
- Infusion Pump/Parenteral Delivery Error
- Inadequate Monitoring
- Preparation Errors

Lack of Knowledge About the Drug



- Inadequate knowledge of :
- **Indications**
- **Dosage**
- Routes of Administration
- Chemical Incompatibilities or Drug Interactions

Lack of Information About the Patient

- **Allergies or Sensitivities**
- **Current Diagnosis**
- Secondary Diagnoses
- Concomitant Medications
- Prior Medical History

Case Study

A 63 yo white male has been receiving enalapril for one year for the treatment of his hypertension. Last week, he experienced some difficulty swallowing and discomfort in the back of his throat. He called his doctor and was told to go to the emergency room at the local hospital. Upon arrival in the ER, the patient was experiencing some mild breathing difficulty and was treated with Benadryl, 50 mg, IM and oxygen by mask. Within 30 minutes, the patient was breathing more comfortably and was admitted to a general medical floor for observation.

The next morning, the patient's wife arrived with a bag of the patient's "other medications", which she said she administered to her husband every day. The nurse called the admitting physician and received permission to administer the patient's other meds, during the course of which, she also administered another dose of enalapril.

The patient was discharged later that day. The day following discharge, the patient suffered an episode of acute angioneurotic edema with dysphagia, lip swelling, airway obstruction, and expired before paramedics could respond.

Conduct a Root Cause Analysis and determine:

What “System Errors” (shown on next slide) Occurred?

What can be done to prevent a recurrence?

Proximal Causes of Medication Errors:

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- Preparation Errors

Enalapril Case Process (Basic Minimum)

