

Patient Safety and Medication Errors: Epidemiology and Prevention Procedures

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Overview

- Backdrop
 - Global picture of safety
 - US data
- Epidemiology of medication safety
- Improving inpatient medication safety
 - CPOE
 - Bar-coding
 - Smart pumps
 - Computerized ADE monitoring
- CPOE and unintended consequences
- Conclusions

Safety

Safety is a systems property.

OM Report, Crossing the Quality Chasm

Every system is perfectly designed to
achieve the results it gets.

Don Berwick



FFP

FFP

FFP

FFP

Fentanyl

Fentanyl

Fentanyl

Fentanyl

FFP
500ml
200ml
Inmed
Solved PC 110
Fentanyl

Fentanyl
20
10
NS
Inmed
Solved PC 110

Fentanyl
100
50
Lactated Ringers
Inmed
Solved PC 110

Handwriting example

Arundin 4 m p d g p

Global Picture of Patient Safety

- Clear from many studies that is an important problem in every country evaluated
 - Adverse event rate in hospitalized patients about 10% in most developed countries
 - Know much less about the developing world
- Know much more about safety in the hospital than safety outside it
 - Yet limited data available suggest that the magnitude of the problem is about as big outside hospitals

Knowledge about Epidemiology, Prevention

- **Varies from country to country**
 - Yet major domains appear to be more similar than different at least in developed countries
 - Medication safety less important in less developed countries—magnitude of issue associate with level of development
- **Need more data about efficacy of interventions**
 - What is feasible in a given setting will depend on resources available
 - Almost no data about prevention from developing world

To Err is Human

- Errors are common
- Errors are costly
- Systems cause errors
- Errors can be prevented and safety can be improved

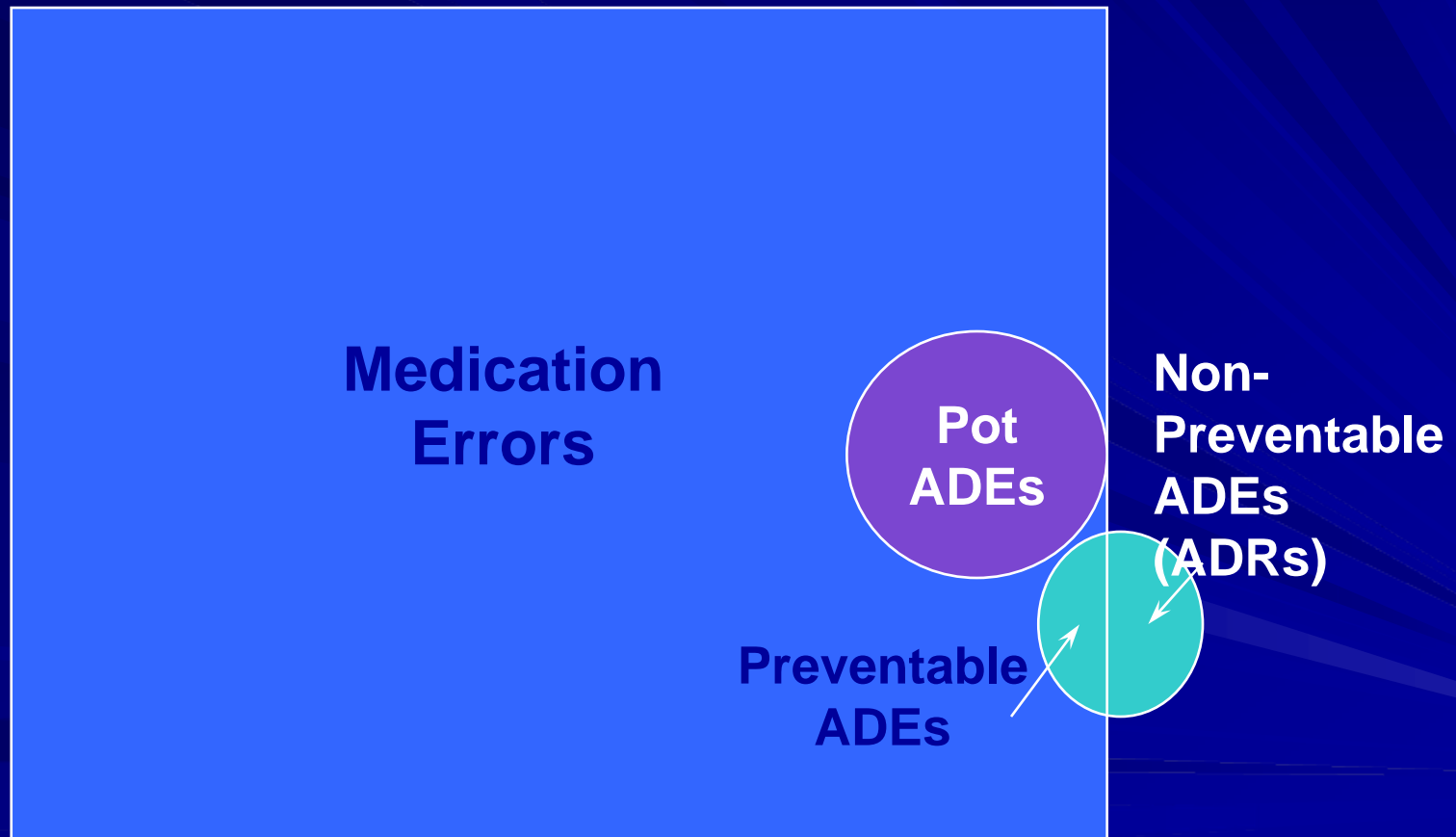
Medication-related adverse events were the single leading cause of injury



