# 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

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## 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 Aspden, Julie Wolcott, J. Lyle Bootman, Linda R. Cronenwett, Editors.
Washington DC; National Academies Press; 2007.

## Deaths From Medication Accidents
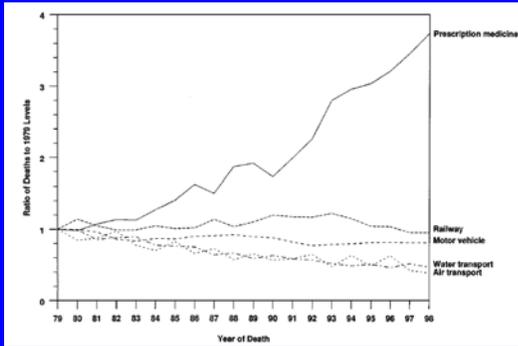


Phillips DP, Breder CC, Annu. Rev. Public Health 2002; 23: 135-50

## Drug Related Morbidity and Mortality Costs

| | |
|---|---|
| Hospital | $121 billion |
| Long Term Care | 33 billion |
| Physician visits | 14 billion |
| Emergency visits | 5 billion |
| Added prescriptions | 3 billion |
| 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

Medication
Errors
(preventable)

Adverse Drug
Events
(ME & ADR)

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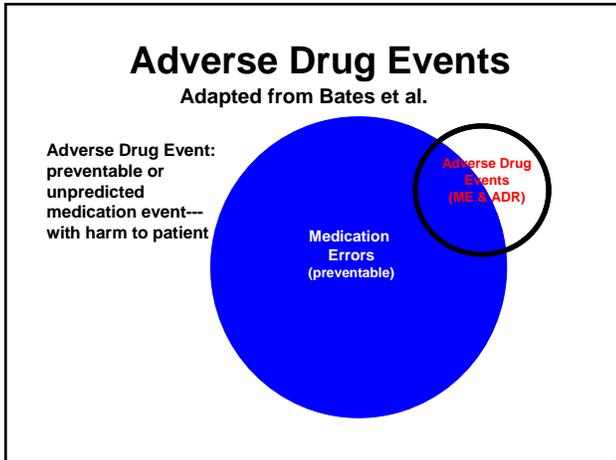
## Cost Impact of ADE's

|  | 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

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## 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.  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

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*Decision to Treat*

Order Written

Interpreted by Nurse → Interpreted by Pharmacist

Transcribed to MAR → Prepared and dispensed

Administered to patient

Physician   Pharmacist
**Monitor Results**
Nurse   Patient   Other

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

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

**Step 4:** Evaluation stage (study the results of the changes implemented during this cycle)
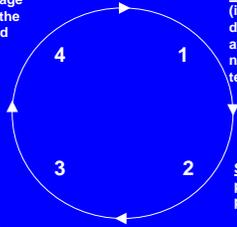
**Step 1:** Planning stage (identify objectives, define data which may be available, define new data needs, plan change or test)

4   1

3   2

**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*

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## Organizational Interests

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

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## 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

Order Written **(56%)**

Interpreted by Nurse          Interpreted by Pharmacist

Transcribed to MAR **(6%)**          Prepared and dispensed **(4%)**

Administered to patient **(34%)**
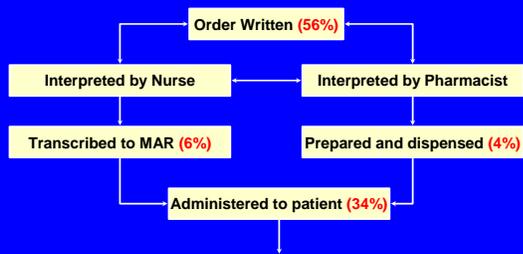
Bates DW, Cullen DJ, et al., JAMA 1995; 274: 29-34

## Error Location in Medication Use Process

MedMARx 2000 Report

**%**

| | |
|---|---|
| 42 | Administration |
| 27 | Documentation |
| 17 | Dispensing |
| 13 | Prescribing |
| 1 | Monitoring |

## Errors in Medication Administration

**Total Error Rate = 19%**

**Excluding Wrong Time = 10%**

Barker et al, Arch Int Med 2002

**%**

| Wrong Time | Omission | Wrong Dose | Wrong Drug |
|---|---|---|---|
| 43 | 30 | 17 | 4 |
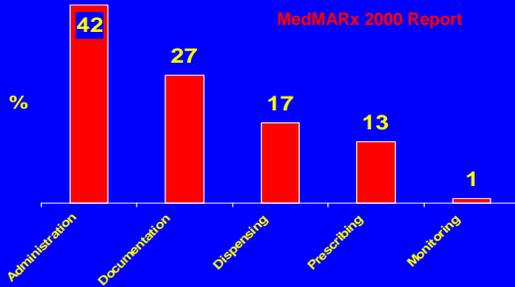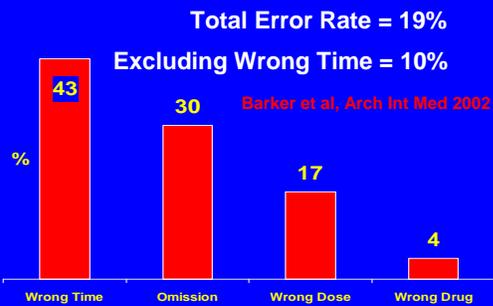
## Errors in ICU Medication Administration

- 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
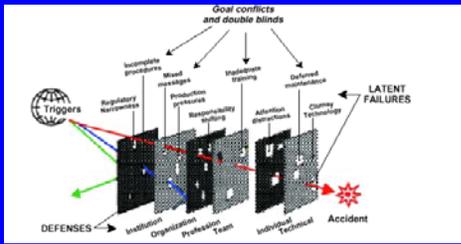


