Safe Use Symposium: A Focus on Reducing Preventable Harm from Drugs in the Outpatient Setting

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Disclosures

• I have nothing to disclose.
Disclaimer

This presentation reflects the views of the author and should not be construed to represent FDA’s views or policies.
First Things First

• Wi-Fi network: FDA-Public
  – Passcode is “publicaccess”

• Opportunities for lunch are limited
  – Consider purchasing lunch from the kiosk to avoid lines at lunchtime
Why are we Having this Meeting?

• For about the last 20 years, there has been a great deal of focus and research on patient safety
  – Most of this has focused on hospitals, where patients receive complex and high acuity care
• But, most interactions with the healthcare system occur outside of hospitals
  – Given the enormous number of outpatient encounters, many preventable harms occur outside of hospitals
• More research is needed to reduce harms and increase safety for patients receiving outpatient care
Safe Use Initiative

• **Mission:** Create and facilitate public and private collaborations within the healthcare community.

• **Goal:** Reduce *preventable harm* by developing, implementing, and evaluating cross sector interventions with partners committed to safe and appropriate medication use.
Conceptual Framework for Non-Preventable Harm

- Indications
- Identified Risks
- Potential Risks
- Missing Information

Unavoidable subset of Identified Risks

Gaps in Current Knowledge
Conceptual Framework for Preventable Harm

- Indications
- Identified Risks
- Potential Risks
- Missing Information

Not incorporating current knowledge when drug is selected

Not taking actions to address the avoidable subset of Identified Risks

Unintended exposures

Intentional misuse
How do you Reduce Preventable Harm?
How do you Reduce Preventable Harm?

- Identify patients at highest risk
How do you Reduce Preventable Harm?

• Identify patients at highest risk
• Provider and facility feedback and/or self-assessment
How do you Reduce Preventable Harm?

- Identify patients at highest risk
- Provider and facility feedback and/or self-assessment
- Make meds easier to use
How do you Reduce Preventable Harm?

• Identify patients at highest risk
• Provider and facility feedback and/or self-assessment
• Make meds easier to use
• Patient education
How do you Reduce Preventable Harm?

• Identify patients at highest risk
• Provider and facility feedback and/or self-assessment
• Make meds easier to use
• Patient education
• Improve communication
How do you Reduce Preventable Harm?

• Identify patients at highest risk
• Provider and facility feedback and/or self-assessment
• Make meds easier to use
• Patient education
• Improve communication

➢ There is no “one size fits all” solution
Safe Use Partners

- Federal agencies
- Healthcare professionals and professional societies
- Pharmacies, hospitals, and other health care entities
- Patients, caregivers, consumers, and their representative organizations
Safe Use Partners

- Federal agencies
- Healthcare professionals and professional societies
- Pharmacies, hospitals, and other health care entities
- Patients, caregivers, consumers, and their representative organizations

= Almost anyone
Drugs with Active Safe Use Projects

Safe Use has 13 current projects. These involve a wide variety of drugs and potential adverse events.

• Opioids
• Antibiotics
• Anti-hyperglycemic agents
• Stimulants
• Pediatric cough and cold medications
• Appearance and Performance Enhancing Substances
• NSAIDS

https://www.fda.gov/Drugs/DrugSafety/SafeUseInitiative/ucm277720.htm
Extramural Research

Safe Use funds projects that “develop innovative methods to create, facilitate, and encourage research in the area of safe medication use that seeks to reduce preventable harm from drugs.”

This is accomplished via the Broad Agency Announcement (BAA), an open and continuous announcement to solicit research proposals.

Details on the BAA can be found at FedBizOpps.gov https://www.fbo.gov/index?s=opportunity&mode=form&id=9c48c509b0bfb19144d50ffc667f9550&tab=core&_cview=1
Thank You
FDA Safe Use Team Contact Information

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Medication Safety: The Evolution From Inpatient To Outpatient: What We Know, What We Still Don’t Know and Why IT Hasn’t Fixed Everything

FDA Safe Use Symposium
David C Classen, MD, MS
University of Utah
Disclosures

- David Classen is an employee of the University of Utah.
- David Classen is an employee/equity holder of Pascal Metrics, a federally certified Patient Safety Organization.
A hospital in Bend, Oregon, says it administered the wrong medication to a patient, causing her death.

Loretta Macpherson, 65, died shortly after she was given a paralyzing agent typically used during surgeries instead of an anti-seizure medication, said Dr. Michel Boileau, chief clinical officer for St. Charles Health System.

He said Macpherson stopped breathing and suffered cardiac arrest and brain damage.

Macpherson came into the ER two days earlier with medication dosage questions after a recent brain surgery.

Three employees involved in the error have been placed on paid leave. The organization is conducting an investigation, but doesn't yet know how the error occurred, Boileau said.

The investigation is looking at every step of the medication process: from how the medication was ordered from the manufacturer, to how the pharmacy mixed, packaged and labeled the drug, to how it was brought to the nurses and administered to the patient.

"We're looking for any gaps or weaknesses in the process, or to see if there has been any human error involved," Boileau said.

The hospital notified the Deschutes County district attorney, who did not immediately return a call for comment.

According to the Bend Bulletin, the doctors determined Macpherson needed an intravenous anti-seizure medication called fosphenytoin, but instead accidentally administered rocuronium, which caused Macpherson to stop breathing and go into cardiac arrest, leading to irreversible brain damage. The hospital took Macpherson off life support Wednesday morning.
Part 3: Pharmacies miss half of dangerous drug combinations

Pharmacists should tell patients about drug interactions that could cause severe harm or death. But testing of 255 pharmacies found that many failed to say a word about the risks. CVS, Walgreens, Wal-Mart and others are promising reforms.  

Impact and updates

Part 1: Finding dangerous drug interactions

The Chicago Tribune teamed with data scientists and pharmacologists to identify pairs of drugs that may increase the risk of a fatal heart condition.

Part 2: Drug mix leaves woman fighting for life

First Becki Conway had a sore throat and cough. Then a rash. Soon, her skin peeled off in sheets.

House backs study of pharmacy safety, consumer needs after Tribune investigation
The Chicago Tribune tested 255 pharmacies to see how often stores would dispense risky drug pairs without warning patients. Fifty-two percent of the tested pharmacies sold the medications without mentioning the potential interaction. (Chicago Tribune)

By Sam Roe, Ray Long and Karisa King
Chicago Tribune

DECEMBER 15, 2016, 8:44 AM

The Tribune reporter walked into an Evanston CVS pharmacy carrying two prescriptions: one for a common antibiotic, the other for a popular anti-cholesterol drug.

Taken alone, these two drugs, clarithromycin and simvastatin, are relatively safe. But taken together they can cause a severe breakdown in muscle tissue and lead to kidney failure and death.

When the reporter tried to fill the prescriptions, the pharmacist should have warned him of the dangers. But that's not what happened. The two medications were packaged, labeled and sold within minutes, without a word of caution.

The same thing happened when a reporter presented prescriptions for a different potentially deadly drug pair at a Walgreens on the Magnificent Mile.

And at a Wal-Mart in Evergreen Park, a Jewel-Osco in River Forest and a Kmart in Springfield.

In the largest and most comprehensive study of its kind, the Tribune tested 255 pharmacies to see how often stores would dispense dangerous drug pairs without warning patients. Fifty-two percent of the pharmacies sold the medications without mentioning the potential interaction, striking evidence of an industrywide failure that places millions of consumers at risk.

