

Quality Assessment of Drug Therapy

Charles E. Daniels, R.Ph., Ph.D.
Pharmacist In Chief
Professor of Clinical Pharmacy
University of California
San Diego, California

March 5, 2009

Patient Concerns

Drug-Drug interaction	70%
Wrong medicine	69%
Cost of treatment	69%
Complications from procedure	69%
Cost of prescription medicines	67%
Hospital acquired infection	49%

ASHP Survey: May 1 and 8, 2002

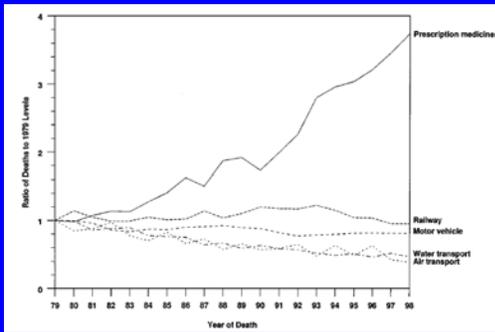
IOM Report: Preventing Medication Errors



- IOM study estimated 1.5 million preventable adverse medication events per year
- One medication error per patient per day

Committee on Identifying and Preventing Medication Errors, Philip Aspdon, Julie Wolcott, J. Lyle Boolsen, Linda R. Cronenwett, Editors. Washington DC: National Academies Press; 2007.

Deaths From Medication Accidents



Phillips DP, Breder CC, Annu. Rev. Public Health 2002; 23: 135-50

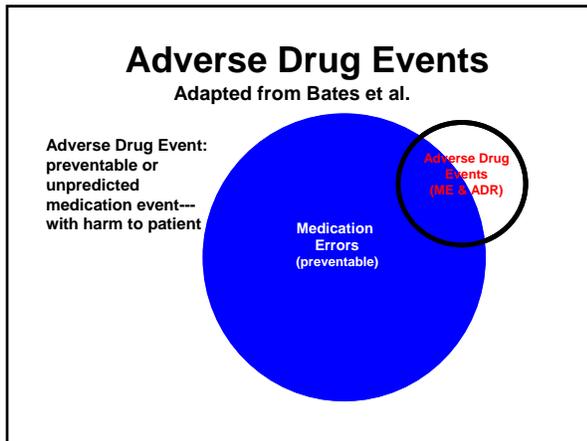
Drug Related Morbidity and Mortality Costs

Hospital	\$121 billion
Long Term Care	33 billion
Physician visits	14 billion
Emergency visits	5 billion
<u>Added prescriptions</u>	<u>3 billion</u>
Total	\$177 billion

Evans, J Am Pharm Assoc, 2001; 41:102-8 (Mar 2001)

Medication Use Quality

- Medication use process/system
- Organizational interests in med use
- Monitoring and improving med use quality & outcomes
- Identifying and reducing med errors



Cost Impact of ADE's

	Increased LOS	Increased Cost
ADE	2.2	\$3,244
Preventable ADE	4.6	\$5,857

Bates DW, et al. The Costs of Adverse Drug Events in Hospitalized Patients. *JAMA*. 1997; 277:307-311

- ### Incidence of Preventable Drug Related Admissions
- Meta-analysis of 15 studies (1980-99)
 - 4.3% (2.5-19%) of all admissions were drug related
 - >50% of drug related admissions are preventable
- Winterstein AG, Bauer BC, Hegler CD, Poole C. Preventable Drug-Related Hospital Admissions. *Ann Pharmacother*. 2002; 36:1139-44

Impact of Preventable Drug Related Admissions

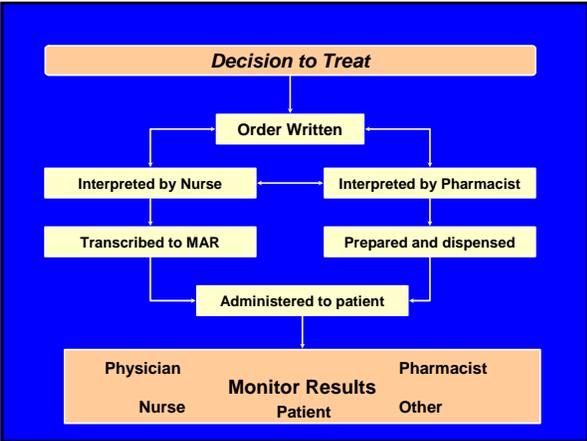
- 158 ADR related admissions over 11 months (24% life threatening)
- 67% inappropriate monitoring of therapy (80% lab abnormality)
- 26% drug-drug interactions
- 595 hospital days (6.1 day LOS)