Overall View of Outpatient Safety

- Much less data about epidemiology or prevention than for inpatients
- Key areas
 - Medication safety
 - Follow-up post-discharge
 - Follow-up of abnormal tests
 - Ambulatory surgery
- Still could use large comprehensive study

Relationships Between Med Errors, Potential ADEs and ADEs



Preventing Medication Errors: Epidemiological Review

- Medications harm too many Americans
 - At least 1.5 million people per year
 - Hospitals
 - 400,000 preventable ADEs per year
 - About 1 medication error per patient per day
 - Outpatient setting
 - Also frequent, though data less solid
 - 530,000 ADEs/year in Medicare patients

IOM, 2006 Preventing Medication Errors

Medication Error Frequency and Potential for Harm

In 10,070 Orders

530 Medication Errors 1.4 per admission

35 Potential ADEs

5 Preventable ADEs

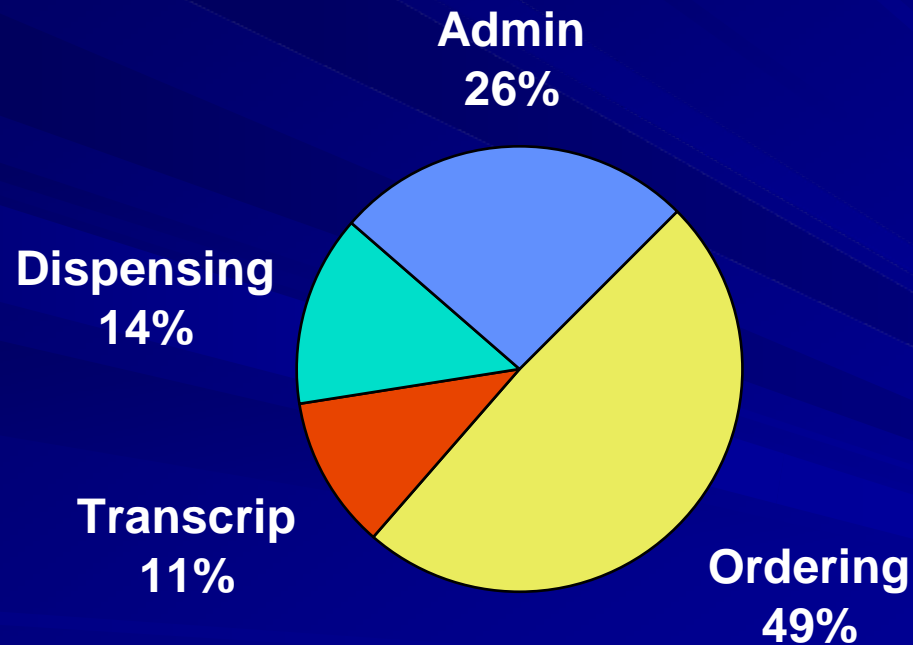
- 1 in 100 medication errors results in an ADE
- 7 in 100 represent potential ADEs

ADE Prevention Study: Key Results

- 6.5 ADEs/100 admissions
 - 28% preventable
 - 3 potential ADEs for every preventable ADE

Bates et al, *JAMA* 1995;274:29-43

Error Stage for Preventable ADEs and PADEs (n=264)



Costs of ADEs

- ADEs are expensive
 - \$2461 per ADE, \$4555 per preventable ADE
 - ADE average similar to Utah figure
 - Annual BWH costs \$5.6 million for all ADEs
 - \$2.8 million for preventable ADEs
- These figures exclude costs of:
 - Injuries to patients
 - Malpractice costs
 - Costs of admissions due to ADEs
- Figures justify investment in prevention efforts

ADE Frequency

- To determine the baseline rate of ADEs in 6 community hospitals in the greater Boston area
- To compare the ADE rates among the hospitals
- To estimate the potential benefit and savings associated with ADE rate reduction

Hug et al, J Gen Intern Med 2010

ADE Rate By Site

	Total	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6
ADE Rate*	15	19.5	11	15.5	17	15	12.5
% Prev	75	72	82	71	85	73	68

**Per 100 admissions*

Range: 11-19.5 for rate
68-85 for percent preventable

Preventable ADEs: Prevention Strategies

Prevention Strategy	% preventable
Drug-lab	27%
Renal check	19%
Drug-age	9%
Drug dose	9%
Drug-specific guidelines	7%
Other	21%
Not preventable with CPOE	19%