CVS, the nation's largest pharmacy retailer by store count, had the highest failure rate of any chain in the Tribune tests, dispensing the medications with no warning 63 percent of the time. Walgreens, one of CVS' main competitors, had the lowest failure rate at 30 percent — but that's still missing nearly 1 in 3 interactions.
Medication Use Is Pervasive

- 2.6 billion drugs prescribed annually
- 4 in 5 adults will use a medication in any given week
- More than 25% of children are on a chronic medication
- IOM’s “Preventing Medication Error” suggests every hospitalized patient is at risk for at least one medication error per day

Scope of Medication Errors

- Serious preventable medication errors occur in:
  - 3.8 million inpatient admissions\(^2\)
  - 3.3 million outpatient visits\(^3\)
- Mortality from preventable medication errors:
  - 7,000 deaths each year\(^4\)


A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care

John T. James, PhD

Objectives: Based on 1984 data developed from reviews of medical records of patients treated in New York hospitals, the Institute of Medicine estimated that up to 98,000 Americans die each year from medical errors. The basis of this estimate is nearly 3 decades old; herein, an updated estimate is developed from modern studies published from 2008 to 2011.

Methods: A literature review identified 4 limited studies that used primarily the Global Trigger Tool to flag specific evidence in medical records, such as medication stop orders or abnormal laboratory results, which point to an adverse event that may have harmed a patient. Ultimately, a physician must concur on the findings of an adverse event and then classify the severity of patient harm.

Results: Using a weighted average of the 4 studies, a lower limit of 210,000 deaths per year was associated with preventable harm in hospitals. Given limitations in the search capability of the Global Trigger Tool and the incompleteness of medical records on which the Tool depends, the true number of premature deaths associated with preventable harm to patients was estimated at more than 400,000 per year. Serious harm seems to be 10- to 20-fold more common than lethal harm.

Conclusions: The epidemic of patient harm in hospitals must be taken more seriously if it is to be curtailed. Fully engaging patients and their advocates during hospital care, systematically seeking the patients’ voice in identifying harms, transparent accountability for harm, and intentional correction of root causes of harm will be necessary to accomplish this goal.

Key Words: patient harm, preventable adverse events, transparency, patient-centered care, Global Trigger Tool, medical errors

(J Patient Saf 2013;00: 00–00)

“All men make mistakes, but a good man yields when he knows his course is wrong, and repairs the evil. The only crime is pride.” — Sophocles, Antigone

Medical care in the United States is technically complex at the individual provider level, at the system level, and at the national level. The amount of new knowledge generated each year by clinical research that applies directly to patient care can easily overwhelm the individual physician trying to optimize the care of his patients. Furthermore, the lack of a well-integrated and comprehensive continuing education system in the health professions is a major contributing factor to knowledge and performance deficiencies at the individual and system level. Guidelines for physicians to optimize patient care are quickly out of date and can be biased by those who write the guidelines. At the system level, hospitals struggle with staffing issues, making suitable technology available for patient care, and executing effective handoffs between shifts and also between inpatient and outpatient care. Increased production demands in cost-driven institutions may increase the risk of preventable adverse events (PAEs). The United States trails behind other developed nations in implementing electronic medical records for its citizens. Hence, the information a physician needs to optimize care of a patient is often unavailable.

At the national level, our country is distinguished for its patchwork of medical care subsystems that can require patients to bounce around in a complex maze of providers as they seek effective and affordable care. Because of increased production demands, providers may be expected to give care in suboptimal working conditions, with decreased staff, and a shortage of physicians, which leads to fatigue and burnout. It should be no surprise that PAEs that harm patients are frighteningly common in this highly technical, rapidly changing, and poorly integrated industry. The picture is further complicated by a lack of transparency and limited accountability for errors that harm patients.

There are at least 3 time-based categories of PAEs recognized in patients that are or have been hospitalized. The broadest definition encompasses all unexpected and harmful experience that a patient encounters as a result of being in the care of a medical professional or system because high-quality, evidence-based medical care was not delivered during hospitalization. The harmful outcomes may be realized immediately, delayed for days or months, or even delayed many years. An example of immediate harm is excess bleeding because of an overdose of an anticoagulant drug such as that which occurred to the twins born to Dennis Quaid and his wife. An example of harm that is not apparent for weeks or months is infection with Hepatitis C virus as a result of contaminated chemotherapy equipment. Harm that occurs years later is exemplified by a nearly lethal pneumococcal infection in a patient that had had a splenectomy many years ago, yet was never vaccinated against this infection risk as guidelines and prompts require.

METHODS

The approach to the problem of identifying and enumerating PAEs was 4-fold: (1) distinguish types of PAEs that may occur in hospitals today, (2) characterize preventability in the context of the Global Trigger Tool (GTT), (3) search contemporary medical literature for the prevalence and severity of PAEs that have been enumerated by credible investigators based on medical
Health IT and Patient Safety:
Building Safer Systems for Better Care
Adverse Events in Hospitals: Case Study of Incidence Among Medicare Beneficiaries in Two Selected Counties
Incidence Rates – of all beneficiaries

- **13.5%**
  - Adverse Events (NQF, HAC, F–I Level)

- **0.6%**
  - NQF Serious Reportable Events

- **1.0%**
  - Medicare Hospital-Acquired Conditions

- **13.5%**
  - Temporary Harm Events (E Level)
ABSTRACT Identification and measurement of adverse medical events is central to patient safety, forming a foundation for accountability, prioritizing problems to work on, generating ideas for safer care, and testing which interventions work. We compared three methods to detect adverse events in hospitalized patients, using the same patient sample set from three leading hospitals. We found that the adverse event detection methods commonly used to track patient safety in the United States today—voluntary reporting and the Agency for Healthcare Research and Quality’s Patient Safety Indicators—fared very poorly compared to other methods and missed 90 percent of the adverse events. The Institute for Healthcare Improvement’s Global Trigger Tool found at least ten times more confirmed, serious events than these other methods. Overall, adverse events occurred in one-third of hospital admissions. Reliance on voluntary reporting and the Patient Safety Indicators could produce misleading conclusions about the current safety of care in the US health care system and misdirect efforts to improve patient safety.
### Exhibit 3

<table>
<thead>
<tr>
<th>Type of adverse event</th>
<th>Severity level</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication-related</td>
<td></td>
<td>100</td>
<td>46</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>150</td>
</tr>
<tr>
<td>Procedure-related (excluding infection)</td>
<td></td>
<td>67</td>
<td>26</td>
<td>5</td>
<td>7</td>
<td>4</td>
<td>109</td>
</tr>
<tr>
<td>Nosocomial infection</td>
<td></td>
<td>30</td>
<td>37</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>72</td>
</tr>
<tr>
<td>Pulmonary/VTE</td>
<td></td>
<td>8</td>
<td>5</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>17</td>
</tr>
<tr>
<td>Pressure ulcers</td>
<td></td>
<td>10</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>11</td>
</tr>
<tr>
<td>Device failure</td>
<td></td>
<td>0</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>Patient falls</td>
<td></td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>10</td>
<td>11</td>
<td>0</td>
<td>3</td>
<td>2</td>
<td>26</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>227</td>
<td>133</td>
<td>11</td>
<td>14</td>
<td>8</td>
<td>393</td>
</tr>
</tbody>
</table>
TRIGGER METHODOLOGIES UNCOVER 10 TO 100 FOLD MORE ADVERSE EVENTS THAN INCUMBENT SYSTEMS

Adverse Event Detection, by Severity Level and Hospital

<table>
<thead>
<tr>
<th>SEVERITY LEVEL</th>
<th>IHI Global Trigger Tool</th>
<th>AHRQ Patient Safety Indicators</th>
<th>Hospital Voluntary Reporting System</th>
</tr>
</thead>
<tbody>
<tr>
<td>E - Temporary Harm</td>
<td>204</td>
<td>23</td>
<td>0</td>
</tr>
<tr>
<td>F - Increased Length of Stay</td>
<td>124</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>G - Permanent Harm</td>
<td>8</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>H - Intervention Needed to Sustain Life</td>
<td>14</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>I - Death</td>
<td>4</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>TOTAL</td>
<td><strong>354</strong></td>
<td><strong>35</strong></td>
<td><strong>4</strong></td>
</tr>
</tbody>
</table>

Source: Classen et al, Health Affairs 2011
Most U.S. hospitals do not measure – much less track and manage – “all cause harm” using clinical data.

