Quality Assessment of Drug Therapy

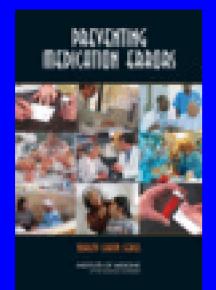
Charles E. Daniels, R.Ph., Ph.D. Pharmacist In Chief Professor of Clinical Pharmacy University of California San Diego, California

Patient Concerns

Drug-Drug interaction70%Wrong medicine69%Cost of treatment69%Complications from procedure69%Cost of prescription medicines67%Hospital acquired infection49%

ASHP Survey: May 1 and 5, 2002

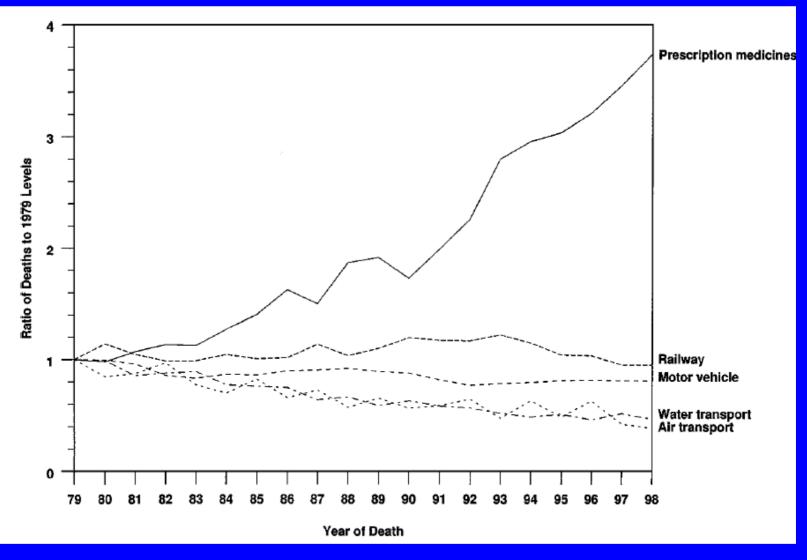
IOM Report: Preventing Medication Errors



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

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 billionLong Term Care33 billionPhysician visits14 billionEmergency visits5 billionAdded prescriptions3 billionTotal\$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

Adverse Drug Events (ME & ADR) Medication Errors (preventable)

Cost Impact of ADE's

	Increased	Increased	
	LOS	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. <u>Ann Pharmacother</u> 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)

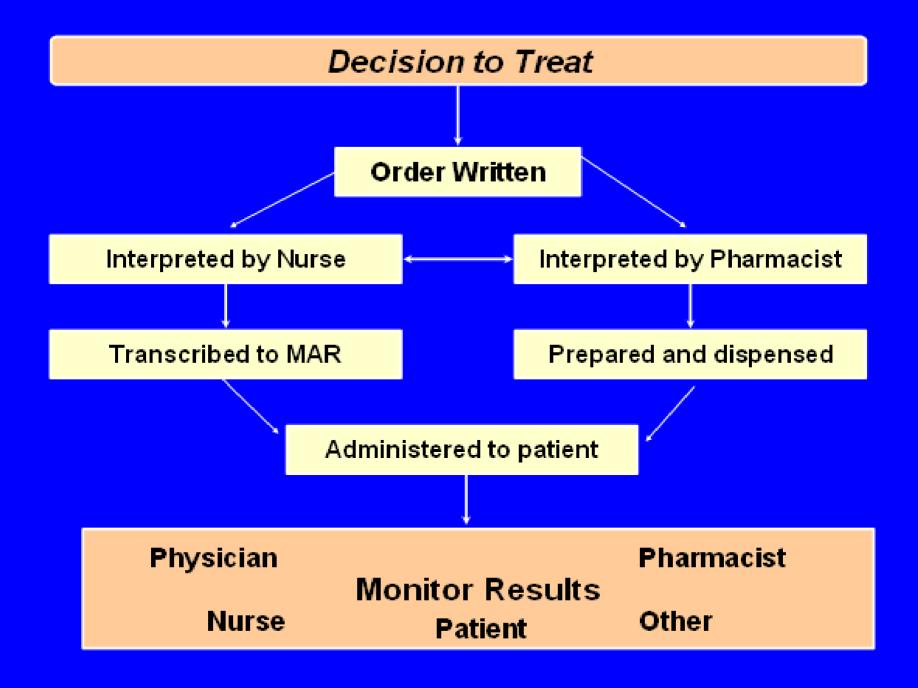
McDonnell PJ and Jacobs MR. Hospital Admissions Resulting from Preventable Adverse Drug Reactions. <u>Ann Pharmacother</u> 2002; 36:1331-6