Reason J. Human Error. Cambridge, England: Cambridge Univ. Press; 1990

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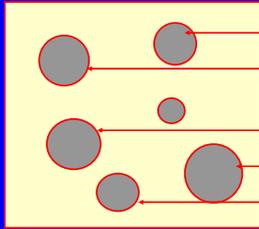
**Latent Errors**
- handwriting
- incomplete information
- order transcription
- unclear labeling
- high workload
- etc

## 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

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**

| Insulin | Heparin | Morphine | Warfarin | Potassium Chloride |
|---------|---------|----------|----------|--------------------|
| 9 | 5 | 4 | 4 | 3 |

**MedMARx 2006 Pediatric**

| Opioids | Antimicrobial | Antidiabetic | Fluid & Elec |
|---------|---------------|--------------|--------------|
| 11.5 | 7.5 | 4.5 | 4.4 |

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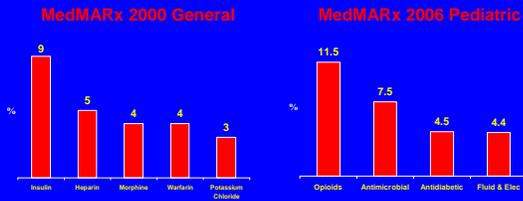
# Specific Factors Related to Errors in Medication Prescribing

| | |
|---|---|
| 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

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# MEDMARX<sub>sm</sub> Reports of Harmful Errors

**MEDMARX 2002 Report**

| Overall | Geriatric |
|---------|-----------|
| 1.7 | 3.5 — 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**

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

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### Total Medication Errors by Month



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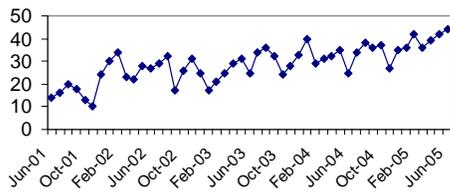
## Use of High Level Data

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

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## 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

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## 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
- 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.

| | | SPENT FY 01 | SPENT FY 02 | SPENT FY 03 | SPENT FY 04 | SPENT FY_05 |
|---|---|---|---|---|---|---|
| 80000 | ANTI-INFECTIVE AGENTS | | | | | |
| 80400 | AMEBICIDES | $0 | $1,522 | $332 | $884 | $1,321 |
| 80800 | ANTHELMINTICS | $2,510 | $996 | $2,623 | $1,231 | $1,834 |
| 81202 | AMINOGLYCOSIDES | $9,457 | $13,457 | $10,351 | $35,468 | $47,014 |
| 81204 | ANTIFUNGAL ANTIBIOTICS | $256,806 | $320,884 | $357,206 | $946,657 | $1,082,165 |
| 81206 | CEPHALOSPORINS | $221,196 | $197,231 | $162,850 | $180,186 | $188,435 |
| 81207 | B-LACTAMS | $59,322 | $77,722 | $77,703 | $90,073 | $112,235 |
| 81208 | CHLORAMPHENICOLS | $626 | $204 | $172 | $771 | $1,331 |
| 81212 | ERYTHROMYCINS | $52,106 | $69,377 | $89,793 | $112,984 | $109,499 |
| 81216 | PENICILLINS | $50,569 | $41,427 | $65,243 | $46,314 | $61,153 |
| 81224 | TETRACYCLINES | $16,872 | $4,427 | $4,788 | $4,569 | $8,820 |
| 81228 | MISCELLANEOUS ANTIBIOTICS | $38,577 | $35,347 | $35,261 | $37,811 | $41,473 |
| 81600 | ANTITUBERCULOSIS AGENTS | $33,141 | $27,937 | $42,335 | $53,318 | $46,223 |
| 81800 | ANTIVIRALS | $658,157 | $1,399,246 | $2,472,982 | $3,251,543 | $3,417,004 |
| 82000 | ANTIMALARIAL AGENTS | $82,141 | $60,942 | $20,848 | $19,051 | $20,577 |
| 82200 | QUINOLONES | $82,319 | $113,064 | $94,705 | $117,380 | $116,301 |
| 82400 | SULFONAMIDES | $7,053 | $6,730 | $3,425 | $3,660 | $2,770 |
| 82600 | SULFONES | $5,207 | $4,839 | $4,651 | $4,972 | $5,366 |
| 83200 | ANTITRICHOMONAL AGENTS | $1,493 | $3,923 | $677 | $924 | $1,454 |
| 83600 | URINARY ANTI-INFECTIVES | $5,974 | $2,009 | $2,142 | $1,632 | $2,836 |
| 84000 | MISCELLANEOUS ANTI-INFECTIVES | $28,489 | $34,661 | $30,211 | $27,401 | $19,394 |
| 80000 | ANTI-INFECTIVE AGENTS TOTAL | $1,612,016 | $2,415,944 | $3,478,297 | $4,936,828 | $5,287,206 |
| 100000 | ANTINEOPLASTIC AGENTS TOTAL | $1,226,067 | $1,564,834 | $1,550,613 | $1,693,797 | $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 seratonin 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  Abnormal Laboratory or other monitoring criteria are reported for all patients on the drug on a regular basis | Digoxin monitoring based upon daily review of digoxin serum levels (49).  Regular review of serum creatinine for patients on aminoglycosides | |
| Prospective | 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

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**



Note: The numbers above the bars represent the number of complete cases submitted by each institution.

# Benchmarking



# Benchmarking

## 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