Quality Assessment
of Drug Therapy

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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 5, 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

Photograph of the cover of the report.

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

Deaths From Medication Accidents

Line chart showing the ratio of deaths to 1979 levels by year of death from 1979 through 1998. Chart compares deaths from prescription medicines to railway, motor vehicle, water transport, and air transport accidents. Over time the number of deaths from medication accidents has greatly increased and now greatly exceeds deaths from those other 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   3 billion**</u>
Total $177 billion

Ernst, J Am Pharm Assn. 2001; 41:192-9 (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

Adverse Drug Events

Adapted from Bates et al.

Adverse Drug Event:
preventable or unpredicted medication event---with harm to patient

Graphic illustration showing a large circle entitled "Medication errors (preventable)" with a smaller half-overlapping circle entitled "Adverse Drug Events (ME & ADR)".

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. <u>JAMA</u>. 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, Sauer BC, Hepler CD, Poole C,
Preventable Drug-Related Hospital Admissions.
Ann Pharmacother 2002; 36:1238-48**

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. <u>Ann Pharmacother</u> 2002; 36:1331-6

Medication Errors

Any <u>preventable</u> 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**

Decision to Treat

Flow chart that begins with decision to treat followed by order written and the various stages that the order goes through while being monitored by various health professionals and the patient once it reaches the patient.

Medical Management Process

Where Adverse Drug Events* Originate
Source Adapted from Bates et al.: JAMA 1995;274:29-34

Flow chart

As Published in *Computerized Physician Order Entry: Costs, Benefits and Challenges*, Feb 2003, AHA

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

A circle is shown with arrows showing clockwise motion and numbers 1, 2, 3, 4 evenly spaced inside the circle. The following explains this graphic illustration.

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

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

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

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

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 judgment 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

Flow chart showing the steps an order goes though including reaching the patient. Specifically, it starts with a order written (56% of errors), then it is interpreted by a nurse and a pharmacist, then it is transcribed to MAR (6% of errors), then prepared and dispensed (4% of errors) and finally administered to the patient (34% of errors).

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

Error Location in Medication Use Process

MedMARx 2000 Report

Bar chart indicating the percent of errors that occur in medication administration (42%), documentation (27%), dispensing (17%), prescribing (13%) and monitoring (1%).

Errors in Medication Administration

Total Error Rate = 19%
Excluding Wrong Time = 10%
Barker et al, Arch Int Med 2002

Bar chart indicating the percent that a medication is given at the wrong time (43%), omission (30%), wrong dose (17%), and wrong drug (4%).

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

Calabrese et al. Intensive Care Med, 2001; 27:1592-1598

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

Graphic illustration

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

Proximal Causes of Medication Errors*

Lack of knowledge of the drug

Lack of information about the patient

Violation of rules

Slips and memory lapses

Transcription errors

Faulty checking of identification

Faulty interaction with other services

Faulty dose checking

Infusion pump and parenteral delivery problems

Inadequate monitoring

Drug stocking and delivery problems

Preparation errors

Lack of standardization

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

Latent Medication System Errors
<u>Latent Errors</u>

Drawing of a square with round holes of various sizes in it and lines leading from the holes to the following captions:

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

Ong 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

MedMARx Reports of
Actual Error or Harm

MedMARx 2000 General

MedMARx 2006 Pediatric

Bar chart showing % of
errors involving insulin (9%), heparin (5%)
morphine (4%), Warfarin (4%) and potassium
Chloride (3%)

Bar chart showing % of
errors involving Opioids (11.5%)
Antimicrobial (7.5%), Anti-
diabetic (4.5%) and fluid & elec (4.4%)

Specific Factors Related to Errors in Medication Prescribing

Decline in renal or hepatic function   **13.9%**

History of medication allergy   **12.1%**

Use of abbreviations   **11.4%**

Incorrect dose calculation   **10.8%**

Lesar et al. JAMA, 1997

MEDMARX^{sm} Reports of Harmful Errors

MEDMARX 2002 Report

Bar chart showing percent overall medication errors (1.5%), and medication errors in Geriatric medicine (3.5%) of which 55% were fatal.