Net Benefits

- Greatest benefits appear to come from ADE reduction, renal dosing
- Smaller but substantial contributions from other arms
- Important to note that will be other benefits that these projected ones

Drugs In Outpatients

- 75% of office visits to PCPs associated with initiation or continuation of a drug
- ADEs appear common, though relatively few data
 - Found in 31.5% of patients recently discharged from hospital
 - ~5% of all patients per year
- Many medication-related claims are in outpatients
- Rate certain to increase as patients discharged quicker and sicker

ADE Outpatient Results

- 2858 patients, 2248 (79%) with prescription drug use
 - 18% self report drug complications
 - 3% ADEs on chart review
- Patients reported:
 - 13%--event could have been prevented
 - 35%--medication was not changed
 - 20%--symptoms lasting longer than 3 months
- Discrepancy between patient reported and chart documented events

IMP Study

- 629 patients
 - 132 non-preventable ADEs 20.9/100 pts
 - 74 preventable ADEs 11.8/100 pts
- Among the 206 ADEs
 - 86% significant, 14% serious
 - 36% preventable
 - 6% (n=13) both serious and preventable

Gandhi, NEJM, 2003

ADEs in Pediatric Outpatients

- 1788 patients
 - 57 preventable ADEs (3% rate)
 - 226 non-preventable ADEs (13%)
- Of preventable ADEs, 40 (70%) were related to parent administration
- Improving communication about medication used appeared to be strategy with greatest potential benefit

Incidence and Severity of Adverse Events after Discharge

- 400 medical inpatients
- Adverse event rate 19%
 - 6% preventable
 - 6% ameliorable
- Of adverse events
 - 66% were ADEs
 - 17% procedure-related

Non-IT Inpatient Approaches

- IT not only way to improve safety by any means
- 66% reduction in preventable ordering ADEs with pharmacist participation in ICU rounds

Leape, JAMA, 2000

- Building a culture of safety is extremely important
 - Team training

Technology and Its Impact

- One major role is to make providers more efficient—can free them to do other things
- Pharmacists—more clinical activities
- Nurses—more patient interactions
- Will likely need to redeploy given workforce shortages

Reengineering Medicine: The Role of IS

- Could be changed by providing external aids
 - Linking medical knowledge and patient-specific data
 - Identifying options
- Without such tools, experts
 - Make errors
 - Overlook available knowledge
 - Don't sufficiently account for uniqueness of patients

Weed LL, Weed L, *Federation Bulletin*, 1994

Ways IT Can Improve Safety

- Prevent errors and adverse events
- Facilitating a more rapid response after an adverse event has occurred
- Tracking and providing feedback about adverse events

Main Strategies for Preventing Errors and AEs Using IT

- Tools to improve communication
- Making knowledge more readily accessible
- Requiring key pieces of information
- Assisting with calculations
- Performing checks in real time
- Assisting with monitoring
- Providing decision support

HIT and Medication Safety

- Computerized physician order entry
- Bar-coding
- Smart pumps
- Computerized ADE monitoring

Inpatient Prevention

- 55% reduction in serious medication error rate with CPOE

Bates, JAMA, 1998

- 83% reduction in overall medication error rate

Bates, JAMIA, 2000

- Cost of each preventable ADE ~ \$6000

Improving Drug Ordering With Order Entry

■ Streamline, structure process

- Doses from menus
- Decreased transcription
- Complete orders required

■ Give information at the time needed

- Show relevant laboratories
- Guidelines
- Guided dose algorithms

■ Perform checks in background

Drug-allergy

Dose ceiling

Drug-drug

Drug-patient characteristic

Drug-laboratory

NEPHROS study

- Effect of real-time decision support for patients with renal insufficiency
 - Of 17,828 patients, 42% had some degree of renal insufficiency

	Interv	Control
Dose	67%	54%
Frequency	59%	35%

- LOS 0.5 days shorter

Guided Prescription for Geriatric Inpatients

- Elderly patients frequently get dosages that are too high, especially initial dosages
- Performed RCT of decision support around dosing for psychoactive drugs
- Was associated with:
 - More frequent recommended dose (29% vs. 19%)
 - Lower fall rate (2.8 vs. 6.4 falls/1000 pt days)
 - Lower frequency of 10-fold overdose (2.8% vs. 5%)
 - No difference in mental status change, LOS
- Clearly beneficial to suggest starting with lower dosage but more room for improvement

Peterson, Arch Intern Med, 2005

Medication Safety: Refining the Rules

- In most systems most alerts get overridden
- We identified a highly selected set of drug alerts for the outpatient setting
- Over 6 months, 18,115 alerts
 - 12,933 (71%) non-interruptive
 - 5,182 (29%) interruptive
 - Of interruptive, 67% were accepted

Shah, JAMIA 2006

How to Prioritize?