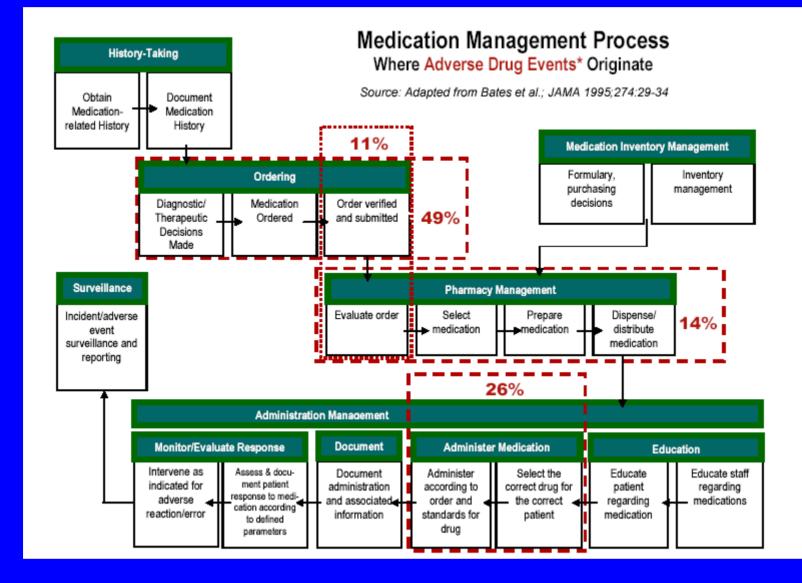
Medication Errors

Any 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





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

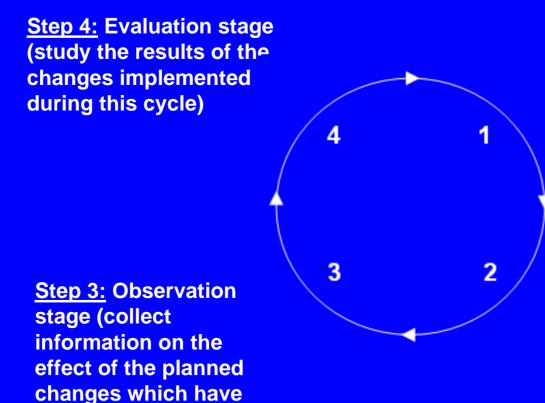
Medication Use Process

- 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



been implemented)

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)

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

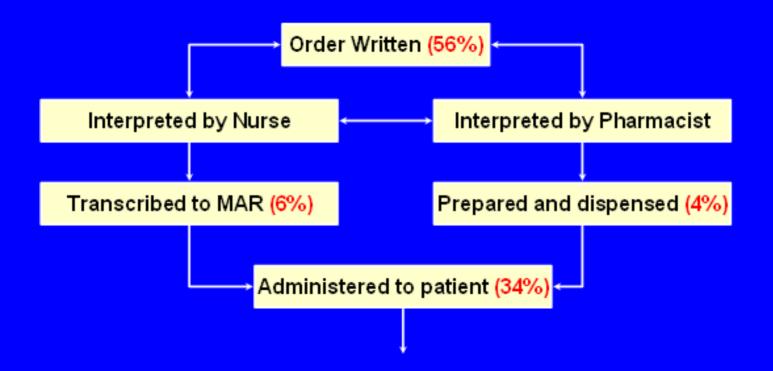
A continuously updated list of medications and related information representing the clinical judgement of physicians, pharmacists, and other experts...