Healthcare Provider

System Level Leadership

Hospital Level Leadership

Clinical Risk & Financial Management

System Office

Risk Trigger® Team

RT TEAM

Data Support for Intervention or Mitigation

Unit Level Team

Clinical Area

EARLY

MATURE

Individual Level Caregiver

Delivery of Care

Episodes of Care – Surveillance & Improvement

Patient Level

ICU

OR

ED

IR

OB

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Meaningful Use—Great for EHR Adoption

Basic EHR adoption increased while certified EHR adoption remained high

Figure 1: Percent of non-Federal acute care hospitals with adoption of at least a Basic EHR with notes system and possession of a certified EHR: 2008-2015

- Certified EHR
- Basic EHR
High Rates of Adverse Drug Events in a Highly Computerized Hospital

Jonathan R. Nebeker, MS, MD; Jennifer M. Hoffman, PharmD; Charlene R. Weir, RN, PhD; Charles L. Bennett, MD, PhD, MPP; John F. Hurdle, MD, PhD

Background: Numerous studies have shown that specific computerized interventions may reduce medication errors, but few have examined adverse drug events (ADEs) across all stages of the computerized medication process. We describe the frequency and type of inpatient ADEs that occurred following the adoption of multiple computerized medication ordering and administration systems, including computerized physician order entry (CPOE).

Methods: Using explicit standardized criteria, pharmacists classified inpatient ADEs from prospective daily reviews of electronic medical records from a random sample of all admissions during a 20-week period at a Veterans Administration hospital. We analyzed ADEs that necessitated a changed treatment plan.

Results: Among 937 hospital admissions, 483 clinically significant inpatient ADEs were identified, accounting for 52 ADEs per 100 admissions and an incidence density of 70 ADEs per 1000 patient-days. One quarter of the hospitalizations had at least 1 ADE. Of all ADEs, 9% resulted in serious harm, 22% in additional monitoring and interventions, 32% in interventions alone, and 11% in monitoring alone; 27% should have resulted in additional interventions or monitoring. Medication errors contributed to 27% of these ADEs. Errors associated with ADEs occurred in the following stages: 61% ordering, 25% monitoring, 13% administration, 1% dispensing, and 0% transcription. The medical record reflected recognition of 76% of the ADEs.

Conclusions: High rates of ADEs may continue to occur after implementation of CPOE and related computerized medication systems that lack decision support for drug selection, dosing, and monitoring.

Arch Intern Med. 2005;165:1111-1116
“Anyone here know how to play Microsoft’s Flight Simulator?”
Relationship between medication event rates and the Leapfrog computerized physician order entry evaluation tool

Alexander A Leung,1 Carol Keoghane,1 Stuart Lipsitz,1 Eyal Zimlichman,1 Mary Amato,1,2 Steven R Simon,1 Michael Coffey,3 Nathan Kaufman,3 Bismarck Cadet,4 Gordon Schiff,1 Diane L Seger,1 David W Bates1

ABSTRACT
Objective The Leapfrog CPOE evaluation tool has been promoted as a means of monitoring computerized physician order entry (CPOE). We sought to determine the relationship between Leapfrog scores and the rates of preventable adverse drug events (ADE) and potential ADE.

Materials and methods A cross-sectional study of 1000 adult admissions in five community hospitals from October 1, 2008 to September 30, 2010 was performed. Observed rates of preventable ADE and potential ADE were compared with scores reported by the Leapfrog CPOE evaluation tool. The primary outcome was the rate of preventable ADE and the secondary outcome was the composite rate of preventable ADE and potential ADE.

Results Leapfrog performance scores were highly related to the primary outcome. A 43% relative reduction in the rate of preventable ADE was predicted for every 5% increase in Leapfrog scores (rate ratio 0.57; 95% CI 0.37 to 0.88). In absolute terms, four fewer preventable ADE per 100 admissions were predicted for every 5% increase in overall Leapfrog scores (rate difference —4.2; 95% CI —7.4 to —1.1). A statistically significant relationship between Leapfrog scores and the secondary outcome, however, was not detected.

Discussion Our findings support the use of the Leapfrog tool as a means of evaluating and monitoring CPOE performance after implementation, as addressed by current certification standards.

Conclusions Scores from the Leapfrog CPOE evaluation tool closely relate to actual rates of preventable ADE. Leapfrog testing may alert providers to potential vulnerabilities and highlight areas for further improvement.

in the rates of preventable ADE and potential ADE—is an arduous and expensive process.9–12 Therefore, for practical reasons, most hospitals seeking to evaluate the effectiveness of a CPOE system are limited to indirect, surrogate measures.

To this effect, the Leapfrog Group has developed an independent, inexpensive, and standardized tool for assessing the performance of a hospital’s CPOE system by using simulation cases. In essence, the Leapfrog CPOE evaluation tool estimates the potential benefit of a CPOE system by testing how it handles a variety of dangerous medication ordering scenarios.8–13 Accordingly, performance scores are presumed to be linked to actual outcomes.1

Objective
The Leapfrog CPOE evaluation tool, presently the only instrument of its kind, has been quickly adopted into practice for monitoring purposes.8–13 However, it still remains uncertain whether Leapfrog performance scores are related to outcomes in real-world settings as empirical evidence is currently lacking.8 Addressing this evidence gap, we sought to determine the relationship between test scores and actual rates of preventable ADE and potential ADE.

MATERIALS AND METHODS
We performed a cross-sectional study to compare the rates of preventable ADE and potential ADE with scores reported by the Leapfrog CPOE evaluation tool. This study was conducted independently of the Leapfrog Group and was approved by the institutional review boards at each hospital site.
Simulations of EHR Use with CPOE

The assessment pairs medication orders that would cause a serious adverse drug event with a fictitious patient.

A physician enters the order …

Coumadin (Warfarin) 5 mg po three times a day.