Patient Admitted

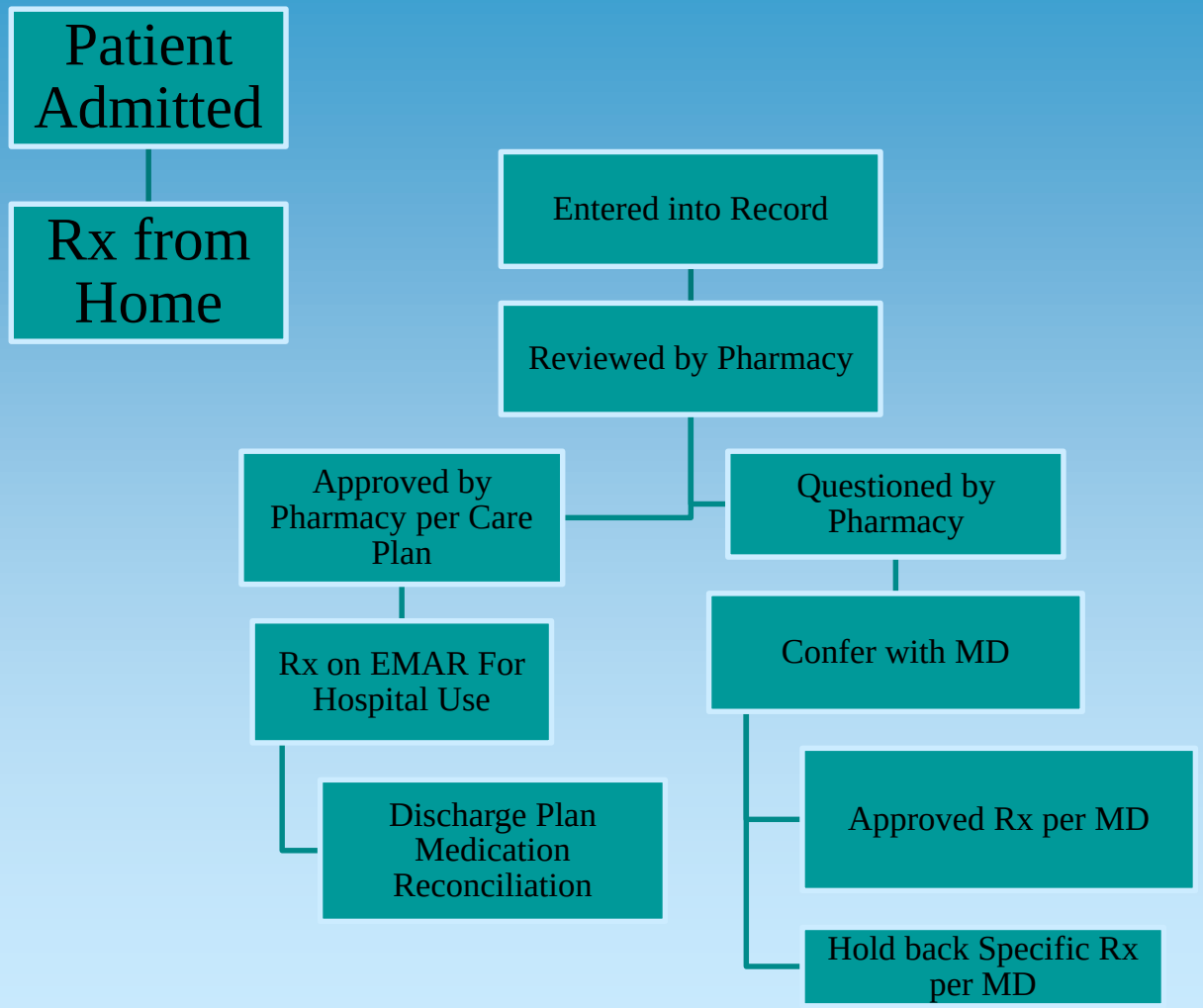
Rx from Home

Nurse obtained “Telephone okay” from MD to administer med brought from home

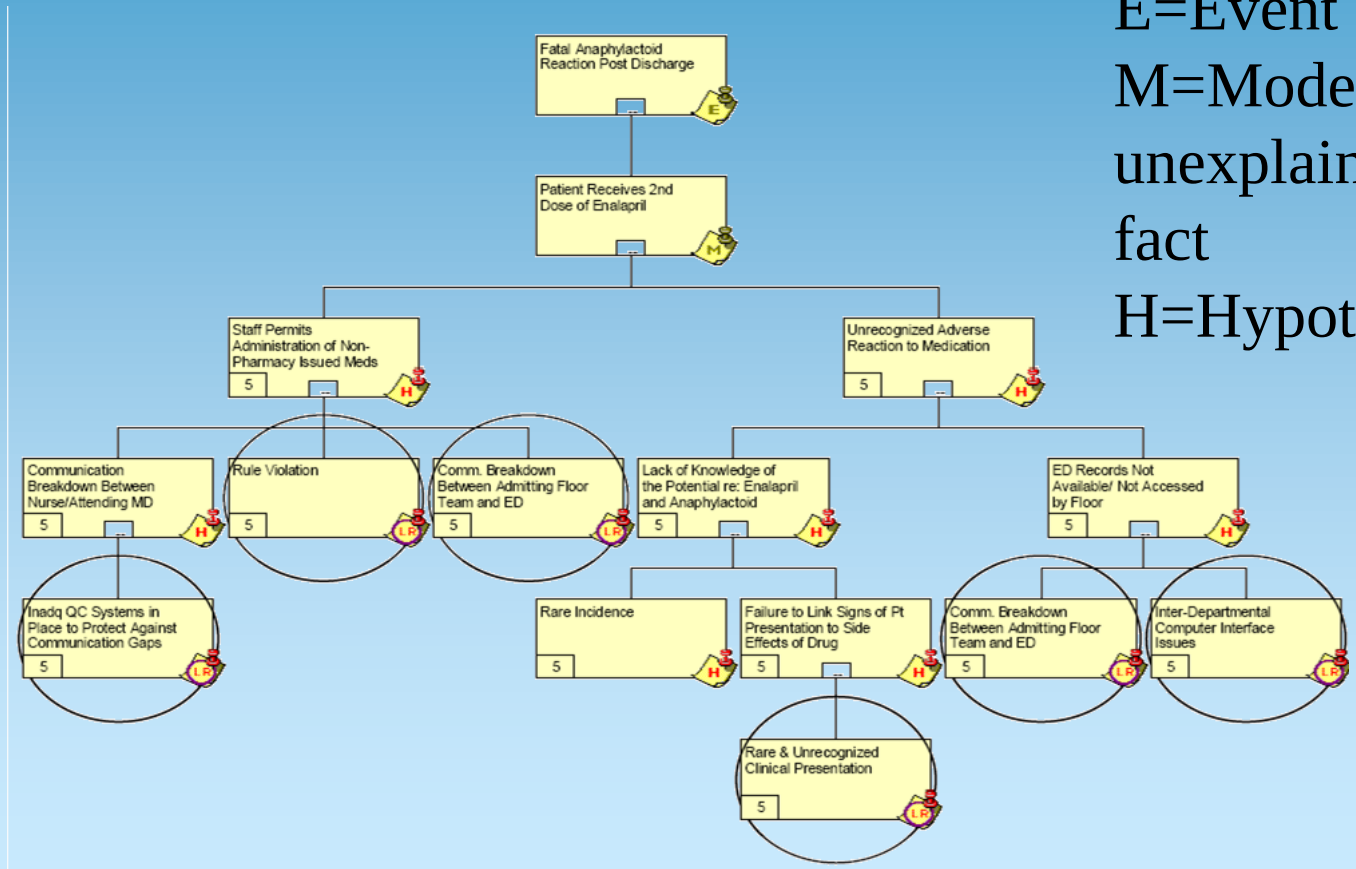
Rx from home given to patient with catastrophic result

Discharge plan; No Medication Reconciliation (Do not give ACEIs to Pt)

Correct Process



The Data (Evidence)-Based Route Cause Analysis (RCA)



E=Event
M=Mode, unexplained fact
H=Hypothesis

Courtesy of Reliability Center, Inc. 2012

Medication Use Process

T r a n s c r i p t i o n

Prescribing -> Dispensing -> Administering -> Monitoring

C o m m u n i c a t i o n

How do the Most Common Types of Medication Errors Arise?