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

Drug Selection

- Safety
- Clinical Effectiveness
- Cost Impact

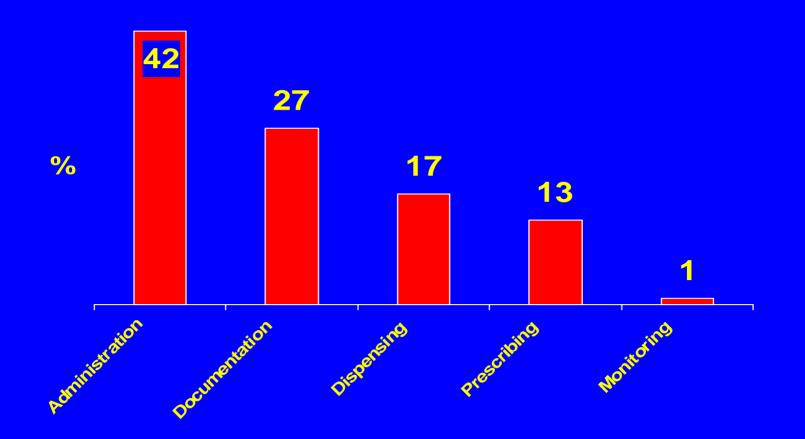
Preventable ADE's



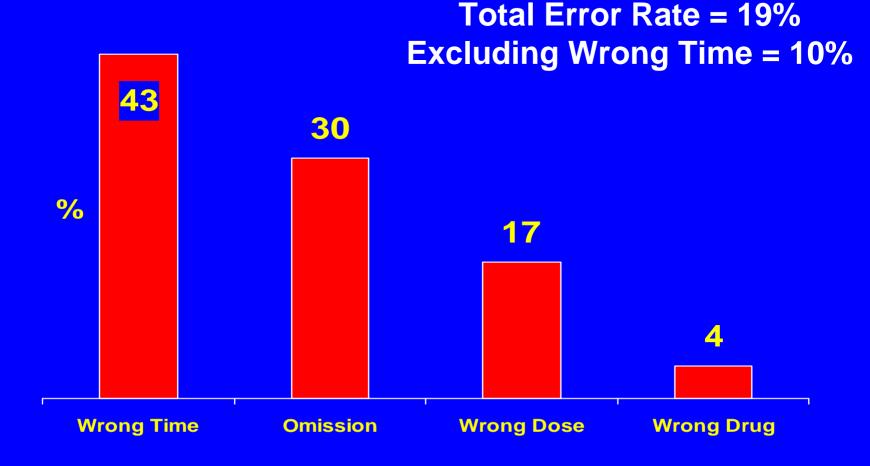
Bates DW, Cullen DJ, et al., JAMA 1995; 274: 29-34

