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

Scott K. Winiecki, MD

Team Lead, Safe Use Initiative

Professional Affairs and Stakeholder Engagement Staff (PASES)

Center for Drug Evaluation and Research,

U.S. Food and Drug Administration

June 15, 2017

FDA U.S. FOOD & DRUG ADMINISTRATION

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

FDA U.S. FOOD & DRUG ADMINISTRATION

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

FDA U.S. FOOD & DRUG ADMINISTRATION

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

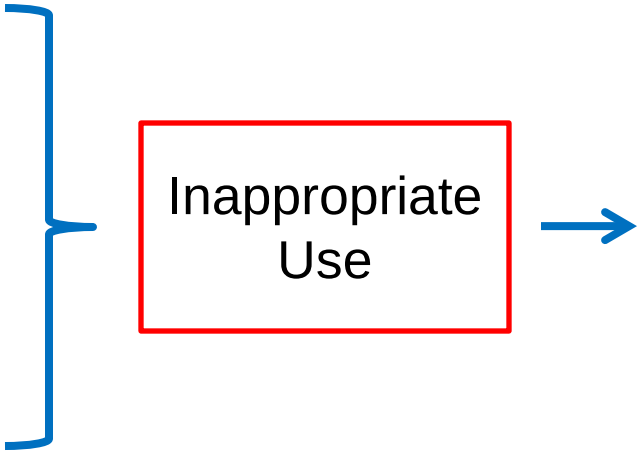
- Indications
- Identified Risks
- Potential Risks
- Missing Information

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

FDA U.S. FOOD & DRUG ADMINISTRATION

Thank You

FDA Safe Use Team Contact Information

Scott K. Winiecki, MD

- Email: scott.winiecki@fda.hhs.gov or CDERSafeUseInitiative@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

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

CBS/AP / December 4, 2014, 6:11 PM

Hospital medication error kills patient in Oregon

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.

DANGEROUS DOSES DEC. 15, 2016

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. MORE›

DANGEROUS DOSES FEB. 11, 2016

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.

DANGEROUS DOSES FEB. 11, 2016

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.

Impact and updates

DANGEROUS DOSES APR. 28, 2017

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-tw
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

Institute of Medicine (IOM). Preventing medication errors. Washington, DC: National Academies Press; 2006.

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]

Notes

2. Massachusetts Technology Collaborative (MTC) and NEHI, 2008. *Saving Lives, Saving Money: The Imperative for CPOE in Massachusetts.* Updated to 2008 figures. Cambridge, MA: NEHI, 2008. Available at: http://www.nehi.net/publications/8/saving_lives_saving_money_the_imperative_for_computerized_physician_order_entry_in_massachusetts_hospitals.
3. Center of Information Technology Leadership (CITL), *The Value of Computerized Provider Order Entry in Ambulatory Settings*. Updated to 2007 figures. Available at: http://www.partners.org/cird/pdfs/CITL_ACPOE_Full.pdf. Last accessed October 2011.
4. Institute of Medicine (IOM). *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 1999.

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.[1] 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.[2] Guidelines for physicians to optimize patient care are quickly out of date and can be biased by those who write the guidelines.[3–5] 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.[6] 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.[7] 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.[8,9]

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.[10] 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.[11] 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.[12]

METHODS

The approach to the problem of identifying and enumerating PAEs was 4-fold: (1) distinguish types of PAEs that may occur in hospitals, (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

From the Patient Safety America, Houston, Texas.
Correspondence: John T. James, PhD, Patient Safety America, 14503 Windy Ridge Lane, Suite 200, Houston, TX 77062 (email: john.t.james@earthlink.net).
The author discloses no conflict of interest.
Sources of support: none.

Health IT and Patient Safety:

Building Safer Systems for Better Care

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Advising the nation / Improving health

US Government Study

ADVERSE EVENTS IN HOSPITALS: CASE STUDY OF INCIDENCE AMONG MEDICARE BENEFICIARIES IN TWO SELECTED COUNTIES

Daniel R. Levinson
Inspector General

December 2008
OEI-06-08-00220

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)

By David C. Classen, Roger Resar, Frances Griffin, Frank Federico, Terri Frankel, Nancy Kimmel, John C. Whittington, Allan Frankel, Andrew Seger, and Brent C. James

'Global Trigger Tool' Shows That Adverse Events In Hospitals May Be Ten Times Greater Than Previously Measured

DOI: 10.1377/hlthaff.2011.0190
HEALTH AFFAIRS 30,
NO. 4 (2011): –

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.

David C. Classen (dclassen@csc.com) is an associate professor of medicine at the University of Utah, in Salt Lake City.

Roger Resar is a senior fellow at the Institute for Healthcare Improvement, in Cambridge, Massachusetts.

Frances Griffin is a faculty member at the Institute for Healthcare Improvement.

Frank Federico is an executive director at the Institute for Healthcare Improvement.

Terri Frankel is a director at the Institute for Healthcare Improvement.

Nancy Kimmel is director of quality and safety at the Missouri Baptist Medical Center, in St. Louis.

EXHIBIT 3

Adverse Events In Three Study Hospitals Detected By All Methods, By Severity Level

Type of adverse event	Severity level					
	E	F	G	H	I	Total
Medication-related	100	46	2	2	0	150
Procedure-related (excluding infection)	67	26	5	7	4	109
Nosocomial infection	30	37	2	2	1	72
Pulmonary/VTE	8	5	2	0	2	17
Pressure ulcers	10	1	0	0	0	11
Device failure	0	6	0	0	0	6
Patient falls	2	1	0	0	0	3
Other	10	11	0	3	2	26
Total	227	133	11	14	8	393

TRIGGER METHODOLOGIES UNCOVER 10 TO 100 FOLD MORE ADVERSE EVENTS THAN INCUMBENT SYSTEMS

Adverse Event Detection, by Severity Level and Hospital

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

Source: Classen et al, Health Affairs 2011

VIEWPOINT

The Future of Quality Measurement for Improvement and Accountability

Patrick H. Conway, MD, MSc
Farzad Mostashari, MD, MPH
Carolyn Clancy, MD

surement system requires ongoing c
public and private sectors. Federal pr
established by statute and started or
surement is often setting-specific;

JAMA Editorial, June 5, 2013 from clinical leaders at CMS, ONC, AHRQ

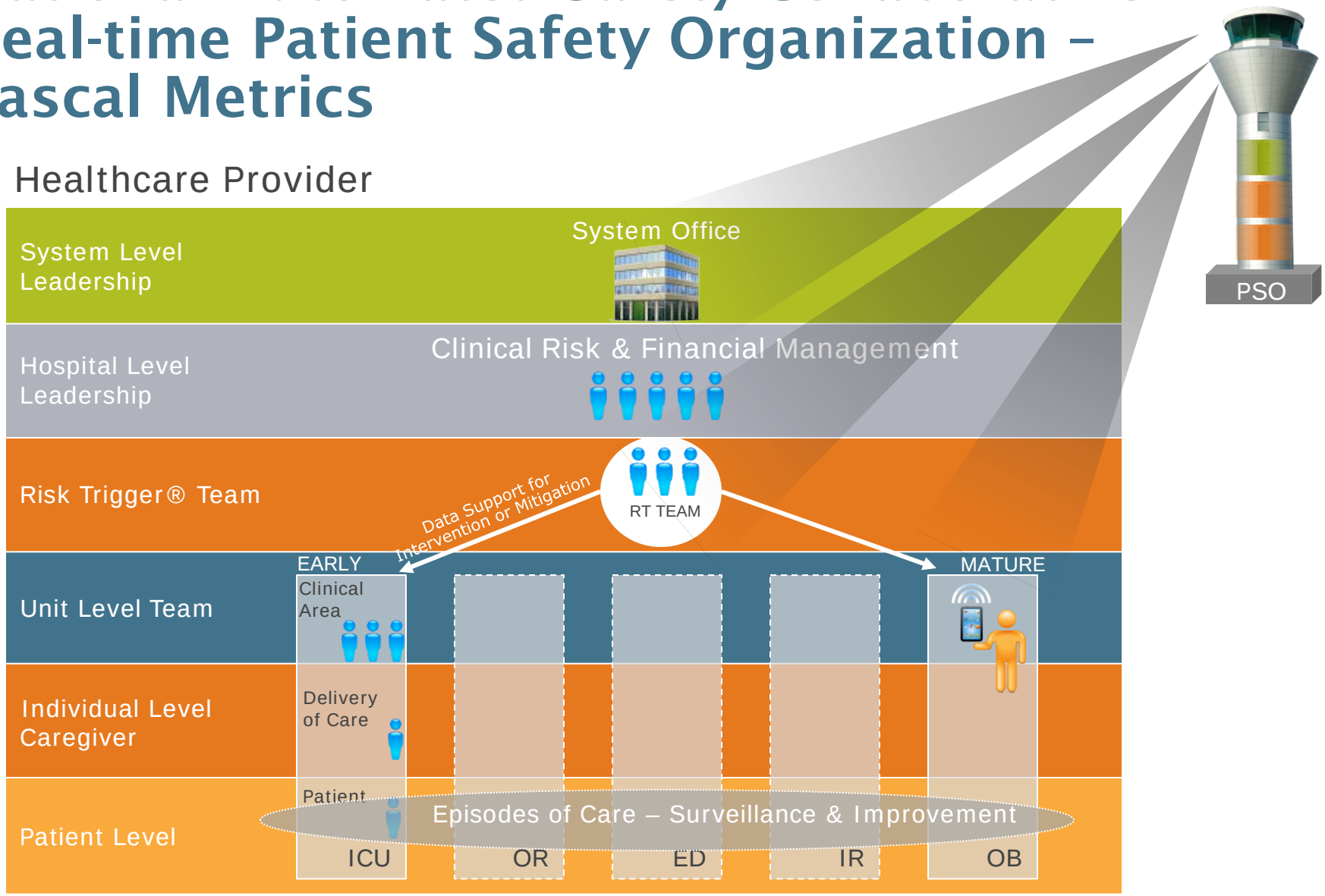
Most U.S. hospitals do not measure – much less track and manage – "all cause harm" using clinical data

Table. National Quality Strategy Domains: Current and Future Measure Examples

Quality Dimension[a]	Examples	
	Current Measures	Future Measures
Safety	Central-line infections; claims-based health care–acquired conditions	All-cause patient harm including clinical data
Care coordination	Care transitions measure (3-item patient report); hospital readmissions	Readmissions across settings; care transition composite; patient-reported care coordination across settings
Clinical care	Seting-specific clinical process of care measures by condition	Patient-centered and patient-reported outcome measures; outcome measures for patients with multiple chronic conditions
Population and community health	Smoking; immunizations	Determinants of health; reduction in disparities
Patient experience and engagement	Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys	Multimodal collection of patient experience; shared decision making and engagement
Cost and efficiency	Cost for individual episodes around hospitalization	Costs across episodes with shared accountability; total cost of care for populations

[a] Adapted from the US Dept of Health and Human Services.[1]

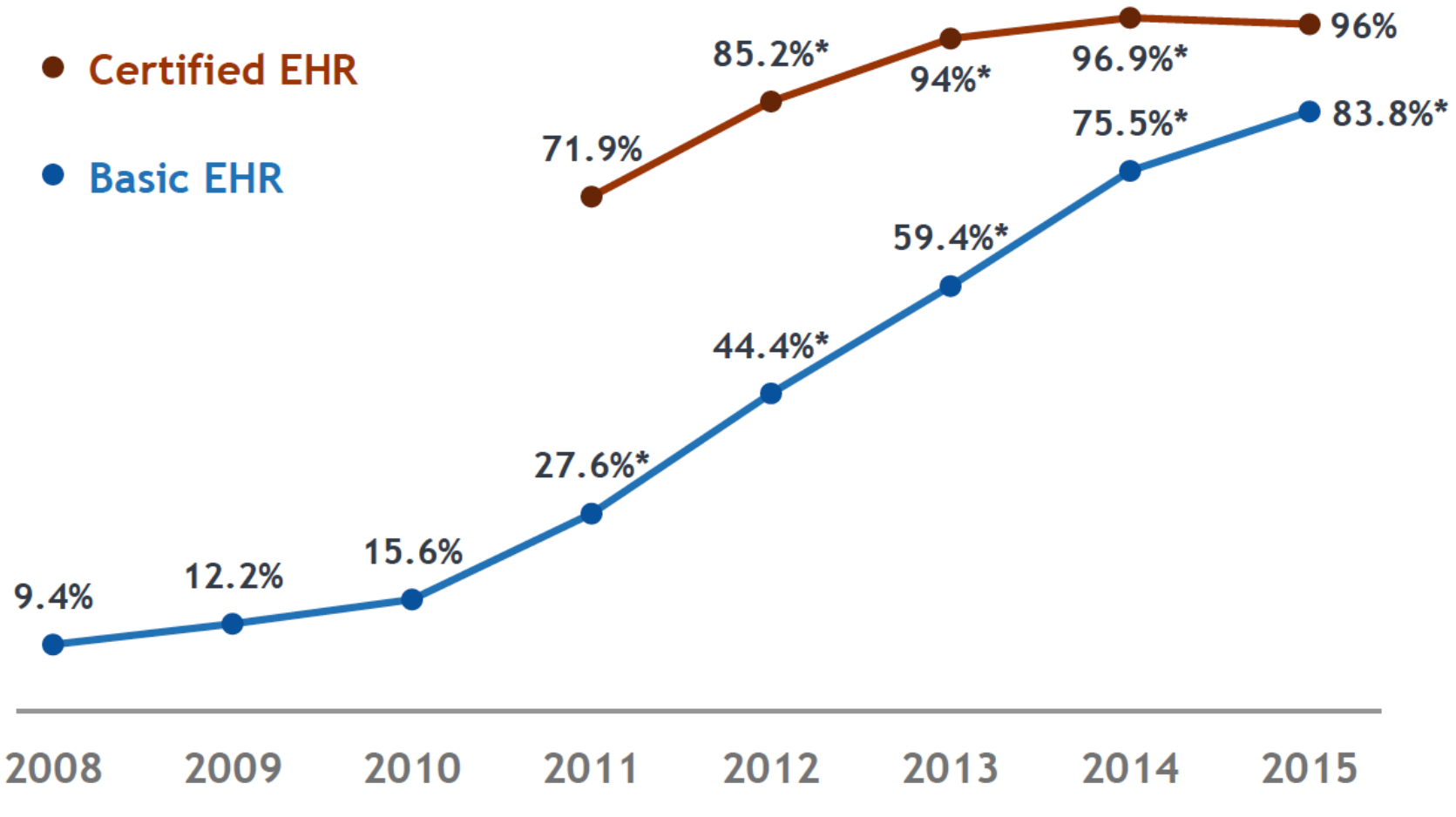
National Automated Safety Collaborative: Real-time Patient Safety Organization – Pascal Metrics



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



ORIGINAL INVESTIGATION

High Rates of Adverse Drug Events in a Highly Computerized Hospital

ARCHIVES EXPRESS

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).