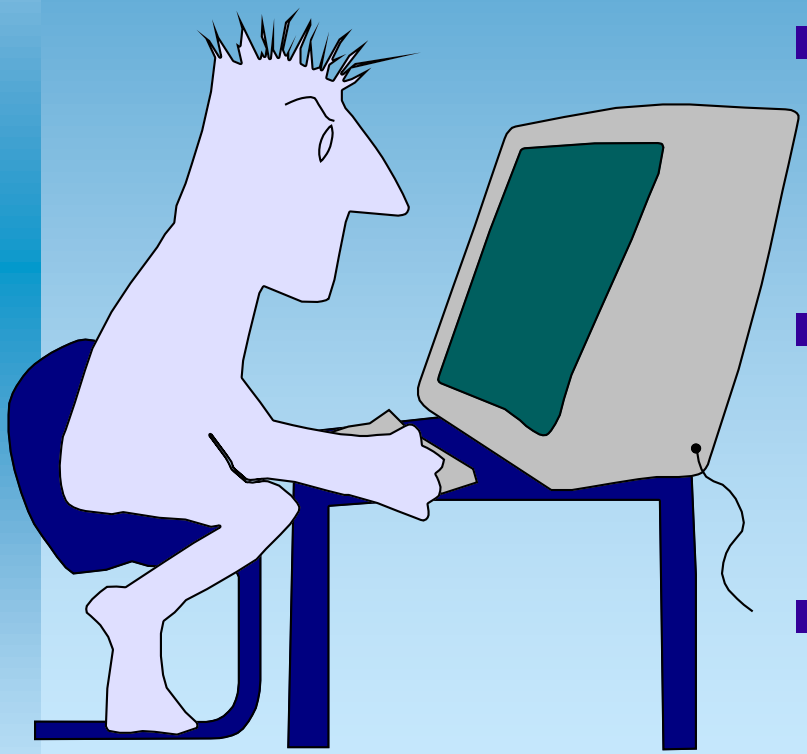
- Physician ordering: 39-49%
- Nursing administration: 26-38%
- Transcription error: 11-12%
- Pharmacy dispensing error: 11-14%

Source: Bates et al JAMA 1995;274(1):29-34 & Leape et al JAMA 1995;274(1):35-43.

Slips and Memory Lapses

- **Mental Lapses**
- **Intellectual Errors**
- *Stress*
- **Attention Diverted by:**
- **Page**
- Someone Talking to You
- Phone Call
- **You're Only Human**

Why Use CPOE?



- MD computerized order entry decreased serious medication errors 55% and
- Potential undetected Adverse Drug Experiences (ADE) declined 84%
- Bates et al JAMA 1998;280:1311-1316