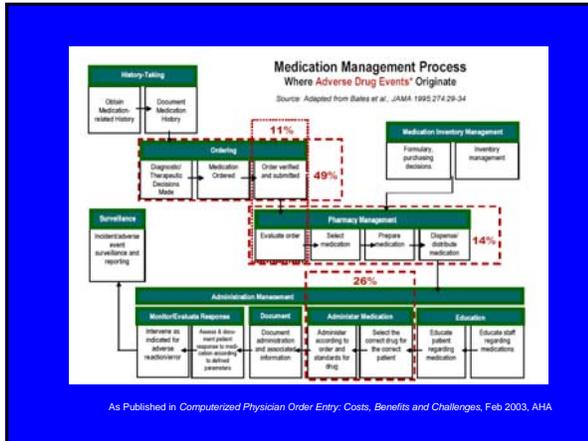
McDonnell PJ and Jacobs MR. Hospital Admissions Resulting from Preventable Adverse Drug Reactions. *Ann Pharmacother* 2002; 36:1331-6

Medication Errors

Any **preventable** event that may cause or lead to inappropriate medication use or patient harm while medication is in the control of the health care professional, patient or consumer

National Coordinating Council for Medication Error Reporting and Prevention





Medication Use Process

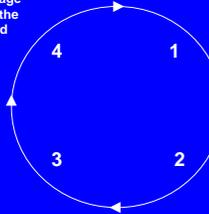
- Complex system
- Opportunities for error
- Impacts patient care and research

Process Improvement

- Focus on systems
- Data driven
- Iterative Cycle Concept

Shewhart Cycle in Quality Improvement

Step 4: Evaluation stage
(study the results of the changes implemented during this cycle)



Step 1: Planning stage
(Identify objectives, define data which may be available, define new data needs, plan change or test)

Step 3: Observation stage
(collect information on the effect of the planned changes which have been implemented)

Step 2: Implementation or pilot stage
(complete the planned changes or test)

The Shewhart cycle is repeated multiple cycles with expected improvements implemented in each new cycle

Organizational Interests

- What to use
- When to use it
- How to use it
- Is it cost-effective
- Will it be used safely

Pharmacy and Therapeutics Committee

Focus for medication related activities within a health care organization

P&T Committee Overview

- Medical Staff Committee
- Oversight of medication use in the organization
- Staff experts in the medication use process

P & T Committee Role

- Medication related policies
- Formulary drug selection and review
- Evaluate medication use and improve performance
- Educate

Medication Policy Issues

- Medication selection and quality
- Medication prescribing
- Medication administration

Formulary

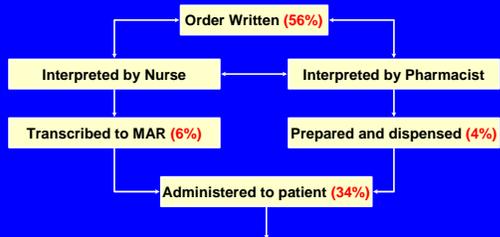
A continuously updated list of medications and related information representing the clinical judgement of physicians, pharmacists, and other experts...

Principles of a Sound Drug Formulary System, 2000
<http://www.usp.org/pdf/EN/patientSafety/pSafetySndFormPrinc.pdf>

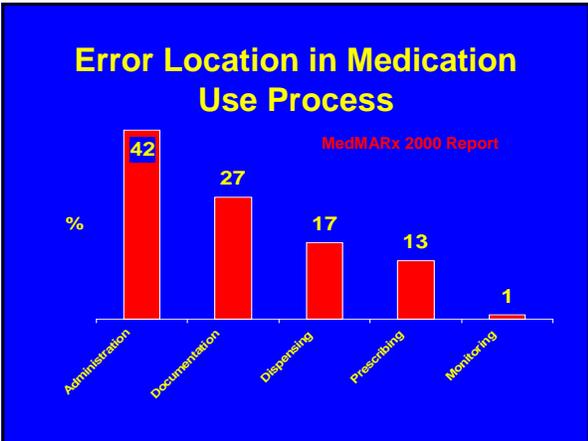
Drug Selection

- Safety
- Clinical Effectiveness
- Cost Impact

Preventable ADE's



Bates DW, Cullen DJ, et al., JAMA 1995; 274: 29-34





- ### Errors in ICU Medication Administration
-
- Med Administration Errors (3.3%)
 - Vasoactive Drugs (33%)
 - Sedative / Analgesics (26%)
 - Wrong Infusion Rate (40%)
 - Pharmacist Involvement cited in low rate
- Colaprese et al, Intensive Care Med, 2001; 27:1590-1595.

MEDICATION ERROR DEATHS

FDA Adverse Events Reporting System 1993-98

Error Type	%
Wrong dose	41
Wrong drug	16
Wrong route	9.5

Phillips J, Meam S, Brinker A, et al. Retrospective analysis of mortalities associated with medication errors. Am J Health-sys Pharm, 2001; 58:1835-41.