- ROI of inpatient CPOE evaluated
- Cumulative net savings were \$16.7 million over 10 years, and net operating \$9.5 million
- Leading contributors
 - Renal dosing guidance
 - Tools to help nurses
 - Specific drug guidance
 - Adverse drug event prevention

Kaushal, JAMIA 2006

Recent Reviews of CPOE and Medication Safety

- CPOE and medication errors—66% reduction in prescribing errors on average

Shamliyan et al, Health Services Res 2008

- CPOE and ADEs—ten studies, five showed decrease in ADE rates, 4 showed non-significant trends, 1 showed no effect

Wolfstadt et al, J Gen Intern Med 2008

Take-Away Messages of Smart Pump Controlled Trial

- Serious IV med errors were frequent and could be detected using smart pumps
- However, no impact on the serious med error or preventable ADE rate was found
 - Likely because of poor compliance
- Behavioral and technologic factors must be addressed if smart pumps are to achieve their potential for improving medication safety

Rothschild et al, Crit Care Med 2005

Infusion Therapy: Variation in Practice in 100 Hospitals

- Average of 84 drugs per hospital
- Average 8.5 names/drug across all hospitals
- Inconsistent continuous dosing units for same drug
 - Average of 3 dosing units per drug overall
 - 74% of drugs had more than one continuous dosing unit (range 1-11)
 - Average of 15 different continuous dosing units/hospital
 - Range of 8-24 dosing units/hospital (possible 42)
 - Does not include bolus dosing

Background:

Epidemiology of Dispensing Errors

- Dispensing errors are relatively common in hospital pharmacies because of the high volume of medications dispensed.
 - More than 44,000 errors occur per year in a 735-bed hospital (6 million doses/yr).
- Many dispensing errors have the potential to harm patients.
 - More than 9500 errors with potential to harm patients occur per year in a 735-bed hospital.
 - Only 1/3 of these serious errors intercepted prior to administration.

Deaths of 3 babies in Indiana spotlight medication mix-ups

By Tom Davies
ASSOCIATED PRESS

INDIANAPOLIS — Early last Saturday, nurses at an Indianapolis hospital went to the drug cabinet in the newborn intensive care unit to get blood thinner for several premature babies.

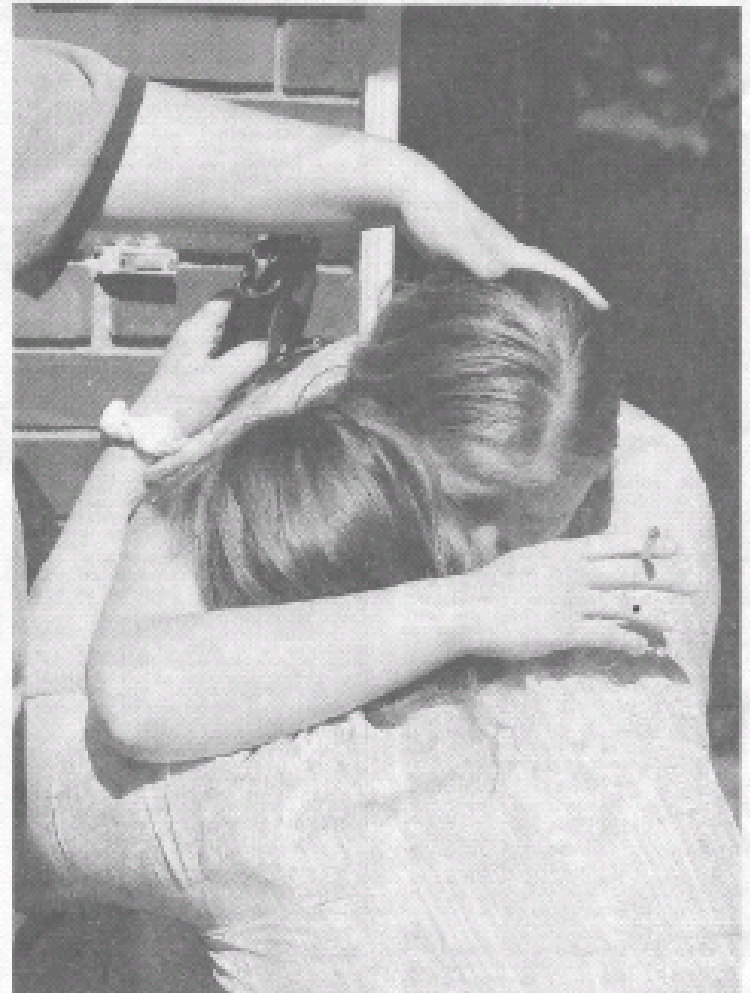
The nurses didn't realize that a pharmacy technician had mistakenly stocked the cabinet with vials containing a dose 1,000 times stronger than what the babies were supposed to receive. And they apparently didn't notice that the label said "heparin," not "hep-lock," and that it was dark blue instead of baby blue.

Those mistakes led to the deaths of three infants. Three others also suffered overdoses but survived.

Now, their families, hospital officials, and prosecutors are asking the same question: How could this happen?