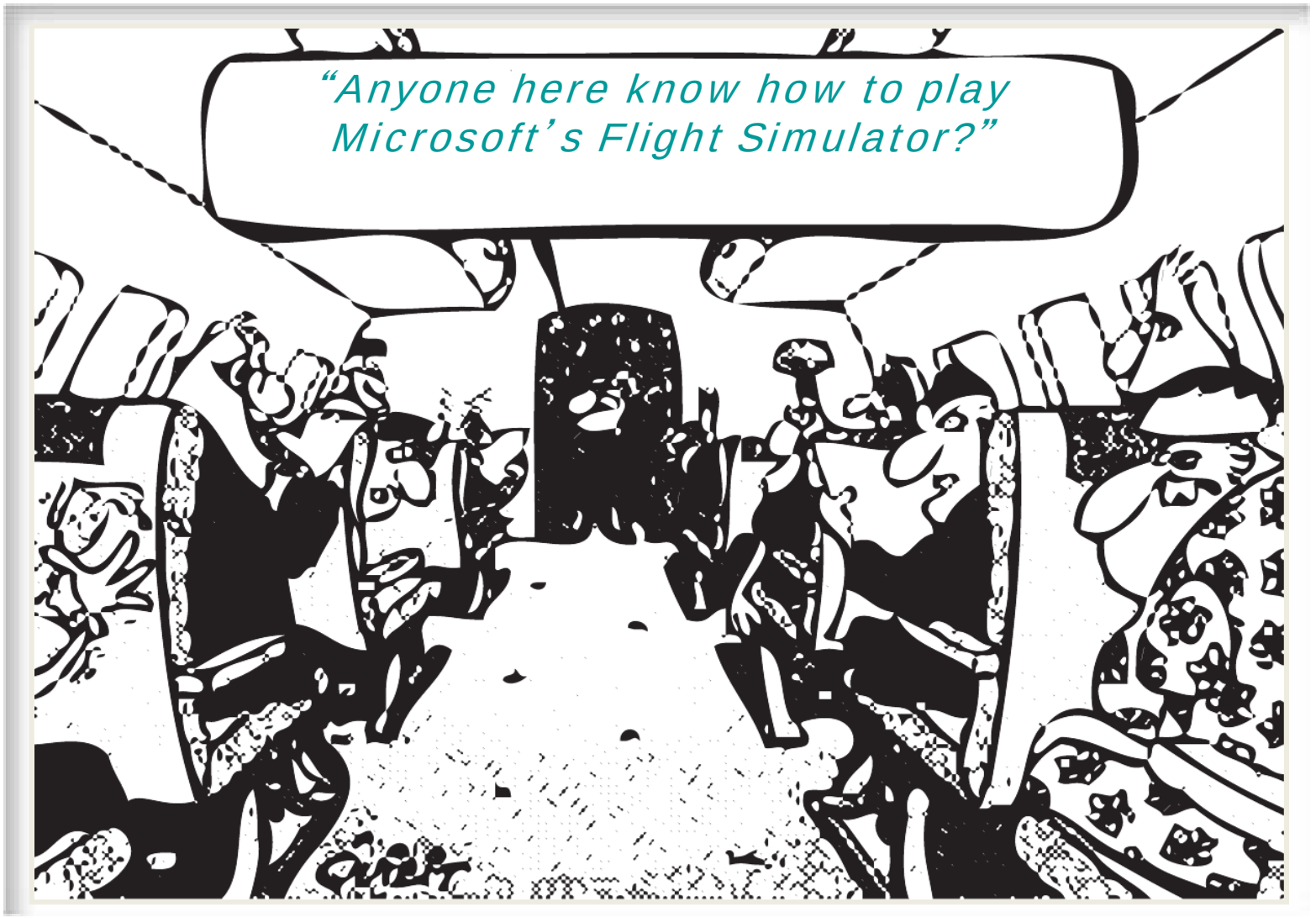
Methods: Using explicit standardized criteria, pharmacists classified inpatient ADEs from prospective daily reviews of electronic medical records from a random sample of all admissions during a 20-week period at a Veterans Administration hospital. We analyzed ADEs that necessitated a changed treatment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

AHRQ/NQF/Leapfrog EHR Flight Simulator



Relationship between medication event rates and the Leapfrog computerized physician order entry evaluation tool

Alexander A Leung,[1] Carol Keohane,[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 Bates[1]

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.[1 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.[1 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 14] 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.

Patient AB

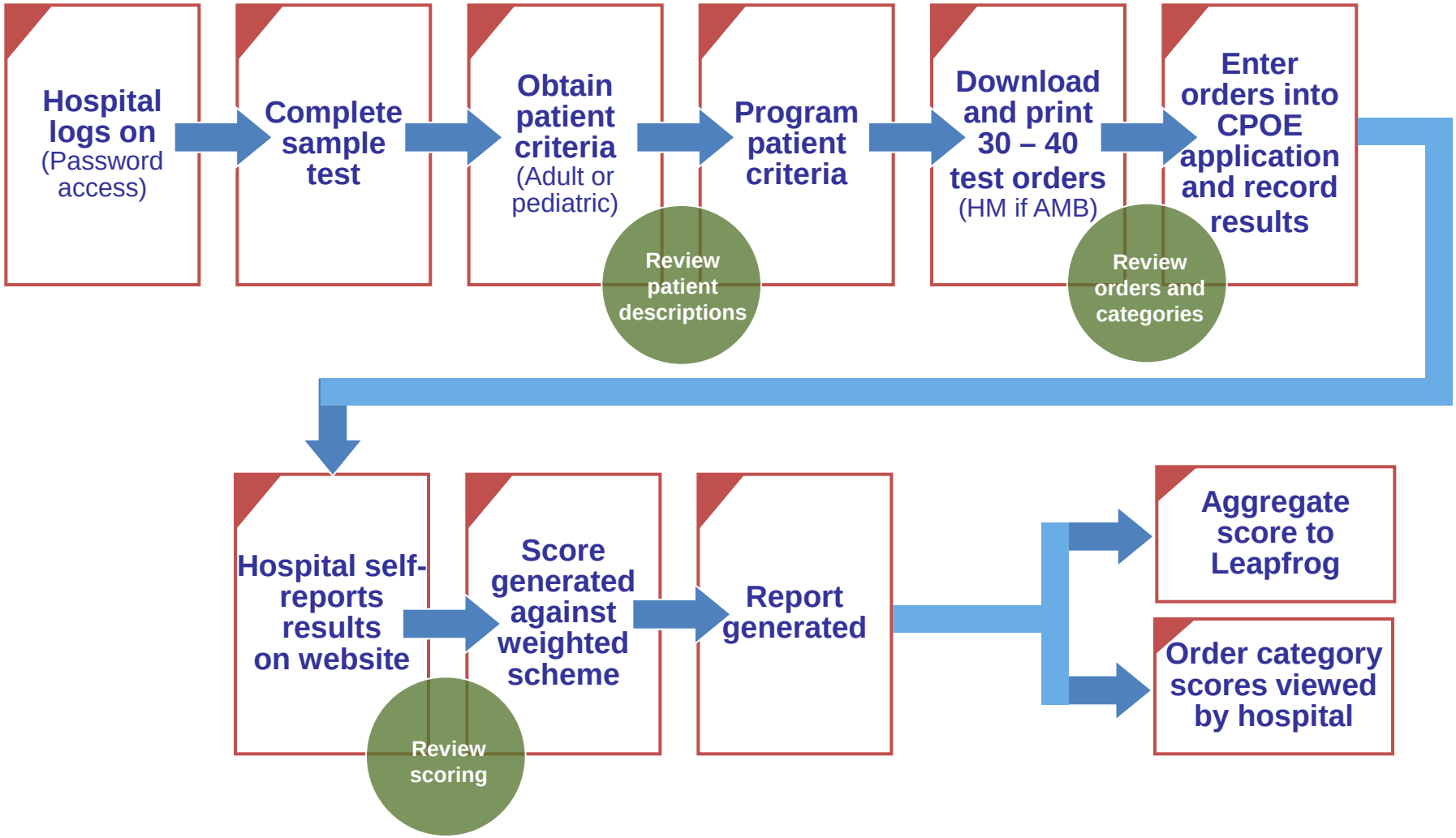
Female
52 years old
Weighs 60 kg
Allergy to morphine
Normal creatinine

A physician enters the order …

and observes and records the type of CDS-generated advice that is given (if any).

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

AHRQ/NQF/Leapfrog Assessment Tool (cont'd)



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

DOI: 10.1377/hlthaff.2010.0160
HEALTH AFFAIRS 29,
NO. 4 (2010): 655–663

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.**

Jane Metzger (jmetzger2@csc.com) is a principal researcher at CSC Healthcare in Waltham, Massachusetts.

Emily Welebob is an independent consultant in Indianapolis, Indiana.

David W. Bates is division chief for general internal medicine at Brigham and Women's Hospital in Boston, Massachusetts.

Stuart Lipsitz is a researcher at Brigham and Women's Hospital.

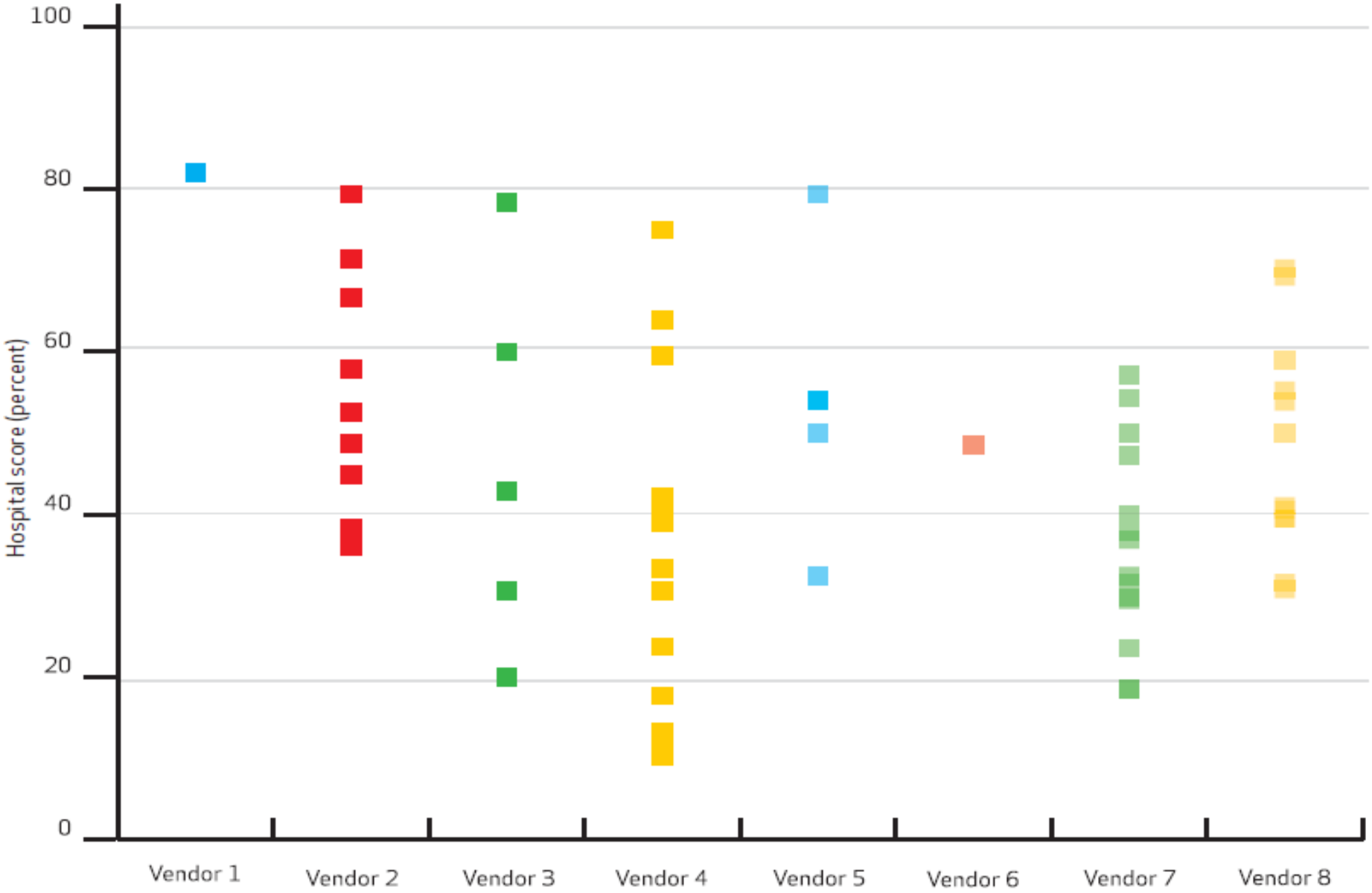
David C. Classen is an associate professor of medicine at the University of Utah in Salt Lake City, and is also with CSC Healthcare.

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

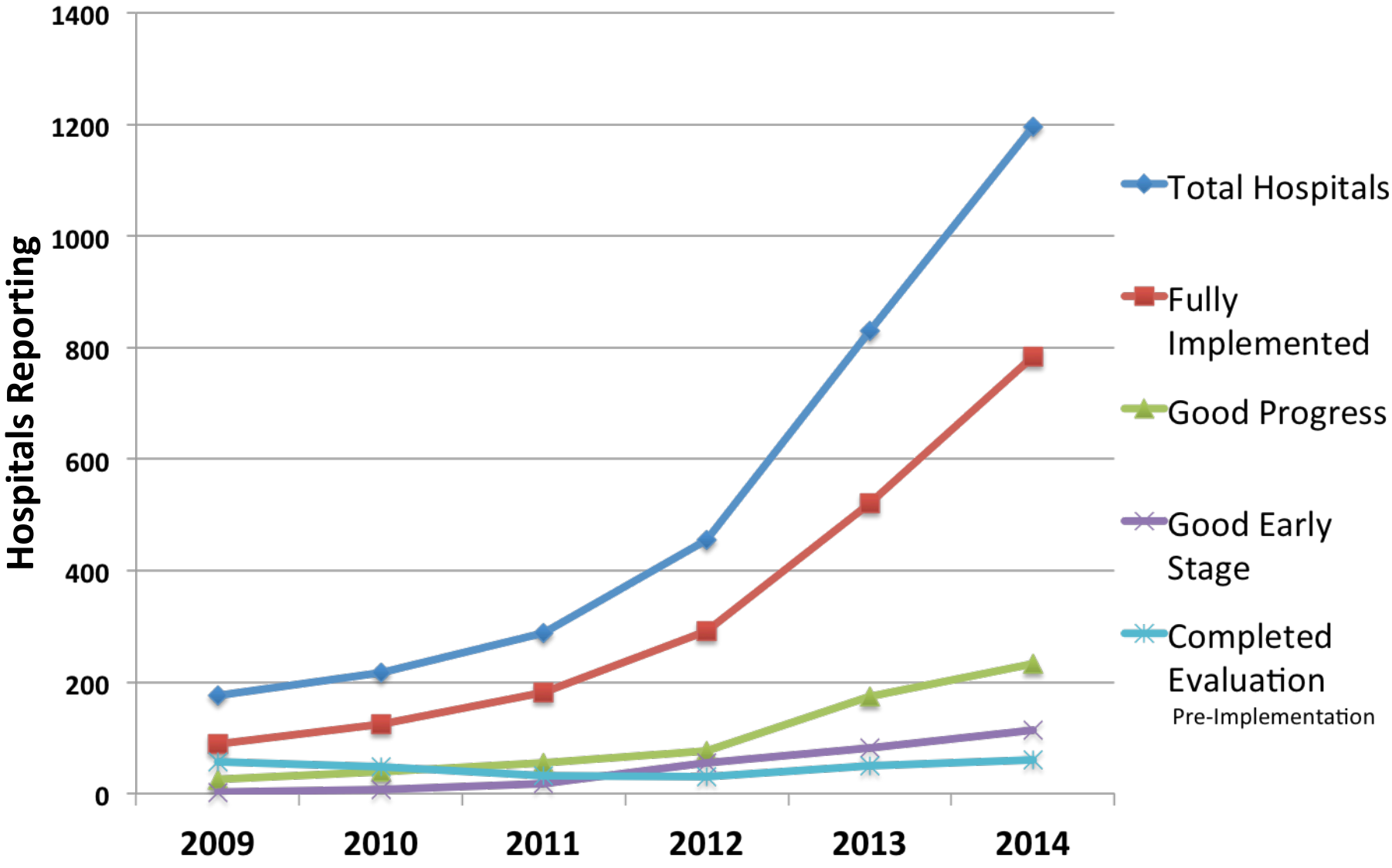
In this application of clinical decision support, physicians are made aware of potential safety issues that can result—for example, when ampicillin is given to a patient with a known allergy to penicillin, or the dose being ordered for a pediatric patient is much higher than the therapeutic range for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