Sources of Errors and Elements of Defense Against Them

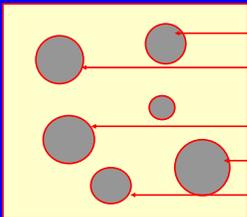
Reason J. Human Error. Cambridge, England: Cambridge Univ. Press; 1990

Proximal Causes of Medication Errors*

Lack of knowledge of the drug	Faulty dose checking
Lack of information about the patient	Infusion pump and parenteral delivery problems
Violation of rules	Inadequate monitoring
Slips and memory lapses	Drug stocking and delivery problems
Transcription errors	Preparation errors
Faulty checking of identification	Lack of standardization
Faulty interaction with other services	

* Adapted from Leape LL, et al. Systems analysis of adverse drug events. JAMA 1995;274:35-43

Latent Medication System Errors



- Latent Errors
- handwriting
 - incomplete information
 - order transcription
 - unclear labeling
 - high workload
 - etc

Workload and Outcomes

	IP Mortality	30-day Re-admit	LOS	Total Costs
Team admissions that day	1.09*		3.09*	2.31*
Average Census			-5.30*	-5.11*

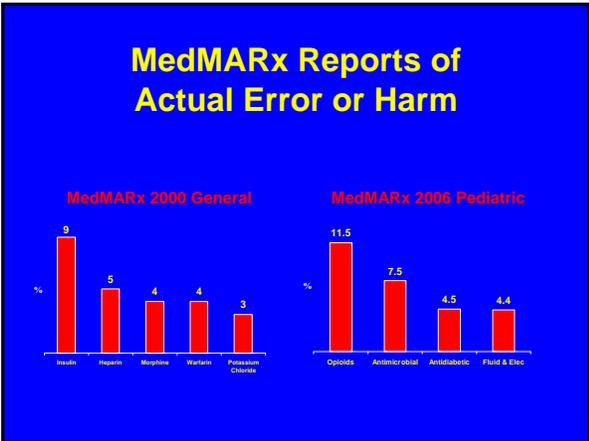
*Significant Multivariate House Staff Effects

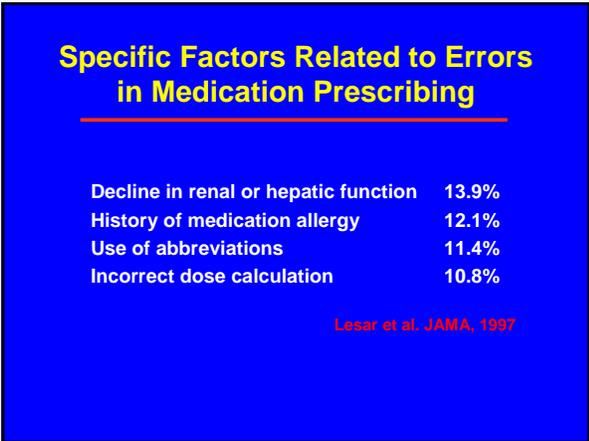
Ding et al., Arch Intern Med 2007; 167: 47-52

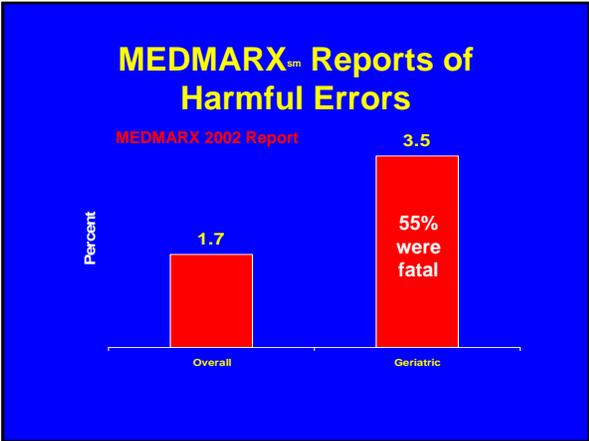
Prescribing Errors by Medication Category

Antimicrobials	40%
Cardiovascular	18%
Gastrointestinal	7%
Narcotic analgesics	7%

Lesar et al. JAMA, 1997



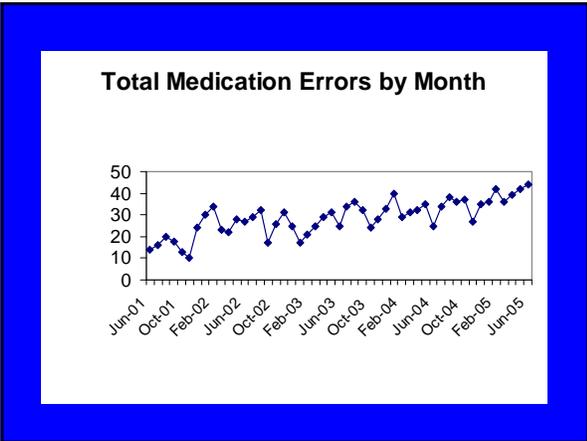




Safeguard Against Errors in High-Risk Drugs

- Build in System Redundancies
- Use Fail-Safes
- Reduce Options
- Use Forcing Functions
- Externalize or Centralize Error-prone Processes
- Store Medications Appropriately
- Screen New Products
- Standardize and Simplify Order Communication
- Limit Access
- Use Constraints
- Use Reminders
- Standardize Dosing Procedures
- Use Differentialization