Experts say last weekend's overdoses at Methodist Hospital illustrate that, despite national efforts to reduce drug errors, the system is still fragile and too often subject to human error.

"I see what happened here as depressingly normal," said Dr. Albert Wu of Johns Hopkins University, coauthor of an Institute of Medicine report that estimated more than 1.5 million Americans

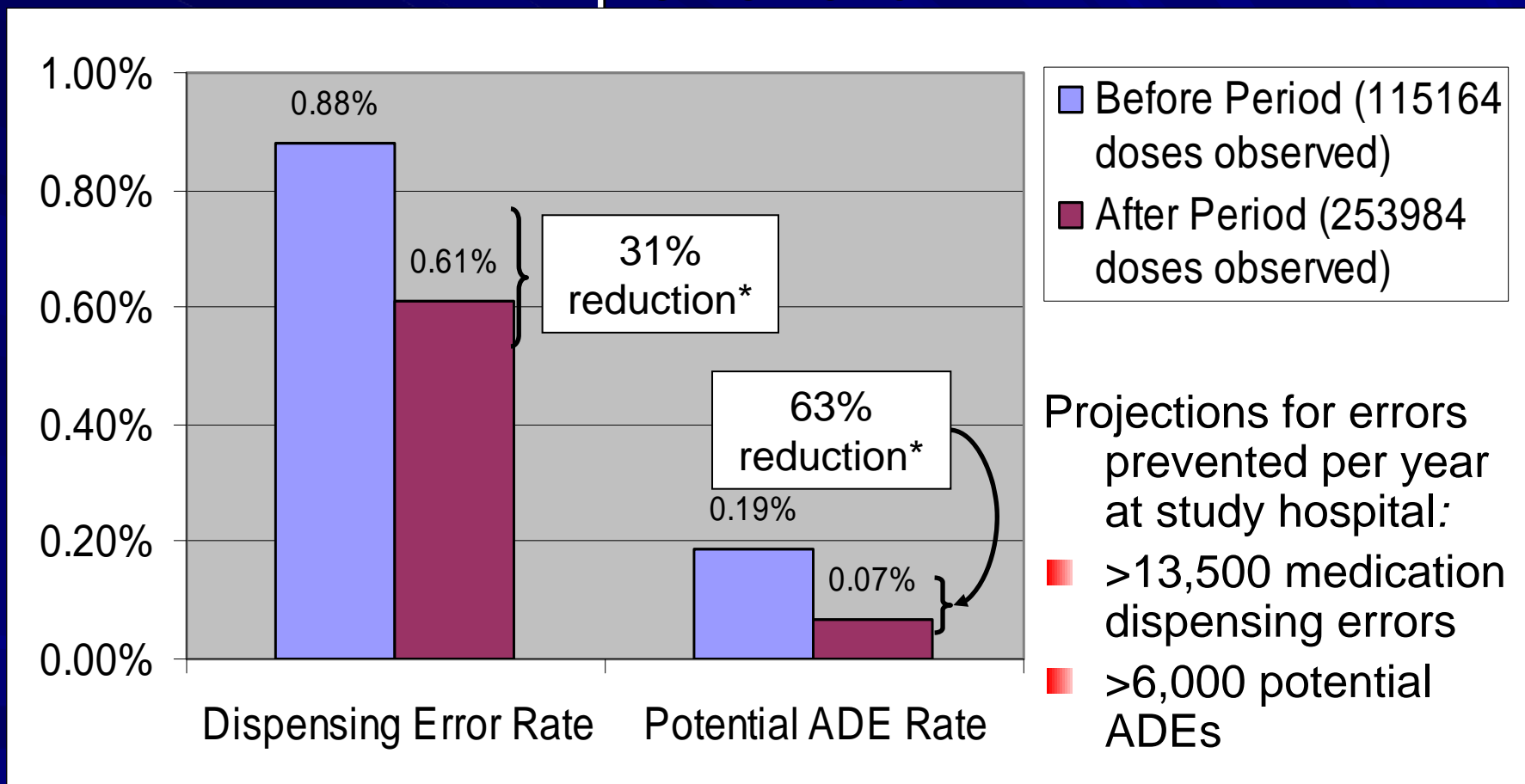


MICHAEL CONROY/ASSOCIATED PRESS

Heather Jeffers (facing camera) was consoled by her mother Wednesday in Indianapolis. Jeffers's daughter, Thursday Dawn

Clinical
Consequences
Of a Cart Fill
Error

Dispensing Errors and Potential ADEs: Before and After Barcode Technology Implementation



* $p < 0.0001$ (Chi-squared test)

Poon, *Ann Intern Med*, 2006

Formal Cost Benefit Analysis Results

- 5-year cumulative costs = \$2.3M
 - \$1.4M one-time investment (pre go-live, first 2 years)
 - \$343K/yr recurring (post go-live, last 3 years)
- 5-year cumulative benefits = \$5.5M
- 5-year cumulative net benefit = \$3.3M
- Break-even within 1st year after go-live