Error Location in Medication Use Process

MedMARx 2000 Report



Errors in Medication Administration



Barker et al, Arch Int Med 2002

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

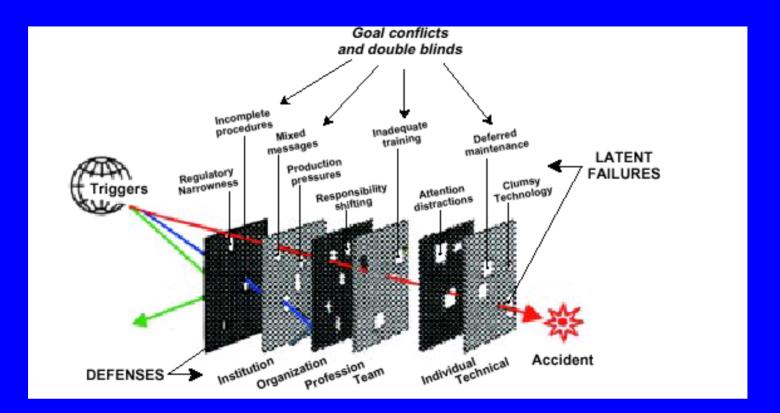
MEDICATION ERROR DEATHS

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



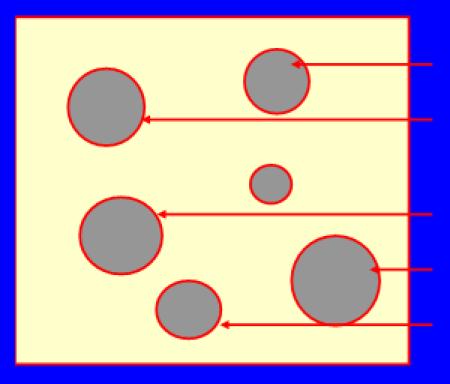
Reason J. Human Error. Cambridge, England: Cambridge Univ. Press; 1990

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 *Significant Mu	Iltivariate House S	Staff Effects	-5.30*	-5.11*

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

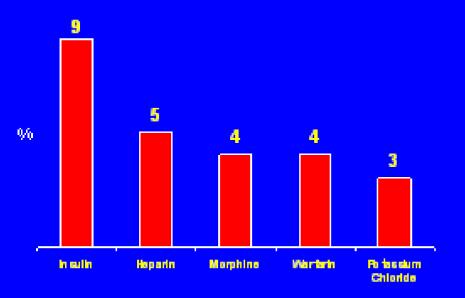
Prescribing Errors by Medication Category

Antimicrobials40%Cardiovascular18%Gastrointestinal7%Narcotic analgesics7%

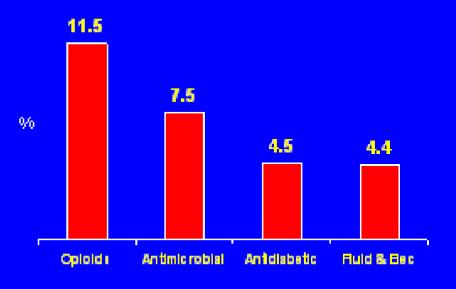
Lesar et al. JAMA, 1997

MedMARx Reports of Actual Error or Harm

MedMARx 2000 General



MedMARx 2006 Pediatric

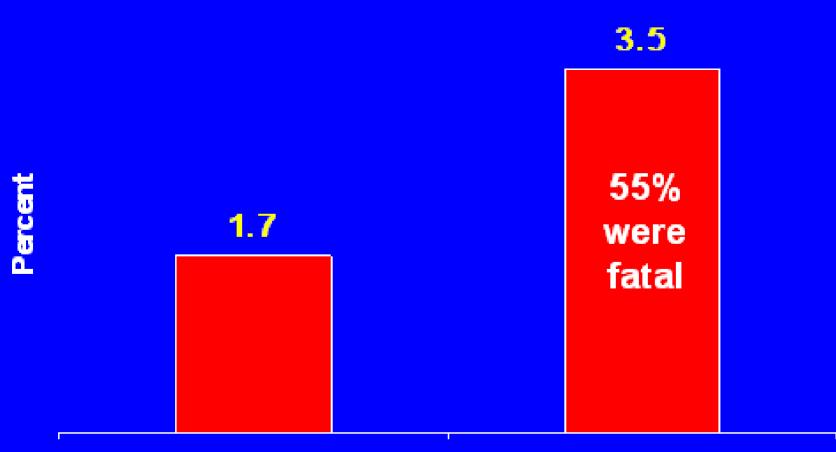


Specific Factors Related to Errors in Medication Prescribing

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

MEDMARXsm Reports of Harmful Errors



Overall

Geriatric

MEDMARX 2002 Report

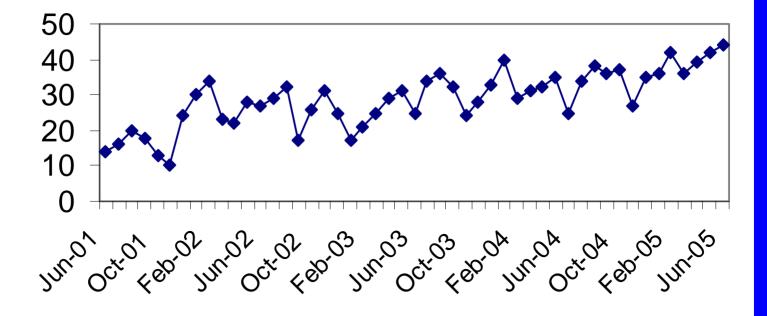
Safeguard Against Errors in High-Risk Drugs