* Adapted from Cohen MR, Kilo CM. High-Alert Medications: Safeguarding against errors. In Medication Errors. Washington: American Pharmaceutical Association; 1999



Use of High Level Data

- Shows interesting trends
- Better for global evaluation
- No detail to work with

Pitfalls of High Level Data

- Cause unclear
- Potential false conclusions

Medication Errors by Quarter

	Quarter												Mean
	Jun-02	Sep-02	Dec-02	Mar-03	Jun-03	Sep-03	Dec-03	Mar-04	Jun-04	Sep-04	Dec-04	Mar-05	
Wrong Drug	5	3	6	2	10	2	4	5	4	8	2	2	4.4
Wrong Dose	11	17	8	13	6	12	18	17	21	15	22	14	14.5
Duplicate Dose	10	4	3	8	2	16	4	11	9	11	6	17	8.4
Wrong Route	3	2	4	0	2	1	1	5	3	0	3	1	2.1
Wrong Time	15	25	12	33	15	19	27	31	17	26	10	29	21.6
Wrong Fluid	6	7	4	10	3	8	7	5	8	2	3	2	5.4
Wrong Rate	16	20	12	17	21	8	24	8	11	19	23	14	16.1
Wrong Device	2	0	0	1	3	1	4	2	0	1	2	2	1.5
IV Infiltration	0	2	1	0	3	2	0	0	4	0	2	0	1.2
TOTAL	68	80	50	84	65	69	89	84	77	82	73	81	75.2

Broad-based Information Sources

- Near misses
- Patient specific events
- Aggregated hospital-wide occurrence data
- External medication error data
- Hospital quality improvement data
- Therapeutic trends & changes
- Hospital programatic information

Epidemiology of Medication Errors

- Collect the numbers
- Read between the lines
- Look for common threads
- Try to link together

Admission Order Medication Omissions

- Review of ongoing meds not ordered by MD at admission
- 53% of patients had at least 1 unintended discrepancy
- 37% had potential for harm

Cornish, Arch Intern Med 2005; 165:424-429

Admission Order Medication Omissions

<i>Type</i>	<i>Frequency</i>
Omission	65
Dose	35
Frequency	24
Incorrect drug	16
Total	140

Cornish, Arch Intern Med 2005; 165:424-429

IOM Recommendations on: Preventing Medication Errors

- Stronger consumer role (self-management)
- Enhance consumer information sources
- Complete patient-information & decision support tools
- Improved drug labeling
- Standardize drug-related health information technologies
- Broad research agenda on safe and appropriate med use with funding

Medication Use Evaluation

A performance improvement method that focuses on evaluating and improving medication-use processes with the goal of optimal patient outcomes

American Society of Health-System Pharmacists, 1996

Selection of MUE Projects

- known or suspected to cause adverse reactions or drug interactions
- affects large number of patients or medication is frequently prescribed
- potentially toxic or causes discomfort at normal doses
- under consideration for formulary retention, addition, or deletion
- expensive
- used in patients at high risk for adverse reactions
- critical component of care for a specific disease, condition, or procedure
- most effective when used in a specific way
- suboptimal use would have a negative effect on patient outcomes or system costs

*Adapted from American Society of Health-System Pharmacists. ASHP guidelines on medication-use evaluation. Am J Health Syst Phar 1996;53:1953-5.

Computer Facilitated Order Errors

- Computerized prescriber order entry error opportunities
- 22 types of errors facilitated by CPOE system
- Many can be corrected by investigation and improvement

Koppel, JAMA 2005; 1197-1203

Computer Facilitated Errors

- 20% of MedMARx reports involved computer related interaction
- 71% did not reach patient
- 0.74% did actual harm
- Automated dispensing machines

MedMARx 3rd Anniversary Data Report, 2005

Simulation of Technology Impact

- Computer simulation of integrated medication use system

Concluded

- 1,226 days of excess hospitalization
- \$1.4 million associated costs

Andersson, JAMA 2002; 9: 479-80

Drug Name Selection

- Lambert (Drug Safety, 2005)
- Lambert (AJHP, 1997)
- Lambert (Medical Care, 1999)

Summary of Medication Use Quality Issues

- Complex process prone to error
- Drug use can be improved
- ADE risks can be reduced