Software Features

- Bidirectional links to pharmacy
- Screens display if the pharmacist has approved an order
- If not approved nurse can prioritize when medication needs to be approved
- Automatic paging capability in the system

Emartest, Lisa
18919001 (BWH) 01/01/1980 (24 yrs.) F 17A 121 11/14/2003 12:03 CL02

Takeoff Screen eMAR Screen Reports View eMAR Medication Administration Record

Take-Off Allergies: free text aller>> Aspirin Codeine

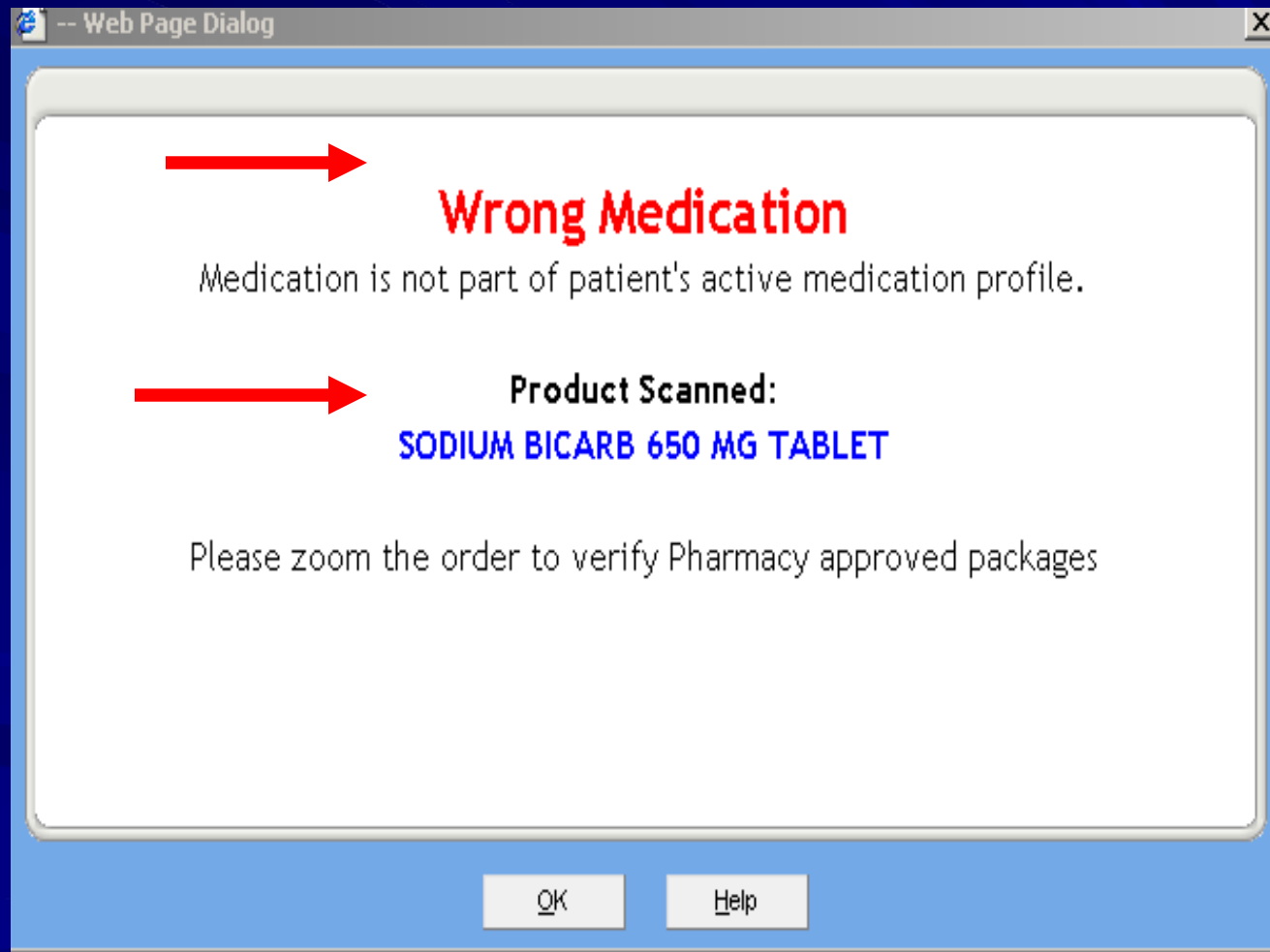
Status	Pending Orders	Notation	Priority	Take Off	First Dose	Schedule
1.	IV MAGNESIUM SULFATE 2 gm/hr in STERILE WATER X 24 H		2	<input type="checkbox"/>	Not Approved in RX	N/A
2.	MAGNESIUM SULFATE 6 grams IV x1		2	<input type="checkbox"/>	Not Approved in RX	Times one
3.	LAB MG, 6 hours after starting new dose of MG (08/18)			<input checked="" type="checkbox"/>		
4.	URGENT TRANSFUSE 2 bags RBC PRBC over 2 hrs each bag			<input checked="" type="checkbox"/>		N/A