- 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

Total Medication Errors by Month



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												
	Jun-02	Sep-02	Dec-02	Mar-03	Jun-03	Sep-03	Dec-03	Mar-04	Jun-04	Sep-04	Dec-04	Mar-05	Mean
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

Туре	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

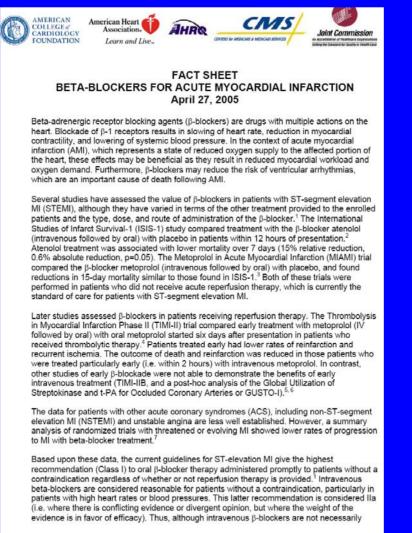
- used in patients at high risk for adverse reactions
- critical component of care for a specific disease, condition, or procedure
- most effective when used in a specific way
- suboptimal use would have a negative effect on patient outcomes or system costs

•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-INI	FECTIVE 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-INI	FECTIVE AGENTS TOTAL	\$1,612,016	\$2,415,944	\$3,478,297	\$4,936,828	\$5,287,206
100000	ANTINE	OPLASTIC 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
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 <u>posocomial</u> adverse medication event	process
	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	Regular review of serum creatinine for patients on aminoglycosides	
Prospective	drug on a requiar basis 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 (<u>ketorolac</u>) (50); Restricted antibiotics	

Evidence Based Guidelines



FACT SHEET - BETA-BLOCKERS FOR ACUTE MYOCARDIAL INFARCTION Page 1 of 3 (April 2005)