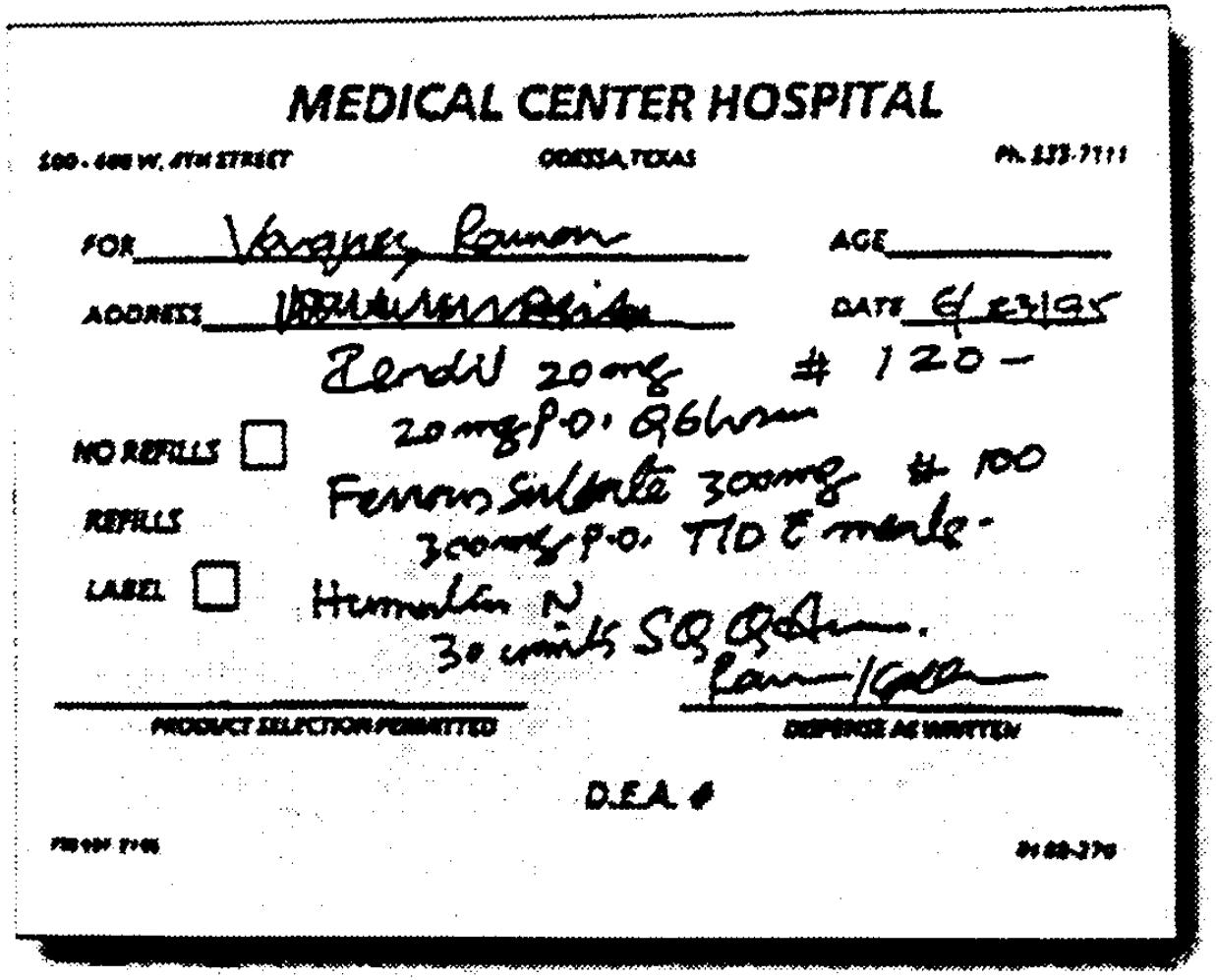
Still Problems With CPOE

- **CPOE Software Differ**
- **In 2003, the USP found that 57.9% of CPOE involved Lack of Knowledge**
- Computer Entry ranked as the 4th leading cause of errors in 2003
- 67% of errors occurred during the prescribing phase
- 56.5% of all computer entry errors resulted from distraction
- JC Pt Safety Goal: Must reconcile medications across a continuum of care

Errors in Prescription Writing

- **Legibility - Poor Handwriting is Not a Joke !**
  Lamisil vs. Lamictal
- **Dosage: Start Low - Go Slow !**
- **How many pills? How many refills?**
  For how long?
- **Use of Unapproved Abbreviations, eg "U", QOD, QD (JC Pt. Safety Goals)**
- **Brand vs. generic name mix-ups**
  enalapril (Vasotec) vs. Elderpryl (selegiline)

Portrait of a Poor Prescription



MEDICAL CENTER HOSPITAL

500 - 600 W. 8TH STREET ODESSA, TEXAS PH. 333-7111

FOR Virginia Lamon AGE

ADDRESS DATE 6/23/95

Rx Lasix 20 mg # 120 -
20 mg p.o. q 6 hrs

NO REFILLS ☐ Ferrous Sulfate 300 mg # 100
300 mg p.o. TID c meals

REFILLS

LABEL ☐ Humulin N
30 units SQ q 8 hrs.