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
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

Total Medication Errors by Month

Line chart showing these errors that crept up in numbers over time beginning with approximately 12 errors in June 2001 up to approximately 45 in June 2005.

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

Chart detailing the errors including wrong drug, wrong dose, duplicate dose, wrong route, wrong time, wrong fluid, wrong rate, wrong device, and wrong IV infiltration by quarter. The total number of errors increased over time from 68 in June 2002 to 81 in March 2005.

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 programmatic 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

Type	Frequency
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

used in patients at high risk for adverse reactions

affects large number of patients or medication is frequently prescribed

critical component of care for a specific disease, condition, or procedure

potentially toxic or causes discomfort at normal doses

most effective when used in a specific way

under consideration for formulary retention, addition, or deletion

suboptimal use would have a negative effect on patient outcomes or system costs

expensive

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

A chart is shown that indicates that during FY 01 through FY 05 the amount spent on anti-infective agents went from $1,612,016 in FY 01 to $5,287,206 in FY 05. In addition, the chart indicates that in FY 01 $1,226,067 was spent on Antineoplastic agents and by FY 05 the amount spent on those agents was $1,866.450.

Review Category	Data Collection Model (s)	Typical Application	Comments
Retrospect	Data is collected for a fixed period which may be archival or accumulation of new patients for a fixed period of time	Data archive search for prescribing patterns of patients on serotonin antagonist antiemetic drugs	Supports large scale epidemiologic approach

No active intervention to change medication use patterns occurs due to the post-hoc data collection process |
Concurrent	Each new order generates an automatic review of previously approved criteria for use within a specified period of the initiation of therapy	Review of naloxone to investigate possible nosocomial adverse medication event	
	Laboratory or other monitoring criteria are reported for all patients on the drug	Digoxin monitoring based upon daily review of digoxin serum levels (49).	
	Abnormal Laboratory or other monitoring criteria are reported for all patients on the drug on a regular basis.	Regular review of serum creatinine for patients on aminoglycosides	
	Each new order for the drug is evaluated for compliance with previously approved criteria for use. Variance to the criteria require intervention prior to initiation of therapy	Medication use guidelines (ketorolac) (50);

Restricted antibiotics | |

Evidence Based Guidelines

Photograph of a Fact Sheet on Beta-Blockers for Acute Myocardial Infarction dated April 27, 2005

www.guidelines.gov

Benchmarking

Primary Indication for NovoSeven™ Use

37.8% (119/315) of patients received NovoSeven for prevention of bleed

62.2% (196/315) of patients received NovoSeven for treatment of active bleed

Primary Indication for NovoSeven Use by Institution

Bar chart showing % of cases. The numbers above the bars represent the number of complete cases submitted by each institution.

Benchmarking

Chart showing C6- Medication until first dose of antifungal medication – Page 1 of 2

Benchmarking

Photograph of a document called Key Indicator Report – Sample Hospital, July-September 2005 (Q3)

Photograph of a Quality Report for a Hospital.

National Quality Improvement Goals. Condition: Heart Attack Care

Reporting Period: July, 2004 – June, 2005

Computerized
Laboratory Alerts

Flashing Computerized Alert for low Potassium

Increased follow-up monitoring

Increased K+ intervention rate

Decreased hypokalemia at discharge

Paltiel, Arch Intern Med 2003; 163:200-204

Computerized Order Entry

Taylor (Pediatrics, 2008)

Feldstein (Arch Intern Med, 2006)

Mekhjian (JAMIA, 2002)

Nightingale (BMJ, 2000)

Bates (JAMA, 1998; JAMIA, 1999)

Raschke (JAMA, 1998)

Claussen (Ann Intern Med, 1996)

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 5th 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

Anderson, JAMIA 2002; 9: 479-90

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

Photograph of various medications (tablets, capsules, and vials).