Patient AB

Female
52 years old
Weighs 60 kg
Allergy to morphine
Normal creatinine

and observes and records the type of CDS-generated advice that is given (if any).
AHRQ/NQF/Leapfrog Assessment Tool (cont’d)

1. **Hospital logs on (Password access)**
2. **Complete sample test**
3. **Obtain patient criteria (Adult or pediatric)**
4. **Program patient criteria**
5. **Download and print 30 – 40 test orders (HM if AMB)**
6. **Enter orders into CPOE application and record results**

**Flowchart:**
- Hospital self-reports results on website
- Score generated against weighted scheme
- Report generated
- Aggregate score to Leapfrog
- Order category scores viewed by hospital

**Review:**
- Patient descriptions
- Orders and categories
- Scoring
Focus on Quality

By Jane Metzger, Emily Welebob, David W. Bates, Stuart Lipsitz, and David C. Classen

Mixed Results In The Safety Performance Of Computerized Physician Order Entry

Abstract Computerized physician order entry is a required feature for hospitals seeking to demonstrate meaningful use of electronic medical record systems and qualify for federal financial incentives. A national sample of sixty-two hospitals voluntarily used a simulation tool designed to assess how well safety decision support worked when applied to medication orders in computerized order entry. The simulation detected only 53 percent of the medication orders that would have resulted in fatalities and 10–82 percent of the test orders that would have caused serious adverse drug events. It is important to ascertain whether actual implementations of computerized physician order entry are achieving goals such as improved patient safety.

Many people have suggested that electronic health records represent essential infrastructure for the provision of safe health care in the United States. For several years, the Institute of Medicine, the Leapfrog Group, the National Quality

In this application of clinical decision support, physicians are made aware of potential safety issues that can result—for example, when ampicillin is given to a patient with a known allergy to penicillin, or the dose being ordered for a pediatric patient is much higher than the therapeutic range for a child of this age and weight. Prescrib-
EXHIBIT 2

Hospital Scores For Detection Of Test Orders That Would Cause An Adverse Drug Event In An Adult Patient According To The Software Product (Vendor) Implemented
Orders Handled Correctly by Checking Category

% Handled Correctly

- Duplication
- Allergy
- Drug Drug
- Route
- Drug Dx
- Corollary
- Lab

Year:
- 2009
- 2010
- 2011
- 2012
- 2013
- 2014
# Ambulatory Adverse Drug Events (ADEs): After Hospital Discharge

<table>
<thead>
<tr>
<th>Type of Adverse Event</th>
<th>Incidence</th>
<th>Type of Injury</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/n (%)</td>
<td>Adverse Drug Event</td>
</tr>
<tr>
<td>All</td>
<td>76/400 (19 [15–23])</td>
<td>50 (66)</td>
</tr>
<tr>
<td>Preventable</td>
<td>23/400 (6 [4–8])</td>
<td>12 (50)</td>
</tr>
<tr>
<td>Ameliorable</td>
<td>24/400 (6 [4–8])</td>
<td>19 (76)</td>
</tr>
</tbody>
</table>

*Table 2. Type of Injury and Incidence of All Adverse Events, Preventable Adverse Events, and Ameliorable Adverse Events*
ED Visits for ADEs

- Estimate of 4 ED visits for ADEs per 1000 individuals annually in 2013 and 2014

- 27.3% resulted in hospitalization

- Anticoagulants, antibiotics, and diabetes agents were implicated in an estimated 46.9%, which included clinically significant AEs
  - hemorrhage (anticoagulants)
  - moderate to severe allergic reactions (antibiotics)
  - hypoglycemia with moderate to severe neurological effects (diabetes agents)

- Older adults experienced the highest hospitalization rates (43.6%)
JAMA Study– Ambulatory Medication Safety In the Elderly

- Conducted in Medicare HMO Population
- Aggressive ascertainment of ADE’s by multiple methods including several forms of “Triggers”
- ADE’s Common in the Elderly—Many Preventable- 5%
- Preventable Problems in Ordering and Adequate Monitoring
- 2,000,000 ADEs; in Medicare population

Ambulatory Medication Safety Studies

NEJM Study- Ambulatory Medication Safety In Private Clinic Setting

- Similar methodology as above
- Conducted in 4 Primary Care Clinics
- Aggressive ascertainment as above plus patient query (Not used in JAMA Study)
  - Patient reports identified 3 fold greater than chart review
- 24% of patients experience ADE within a year
- Many preventable or Ameliorable
  - Many ADE’s not diagnosed despite clear symptoms

Community Pharmacy Safety

- Range of dispensing errors in community pharmacies and ambulatory care pharmacies range from 1-24% depending on how study was conducted


- Nationwide, observation-based study of dispensing errors inspected 5,784 prescriptions, revealing 91 errors (1.57%) and 74 “near errors” (1.28%)


- Overall dispensing error rate was 1.3% (77 errors among 4,481 prescriptions); range, 0 –12.8%
  
  –Of 77 identified errors, 5 (6.5%) were judged to be clinically important
  
  –At a rate of about 4 errors per day, pharmacy filling 250 prescriptions daily
  
  –Estimated 51.5 million errors occur during filling of 3 billion prescriptions each year

Cisapride Ambulatory Safety Study

- Studied occurrence of Cisapride physician co-prescribing and pharmacy co-dispensing of Cisapride with contraindicated drugs
- Study period 1993-1998
  - Emphasis after new warnings published in early 1995
- Used Managed Care Database
  - Exclusions included Incomplete Data, Kids, Insurance Coverage Duration
- 131,485 dispensed prescriptions after warnings
- 4144 prescriptions overlapped with contraindicated drugs
  - 50% same Physician
  - 89% Same Pharmacy

Jones et al JAMA. 2001;286:1607-1609
Pharmacy Computer Field Test of Unsafe Orders

1. Cephradine oral suspension IV
2. Ketorolac 60mg IV (aspirin allergy)
3. Vincristine 3mg IV for one dose (2 year old)
4. Colchicine 10mg IV for one dose (adult patient)
5. Cisplatin 204mg IV for one dose (26 Kg child)
6. Nizatidine 300mg hs (patient on famotidine)
7. Colchicine 1mg IV q4h for 8 doses
8. Ketoconazole 200mg daily (patient on cisapride)
9. Tobramycin 120mg IV q8h (CrCL = 10 ml/min)
10. Acetaminophen (patient on Percocet)
ISMP 2005 Pharmacy Computer Field Survey Results

• 4 of 182 systems were able to detect all errors
• Dosage alerts based in weight or BSA decreased from 37% to 25%
• Less than 50% alerted to an order for flu vaccine for a patient with an egg allergy
• Only 1/3 alerted to a fatal route of administration
ISMP 2005 Pharmacy Computer Field Survey Results

• 9 of 10 allowed pharmacy to bypass alert
  – Most by pressing a function key
• Only 1 in 5 intercepted a contraindicated drug based on a diagnosis
• Only 50% of systems allowed tallman lettering for look-alike drug names
CPOE/EHR Systems—MED Error Prevention

Figure 1. Vulnerability Across Different E-Prescribing Platforms to Prevent Specific Types of Prescribing Error Scenarios

- Drug-disease interaction
- Adjacency error (menu pick error)
- Wrong frequency for drug form
- Wrong dose for indication
- Wrong form or route (wrong sig)
- Wrong dispensed amount
- Wrong units (insulin IU vs ml)
- Duplicate, same exact drug
- Duplicate (Different drug but same ingredients)
- Allergy
- Drug-drug interactions
- Omission errors
- 1000 fold overdose (levothyroxine, mg vs ug)

Note: A completely safe system would achieve a score of "5," and a completely unsafe system would score "1." Averages reflect the aggregate score from testing each scenario in 13 different CPOE platforms. Data from Schiff et al., 2015.28
Selected medication safety risks to manage in 2016 that might otherwise fall off the radar screen—Part I

It would be an incredibly arduous and near impossible task to list all the risks associated with medication use that could lead to harmful medication errors. This is often at the heart of wondering where to start to improve medication safety, and why people frequently resort to playing “whack-a-mole,” addressing risks only after they pop up and become visible after an adverse event. It’s also one of the primary reasons ISMP has established the Targeted Medication Safety Best Practices for Hospitals—to help create a sharp lens with which to focus improvement efforts on a few best practices that we are confident will prevent patient harm.