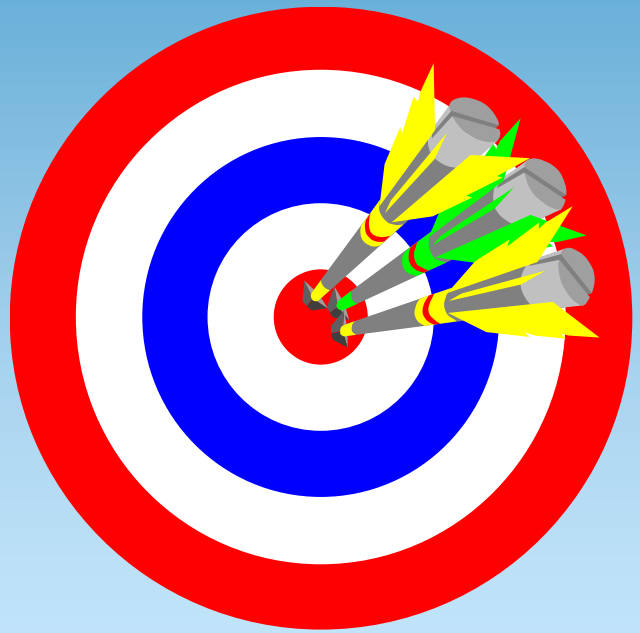
PRODUCT SELECTION PERMITTED DISPENSE AS WRITTEN

D.E.A. #

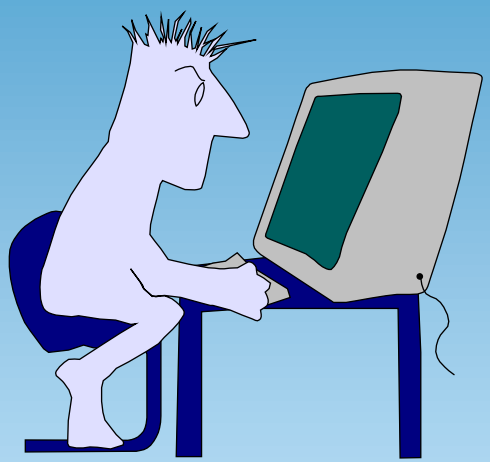
Source: AMA Website

The Correct Drug was . . .

- **Final Answer: Isordil** not **Plendil** which was dispensed and caused fatal hypotension for which both the MD and RPh were held jointly liable for almost $500,000.



Transcription Errors
"Look-Alike" and "Sound Alike" Names



Confusion Over: **Drug Names** or **Handwriting**

- **Larocin 250 mg vs. Lanoxin 0.250 mg (Larocin changed to Larotid after mix-up)**
- **Losec changed to Prilosec after confusion with Lasix**
- Heparin 1000**U** sc q 4 hrs Can't abbreviate Units, you risk a ten-fold OD!

More Sound-alike, Look-alike Drugs

- Amicar
- Cardura
- Darvocet
- Effexor
- hydrocodone
- MS Contin
- Tramadol
- Zestril
- Zocor
- Oxycontin
- hydroxyzine
- lorazepam
- Omacar
- Coumadin
- Percocet
- Effexor XR
- oxycodone
- Oxycontin
- trazodone
- Zyprexa
- Zyrtec
- oxycodone
- hydralazine
- alprazolam

Avoiding Prescription Errors

- Write Legibly
- Don't Guess
- Be Careful with "look alike" names, e.g., Elderpryl vs enalapril
- Consider writing in the indication to further avoid confusion, e.g., Elderpryl for Parkinson's Disease
- Avoid ten-fold dosing errors: write 1 mg instead of 1.0 mg.
- Conversely, write: 0.250 mg Lanoxin, not .250 mg, where decimal can be lost
- Write 4 times per day not 4 x daily; Is this qid or for 4 consecutive days?

Avoiding Ambiguity in Prescription Writing

- Consider writing the **condition for which the medication is indicated** on the prescription, under the drug name.
- Examples:
- Lamictal 100 mg bid for **seizures**
- Lamisil 250 mg daily for **fungal infection**

Avoiding Ambiguity in Prescription Writing

- Consider writing both the Brand name and the generic name of the medication
- Examples:
- **Vasotec (enalapril)** 2.5 mg daily for hypertension
- **Elderpryl (selegiline)** 5 mg bid for Parkinson's Disease

Hint: When it Comes to Zeroes- Always Lead and Never Follow!

Always write: **1 mg** not **1.0 mg**

eg, Lanoxin 0.125 mg vs Xanax 1.0 mg hs

Correct Incorrect*

*Should be written: Xanax 1 mg hs

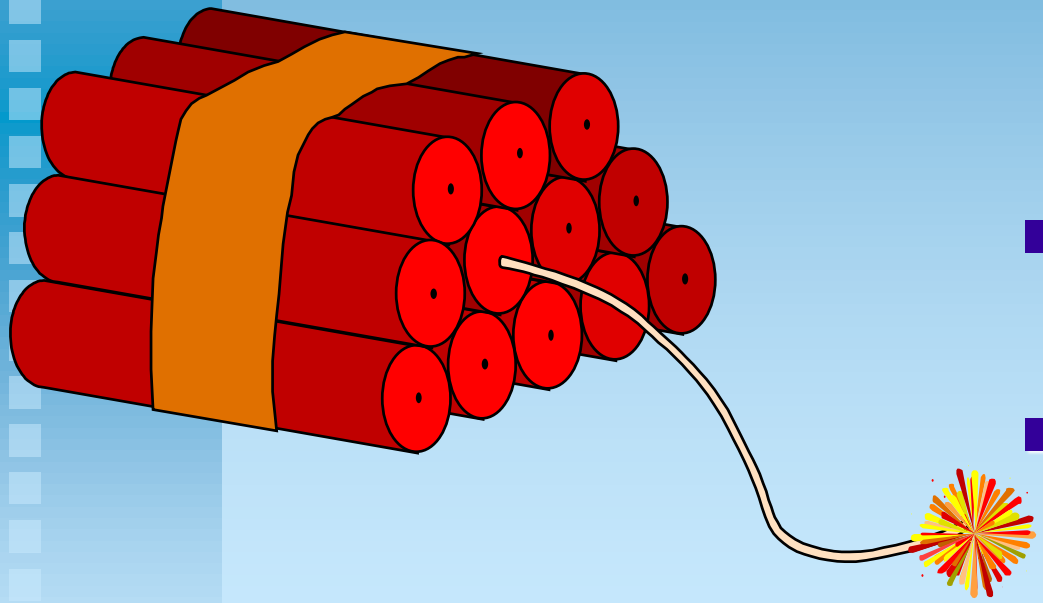
Patient Factors Influencing the Drug Selection Process