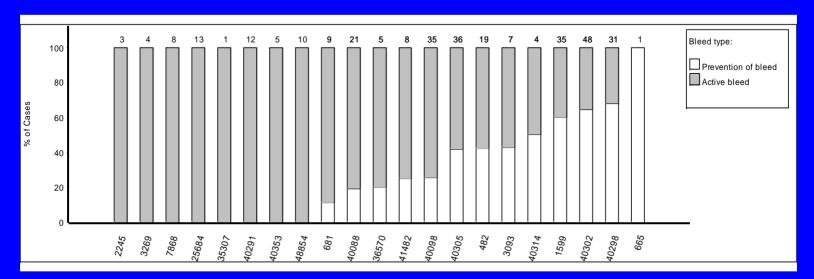
www.guidelines.gov

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

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

Benchmarking

C6 - Medication until first dose of antifungal medication - Page 1 of 2											
Hosp ID	N	Alemtuzumab	Aminoglycoside	Antithymocyte/i ymphocyte	Azathioprine	Basiliximab	Cladribine or Fludarabine	Colony- stimulating	Cyclophospham Ide	Cyclosporine	Dacilzumab
1	30	0.0% (0)	10.0% (3)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
2	31	0.0% (0)	6.5% (2)	71.0% (22)	3.2% (1)	19.4% (6)	0.0% (0)	6.5% (2)	3.2% (1)	41.9% (13)	0.0% (0)
5	29	0.0% (0)	3.4% (1)	20.7% (6)	24.1% (7)	10.3% (3)	0.0% (0)	0.0% (0)	0.0% (0)	37.9% (11)	0.0% (0)
13	6	0.0% (0)	0.0% (0)	50.0% (3)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	66.7% (4)	0.0% (0)
14	5	0.0% (0)	20.0% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	40.0% (2)	80.0% (4)
17	30	0.0% (0)	0.0% (0)	3.3% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
27	30	46.7% (14)	13.3% (4)	10.0% (3)	0.0% (0)	6.7% (2)	0.0% (0)	3.3% (1)	0.0% (0)	23.3% (7)	10.0% (3)
28	20	0.0% (0)	0.0% (0)	40.0% (8)	0.0% (0)	5.0% (1)	0.0% (0)	10.0% (2)	0.0% (0)	5.0% (1)	0.0% (0)
34	30	30.0% (9)	20.0% (6)	26.7% (8)	0.0% (0)	26.7% (8)	0.0% (0)	3.3% (1)	6.7% (2)	13.3% (4)	16.7% (5)
40	28	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	3.6% (1)	0.0% (0)
55	30	0.0% (0)	13.3% (4)	50.0% (15)	0.0% (0)	20.0% (6)	0.0% (0)	0.0% (0)	0.0% (0)	70.0% (21)	0.0% (0)
57	23	0.0% (0)	21.7% (5)	0.0% (0)	0.0% (0)	87.0% (20)	0.0% (0)	0.0% (0)	0.0% (0)	4.3% (1)	0.0% (0)
61	30	0.0% (0)	6.7% (2)	26.7% (8)	6.7% (2)	73.3% (22)	0.0% (0)	3.3% (1)	0.0% (0)	53.3% (16)	0.0% (0)
69	29	0.0% (0)	0.0% (0)	20.7% (6)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	48.3% (14)	55.2% (16)
76	30	0.0% (0)	3.3% (1)	16.7% (5)	20.0% (6)	20.0% (6)	0.0% (0)	0.0% (0)	0.0% (0)	50.0% (15)	0.0% (0)
77	30	23.3% (7)	0.0% (0)	76.7% (23)	3.3% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	6.7% (2)	0.0% (0)
79	30	0.0% (0)	0.0% (0)	6.7% (2)	3.3% (1)	0.0% (0)	0.0% (0)	6.7% (2)	3.3% (1)	10.0% (3)	36.7% (11)
274	16	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	6.3% (1)	0.0% (0)	0.0% (0)	0.0% (0)
Total	457	6.6% (30)	6.3% (29)	24.1% (110)	3.9% (18)	16.2% (74)	0.0% (0)	2.2% (10)	0.9% (4)	25.2% (115)	8.5% (39)

Benchmarking

_ _ _ _ _ _ _

Key Indicator Report

Tuesday, February 28, 2006

Sample Hospital

Jul - Sep 2005 (03)