We introduced the 2016-2017 Targeted Best Practices in our December 17, 2015 newsletter (www.ismp.org/sc?id=417). In this week’s issue, we thought it might be useful to describe other selected medication safety risks that might otherwise fall off the radar screen unless an adverse event happens to draw attention to them. Again, there is an overabundance of risks to choose from, but we thought these particular, serious risks may not otherwise garner attention without mention. We have selected one risk from each of ISMP’s 10 Key Elements of the Medication Use System™ as vulnerabilities in these system elements cause errors. In Part I, we cover five of the Key Elements related to the management of patient information and drug information, how information is communicated to staff, how information is presented on drug labels and packages, how healthcare providers package medications prior to administration, and how patients are educated. Part II will cover the remaining five Key Elements associated with medication storage, the environment, medication devices and technology, human resources, and culture.
ISMP Safety Alert Recs 2016

- Patient Information—Placing Orders on The Wrong Patient’s Electronic Health Record (EHR)
- Drug Information—Nursing references promote unnecessary IV medication dilution
- Communication—in the EHR confusing the available concentration as the patient’s dose
- Manufacturer Packaging—per liter electrolyte content on label of various IV bag sizes
- Practitioner Packaging—drawing more than one dose into a syringe.
- Patient Education—Discharged patients do not understand discharge medications
ISMP Safety Alert Recs 2016

- Drug Storage—Improper and unsafe vaccine storage
- Environmental Factors—Poor quality lighting
- Medication Device Use—Failure to disinfect ports and use sterile caps
- Staff Competency—IV practices based on apprentice learning
- Culture—HR policies that conflict with a just culture
The Medication Use Process

Adverse Drug Events (ADEs) and Medication Errors

History-Taking
- Obtain medication-related history
- Document medication history, Reconcile Meds

Prescribing Errors = 39%
ADEs = 49%

Diagnostic/Therapeutic Decisions Made
- Medication ordered
- Order verified and submitted

ADEs = 11%
Transcription Errors = 12%

Ordering-Transcribing
- Medication ordered
- Order verified and submitted

Procurement
- Formulary, purchasing decisions
- Inventory management

Procurement
- ADEs =14%
Dispensing Errors = 11%

Pharmacy Management
- Evaluate /approve order
- Select medication
- Prepare medication
- Dispense/ distribute medication
- Drug Use Evaluation

ADEs = 26%
Admin Errors = 38%

Quality Assurance
- Incident/ adverse event surveillance and reporting

Pharmacy Management
- ADEs = 49%

Administration Management
- Intervene as indicated for adverse reaction/ error
- Assess & document patient response to medication according to defined parameters
- Document administration and associated information
- Administer according to order and standards for drug
- Select the correct drug for the correct patient
- Educate patient regarding medication
- Educate staff regarding medications

Medication Management Process
With Specific Technologies

History-Taking
- Obtain Medication-related History
  - Document Medication History

Prescriber Order Entry
- Diagnostic/Therapeutic Decisions Made
  - Medication Ordered
  - Order verified and submitted

Ordering
- Prescription
  - Evaluate order
    - Select medication
    - Prepare medication
    - Dispense/distribute medication

Inventory Systems (wholesalers)
- Formulary, purchasing decisions
- Inventory management

Pharmacy Management
- Evaluate order
- Select medication
- Prepare medication
- Dispense/distribute medication

Pharmacy Information Systems

Automated Surveillance Systems

Surveillance
- Incident/adverse event surveillance and reporting

Administration Management
- Monitor/Evaluate Response
- Document
- Administer Medication
- Education

Monitor/Evaluate Response
- Intervene as indicated for adverse reaction/error
- Assess and document patient response to medication according to defined parameters

Document
- Document medication administration and associated information

Administer Medication
- Administer according to order and standards for drug
- Select the correct drug for the correct patient

Education
- Educate patient regarding medication
- Educate staff regarding medications

Patient Education

Improving medication safety: Development and impact of a multivariate model-based strategy to target high-risk patients

Tri-Long Nguyen¹,²,³,⁴*, Géraldine Leguelinel-Blache¹,², Jean-Marie Kinowski¹,², Clarisse Roux-Marson¹,², Marion Rougier⁵, Jessica Spence³,⁴, Yannick Le Manach³,⁴, Paul Landais²,⁶

¹ Department of Pharmacy, Nîmes University Hospital, Nîmes, France, ² Laboratory of Biostatistics, Epidemiology, Clinical Research and Health Economics, University Institute of Clinical Research, Montpellier University, Montpellier, France, ³ Departments of Anesthesia, Michael DeGroote School of Medicine, Faculty of Health Sciences, McMaster University, Hamilton, Ontario, Canada, ⁴ Population Health Research Institute, David Braley Cardiac, Vascular and Stroke Research Institute, Perioperative Medicine and Surgical Research Unit, Hamilton, Ontario, Canada, ⁵ Department of General Medicine, Nîmes University Hospital, Nîmes, France, ⁶ Department of Biostatistics, Epidemiology, Clinical Research and Health Economics, Nîmes University Hospital, Nîmes, France

* longbacon.nguyen@gmail.com
### Table 3. Multivariate model predicting in-hospital significant medication errors (PRISMOR).

<table>
<thead>
<tr>
<th></th>
<th>Corrected log-odds ratio*</th>
<th>Estimated odds ratio [95% CI]</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Constant</strong></td>
<td>-3.83</td>
<td>0.02</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>((\text{Age/100})^2)</td>
<td>7.07</td>
<td>2 079.74 [10.26; 421 510.51]</td>
<td>0.005</td>
</tr>
<tr>
<td>((\text{Age/100})^3)</td>
<td>-6.26</td>
<td>0.00 [0.00; 0.20]</td>
<td>0.010</td>
</tr>
<tr>
<td>Number of prescribed drugs</td>
<td>0.14</td>
<td>1.16 [1.10; 1.23]</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Treatment initiated before admission</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>0</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1.60</td>
<td>5.64 [2.38; 13.36]</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Best possible medication history available</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>0</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>-0.64</td>
<td>0.50 [0.37; 0.67]</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Psycholeptics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>0</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>0.31</td>
<td>1.39 [0.96; 2.02]</td>
<td>0.084</td>
</tr>
<tr>
<td>Blood substitutes and perfusion solutions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>0</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>-0.16</td>
<td>0.84 [0.62; 1.15]</td>
<td>0.295</td>
</tr>
<tr>
<td>Type of hospital admission</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical</td>
<td>0</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Surgical</td>
<td>0.29</td>
<td>1.36 [1.00; 1.87]</td>
<td>0.061</td>
</tr>
<tr>
<td>Hospital admission within previous 30 days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>0</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>-0.36</td>
<td>0.68 [0.44; 1.04]</td>
<td>0.067</td>
</tr>
<tr>
<td>Admission from emergency room</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>0</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>0.27</td>
<td>1.34 [0.92; 1.94]</td>
<td>0.123</td>
</tr>
<tr>
<td>Admission time</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day</td>
<td>0</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Night</td>
<td>-0.18</td>
<td>0.83 [0.58; 1.18]</td>
<td>0.296</td>
</tr>
<tr>
<td>Admission from an outside institution</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>0</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>-0.51</td>
<td>0.58 [0.21; 1.60]</td>
<td>0.299</td>
</tr>
</tbody>
</table>
Fig 3. Comparison of two strategies to focus interventions on high-risk patients: decision-making supported by the predictive model versus decision-making based on age.