1. Renal Disease
2. Hepatic Disease
3. Level of CYP Isoenzymes [*clinically available*]
4. Interaction with other drugs being taken
5. Allergic response in past
6. Prior experience resulting in an ADE

Criteria to be Considered

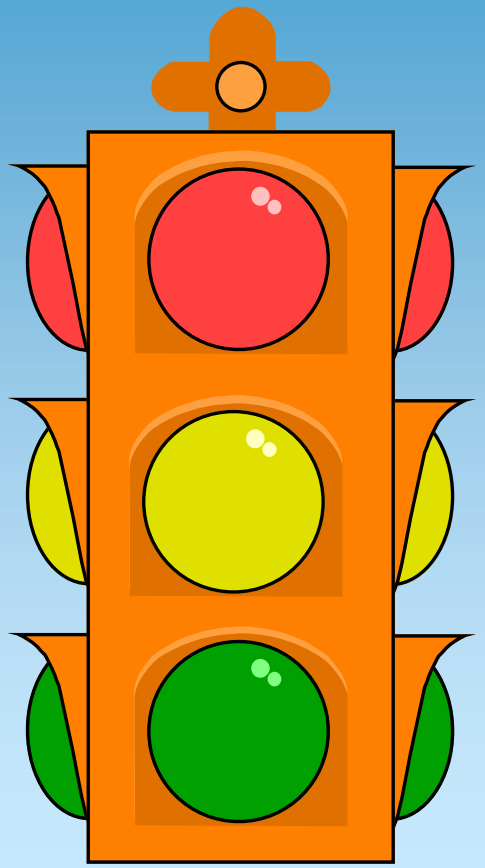
- Number of Drugs being taken
- Long Acting & Administration Ability
- CYP interference
- Creatinine Clearance
- T/E Code rating (Therapeutic Index, TI)
- No Patient should be financially penalized because of a medical/pharmacologic problem.

The “First Year” Effect



- Patients exposed to new drug increases from thousands to hundreds of thousands or millions,
- New adverse reactions emerge, or
- Previous incidence takes on new perspective.

For example: The Short Life of Omniflox (temofloxacin)



- Introduced: Jan 1992
- First Rx: February 24
- Voluntarily withdrawn: June 9th - 15 weeks
- US Clin Trials 4,600 pts
- Mkt'd in 8 countries Est. 300,000 pts rec'd drug worldwide

Pre- vs Post- Marketing Adverse Drug Reaction Reports

- Pre-Marketing
- 4,261 pts
- Incidence > 1% N,V,D, headache, rash, itching
- Labs: Incr. BUN & creatinine
- Renal Failure <0.1%

- Post-Marketing
- fewer than 300,000 pts
- 1,700 non-fatal ADRs reported to FDA
- 54 cases of Acute Renal Failure, 113 cases of hemolytic anemia
- 60 deaths, 25-50 may be related; Globe 1/94

Number of Patients Required With No Background Incidence of Adverse Reactions*

Expected incidence of adverse reaction	Required number of adverse reactions		
	1	2	3
1 in 100	300	480	650
1 in 200	600	900	1,300
1 in 1,000	3,000	4,800	6,500
1 in 2,000	6,000	9,600	13,000
1 in 10,000	30,000	48,000	65,000

*From: Stephens, MDB. The Detection of New Adverse Drug Reactions. Second Edition. New York: Stockton Press; 1988. In: Lewis, JH. Risk/Benefit Assessment of New Drugs: Perspectives of a Former FDA Advisory Committee Member. Drug Information Journal. 1993;27:1037.

Other Post-1960s Fiascoes We Have Known and Loved

- **1970s**
- **DES**
- IUDs
- DPT/MMR
- **1980s**
- Oraflex, Zomax, Suprofen
- Generic Drugs
- Bendectin
- **1990s**
- L-Tryptophan - EMS
- Omniflox - 5-month life
- Toradol - 5-day labeling
- Imitrex - First-Year Effect
- Silicone Breast Implants
- Fen-Phen - "Off-Label" use
- Duract - Where is Dr. Kelsey when we still need her?