EXHIBIT 2

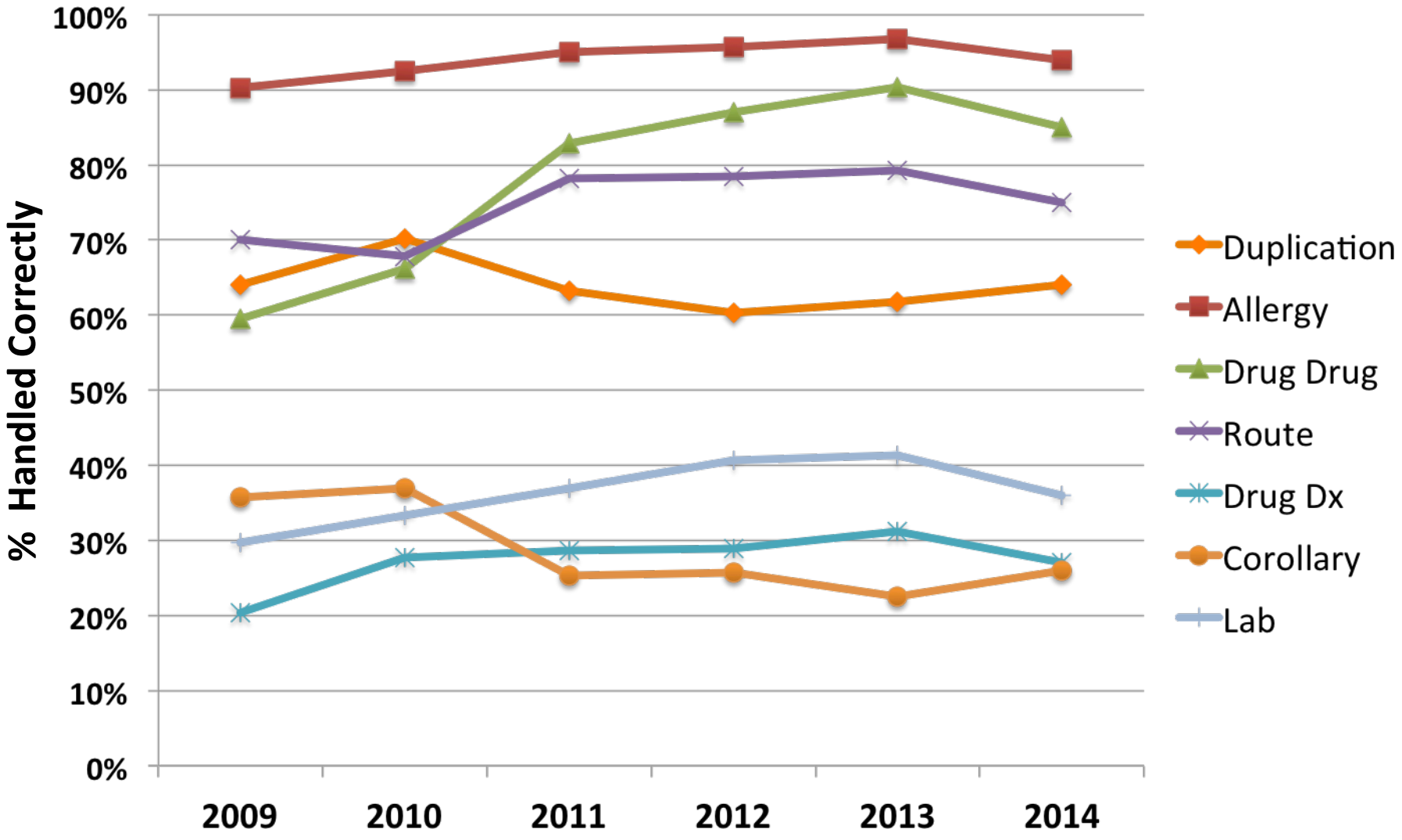
Hospital Scores For Detection Of Test Orders That Would Cause An Adverse Drug Event In An Adult Patient According To The Software Product (Vendor) Implemented



AHRQ EHR/CPOE Flight Simulator Use



Orders Handled Correctly by Checking Category



Ambulatory Adverse Drug Events (ADEs): After Hospital Discharge

Table 2. Type of Injury and Incidence of All Adverse Events, Preventable Adverse Events, and Ameliorable Adverse Events*

Type of Adverse Event	Incidence	Type of Injury				
		Adverse Drug Event	Procedure Related	Nosocomial Infection	Fall	Other
	n/n (%)	← *n (%)* →				
All	76/400 (19 [15–23])	50 (66)	13 (17)	4 (5)	3 (4)	11 (15)
Preventable	23/400 (6 [4–8])	12 (50)	2 (8)	0 (0)	2 (8)	9 (38)
Ameliorable	24/400 (6 [4–8])	19 (76)	3 (12)	1 (4)	0 (0)	2 (8)

Ann Intern Med. 2003;138:161-167.

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%)

Ambulatory Medication Safety Studies

- **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

Gurwitz JH, Field TS, Harrold LR et al. Incidence and preventability of adverse drug events among older persons in the ambulatory setting. *JAMA.* 2003 Mar 5;289(9):1107-16.

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

Gandhi TK, Weingart SN, Borus J et al. Adverse Drug Events in Ambulatory Care. *N Engl J Med.* 2003; 348:1556-64.

Community Pharmacy Safety

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

Flynn EA, Barker KN. Research on errors in dispensing and medication administration. In: Cohen MR, eds. Medication errors. 2nd ed. Washington, DC: American Pharmacists Association; 2007:15-41.

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

Flynn EA, Dorris NT, Holman GT et al. Medication dispensing errors in community pharmacies: A nationwide study. In Proceedings of the Human Factors and Ergonomics Society 46th Annual Meeting. Santa Monica, CA: SAGE Publications; 2002:1448-51.

- 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

Flynn EA, Barker KN, Carnahan BJ. National observational study of prescription dispensing accuracy and Safety in 50 pharmacies. *J Am Pharm Assoc.* 2003; 43:191-200.

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 Medication Safety Alert Volume 4, Issue 3, February 10, 1999

ISMP 2005 Pharmacy Computer Field Survey Results

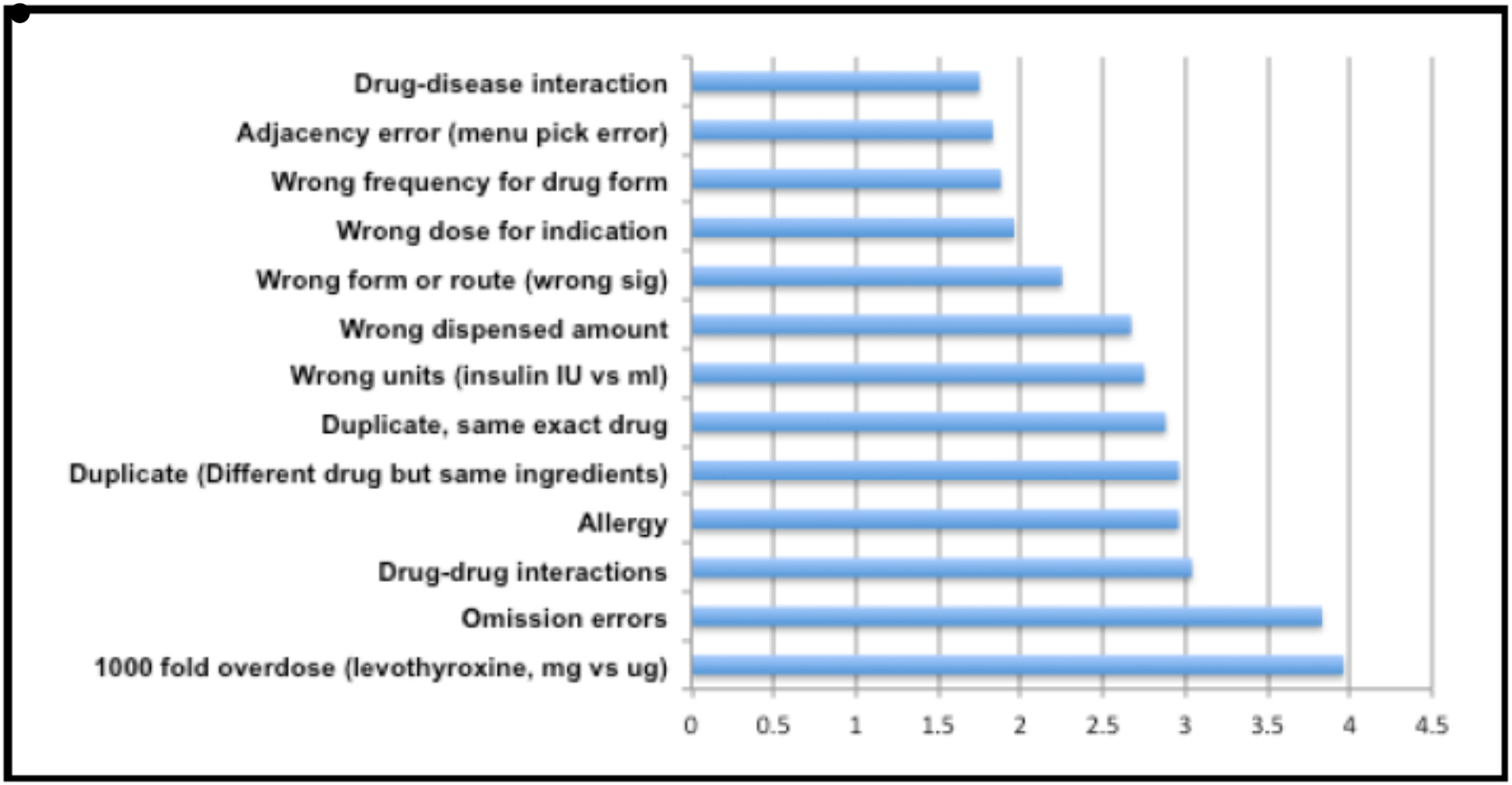
- 4 of 182 systems were able to detect all errors
- Dosage alerts based in weight or BSA decreased from 37% to 25%
- Less than 50% alerted to an order for flu vaccine for a patient with an egg allergy
- Only 1/3 alerted to a fatal route of administration

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



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]

January 28, 2016 ▪ Volume 21 Issue 2

ISMP

Acute Care
ISMP Medication Safety Alert!®

CELEBRATING 20 YEARS

Educating the Healthcare Community About Safe Medication Practices

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 a 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.

SAFETY briefs

Pen device for U-500 insulin makes great sense. As mentioned in our last newsletter, the US Food and Drug Administration (FDA) has approved **HUMULIN R U-500 KWIKPEN** (insulin human injection) (500 units/mL) in a prefilled pen device. U-500 insulin is indicated for patients with type 1 and type 2 diabetes who need more than 200 units of insulin per day. The U-500 pen holds a 3 mL, 1,500 unit insulin cartridge and is the same size as other Lilly pens but dials in 5-unit increments rather than 1-unit increments (**Figure 1**). The device has an aqua pen body to differentiate it from other insulin pens. Until now, U-500 insulin was only available in a vial, and since there is no U-500 syringe, it had to be administered with either a U-100 insulin syringe that required a dose conversion to U-100 markings, or a tuberculin (TB) syringe that required conversion to volume markings.

Figure 1. New Humu**LIN** R U-500 KwikPen dials

ISMP Safety Alert Recs 2016

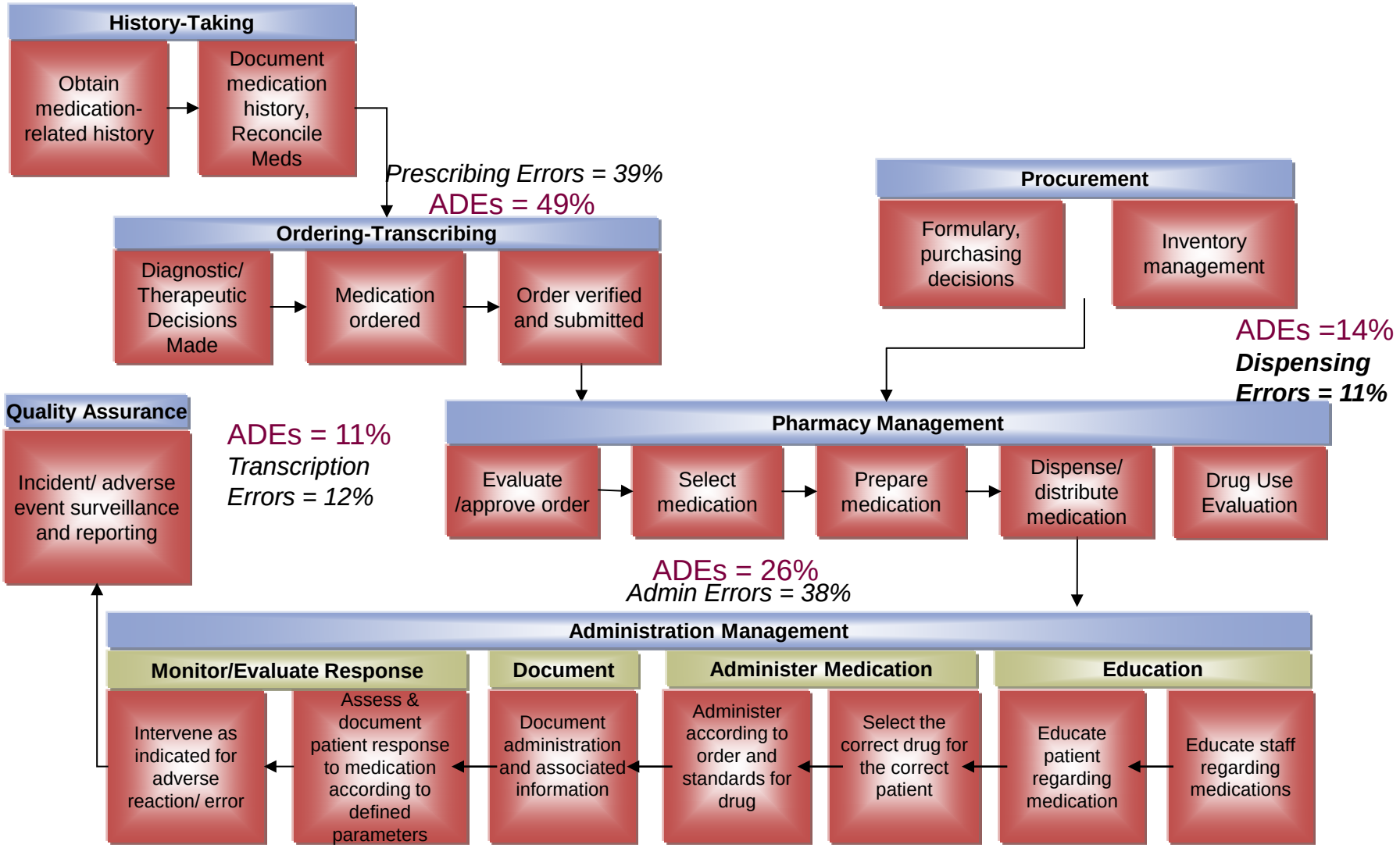
- Patient Information—Placing Orders on The Wrong Patient's Electronic Health Record (EHR)
- Drug Information—Nursing references promote unnecessary IV medication dilution
- Communication—In the EHR confusing the available concentration as the patient's dose
- Manufacturer Packaging—per liter electrolyte 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