doi:10.1371/journal.pone.0171995.g003
Patient RISE Collaborative Project

• Funded by RWJF
• Participating Centers
  – University of Utah (David Classen)
  – Brigham and Women’s Hospital (David Bates)
  – Pascal Metrics PSO (Drew Ladner)
• Project Aims
  – Aim 1: Use existing PSO model to complement sharing of real time safety information with patients and families
  – Aim 2: Design and implement patient and family facing patient safety dashboard and patient safety checklists
  – Aim 3: Test and evaluate the use of a generalized patient safety dashboard across inpatient and post-discharge within a particular integrated care management model
### My Safety Advisor

#### Overall Risk Score

- **High Risk**
- **Moderate Risk**
- **Low Risk**

**1d 3d 1wk 1mo all**

<table>
<thead>
<tr>
<th>My Safety Issues</th>
<th>Questions you should ask</th>
<th>Things you can do</th>
<th>More Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Today</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>You have tested positive for a bacteria in your urine</td>
<td>Why did this happen?</td>
<td>Talk to your doctor and nurses to make sure you understand why this happened and how this should be treated, and how it can be avoided in the future. Make sure you understand the source of this infection and how it is being treated. If you leave the hospital with a urinary catheter in place make sure you have detailed instructions for how to care for it.</td>
<td><a href="#">Medline Plus on Urine Culture</a></td>
</tr>
<tr>
<td></td>
<td>What can I do to prevent this from happening again?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>What will you do to prevent this from happening again?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Yesterday</strong></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Your stool has tested positive for a bacteria called C. difficile</td>
<td>Why did this happen?</td>
<td>Always wash your hands and nails before eating and after using the restroom. Make sure everyone who treats you in the hospital (doctors, nurses, therapists, etc.) wash their hand before and after seeing you. At home make sure all clothes are washed with soap and bleach.</td>
<td><a href="#">Medline Plus on C. Difficile</a></td>
</tr>
<tr>
<td></td>
<td>What can I do to prevent this from happening again?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>What will you do to prevent this from happening again</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Make note of your question here...</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
1. Epidemiologic Study of Ambulatory Harm

2. Engage Patients and Care Givers as Equal Partners in Safety Improvement

3. Broaden Safety Improvements to Episodes of Care Approach

4. Build Ambulatory Safety Research Networks
Medication Without Harm: WHO’s Third Global Patient Safety Challenge

In 1960, Alphonse Chapanis, turned his attention from engineering to health care. In a study of medication-related errors in a 1100-bed hospital, he and his colleague identified seven sources of such errors potentially leading to harm to a patient: medicine omitted, or given to the wrong patient, at the wrong dose, as an unintended extra dose, by the wrong route, at the wrong time, or as the wrong drug entirely. Almost 60 years later, these same types of errors still happen worldwide. Later that year in a follow-up policy paper, Chapanis identified four areas of recommendations that could prevent harm and remain relevant today: written communication, medication procedures, the working environment, training, and education. Indeed, it is difficult to avoid the conclusion that had the recommendations from this revelatory patient safety research been assiduously followed over the past five decades, hundreds of thousands fewer patients would have been killed or seriously harmed by the medicines intended to make them well.

Beginning in 2004, WHO, working in partnership with the then World Alliance for Patient Safety, initiated two Global Patient Safety Challenges, Clean Care is Safer Care and Safe Surgery Saves Lives. These challenges mobilised worldwide commitment and action to reduce health-care-associated infections and risk associated with surgery, respectively. At the second Global Summit of Health Ministers on Patient Safety in Bonn, Germany, on March 29, 2017, the Director-General of WHO announced that the Third Global Patient Safety Challenge, Medication Without Harm, would address medication safety.

The previous challenges secured strong and early commitment from health ministers, professional bodies, regulators, health leaders, civil society, and health-care practitioners. The action required to deliver the goals of each was broadly similar: an evidence-based analysis of the key problems and solutions; an invitation to WHO member states and other relevant parties to pledge, or sign-up, to address the aims of the challenge; high-profile actions to generate passion and enthusiasm; facilitation...
QUESTIONS?

Comments
Medication Safety in the Ambulatory Setting

Tejal Gandhi, MD, MPH, CPPS
Chief Clinical and Safety Officer
Institute for Healthcare Improvement
Associate Professor of Medicine
Harvard Medical School
Patient Safety Is a Public Health Issue

• Despite progress, preventable harm remains unacceptably frequent
  – Significant mortality and morbidity
  – Quality of life implications
  – Adversely affects patients in every care setting
Project Objectives

- Convene expert panel
- Examine the state of patient safety 15 years after the release of the Institute of Medicine’s seminal report
- Forge a path forward to prioritize further improvements
The Free From Harm Report

Download the full PDF report for free at:

www.npsf.org/free-from-harm

Thank you to AIG for their generous support of this project.
Current State of Patient Safety

• Evidence mixed but panel overall felt that health care is safer
• More work to be done
• While limited, progress notable
  – Young field
  – Still developing scientific foundations
  – Received limited investment
• Improving patient safety is a complex problem
  – Requires work by diverse disciplines to solve
Total Systems Approach Needed

• Advancing patient safety requires an overarching shift from reactive, piecemeal interventions to a total systems approach

• Need to embrace wider approach beyond specific, circumscribed initiatives to generate change

• Fundamental finding: Initiatives can advance only with a key focus on teamwork, culture and patient engagement
Eight Recommendations for Achieving Total Systems Safety

1. Ensure that leaders establish and sustain a safety culture

Improving safety requires an organizational culture that enables and prioritizes safety. The importance of culture change needs to be brought to the forefront, rather than taking a backseat to other safety activities.

2. Create centralized and coordinated oversight of patient safety

Optimization of patient safety efforts requires the involvement, coordination, and oversight of national governing bodies and other safety organizations.

3. Create a common set of safety metrics that reflect meaningful outcomes

Measurement is foundational to advancing improvement. To advance safety, we need to establish standard metrics across the care continuum and create ways to identify and measure risks and hazards proactively.

4. Increase funding for research in patient safety and implementation science

To make substantial advances in patient safety, both safety science and implementation science should be advanced, to more completely understand safety hazards and the best ways to prevent them.
Patients deserve safe care in and across every setting. Health care organizations need better tools, processes, and structures to deliver care safely and to evaluate the safety of care in various settings.

Workforce safety, morale, and wellness are absolutely necessary to providing safe care. Nurses, physicians, medical assistants, pharmacists, technicians, and others need support to fulfill their highest potential as healers.

Patients and families need to be actively engaged at all levels of health care. At its core, patient engagement is about the free flow of information to and from the patient.

Optimizing the safety benefits and minimizing the unintended consequences of health IT is critical.
What is Safety Across the Continuum?

- Most studies have been done in primary care settings
- But we can’t forget …
  - Specialty practices
  - Ambulatory surgical centers
  - Dialysis centers
  - Physician offices
  - Nursing homes
  - Rehabs
  - Care in the home (including large variety of devices)
  - And many others …
What do we know about safety across the continuum?