			ul - Sep 2	2005 (Q	3)			i - Sep 20	05 (rece	nt year)	
		Relative		Percentile		UHC	Relative		Percentile	_	UHC
	1	Performance	Observed	Rank	Target	Median	Performance	Observed	Rank	Target	Median
UHC Key Performance Metrics											
Clinical Effectiveness											
Post-Surgical Mortality	(obs/exp)	•	0.75	33%	1.00	0.87	00	0.76	29%	1.00	0.87
Medical Mortality (AHRQ Populations)	(obs/exp)	•	0.80	4196	1.00	0.84	•	0.83	42%	1.00	0.86
Readmission Rate	(%)		4.7	59%		4.4		5.0	52%		4.9
JCAHO Core MeasureAMI*	(%)										
JCAHO Core MeasureHeart Failure*	(%)										
JCAHO Core MeasurePneumonia*	(%)										
JCAHO Core MeasureSIP*	(%)										
Efficiency											
Cost/CMI-Adj Discharge (WI-Adj)	(\$ / pt)	00	6,288	896	8,363	9,399	00	6,761	5%	8,130	9,061
Cost/CMI-Adj Disch Net Bad Debt (WI-Adj)	(\$ / pt)	00	6,147	8%	7,898	8,635	00	6,656	7%	7,805	8,322
Supply Cost/CMI-Adj Discharge	(\$ / pt)	<u>_</u>	2,283	79%	1,723	2,035	<u>_</u>	2,416	87%	1,612	1,957
Supply Cost % Net Operating Revenue	(%)	•	26.8	93%	15.9	19.4	•	27.1	96%	15.8	19.1
IP Drug Exp/Rx Intensity-Weight Discharge	(\$ / pt)	ō	148	30%	141	179	Ō	143	28%	142	177
Labor Cost (WI-Adj)/CMI Adj Discharge	(\$ / pt)	00	2,733	8%	3,788	4,243	00	2,758	7%	3,622	4,042
FTEs/CMI AOB	(FTE/bed)	00	2.4	296	3.7	4.2	80	2.5	5%	3.6	4.0
LOS Ratio	(obs/exp)	õ	0.96	3496	1.00	1.02	õ	1.00	40%	1.00	1.01
Financial Stability	(
Net Days A/R	(Days)				43.7	48.3				43.2	49.1
Net Operating Revenue/CMI-Adj Discharge	(\$ / pt)	<u> </u>	8,512	12%	11,725	10,116	<u></u>	8,894	22%	11,269	9,996
Operating Margin Percentage	(%)	Θo	18.7	96%	10.0	8.3	ōo	18.4	92%	12.5	8.1
Patient Centeredness											
Inpatient Satisfaction	(100=best)	0	85.8	86%	84,4	82.5	0	85.4	84%	84.2	82.6
Safety											
Death in Low-Mortality DRGs	(Rate/1000)	0	0.00	57%	0,78	0.00	0	0.00	17%	0.86	0.47
AHRQ Surgery-Related Safety Summary	(failure rate)	ŏ	2	6296	3	2	2	5	93%	3	2
	the second second	- Q1	_						2.2.14		_

oend

Substantially Worse than Target

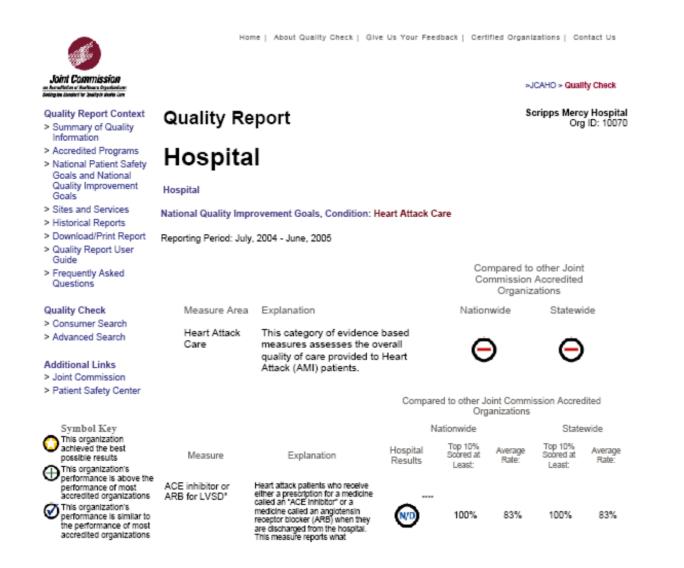
Worse than Target Within Target Range

OO Substantially Better than Target

S No Data From Your Institution

ĩ Interpret with Caution. This is an introductory measure and is subject to revision. * JCAHO data availability lags the other indicators.

Note: Targets have been set specific to each individual metric. AHRQ and JCAHO targets are used when available and appropriate. See detail pages for target ranges.



http://jcwebnoc.jcaho.org/qualitycheck/QualityReport.aspx?hcoid=10070&x=nqig&program=Hospital&mst=Heart Attack Care&... 3/5/2006

Computerized Laboratory Alerts

- Flashing Computerized Alert for low Potassium
- Increased follow-up monitoring
- Increased K+ intervention rate
- Decreased hypokalemia at discharge

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

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