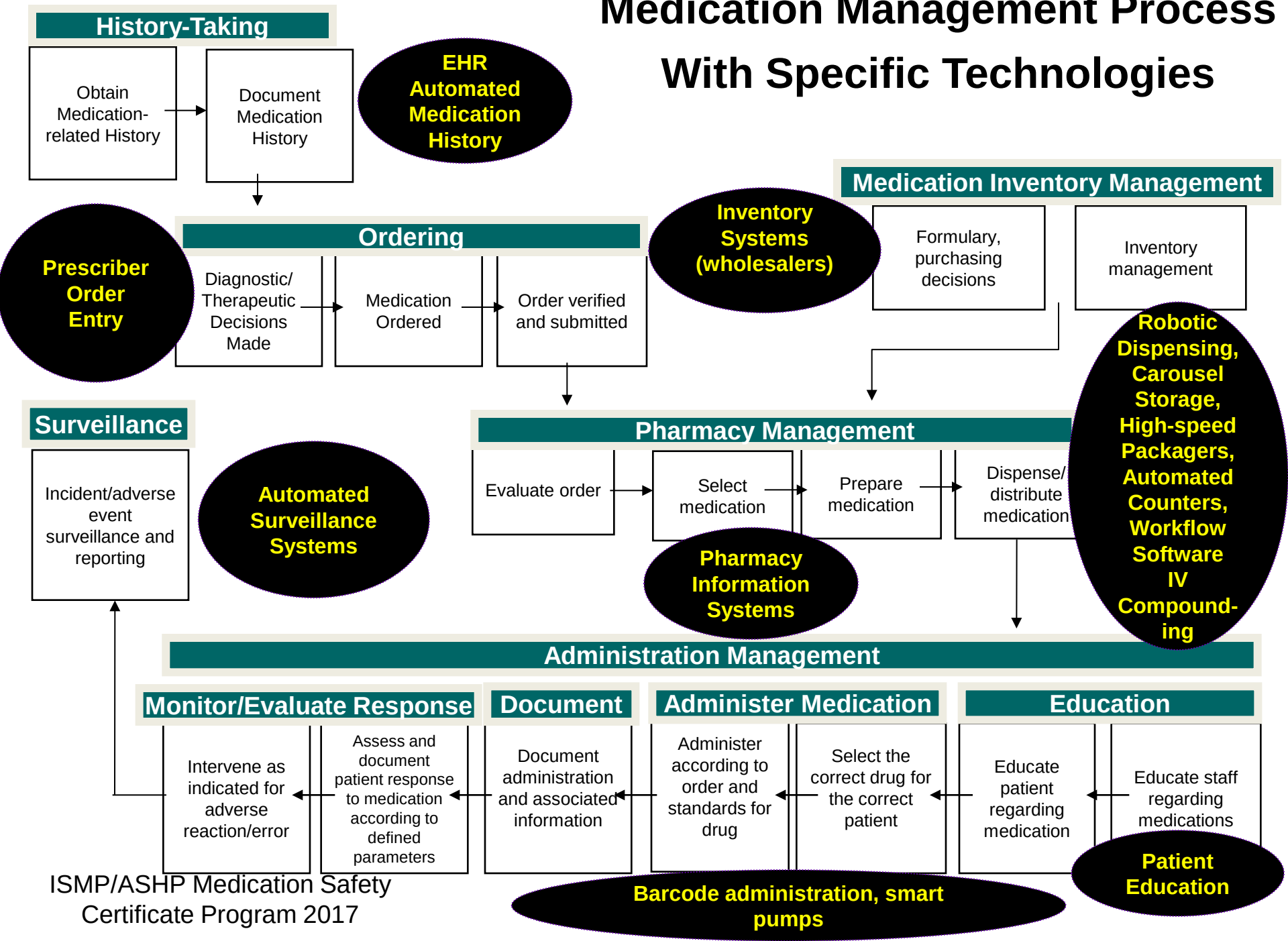
The Medication Use Process

Adverse Drug Events (ADEs) and Medication Errors



Kilbridge P, Classen DC. A process model of inpatient medication management and information technology interventions to improve patient safety. Research Series, Issue 1, Irving, TX: Vizient; 2001:1–89. ISMP/ASHP Medication Safety Certificate Program 2017

Medication Management Process With Specific Technologies



PLOS ONE

RESEARCH ARTICLE

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

Tri-Long Nguyen[1,2,3,4]*, Géraldine Leguelinel-Blache[1,2], Jean-Marie Kinowski[1,2], Clarisse Roux-Marson[1,2], Marion Rougier[5], Jessica Spence[3,4], Yannick Le Manach[3,4], Paul Landais[2,6]

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).

		Corrected log-odds ratio*	Estimated odds ratio [95% CI]	*P*
Constant		-3.83	0.02	< 0.001
$(Age/100)^2$		7.07	2 079.74 [10.26; 421 510.51]	0.005
$(Age/100)^3$		-6.26	0.00 [0.00; 0.20]	0.010
Number of prescribed drugs		0.14	1.16 [1.10; 1.23]	< 0.001
Treatment initiated before admission	No	0	1.00	
	Yes	1.60	5.64 [2.38; 13.36]	< 0.001
Best possible medication history available	No	0	1.00	
	Yes	-0.64	0.50 [0.37; 0.67]	< 0.001
Psycholeptics	No	0	1.00	
	Yes	0.31	1.39 [0.96; 2.02]	0.084
Blood substitutes and perfusion solutions	No	0	1.00	
	Yes	-0.16	0.84 [0.62; 1.15]	0.295
Type of hospital admission	Medical	0	1.00	
	Surgical	0.29	1.36 [1.00; 1.87]	0.061
Hospital admission within previous 30 days	No	0	1.00	
	Yes	-0.36	0.68 [0.44; 1.04]	0.067
Admission from emergency room	No	0	1.00	
	Yes	0.27	1.34 [0.92; 1.94]	0.123
Admission time	Day	0	1.00	
	Night	-0.18	0.83 [0.58; 1.18]	0.296
Admission from an outside institution	No	0	1.00	
	Yes	-0.51	0.58 [0.21; 1.60]	0.299

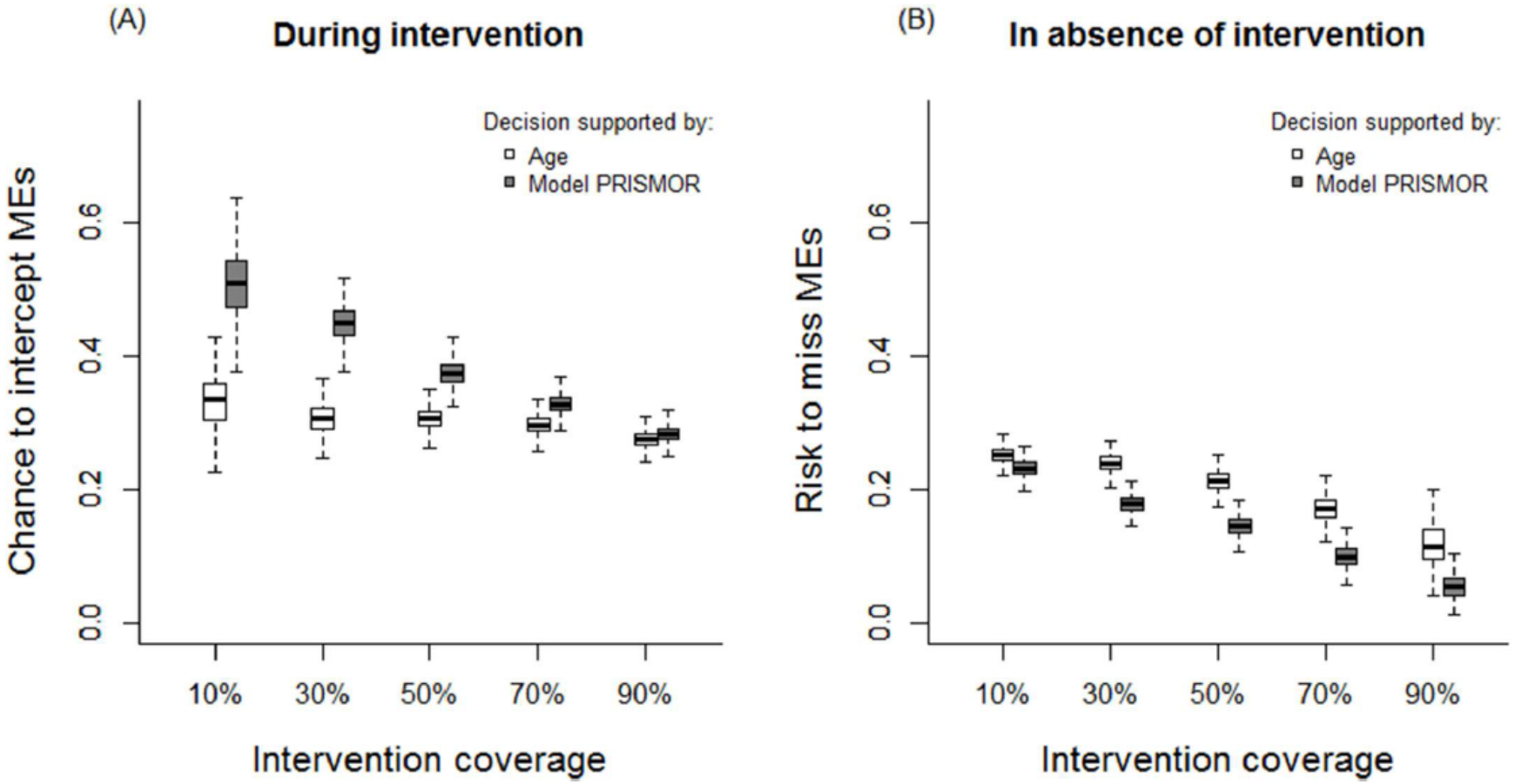


Fig 3. Comparison of two strategies to focus interventions on high-risk patients: decision-making supported by the predictive model *versus* decision-making based on age.

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

John Smith

Born: 1/1/1960

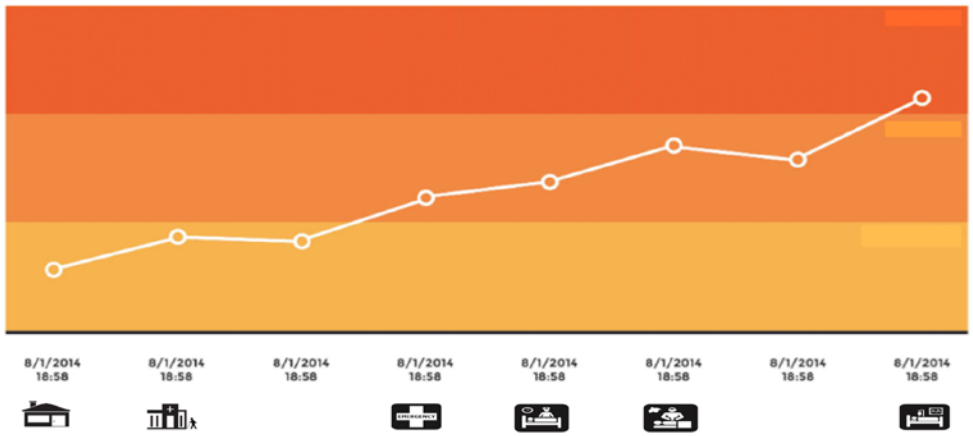
My Safety Advisor

Nurse Manager:

Jill Jones

Contact info

Overall Risk Score



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

My Safety Issues	Questions you should ask	Things you can do	More Information
Today			
You have tested positive for a bacteria in your urine	Why did this happen? What can I do to prevent this from happening again? What will you do to prevent this from happening again?	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	Medline Plus on Urine Culture
Yesterday			
Your stool has tested positive for a bacteria called C. difficile	Why did this happen? What can I do to prevent this from happening again? What will you do to prevent this from happening again *Make note of your question here...*	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	Medline Plus on C. Difficile

Improving Ambulatory Patient Safety

Learning From the Last Decade, Moving Ahead in the Next

Matthew K. Wynia, MD, MPH
David C. Classen, MD, MS

The 1999 Institute of Medicine report *To Err Is Human: Building a Safer Health System*[1] launched the modern patient safety movement by estimating a large number of yearly error-related deaths among hospitalized patients in the United States.[1] But 12 years later, there are no reliable data on how many patients in the United States are injured or die each year because of errors in ambulatory settings. The number may be substantial; 52% of paid medical malpractice claims in 2009 were for events in the outpatient setting, and two-thirds of these claims involved major injury or death.[2]

More than 10 years ago, a group of experts convened by the Agency for Healthcare Research and Quality (AHRQ) reported that "medical error and injury are substantial in ambulatory care, [but] there has been little systematic research specifically aimed at patient safety questions in ambulatory care."[3] To jump-start a new research agenda, the conferees made 11 specific recommendations. Virtually none have been implemented.

What Happened?

Marking the 10-year anniversary of *To Err Is Human* recently, experts have noted some modest improvements in hospital safety while emphasizing the "frustratingly" slow pace of change despite substantial investments in research and numerous policy and regulatory activities.[4] However, in ambulatory safety no such multifaceted efforts have been made and there are few data to suggest any improvement; in fact, there are few data at all.

A recent review of research on ambulatory safety between 2000 and 2010, including published literature, private initiatives, government grants, and legislative and regulatory efforts,[5] found that major gaps persist in understanding of ambulatory safety and virtually no credible studies have shown how to improve it; studies have come mainly from a few unique centers and largely rely on self-reported data.

The reasons for this relative lack of studies on ambulatory safety are diverse. Inpatient safety consumed many of the available resources, researchers tend to work in academic hospitals and focus on the inpatient setting rather than the ambulatory setting, and other infrastructure for ambulatory safety research is diffuse or nonexistent. Compounding these factors are some inherent differences between the inpatient and outpatient settings. In particular, hospitalized patients experience more errors of commission, such as surgical injuries, whereas errors of omission, such as diagnostic delays, are a greater concern in outpatient facilities,[6] which could contribute to a sense that errors that occur during inpatient care have more serious ramifications. Also, the role of patients in self-care is often more complex in the ambulatory setting, making the study of adverse events more difficult than in the inpatient setting.

Ambulatory Patient Safety in the Next Decade

Following this "lost decade" in ambulatory safety, a new, refocused national agenda is needed. The following proposal suggests national adoption of 5 core aims for improving ambulatory patient safety, to be accomplished over the next 10 years.

First, collect basic data on how many patients experience health care–related harms in the ambulatory setting by conducting a large national study on the epidemiology of ambulatory patient safety. Epidemiologic studies of inpatient error were helpful for understanding inpatient safety and critical for building public support for efforts to improve. The concept of a national ambulatory safety study was raised by the AHRQ conferees 10 years ago but was seen as posing logistic and political challenges and deemed "valuable, but not essential to improving ambulatory patient safety."[3] In retrospect, this judgment was probably incorrect. A national incidence study on the epidemiology of ambulatory patient harms is an essential starting point for efforts to improve safety in the outpatient arena. This investigation should use accepted tools, like an outpatient global trigger tool to screen for errors, followed by chart review to detect harms in a large sample of ambulatory clinic settings, including ambulatory practices affiliated with large systems, like Kaiser or the Department of Veterans Affairs, as well as small, office-based practices.

Second, identify an early achievable goal. Although research on ambulatory safety is relatively meager, some valuable lessons have been learned. Attention and resources

Author Affiliations: Center for Patient Safety, American Medical Association, Chicago, Illinois (Dr Wynia); University of Utah, Salt Lake City (Dr Classen).
Corresponding Author: Matthew K. Wynia, MD, MPH, Center for Patient Safety, American Medical Association, 515 N State St, Chicago, IL 60654 (matthew.wynia@ama-assn.org).