• **Medication safety**
• Transitions of care
• Missed and delayed diagnosis
  - Test result follow-up
  - Referral management

Just the tip of the iceberg ...
Adverse Drug Events

25% (162/661) of primary care patients had an adverse drug event (ADE)

- 13% (24) serious
- 11% (20) preventable
- 28% (51) ameliorable
- 6% (13) both serious and preventable or ameliorable

Gandhi et al. NEJM. April 2003
Outpatient Prescribing Errors

- 1879 prescriptions reviewed from 4 academic practices
  - Medication error rate ~8%
  - More advanced computer prescribing checks with decision support would have prevented 95% of potential ADEs
  - Majority of prevention from completion prescriptions, drug-dose, and drug-frequency checking

  Gandhi et al. *JGIM*. 2005

- Study of community practices found error rate of 37%
  - Legibility issues very common

  Abramson et al. *JAMIA*. 2012
E-prescribing Impact

• One study of 15 providers before and after implementation of e-prescribing
  ▪ Error rates reduced from 42/100 prescriptions to 6/100 prescriptions

  Kaushal et al. *JGIM*. 2010

• Another pre-post study
  ▪ Prescription errors decreased from 18% to 8%

  Devine et al. *JAMIA*. 2010
E-prescribing

• E-prescribing with decision support has high potential for reducing serious medication errors

• Need to improve current decision support
  - Streamlined knowledge bases and tiered alerting have higher acceptance rates
  - What is our ideal acceptance rate? Sensitivity/specificity? Best way to display?

• More work needs to be done to maximize the clinical benefits
Safety Issues in Nursing Homes

- Nearly 1 in 3 Medicare beneficiaries who went to SNFs (35 days or fewer; avg 15 days) experienced an adverse event
  - 59% preventable; many as a result of failure to monitor or delay in care
  - More than half of the residents who experienced harm were hospitalized
  - Most common: medication related (37%), resident care (37%), infections (26%)

OIG report. 2014.
Safety Issues in Home Care

• Home care adverse event rate per client-year is 10%

• 56% of AEs were judged preventable
  - The most frequent were injuries from falls, wound infections, psychosocial, behavioral or mental health problems, and medication errors
  - Clients’ decisions or actions contributed to 48.4% of AEs, informal caregivers 20.4% of AEs, and health care personnel 46.2% of AEs

Blais et al. BMJ Qual Saf. 2013
Medication Reconciliation

• One study, using phone follow-up 3-5 days after discharge found
  • 29% of patients NOT taking a medication on their discharge list, taking a different dose or frequency, or taking an additional medication

• Vanderbilt Inpatient Cohort Study
  • Approx. 50% taking 1 or more discordant medications
  • More common among patients with lower numeracy or health literacy

Schnipper et al. *Arch Int Med.* 2006
Non-Adherence

- Estimates are that 125,000 Americans die annually due to poor medication adherence

- Poor medication adherence results in roughly 33 to 69% of medication-related hospital admissions, at a cost of roughly $100 billion per year

- In one study of 195,000 newly prescribed e-prescriptions, only 72% were filled
  - Non-adherence was common for medications for chronic conditions such as hypertension, diabetes, hyperlipidemia

- “Medication non-adherence: A diagnosable and treatable condition”
  - Often undetected and untreated
  - Clinicians not trained to screen or treat
  - Need to understand patient beliefs and values

Osterberg et al. *NEJM*. 2005  
Fischer et al. *JGIM*. 2010  
Marcum et al. *JAMA* editorial. 2013
Non-Adherence

• Much work needs to be done to determine best strategies for improving adherence
• Need to match intervention with specific patient’s needs
  - Pharmacist interventions
  - Patient portals
  - Pill monitoring technology
    - Electronic pill caps, smart blister packaging
  - Electronic monitors
    - Biometric monitors, activity monitors, digital scales
  - Mobile health
    - Text messaging, interactive voice response, smartphone apps
  - Feedback of adherence to ordering physician through technology

Zullig L, et al. JAMA 2013
Polypharmacy

- Prevalence of polypharmacy among the adult population is increasing
  - U.S. adults using 5 or more prescription drugs increased from an estimated 8.2% to 15% between 1999–2000 and 2011–2012, according to a nationally representative survey (Kantor et al., 2015)
  - Particularly a risk in elderly patients (Maher et al., 2014)

- Safety issues
  - Adverse drug events (Bourgeois et al., 2010)
  - Drug-Drug interactions (Qato et al., 2016)
  - Medication errors (Koper et al., 2013)
  - Hospital readmissions (Toh et al., 2014)
  - Difficulty with understanding medications (Marvanova et al., 2011)
  - Inadequate communication about a patient’s medications between different health care providers involved in the patient’s care (Marcum et al., 2012)
Polypharmacy Interventions

Types of approaches

- Holistic strategies for reducing medication use and improving appropriateness
  - Deprescribing (Thompson and Farrell, 2013)
  - Conservative prescribing (Schiff et al., 2011)

- Technology-facilitated solutions incorporating electronic health records and tools such as computerized decision support (Clyne et al., 2012)

- Established screening criteria and algorithms (Beers criteria, STOPP/START) (Farrell et al., 2013)

- A number of national initiatives already established or in development address issues of polypharmacy and medication overuse. Examples include:
  - Choosing Wisely campaign
  - Canadian Deprescribing Network (Tannenbaum et al., 2017)
  - Scotland campaign
Health Literacy – A Serious Issue Across the Continuum

“Nearly 9 out of 10 US adults have difficulty using the everyday health information that is routinely available in our health care facilities, retail outlets, media and communities.”

HHS. National Action Plan to Improve Health Literacy. 2010
Prevalence of limited health literacy

Data from the only population-level study of health literacy skills conducted to date show the prevalence of LHL.

Koh et al. *Health Aff.* 2012
National Assessment of Adult Literacy (NAAL). 2003
Levels of Health Literacy

Below Basic and Basic

- Over a third (36%) of US adults have below basic or basic health literacy
- These patients “may fail to understand critically important warnings on the label of an over-the-counter medication.”

Levels of Health Literacy

Intermediate

- 53% of US adults have intermediate health literacy
- These patients are able to “perform moderately challenging activities, such as summarizing written text, determining cause and effect and making simple inferences.”\(^1\)
- But they may still “find it difficult to define a medical term from a complex document about an unfamiliar topic.”\(^2\)

\(^1\) CDC, *Health Literacy for Public Health Professionals*. 2014
\(^2\) Koh et al. *Health Aff.* 2012
What can providers do?

• Slow down
• Limit, but repeat, information at every visit
• Avoid medical jargon
• Use illustrations to explain important concepts
• Use easy-to-read written materials
• Make visits interactive
• Use “teach-back” to gauge comprehension

Critical for patient engagement around medications!