More Withdrawn Drugs

- **Posicor® - too many interactions**
- **Rezulin® - liver toxicity**
- Raxar® - cardiac arrhythmias
- **Propulsid® - too many interactions**
- Seldane/Hismanyl® - long QT syndrome
- **Rotashield®** - infant bowel obstruction
- Lotronex® - off Nov 2000 GI ADRs & deaths; Re-instituted 2002 w/pt FU
- Baycol® (are other "statins" to follow?)
- Vioxx® & Bextra®– MIs & CVAs

Urgent news for people who took BAYCOL®

Many consumers who took the cholesterol lowering drug **BAYCOL®** have developed an illness called **Rhabdomyolysis** that causes **kidney failure, muscle pain and weakness, and even death.** Kidney failure is often accompanied by **darkened, discolored urine.** **BAYCOL®** has been withdrawn from sale. If you or a loved one took **BAYCOL®** and experienced any of these health problems, call us immediately so that we can consider your potential claim against the drug manufacturer.

Your legal rights have **time deadlines**, so call **today** (open 7 days/week) toll free from anywhere in the U.S. at **1-800-THE-EAGLE** for a **free consultation.** We practice law only in Arizona, but associate with lawyers throughout the U.S. to help people across the country.

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Drug Interactions

- Pharmacokinetic
- Pharmacodynamic

Pharmacokinetic

- Absorption
- Distribution
- Metabolism
- Excretion

Metabolism

- Carried out in liver by CYP-450 enzymes, of which there are 5 families:
- **CYP3A4 (54%)** (eg, methadone)
- **CYP2D6 (25%)** (eg, codeine, methadone, hydrocodone, oxycodone)
- CYP2C (17%)
- CYP 1A2 (2%) (eg, methadone)
- CYP2E1 (2%) (eg, ETOH & acetaminophen)

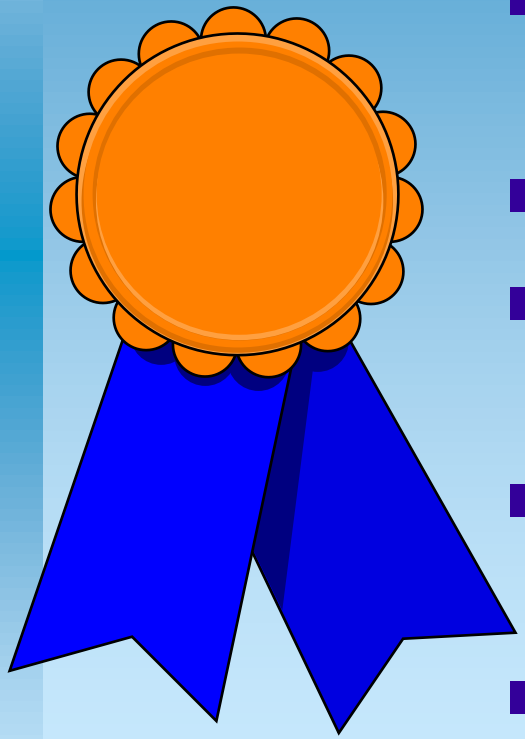
The USP's MedMARx System

- The United States Pharmacopeia (USP) has established a nationwide program for reporting Medication Errors
- Notice the emphasis is now on **Medication Errors** rather than **Adverse Drug Reactions**
- Errors are categorized according to severity and outcome (see next slide).
- Hospitals pay a fee to join the program and receive software; Anyone can report to MERP

USP MedMARx Reporting Program Severity Levels and Outcomes

- Category A - Circumstances can cause error
- B: Error occurred - didn't reach pt -"near miss"
- C: Error occurred - reached pt-> no harm
- D: Error occurred - **no harm->monitoring**
- E: Error occurred - **tx required -> temp harm**
- F: Error occurred->**initial or prolonged hosp**
- G: Error occurred-> **permanent pt harm**
- H: Error occurred-> **near-death event**
- I: Error occurred -> **resulted in pt death**

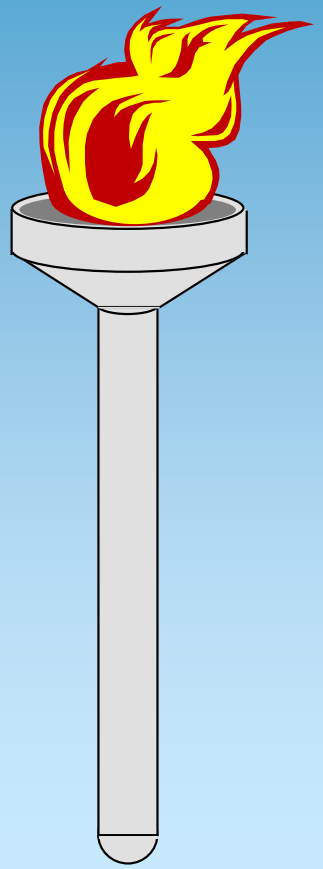
Benefits of Reducing Medication Errors in the ICU



- 92% of errors involved MD ordering
- Preventable ADEs decreased 66%
- 12% of time cheaper or safer drugs were recommended by PharmD.
- Each preventable ADE costs approximately $4,685
- Estimated savings/year: $270,000
- Leape et al JAMA 1999;282:267-70

Benefits of Reducing Medication Errors

- Optimize Therapeutics
- Improve Care
- Increase Pt Satisfaction
- Decrease ADRs
- Reduce Risk of Litigation
- $ave Money
- 30 Day Rule
- Do it Right!