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

the WHO Global Patient hallenge on Medication t Harm see http://www.who.int/patientsafety/medication-safety/en/

In 1960, Alphonse Chapanis, turned his attention from engineering to health care. In a study of medication-related errors in a 1100-bed hospital,[1] 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,[2] 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[3] and Safe Surgery Saves Lives.[4] 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.[5]

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

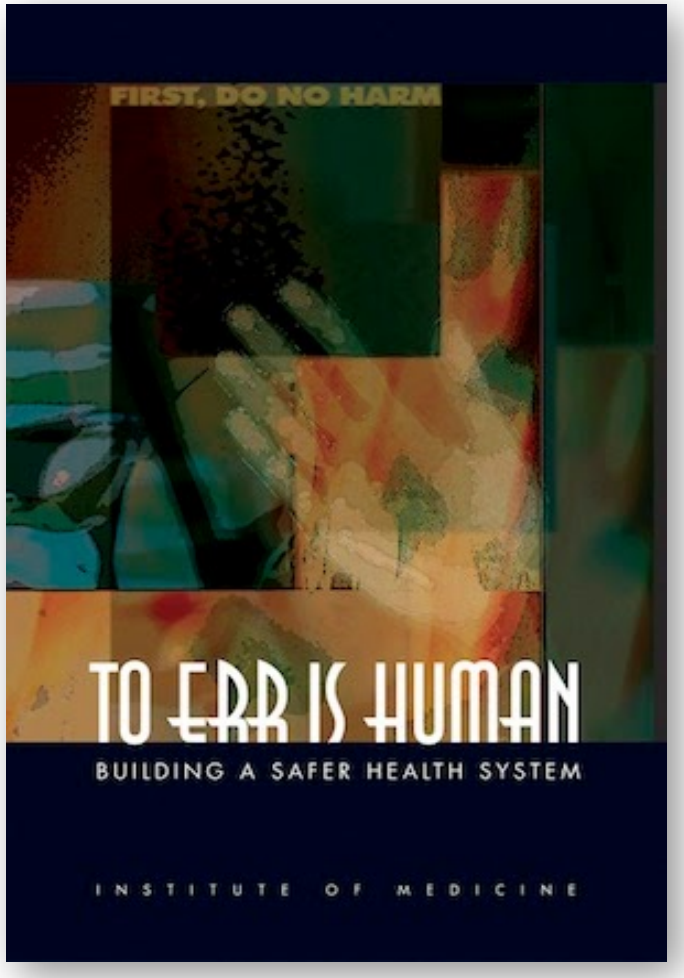
Medication Safety in the Ambulatory Setting

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

Institute for Healthcare Improvement
NPSF
TOGETHER FOR SAFER CARE

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.

Institute for Healthcare Improvement
NPSF
TOGETHER FOR SAFER CARE

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

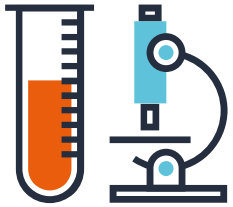
Improving safety requires an organizational culture that enables and prioritizes safety. The importance of culture change needs to be brought to the forefront, rather than taking a backseat to other safety activities.

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.

Institute for Healthcare Improvement

NPSF

TOGETHER FOR SAFER CARE

Eight Recommendations for Achieving Total Systems Safety

5. ADDRESS SAFETY ACROSS THE ENTIRE CARE CONTINUUM

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.

6. SUPPORT THE HEALTH CARE WORKFORCE

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.

7. PARTNER WITH PATIENTS AND FAMILIES FOR THE SAFEST CARE

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.

8. ENSURE THAT TECHNOLOGY IS SAFE AND OPTIMIZED TO IMPROVE PATIENT SAFETY

Optimizing the safety benefits and minimizing the unintended consequences of health IT is critical.

Institute for Healthcare Improvement

NPSF

TOGETHER FOR SAFER CARE

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

Institute for Healthcare Improvement NPSF

TOGETHER FOR SAFER CARE

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

Institute for Healthcare Improvement NPSF

TOGETHER FOR SAFER CARE

Institute for Healthcare Improvement

NPSF

HER FOR SAFER CARE

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
Mixon et al. *Mayo Clin Proc.* 2014

Non-Adherence

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

McCarthy. *Bus Health.* 1998

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

Osterberg et al. *NEJM.* 2005

- 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

Fischer et al. *JGIM.* 2010

- "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

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."

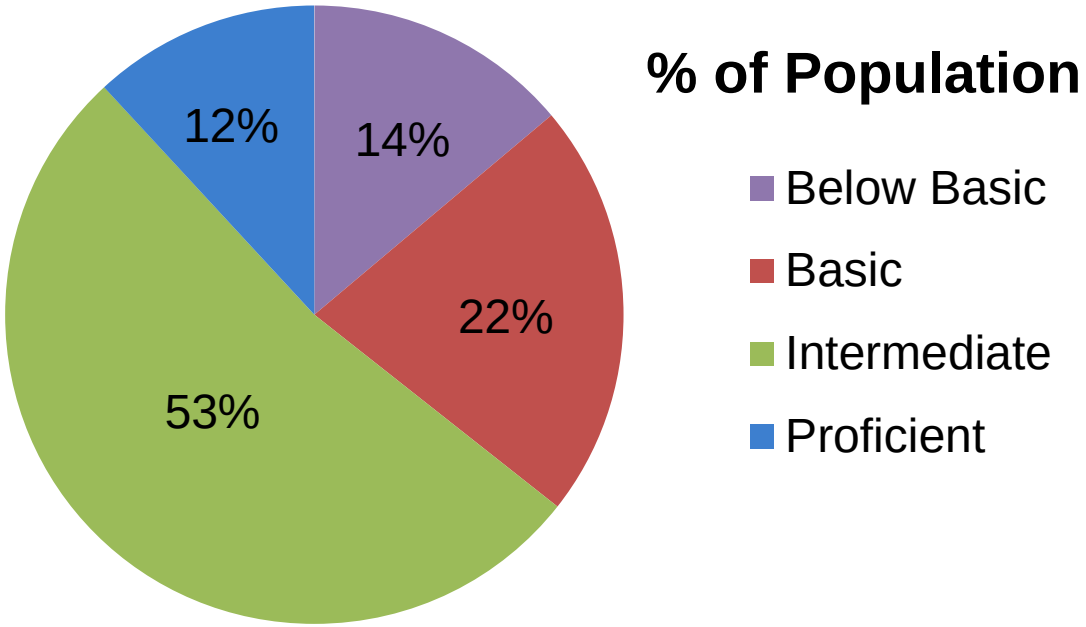
HHS. *National Action Plan to Improve Health Literacy*. 2010

Institute for Healthcare Improvement NPSF

TOGETHER FOR SAFER CARE

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

Institute for Healthcare Improvement
NPSF
TOGETHER FOR SAFER CARE

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.”

Koh et al. *Health Aff.* 2012

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
Koh et al. *Health Aff.* 2012

Institute for Healthcare Improvement NPSF
TOGETHER FOR SAFER CARE

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

  Delbanco et al. *Ann Intern Med.* 2012

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

Disclaimer

- This presentation is for general informational and educational purposes only. Presentations are intended for educational, scholarship and research purposes only and do not replace independent professional judgment. The slides in this presentation were used to accompany a talk given on June 15, 2017. Neither the information contained within these slides, nor the accompanying talk and/or recording construe clinical, business or financial advice.
- The participants reserve the right to change any of their opinions expressed herein at any time, as they deem appropriate.
- The participants have obtained consent from third parties to use any statements or information indicated in this presentation. In addition, data or other information was derived from statements made or published by third parties and have been cited. Any such statements or information should not be viewed as indicating support of such third party for the views expressed herein. No warranty is made that data or information obtained from any third party is accurate.
- The participants shall not be responsible or have any liability for any misinformation contained.

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

Source: Retrieved on June 10, 2017 from https://en.wikipedia.org/wiki/Pharmacovigilance

Drug Safety is a Big Problem….

and it is not Going Away

10,000

Prescription medications in U.S.

Buckley, M. (2017, May 15). Inefficiency of Paper Medical Records | Electronic Medical Records Prevent Error. Retrieved June 10, 2017, from http://www.practicefusion.com/pages/pr/survey-patients-see-over-18-different-doctors-on-average.html

Medication Errors. . Retrieved June 06, 2017, from https://PSNET.AHRQ.gov/Primers/Primer/23/Medication Errors

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

Reducing Preventable Harm From Medications Too Big for FDA To Do Alone. Retrieved June 06, 2017, from https://Blogs.FDA.GOV/FDAVOICE/INDEX.PHP/2017/05/Reducing-Preventable-Harm-From-Medications-Too-Big-For-FDA-To-Do-Alone

10,000

Prescription medications in U.S.

4 Billion

Prescriptions Dispensed in 2016

Buckley, M. (2017, May 15). Inefficiency of Paper Medical Records | Electronic Medical Records Prevent Error. Retrieved June 10, 2017, from http://www.practicefusion.com/pages/pr/survey-patients-see-over-18-different-doctors-on-average.html

Medication Errors. . Retrieved June 06, 2017, from https://PSNET.AHRQ.gov/Primers/Primer/23/Medication Errors

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

Reducing Preventable Harm From Medications Too Big for FDA To Do Alone. Retrieved June 06, 2017, from https://Blogs.FDA.GOV/FDAVOICE/INDEX.PHP/2017/05/Reducing-Preventable-Harm-From-Medications-Too-Big-For-FDA-To-Do-Alone

Total Number of Retail Prescription Drugs Filled at Pharmacies. (2017, May 30). Retrieved June 11, 2017, from http://www.kff.org/health-costs/state-indicator/total-retail-rx-drugs/?currentTimeframe=0&sortModel=%7B%22colId%22%3A%22Location%22%2C%22sort%22%3A%22asc%22%7D

10,000

Prescription medications in U.S.

4 Billion

Prescriptions Dispensed in 2016

28.4

Estimated number of physicians patients over age 65 see in lifetime

Buckley, M. (2017, May 15). Inefficiency of Paper Medical Records | Electronic Medical Records Prevent Error. Retrieved June 10, 2017, from http://www.practicefusion.com/pages/pr/survey-patients-see-over-18-different-doctors-on-average.html

Medication Errors. . Retrieved June 06, 2017, from https://PSNET.AHRQ.gov/Primers/Primer/23/Medication Errors

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

Reducing Preventable Harm From Medications Too Big for FDA To Do Alone. Retrieved June 06, 2017, from https://Blogs.FDA.GOV/FDAVOICE/INDEX.PHP/2017/05/Reducing-Preventable-Harm-From-Medications-Too-Big-For-FDA-To-Do-Alone

Total Number of Retail Prescription Drugs Filled at Pharmacies. (2017, May 30). Retrieved June 11, 2017, from http://www.kff.org/health-costs/state-indicator/total-retail-rx-drugs/?currentTimeframe=0&sortModel=%7B%22colId%22%3A%22Location%22%2C%22sort%22%3A%22asc%22%7D

10,000

Prescription medications in U.S.

4 Billion

Prescriptions Dispensed in 2016

28.4

Estimated number of physicians patients over age 65 see in lifetime

One-in-Three

Adults in U.S. taking 5 or more medications

Buckley, M. (2017, May 15). Inefficiency of Paper Medical Records | Electronic Medical Records Prevent Error. Retrieved June 10, 2017, from http://www.practicefusion.com/pages/pr/survey-patients-see-over-18-different-doctors-on-average.html

Medication Errors. . Retrieved June 06, 2017, from https://PSNET.AHRQ.gov/Primers/Primer/23/Medication Errors

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

Reducing Preventable Harm From Medications Too Big for FDA To Do Alone. Retrieved June 06, 2017, from https://Blogs.FDA.GOV/FDAVOICE/INDEX.PHP/2017/05/Reducing-Preventable-Harm-From-Medications-Too-Big-For-FDA-To-Do-Alone

Total Number of Retail Prescription Drugs Filled at Pharmacies. (2017, May 30). Retrieved June 11, 2017, from http://www.kff.org/health-costs/state-indicator/total-retail-rx-drugs/?currentTimeframe=0&sortModel=%7B%22colId%22%3A%22Location%22%2C%22sort%22%3A%22asc%22%7D

36

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

Reducing Preventable Harm From Medications Too Big for FDA To Do Alone. Retrieved June 06, 2017, from https://Blogs.FDA.GOV/FDAVOICE/INDEX.PHP/2017/05/Reducing-Preventable-Harm-From-Medications-Too-Big-For-FDA-To-Do-Alone
Medication Errors. . Retrieved June 06, 2017, from https://PSNET.AHRQ.gov/Primers/Primer/23/Medication Errors
Medication Errors - Academy of Managed Care Pharmacy. (n.d.). Retrieved June 6, 2017
Adverse Drug Reactions and Drug-Drug Interactions: Consequences and Costs. (n.d.). Retrieved June 11, 2017, from http://www.amfs.com/news/articles-from-our-experts/adverse-drug-reactions-and-drug-drug-interactions-consequences-and-costs/

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

Reducing Preventable Harm From Medications Too Big for FDA To Do Alone. Retrieved June 06, 2017, from https://Blogs.FDA.GOV/FDAVOICE/INDEX.PHP/2017/05/Reducing-Preventable-Harm-From-Medications-Too-Big-For-FDA-To-Do-Alone
Medication Errors. . Retrieved June 06, 2017, from https://PSNET.AHRQ.gov/Primers/Primer/23/Medication Errors
Medication Errors - Academy of Managed Care Pharmacy. (n.d.). Retrieved June 6, 2017
Adverse Drug Reactions and Drug-Drug Interactions: Consequences and Costs. (n.d.). Retrieved June 11, 2017, from http://www.amfs.com/news/articles-from-our-experts/adverse-drug-reactions-and-drug-drug-interactions-consequences-and-costs/
Roe, S., Long, R., & King, K. (2017, April 14). Pharmacies miss half of dangerous drug combinations. Retrieved June 06, 2017, from http://www.chicagotribune.com/news/watchdog/druginteractions/ct-drug-interactions-pharmacy-met-20161214-story.html

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

Reducing Preventable Harm From Medications Too Big for FDA To Do Alone. Retrieved June 06, 2017, from https://Blogs.FDA.GOV/FDAVOICE/INDEX.PHP/2017/05/Reducing-Preventable-Harm-From-Medications-Too-Big-For-FDA-To-Do-Alone

Medication Errors. . Retrieved June 06, 2017, from https://PSNET.AHRQ.gov/Primers/Primer/23/Medication Errors

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

Adverse Drug Reactions and Drug-Drug Interactions: Consequences and Costs. (n.d.). Retrieved June 11, 2017, from http://www.amfs.com/news/articles-from-our-experts/adverse-drug-reactions-and-drug-drug-interactions-consequences-and-costs/

Roe, S., Long, R., & King, K. (2017, April 14). Pharmacies miss half of dangerous drug combinations. Retrieved June 06, 2017, from http://www.chicagotribune.com/news/watchdog/druginteractions/ct-drug-interactions-pharmacy-met-20161214-story.html

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

$30 - 100 Billion

Estimated unnecessary expense burden on US healthcare payors

Reducing Preventable Harm From Medications Too Big for FDA To Do Alone. Retrieved June 06, 2017, from https://Blogs.FDA.GOV/FDAVOICE/INDEX.PHP/2017/05/Reducing-Preventable-Harm-From-Medications-Too-Big-For-FDA-To-Do-Alone

Medication Errors. . Retrieved June 06, 2017, from https://PSNET.AHRQ.gov/Primers/Primer/23/Medication Errors

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

Adverse Drug Reactions and Drug-Drug Interactions: Consequences and Costs. (n.d.). Retrieved June 11, 2017, from http://www.amfs.com/news/articles-from-our-experts/adverse-drug-reactions-and-drug-drug-interactions-consequences-and-costs/