HRSA, Effective Communications Tools for Healthcare Professionals. 2008
Patient Portals for Patient Engagement

- Patient portals can be used to communicate a wide array of information bi-directionally
  - Appointments
  - Medication lists, problem lists
  - Labs
  - Discharge summaries
  - Health care proxy
  - Health maintenance reminders
  - Medication reminders
Patient Portals

• Showing patients their medication lists in advance of visits can improve med list accuracy
  
  Schnipper et al. JAMIA. 2012

• Diabetic patients using a portal had increased rates of medication adjustment
  
  Grant et al. Arch Intern Med. 2008

• Open Notes study shows patients have more control of their care and better med adherence
  
Outpatient Safety Concepts

• Important to focus on the bigger picture as well as specific risk areas

• Many principles in place in inpatient settings
  - Culture change
  - Event identification and analysis
  - Proactive assessment
  - Projects in high risk areas

• Need to transfer these to outpatient settings
Summary

• Starting to know more about medication risks across the continuum of care and opportunities for intervention
• Also need to focus on developing safety culture and infrastructure
• Focus on systems and process redesign
  - IT is a powerful tool, but much can be done with non-IT processes
• Now is the time to move beyond inpatient to other settings!
Real World Challenges and Opportunities for Improving Outpatient Drug Safety

Heather Sundar, PharmD
Managing Partner
Sundar Healthcare Consulting, LLC
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What We Will Discuss

• Drug Safety is a Big Problem and it is not Going Away
• It’s a Tough Problem To Solve
• How Do We Cut Through This Mess?
• A Glimmer of Hope
What is Drug Safety?

Pharmacovigilance, also known as Drug Safety, is the pharmacological science relating adverse effects with pharmaceutical products through:

- Collection
- Detection
- Assessment
- Monitoring
- Prevention

Drug Safety is a Big Problem....

and it is not Going Away
10,000

Prescription medications in U.S.


Medication Errors - Academy of Managed Care Pharmacy. (n.d.). Retrieved June 06, 2017

10,000 Prescription medications in U.S.

4 Billion Prescriptions Dispensed in 2016
10,000 Prescription medications in U.S.

28.4 Estimated number of physicians patients over age 65 see in lifetime

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Estimated number of physicians patients over age 65 see in lifetime

One-in-Three
Adults in U.S. taking 5 or more medications
2-drug combinations with high probability of causing serious Adverse Drug Reactions


Medication Errors - Academy of Managed Care Pharmacy. (n.d.). Retrieved June 6, 2017

36

2-drug combinations with high probability of causing serious Adverse Drug Reactions

52%

Average % of pharmacies that failed to warn of significant drug/drug interactions
2 Million Hospitalizations annually related to drug and device adverse events

36 2-drug combinations with high probability of causing serious Adverse Drug Reactions

52% Average % of pharmacies that failed to warn of significant drug/drug interactions
Estimated unnecessary expense burden on US healthcare payors

$30 - 100 Billion

Average % of pharmacies that failed to warn of significant drug/drug interactions

52%

2-drug combinations with high probability of causing serious Adverse Drug Reactions

36

2 Million Hospitalizations annually related to drug and device adverse events
Drug Safety is a Tough Problem To Solve
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Why Do Alerts Go Ignored?

• Alert fatigue continues to be a significant problem
• Many alerts are of questionable significance
• Pharmacists and physicians are subjected to numerous alerts
• Patients taking more than 5 drugs will have at least 1 alert
• Unintended consequence of alert fatigue = ignore all alerts

Sources:
First, Detect the Problem...Next, Deal with it

• The patient is the starting place for managing medication
• Medication therapy interventions help patients who are
  • Experiencing adverse effects
  • Are frequently hospitalized
  • Who have a higher number of medications
• Average of 3:1 Return on Investment (ROI)

How Do We Cut Through This Mess?
Top Limitations to Prescription Safety
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Completeness of patient-specific prescription data

Source: Data based on 2017 industry survey
Top Limitations to Prescription Safety

- Completeness of patient-specific prescription data: 31%
- Timeliness of data or intervention to physician: 26%
- Source: Data based on 2017 industry survey
Top Limitations to Prescription Safety

- Access to patient-specific prescription data: 15%
- Completeness of patient-specific prescription data: 31%
- Timeliness of data or intervention to physician: 26%
- 9%
- 4%
- 15%

Source: Data based on 2017 industry survey
Top Limitations to Prescription Safety

- Access to patient-specific prescription data: 15%
- Completeness of patient-specific prescription data: 31%
- Timeliness of data or intervention to physician: 26%
- Lack of post marketing research on newer drugs: 15%
- 4%
Top Limitations to Prescription Safety

- Access to patient-specific prescription data: 31%
- Completeness of patient-specific prescription data: 15%
- Timeliness of data or intervention to physician: 26%
- Lack of post marketing research on newer drugs: 15%
- Willingness to report and knowledge of how to report: 9%

Source: Data based on 2017 industry survey
Top Limitations to Prescription Safety

- Access to patient-specific prescription data
- Completeness of patient-specific prescription data
- Timeliness of data or intervention to physician
- Physician receptivity/attitude to the information
- Lack of post marketing research on newer drugs
- Willingness to report and knowledge of how to report

Source: Data based on 2017 industry survey
What Organizations Are in Best Position to Improve Outpatient Drug Safety?

- Electronic Health Records/E-prescribing: 30%
- Health Plans/Pharmacy Benefit Managers: 25%
- Physician Offices/Health Systems: 20%
- Retail, Mail and Specialty Pharmacies: 25%
- Fully-Funded Government Agencies: 10%
- Health Information Exchanges: 5%
- Pharmaceutical Manufacturers: 0%

Source: Data based on 2017 industry survey
“No one fix prevents medication errors”

Institute of Safe Medication Practices
Limitations to Producing Quality Health Outcomes Research Related to Drug Safety

Source: Data based on 2017 industry survey
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Limitations to Producing Quality Health Outcomes Research Related to Drug Safety

- Collaboration across organizations: 35%
- Access to timely/complete data: 22%
- Access to data – data rights/privacy: 22%
- 9%
- 4%
- 8%

Source: Data based on 2017 industry survey
Limitations to Producing Quality Health Outcomes Research Related to Drug Safety

- Collaboration across organizations: 35%
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Limitations to Producing Quality Health Outcomes Research Related to Drug Safety

- Competing research priorities: 35%
- Misaligned incentives: 22%
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Source: Data based on 2017 industry survey
Top Areas of Research for Prescription Drug Safety That Are Needed

- Polypharmacy
- Medications Paid in the Medical Benefit
- Opioid Utilization and Addiction
- Adverse Drug Events
- Supplement/Herbals Taken with Prescription
- Pre-Market Testing/Post-Marketing Surveillance

Source: Data based on 2017 industry survey
Polypharmacy → Elevated risk due to complexity
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Source: Data based on 2017 industry survey
Medications paid in medical benefit

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Lack of real-time safety reviews
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Source: Data based on 2017 industry survey
Opioid utilization and addiction ➔
Current area of concern
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Source: Data based on 2017 industry survey
A Glimmer of Hope
Potential for Artificial Intelligence and Machine-Learning to Significantly Improve Patient Prescription Drug Use Safety

Impact will be within next 5 – 10 years

Impact will be in less than 5 years

Impact will be 10+ years away

Source: Data based on 2017 industry survey
Exploring the Case for More Automation

• ½ of all life sciences executives plan to adopt cognitive computing for pharmacovigilance in the next 3 years
• There is an increasing variety of connected devices
• There is a tremendous amount of data to be leveraged
• Machine learning and cognitive computing can make this analysis faster and more predictive, separating the signal from the noise

Source:
One Big Caveat

• Data have to be actionable... and the resulting action has to be a good one

• If providers ignore the alerts, more data may not help... unless the data are used to reduce the number of alerts

• Understanding provider behavior and designing for behavior is critical

What We Discussed

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Thank You

For more information, you can reach me at:

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