The 30-Day Rule
Minimizing Readmissions

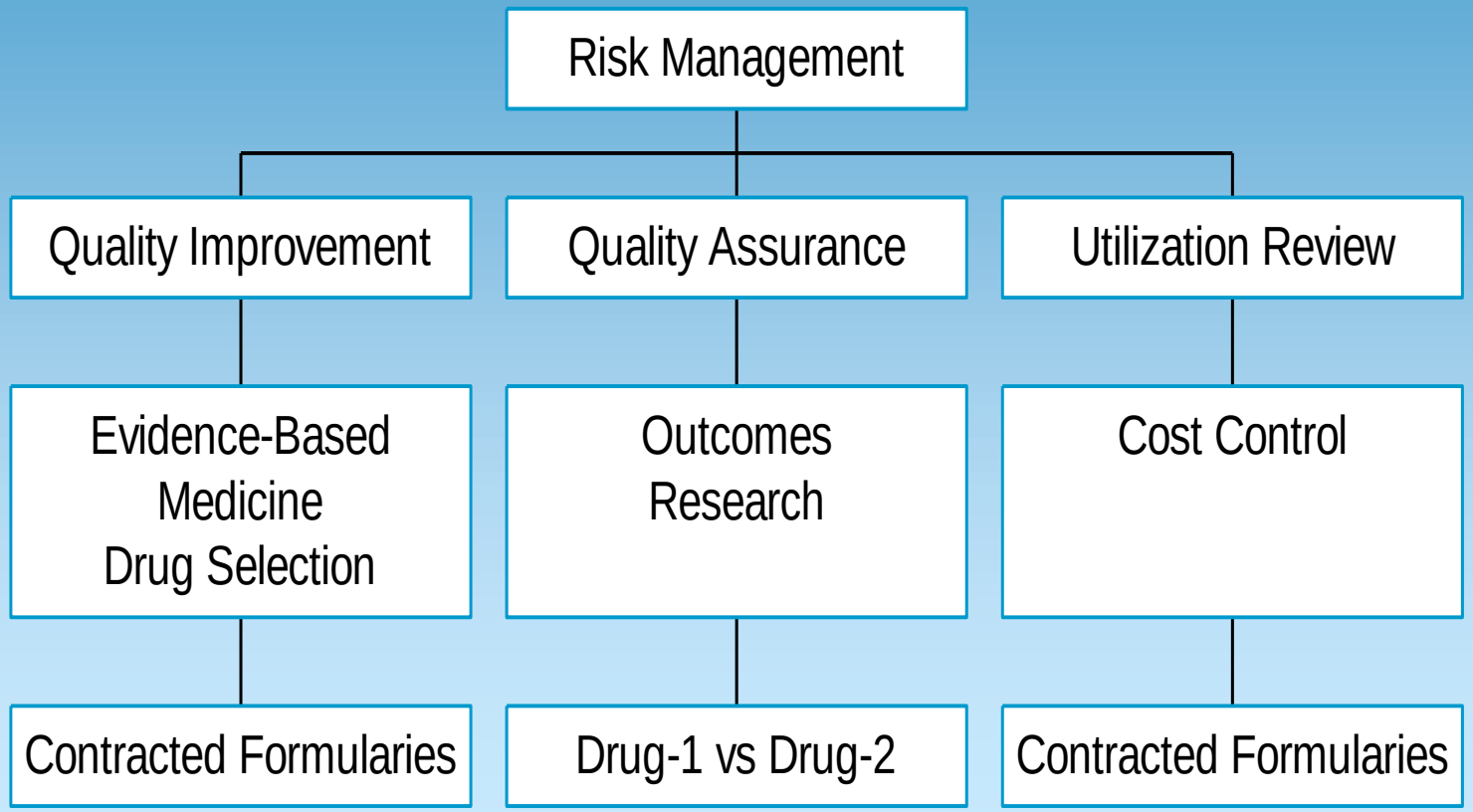
Hospitals Seek to Avoid Penalties by Minimizing Readmissions

Faced with a stiff penalty for unnecessary readmissions, health centers are focused on keeping patients out of the hospital.

By Susan Brink | Aug. 9, 2013 | 4:15 p.m. EDT + More

George Oldt, 82, is afflicted with the double whammy of congestive heart failure and chronic obstructive pulmonary disease, conditions that can make breathing so frighteningly difficult he has to be rushed from his assisted living home in Lewisburg, Pa., to the hospital. It happened most recently in April, and might have happened again in July if it weren't for the close monitoring of a team of health care workers.

Preventing Medication Errors:
Make the Proper Diagnosis & Give the Correct Drug to the Right Patient



Evidence-Based Drug Selection