Roe, S., Long, R., & King, K. (2017, April 14). Pharmacies miss half of dangerous drug combinations. Retrieved June 06, 2017, from http://www.chicagotribune.com/news/watchdog/druginteractions/ct-drug-interactions-pharmacy-met-20161214-story.html

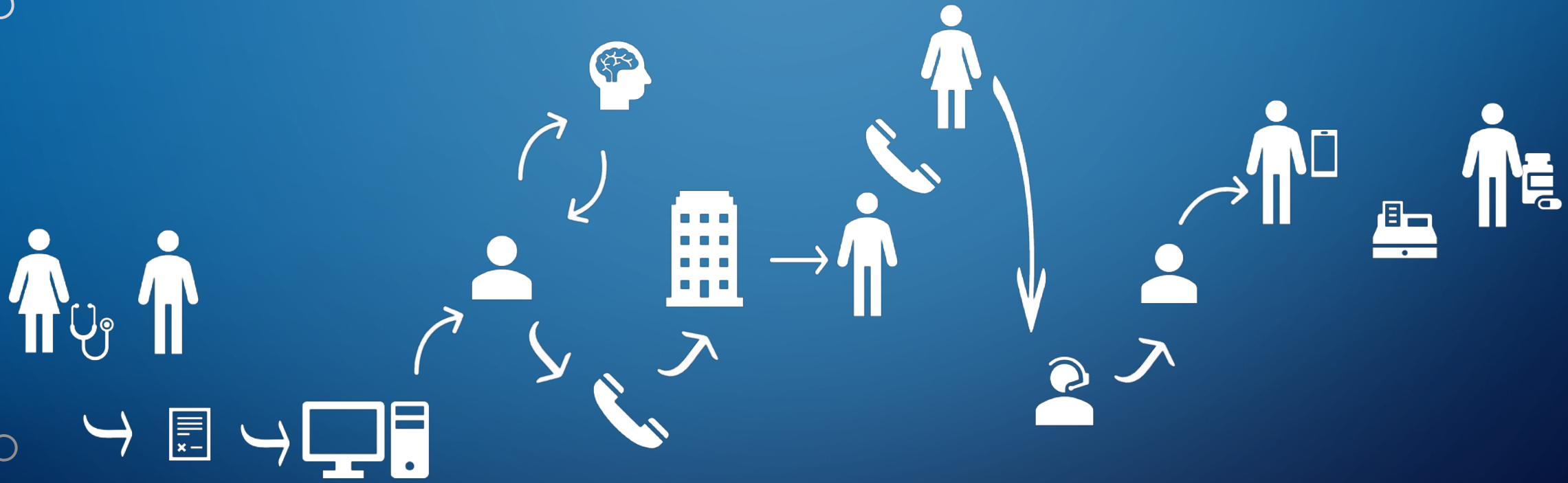
Drug Safety is a Tough Problem To Solve

Drug Safety: A Tough Problem to Solve

Drug Safety: A Tough Problem to Solve

Drug Safety: A Tough Problem to Solve

Drug Safety: A Tough Problem to Solve



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:
Horn JR, et al. Customizing clinical decision support to prevent excessive drug-drug interaction alerts. *Am J Health-Syst Pharm*. 2011;68:662-664.
Cash JJ. Alert fatigue. *Am J Health-Syst Pharm*. 2009;66:2098-2101.
Weingart SN, Toth M, Sands DZ, Aronson MD, Davis RB, Phillips RS. Physician's decisions to override computerized drug alerts in primary care. *Arch Intern Med*. 2003;163:2625-2631.
Issac T, Weissman JS, Davis RB. Overrides of medication alerts in ambulatory care. *Arch Intern Med*. 2009;169:305-311.
https://ehrintelligene.com/news/amp/reducing-alert-fatigue-prevents-pharmacy-medication-errors

First, Detect the Problem…Next, Deal with it

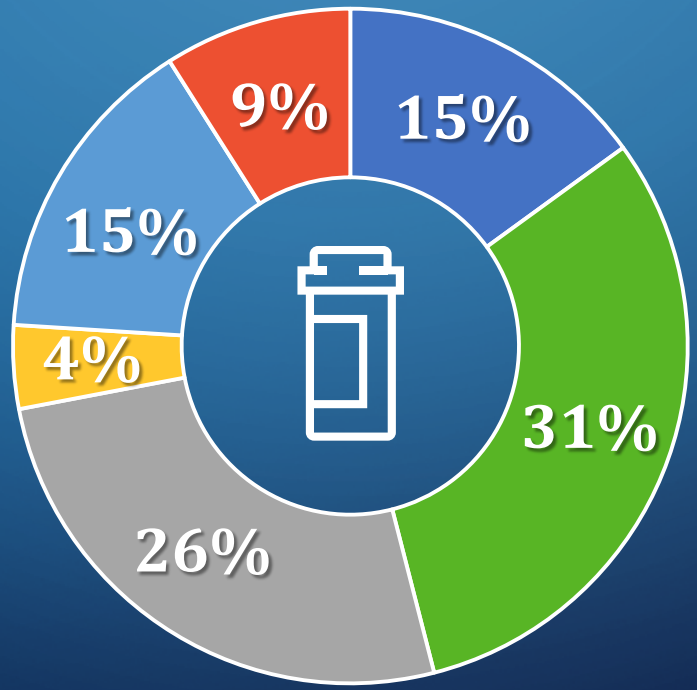
- The patient is the starting place for managing medication
- Medication therapy interventions help patients who are
  - Experiencing adverse effects
  - Are frequently hospitalized
  - Who have a higher number of medications
- Average of 3:1 Return on Investment (ROI)

Source:. Retrieved June 06, 2017, from https://pcpcc.org/sites/default/files/media/medmanagement.pdf

How Do We Cut Through This Mess?

Top Limitations to Prescription Safety

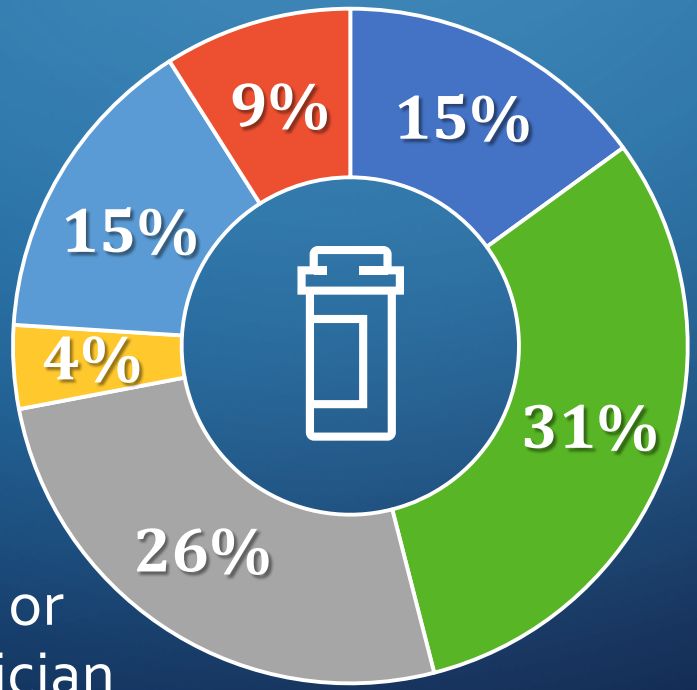
Top Limitations to Prescription Safety



Completeness of patient-specific prescription data

Source: Data based on 2017 industry survey

Top Limitations to Prescription Safety

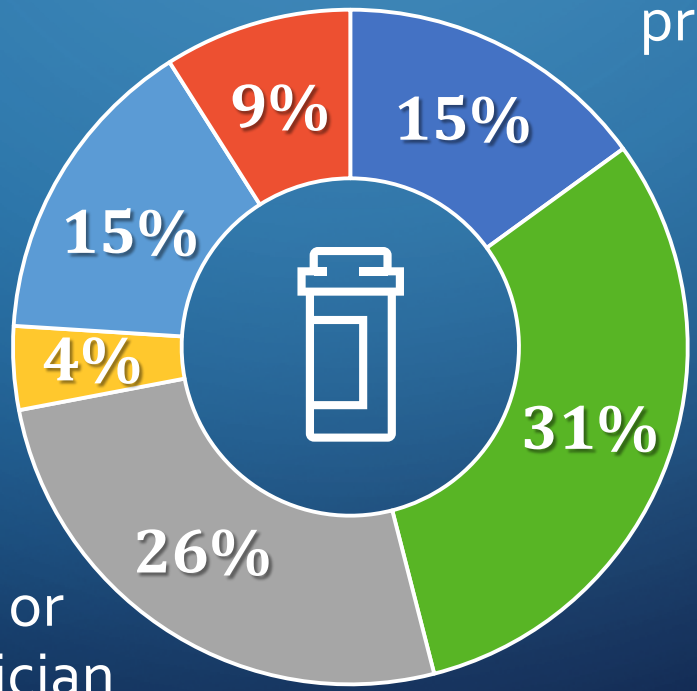


Completeness of patient-specific prescription data

Timeliness of data or intervention to physician

Source: Data based on 2017 industry survey

Top Limitations to Prescription Safety



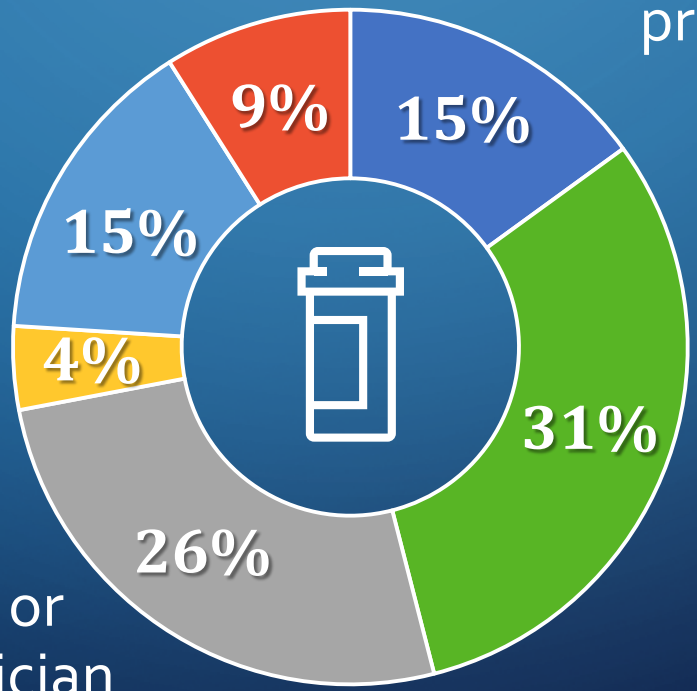
Access to patient-specific prescription data

Completeness of patient-specific prescription data

Timeliness of data or intervention to physician

Source: Data based on 2017 industry survey

Top Limitations to Prescription Safety



Access to patient-specific prescription data

Lack of post marketing research on newer drugs

Completeness of patient-specific prescription data

Timeliness of data or intervention to physician

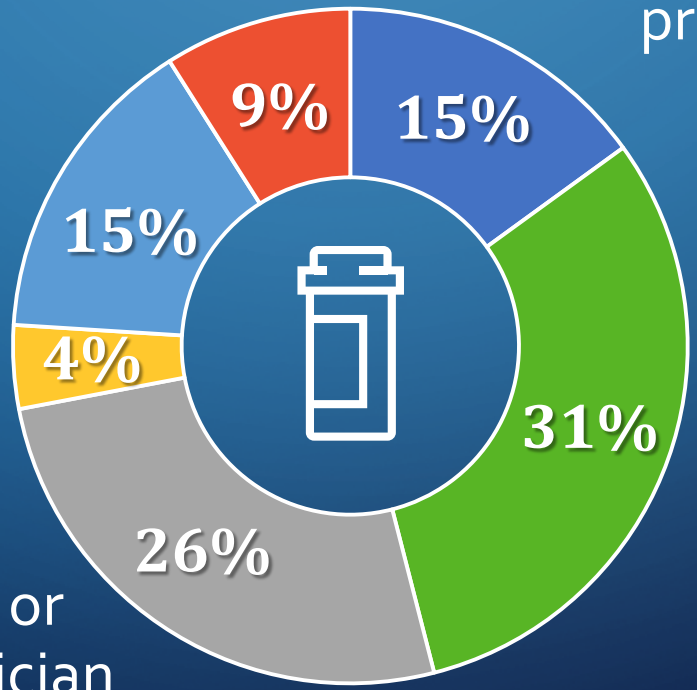
Source: Data based on 2017 industry survey

Top Limitations to Prescription Safety

Willingness to report and knowledge of how to report

Access to patient-specific prescription data

Lack of post marketing research on newer drugs



Completeness of patient-specific prescription data

Timeliness of data or intervention to physician

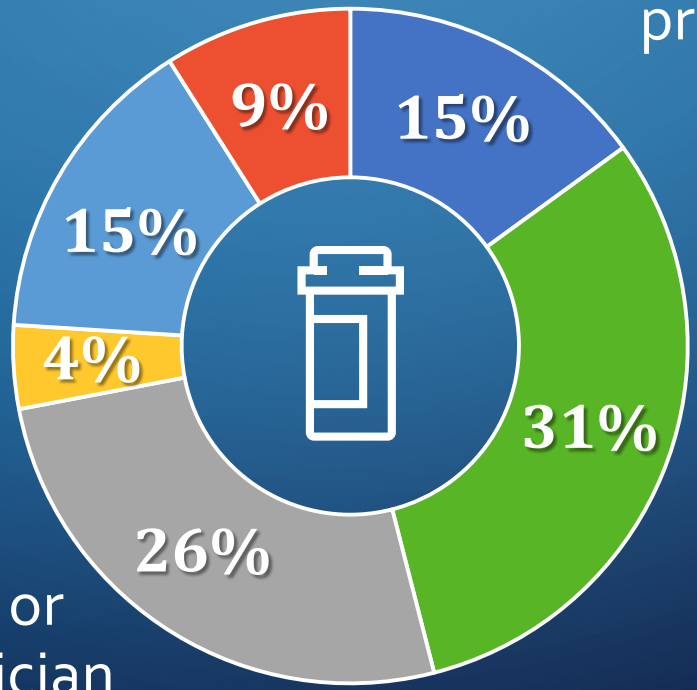
Source: Data based on 2017 industry survey

Top Limitations to Prescription Safety

Willingness to report and knowledge of how to report

Access to patient-specific prescription data

Lack of post marketing research on newer drugs



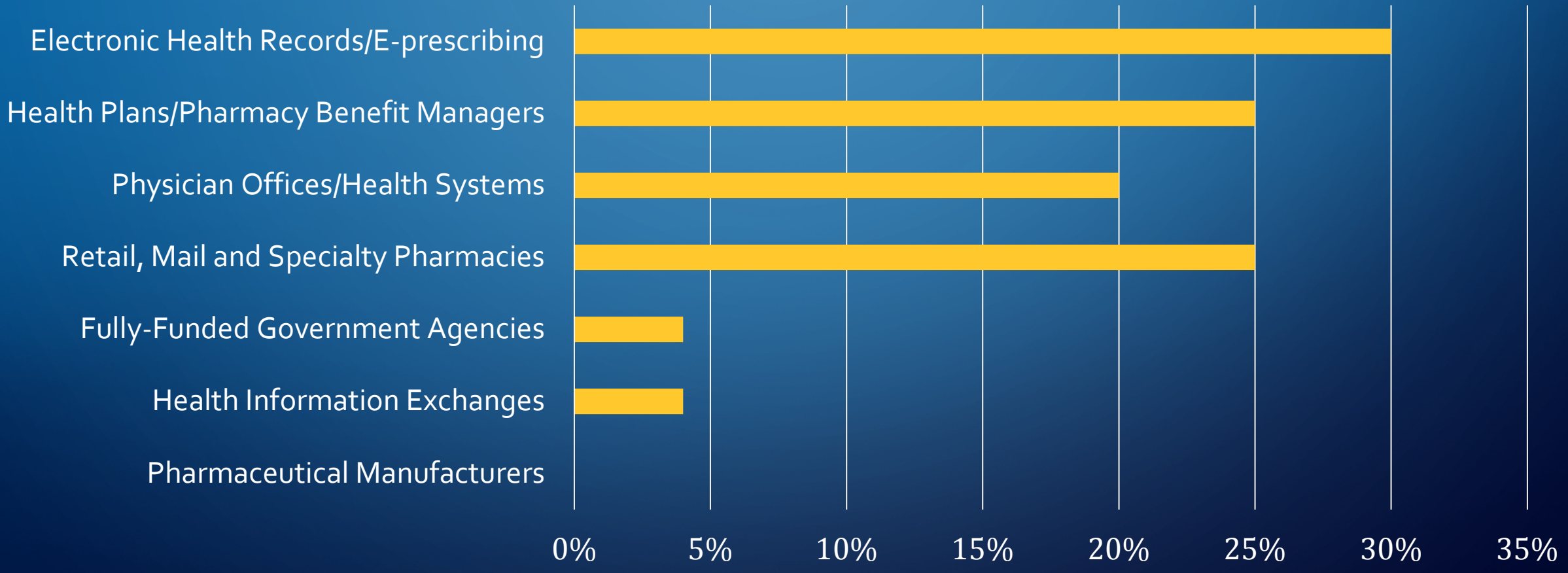
Physician receptivity/attitude to the information

Completeness of patient-specific prescription data

Timeliness of data or intervention to physician

Source: Data based on 2017 industry survey

What Organizations Are in Best Position to Improve Outpatient Drug Safety?