Print Print All Zoom Sign

Error on page. Local intranet

Start | Inbox - Microsoft Outlook | Microsoft PowerPoint - L... | e-MAR link - Message (R... | MAR v.1.1.005 - Take... | 9:37 AM

Wrong Medication Alert



Impact of Barcode Scanning Technology on Administration Errors and Potential Adverse Drug Events

	No Barcode Scanning (n=6712)	Barcode Scanning (n=7314)	Relative Reduction (p-value)
Medication Administration Errors	11.5%	6.7%	41% (p<0.001)
Potential Adverse Drug Events	3.1%	1.6%	50.8% (p<0.001)

Poon et al. NEJM 2010

Impact of EMAR on Nurse Satisfaction and Workflow

- Nurses feel medication administration is safer and more efficient after implementation of barcode technology

Hurley, A et al. Journal of Nursing Administration 2007

- Proportion of time spent on medication administration did not change after barcode/eMAR implementation

- Proportion of time spent in presence of patient increased

Poon E, et al. Journal of Nursing Administration 2008

Computerized ADE Monitoring

- Looks for signals
 - Antidote
 - High serum drug level
- Can then be followed up by pharmacist
- Can use without a lot of other complicated IT (e.g. CPOE)
- BWH estimates savings of \$900,000/year by doing

Jha, JAMIA

Post-Discharge Intervention

- RCT of call by pharmacist 3-5 days post-discharge
- Preventable ADE incidence 1% in intervention group vs. 11% in control group ($p < 0.05$)
- One problem that this isn't reimbursed in most states

Schnipper, Arch Int Med 2005

Putting Together the Inpatient Puzzle

- Many different individual pieces
 - CPOE
 - Bar-coding
 - Point-of-care technology
 - Smart IV pumps
- Most doesn't communicate today
- Also need monitoring, spontaneous reporting

Outpatient Setting

- Computerization of prescribing
 - Getting the right decision support in place
- Post-discharge medication reconciliation
- Detecting adverse drug events

Cedars-Sinai CPOE Implementation

- One of the leading hospitals in U.S.
 - Deep experience with IT, and talent, especially ICU
 - Many providers—about 700 physicians on the private staff
 - Care for many of the wealthiest patients in Beverly Hills area
- Co-developed own CPOE application with a small vendor
- Did billing also from application
- Had extensive preparation

Results of Implementation

- Implementation failed
 - Application had to be turned off, even though it was working
- Physicians complained bitterly
 - Said that too much unnecessary decision support was being displayed
 - Was slow
 - Didn't fit workflow

Some Key Decisions

- Drug-drug interactions were set up as 0-1, so that they had to be all on, or off
 - Couldn't change how many were displayed
 - Physicians felt far too many were being shown
- Leadership told team they would fix problems as they went, while leaving system live

Post-Mortem Analysis

- If Cedars could fail, anyone can
 - Tremendous resources, great team
 - At the same time, several key decisions probably should have been made differently
 - Environment very challenging with so many private staff physicians
- They will do again, and will be successful next time
- Highly desirable to avoid a failure like this

University of Pittsburgh Pediatrics Study

- Studied children transported in for special care
- Mortality rate increased from 2.8% to 6.3% (OR=3.3) after introduction of a commercial CPOE application
- Study design was before-after
 - Other changes were made at same time as CPOE was implemented
 - Overall mortality wasn't reported

Introduction of CPOE

- CPOE was introduced very rapidly—over 6 days!
- After implementation, order entry wasn't allowed until the patient had actually entered hospital and been logged into system
- After CPOE implementation, all drugs including vasoactive agents were moved to central pharmacy
- Pharmacy couldn't process medication orders until after they were activated
- Many order sets weren't available initially
- Result was substantial delays in care delivery

Comments on Han Study

- Study was weak methodologically
- Nonetheless, increase in mortality rate was very large and of obvious concern
 - Introducing substantial delays in this group could easily have caused
- Organization broke many of the rules for implementation
- Essential for other organizations to handle sociotechnical aspects better

Phibbs et al, Pediatrics 2005

Other Pediatric Mortality Studies

- University of Washington PICU study:

Mortality	Before	After
All children	4.22%	3.46%
Transported	9.6%	6.29%

Del Beccaro et al, Pediatrics, 2006

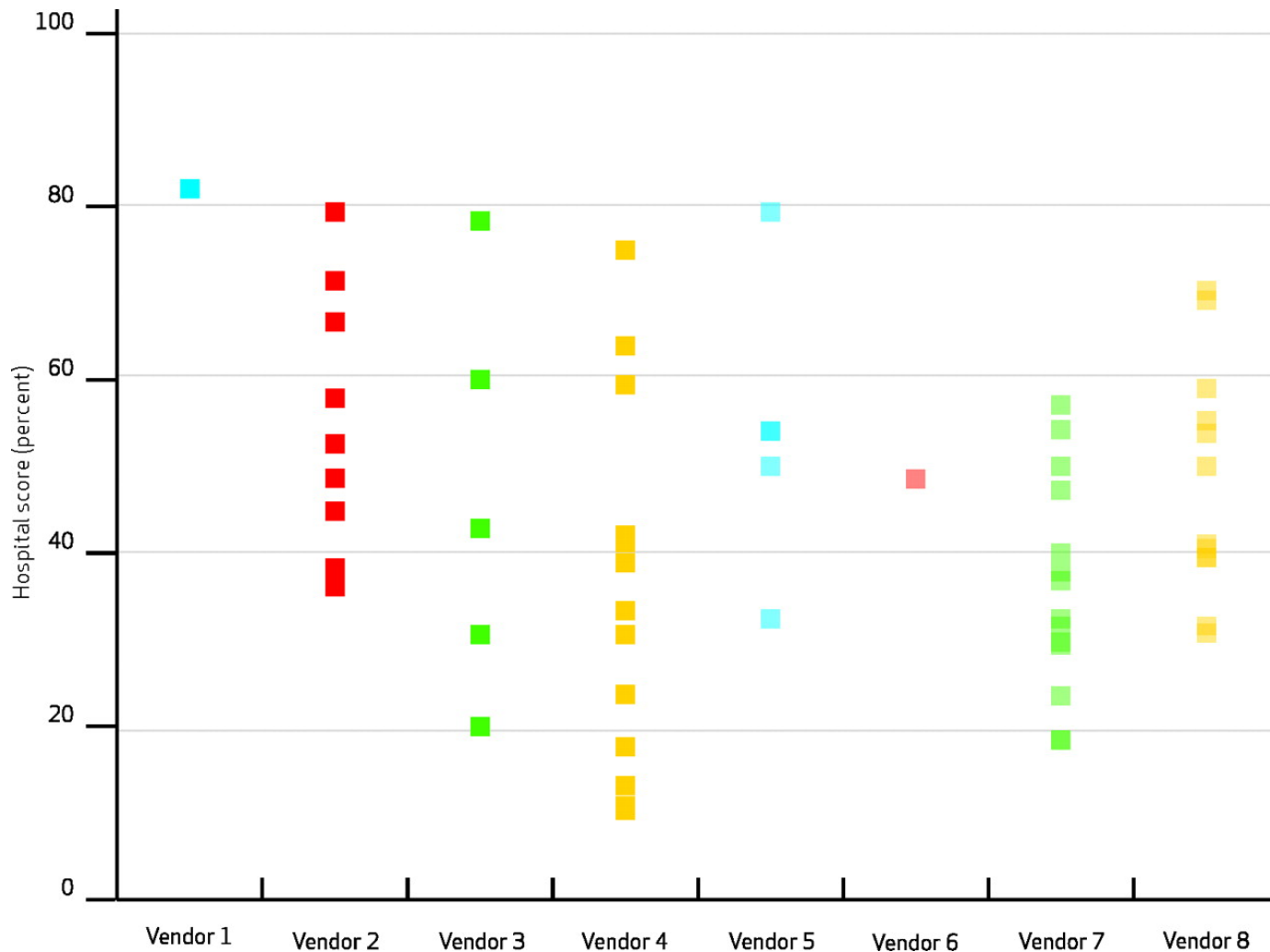
- Montefiore Study—NICU and PICU
 - Mortality 3.16% before, 2.41% after

Keene et al, Pediatr Cri Care Med, 2007

Safety Results of CPOE Decision Support Among Hospitals

- 62 hospitals voluntarily participated
- Simulation detection only 53% of orders which would have been fatal
- Detected only 10-82% of orders which would have caused serious ADEs
- Almost no relationship with vendor

Metzger et al, Health Affairs 2010



Jane Metzger, Emily Welebob, David W. Bates, Stuart Lipsitz, and David C. Classen,
 Mixed Results In The Safety Performance Of Computerized Physician Order Entry,
 Health Affairs, Vol 29, Issue 4, 655-663

HealthAffairs

What Will It Take to Transform Care? Medication Safety

- Key issue is making essential processes more reliable
 - New approaches like CPOE, bar-coding, etc
 - Checklists
 - And central line infection rates (Pronovost)
 - Surgical checklists in the operating room (Gawande)
 - Will likely need dozens of checklists
- Also essential to measure performance in on-going way

Conclusions

- Epidemiology of medication safety demonstrates that is important cause of harm in developed and transitional countries
- Many interventions not involving HIT can improve medication safety
 - Especially having pharmacists in clinical roles
- CPOE is technology that will result in largest improvement in inpatient medication safety
- But are many others:
 - Bar-coding/eMAR
 - Smart pumps
 - Computerized ADE monitor
- All these require addressing cultural issues

Conclusions (II)

- Outpatient setting also great opportunity for improvement
- Any technology will create new problems
 - Need to track these, engineer them out

**“Insanity is doing the
same things the same
way and expecting
different results”**

Albert Einstein



"It was done by a doctor - it's called 'Orders.'"