Source: Data based on 2017 industry survey

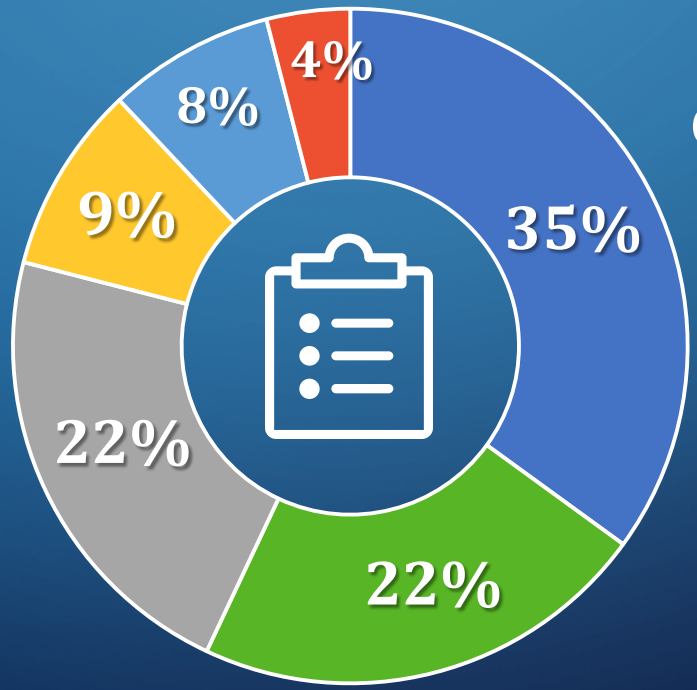
”No one fix prevents medication errors”

Institute of Safe Medication Practices

Limitations to Producing Quality Health Outcomes Research Related to Drug Safety

Source: Data based on 2017 industry survey

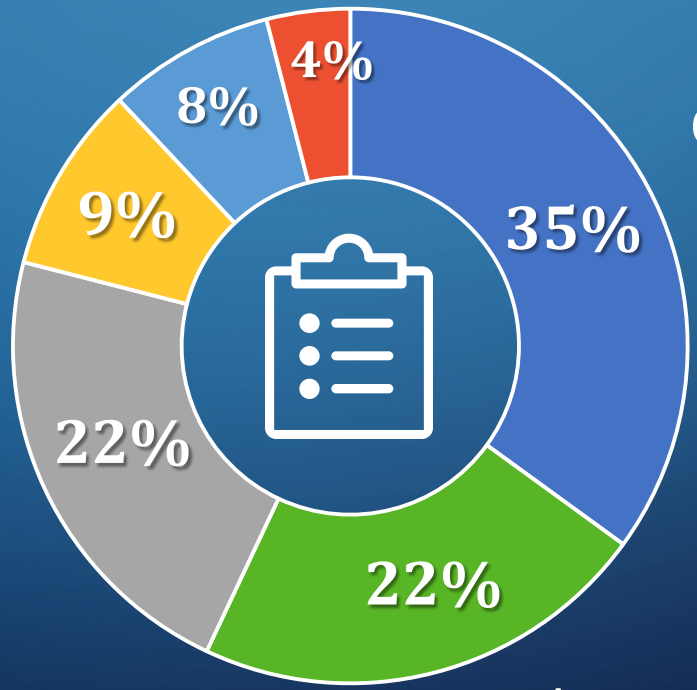
Limitations to Producing Quality Health Outcomes Research Related to Drug Safety



Collaboration across organizations

Source: Data based on 2017 industry survey

Limitations to Producing Quality Health Outcomes Research Related to Drug Safety

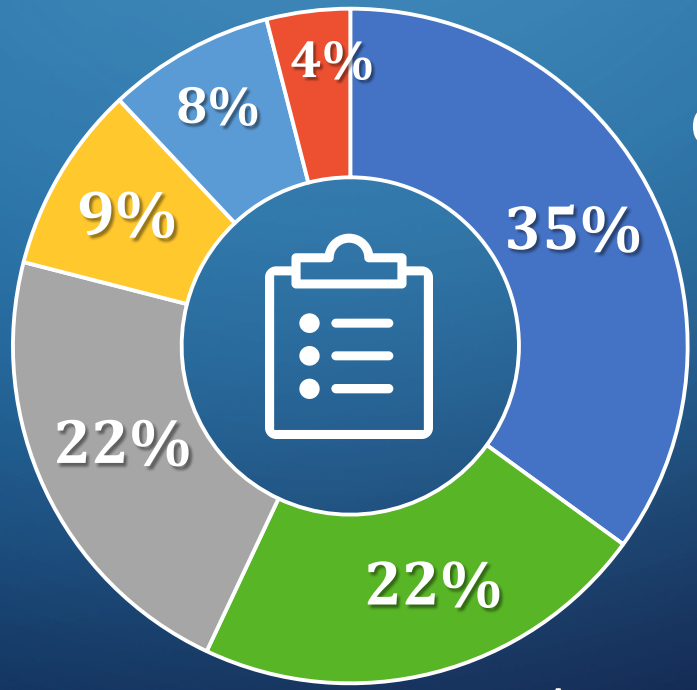


Collaboration across organizations

Access to data – data rights/privacy

Source: Data based on 2017 industry survey

Limitations to Producing Quality Health Outcomes Research Related to Drug Safety



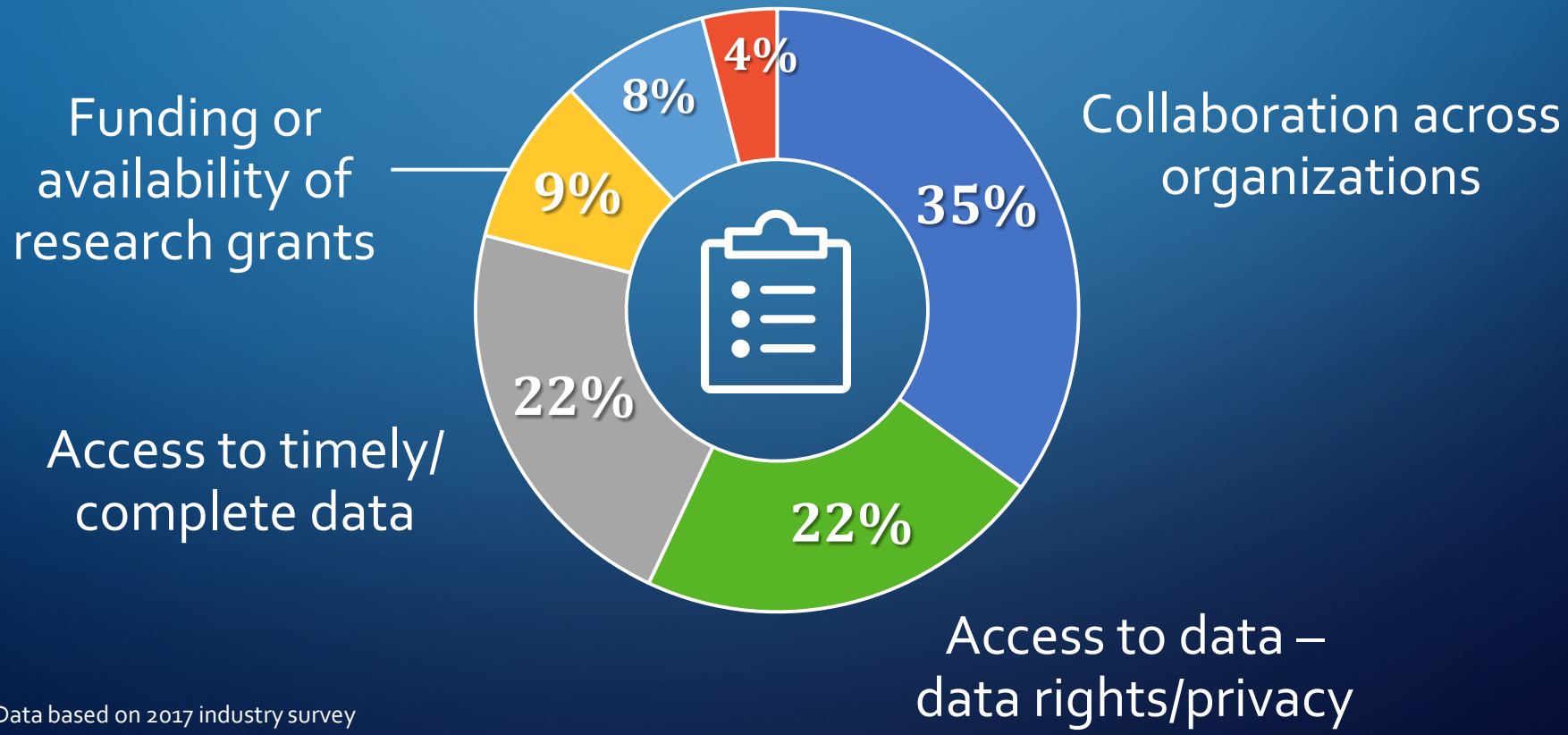
Collaboration across organizations

Access to timely/ complete data

Access to data – data rights/privacy

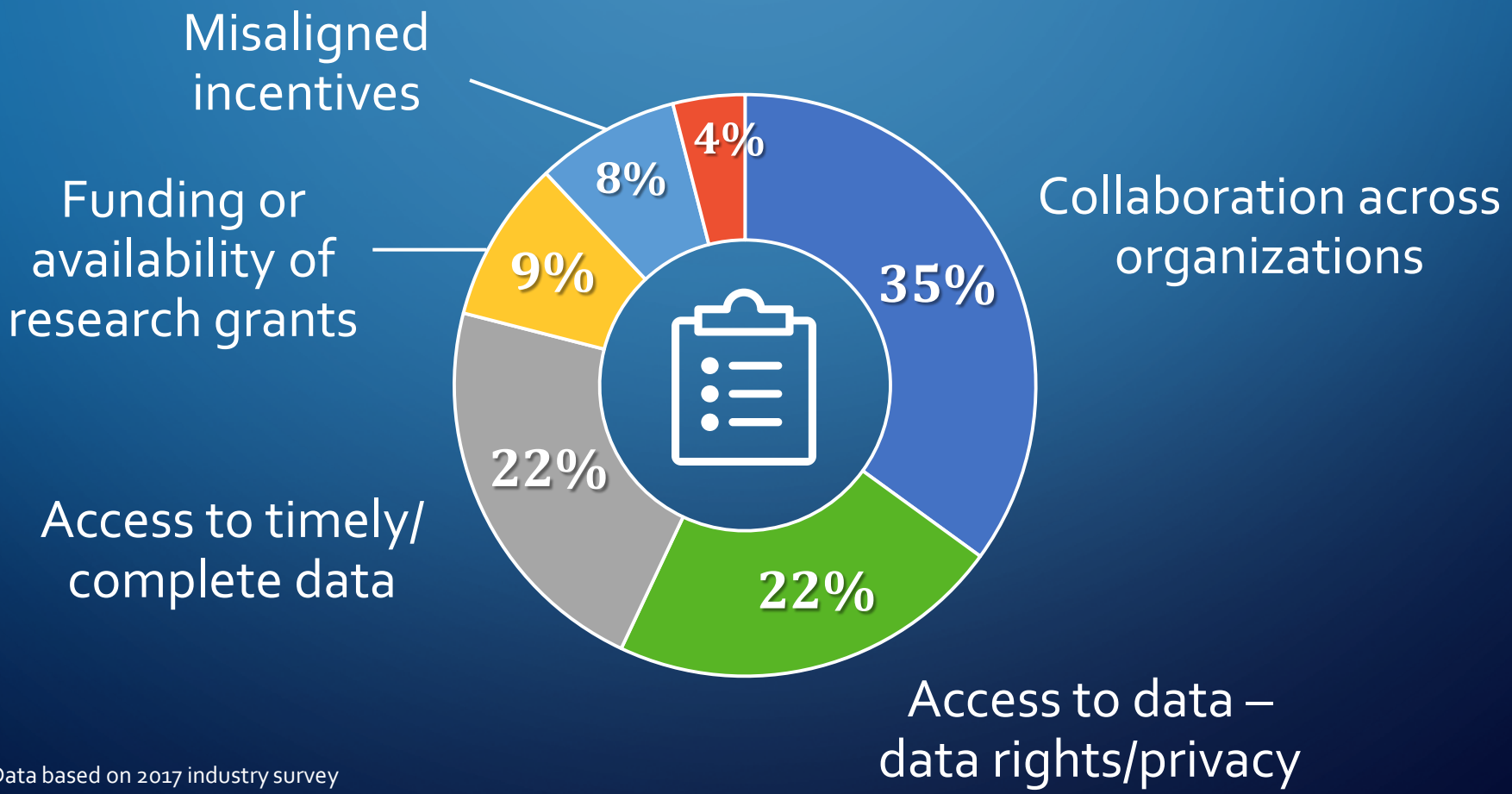
Source: Data based on 2017 industry survey

Limitations to Producing Quality Health Outcomes Research Related to Drug Safety



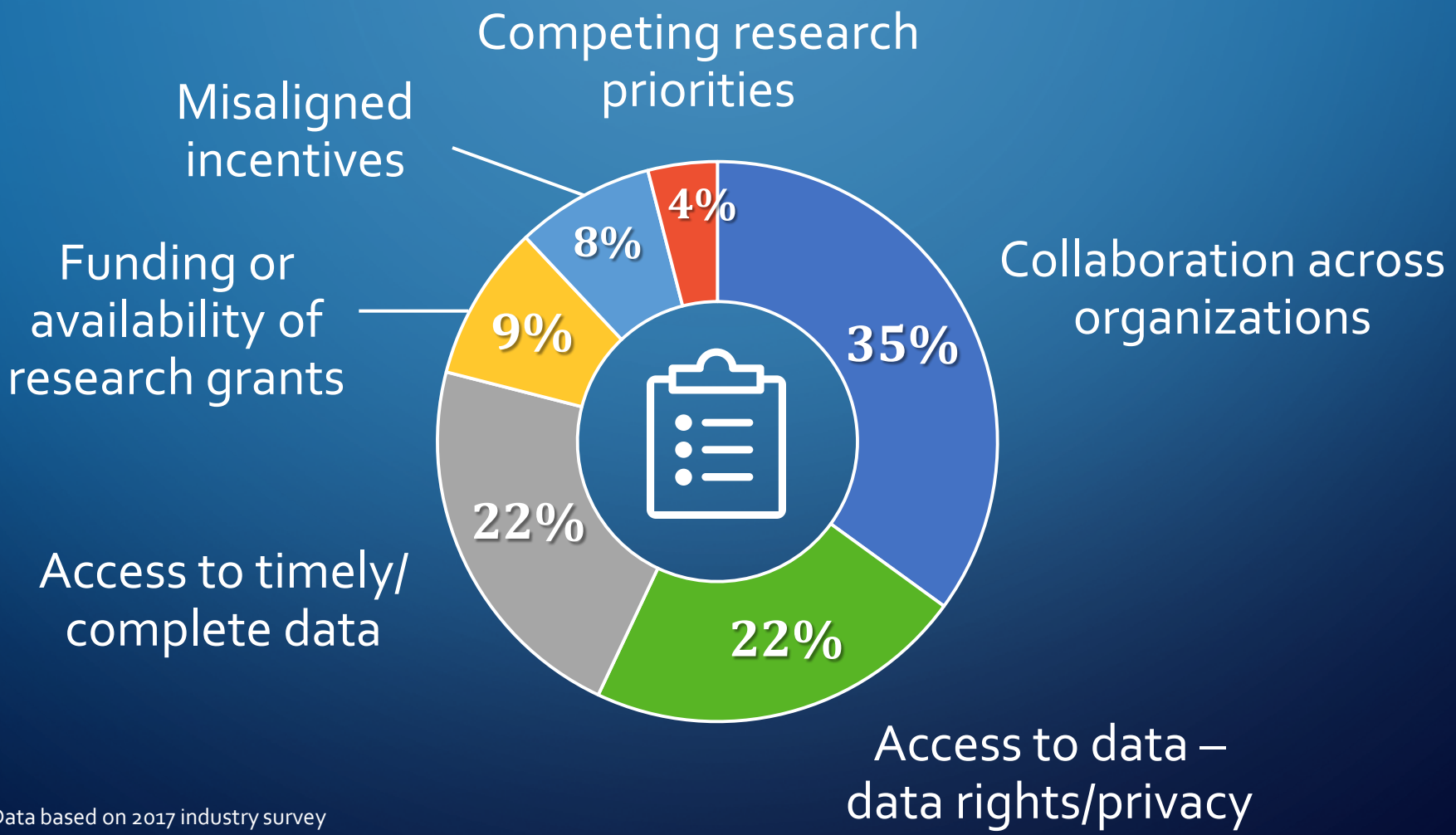
Source: Data based on 2017 industry survey

Limitations to Producing Quality Health Outcomes Research Related to Drug Safety



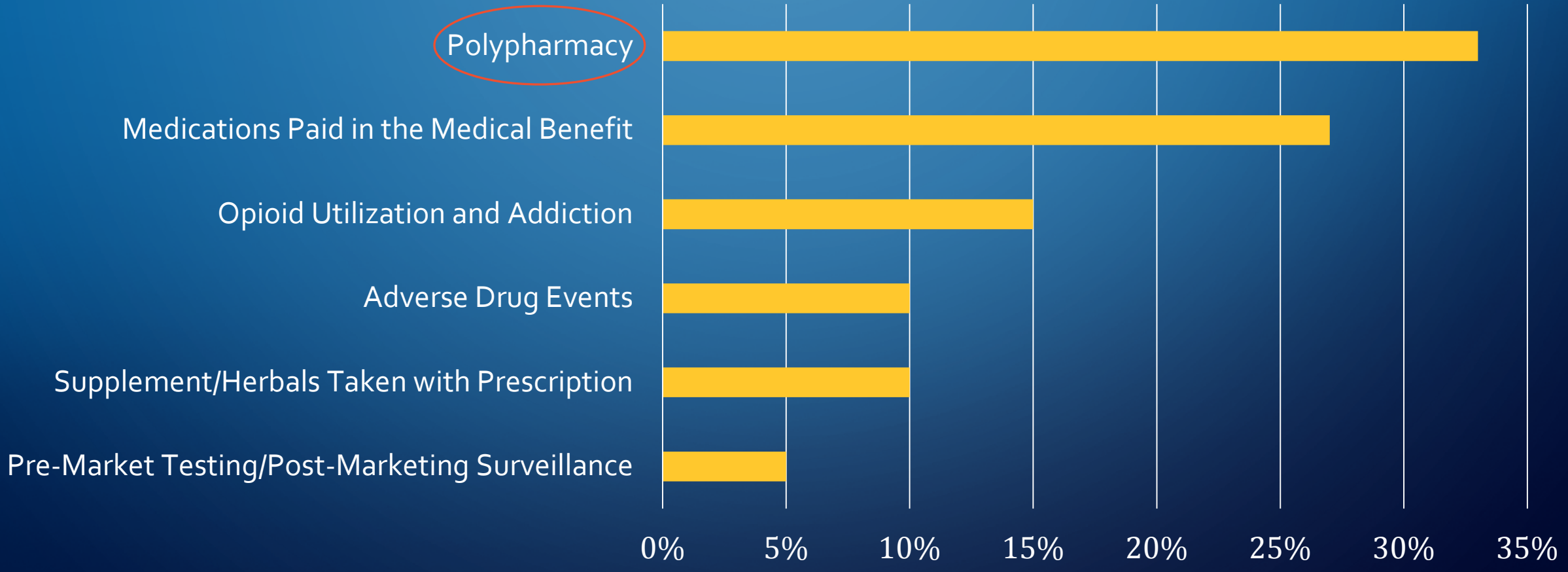
Source: Data based on 2017 industry survey

Limitations to Producing Quality Health Outcomes Research Related to Drug Safety



Source: Data based on 2017 industry survey

Top Areas of Research for Prescription Drug Safety That Are Needed

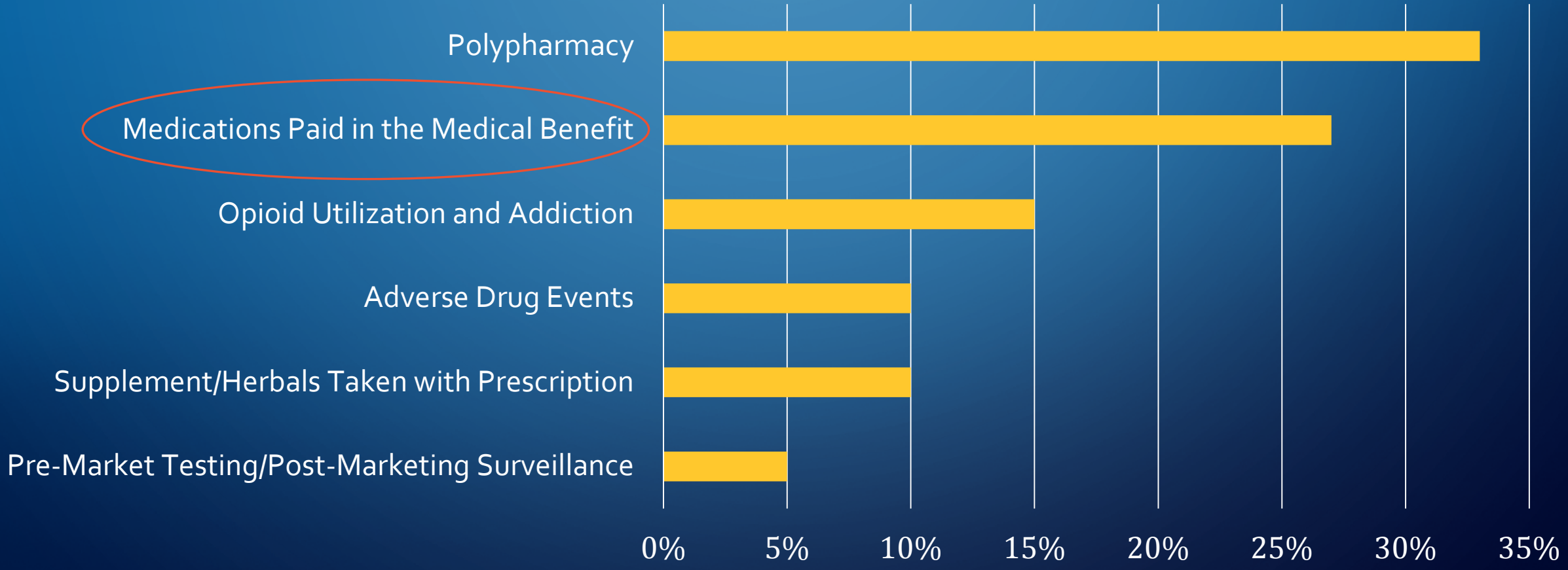


Source: Data based on 2017 industry survey

Polypharmacy →

Elevated risk due to complexity

Top Areas of Research for Prescription Drug Safety That Are Needed



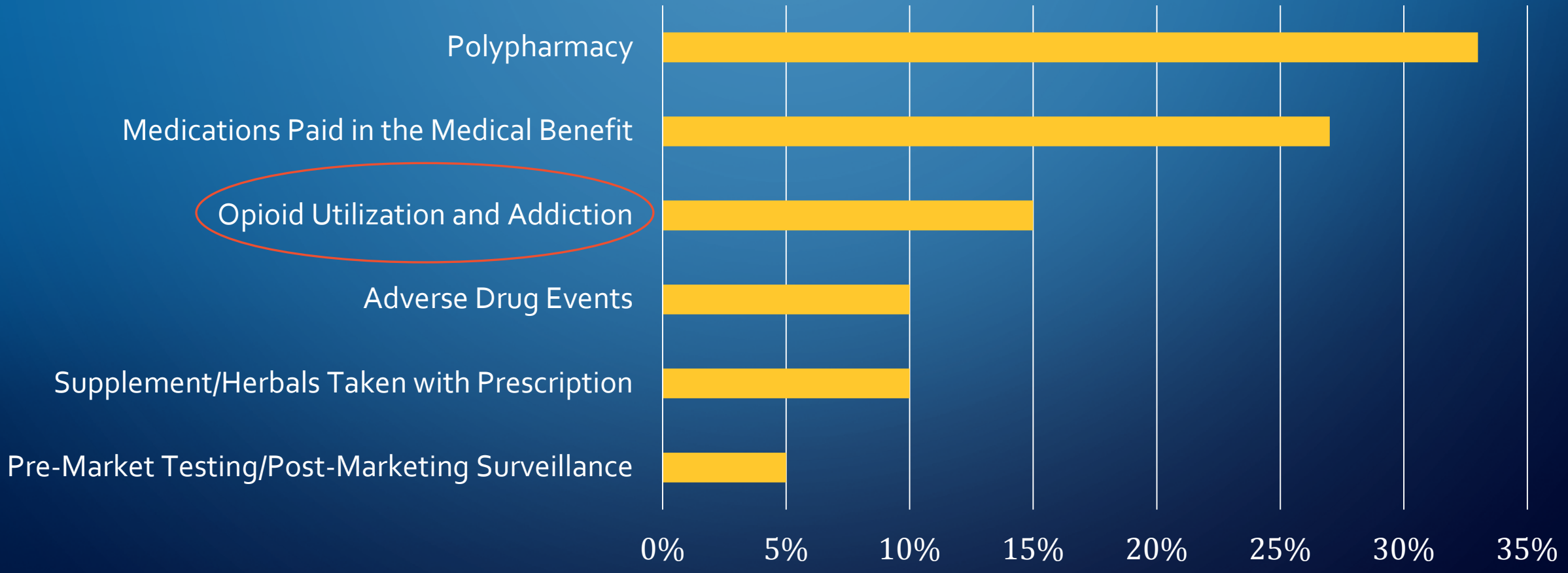
Source: Data based on 2017 industry survey

Medications paid in medical benefit

⬇

Lack of real-time safety reviews

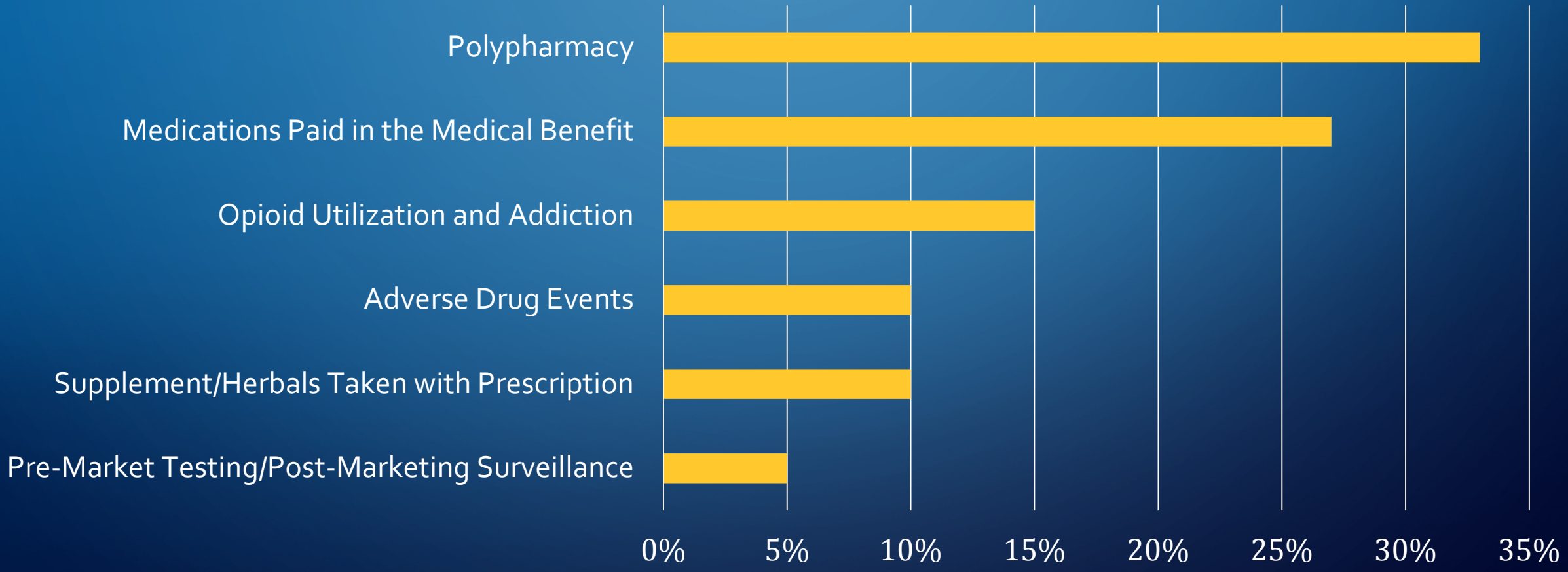
Top Areas of Research for Prescription Drug Safety That Are Needed



Source: Data based on 2017 industry survey

Opioid utilization and addiction → Current area of concern

Top Areas of Research for Prescription Drug Safety That Are Needed



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 10+ years away

Impact will be in less than 5 years

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:
Scaling safety expertise in life sciences. (2017, March 10). Retrieved June 06, 2017, from https://www.ibm.com/services/us/gbs/thoughtleadership/scalingsafety/

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

Nease, B. (2016). *The Power of FIfty Bits: The New Science of Turning Good Intentions into Positive Results*. Harper Business.

What We Discussed

- 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

Thank You

For more information, you can reach me at:

Heather Sundar, PharmD
Sundar Healthcare Consulting, LLC
www.sundarhealthcareconsulting.com

Email: heatherdsundar1@gmail.com
Follow me on Twitter at @SundarHeather