

The background features a light blue grid with white circuit-like lines and binary code (0s and 1s) scattered across it.

Optimizing the Safe Performance of EHRs

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A Patient Safety Case in The HIT Era

- 69 year old women admitted for elective colon resection for diverticuli
- 2 days post op she develops pneumonia and is transferred to the ICU
- On the second ICU day the patient suffers a prolonged period of unrecognized hypotension and is ultimately found to be septic and ultimately dies
- On review of the case a malfunction in the bedside monitor/EHR Interface led to an inaccurate blood pressure reading in the EHR blood pressure display


A Patient Safety Case in The HIT Era

- 27 year old women evaluated in the ER for severe lower abdominal pain
- Taken to surgery for what was felt to be an acute abdomen
- At surgery she was found to be pregnant and the fetus did not survive
- On review of the case a problem with interoperability lead to another patients lower abdominal ultrasound report being inadvertently inserted into this patients EHR record

The Washington Post

To Your Health

Researchers: Medical errors now third leading cause of death in United States



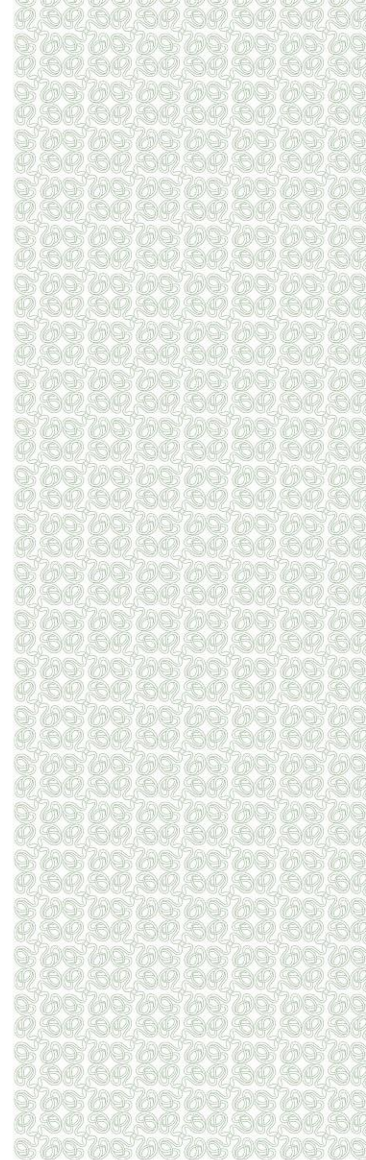
Health IT and Patient Safety:

Building Safer Systems for Better Care



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Unexpected Increased Mortality After Implementation of a Commercially Sold Computerized Physician Order Entry System

Scott Watson, Trung C. Nguyen, Hülya Bayir and
Richard A. Orr

Yong Y. Han, Joseph A. Carcillo, Shekhar T.
Venkataraman, Robert S.B. Clark, Richard A Orr.

Pediatrics 2005;116;1506-1512

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, account-

ing 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

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Financial Disclosure: None.

MULTIPLE BROAD-BASED studies during the past 15 years have demonstrated that adverse drug events (ADEs) account for up to 41% of all hospital admissions and more than \$2 billion annually in inpatient costs.²⁻⁴ Several of these studies have also estimated that as many as a quarter of inpatient ADEs may be preventable through interventions such as computerized physician order entry (CPOE) and related systems.^{3,7} On the basis of these projections and the proven success of these systems in identifying ADEs and reducing medication errors,⁸⁻¹¹ computerized medication processes have been widely promoted as essential to preventing actual ADEs.^{9,12,13}

Recently, some researchers have questioned the extent to which currently available CPOE and related systems are preventing ADEs.¹⁴⁻¹⁶ There are concerns that features of commercial CPOE products vary widely and that few can match the so-

phistication of custom systems developed at institutions that have successfully reduced targeted ADEs.^{13,17-21} Moreover, broad-based surveys of ADEs in institutions that have implemented multiple computerized medication systems have not been published; it is unclear how these interventions together have affected the occurrence of ADEs linked to problems across stages of medication processing (ie, ordering, transcription, dispensing, administration, and monitoring).³

The Veterans Administration (VA) Healthcare System, one of the largest integrated delivery systems in the country, is a leader in patient safety and has actively sought to reduce medication errors using multiple computerized interventions such as CPOE,²²⁻²⁶ bar code-controlled medication delivery,^{9,27,28} a complete electronic medical record,^{1,29-31} automated drug-drug interaction checking,³²⁻³³ and computerized allergy tracking and alerting.³⁰⁻³⁸ The White House has

Recommendation 1 (continued)

- b. The Office of the National Coordinator for Health IT (ONC) should expand its funding of processes that promote safety that should be followed in the development of health IT products, including standardized testing procedures to be used by manufacturers and health care organizations to assess the safety of health IT products.
- c. **ONC and AHRQ should work with health IT vendors and health care organizations to promote post-deployment safety testing of EHRs for high prevalence, high impact EHR-related patient safety risks.**
- d. Health care accrediting organizations should adopt criteria relating to EHR safety.
- e. AHRQ should fund the development of new methods for measuring the impact of health IT on safety using data from EHRs.



SAFER Guides: Safety Assurance Factors for EHR Resilience

Kathy Kenyon, JD MA, Office of the National Coordinator

Joan Ash, PhD MLS, MS, MBA, Oregon Health & Science University

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January 30, 2014

SAFER: Safety Assurance Factors for EHR Resilience

- **Foundational Guides**
 - High Priority Practices
 - Organizational Responsibilities
- **Infrastructure Guides**
 - System Configuration
 - System Interfaces
 - Contingency Planning
- **Clinical Process Guides**
 - Patient Identification
 - Computerized Provider Order Entry with CDS
 - Test Results Reporting and Follow-up
 - Clinician Communication



Recommended Practice

Implementation Status

22 CPOE and CDS functionality are tested to ensure proper operation before go-live and with test patients in the production system before clinical use.[12/16/14](#)[» Checklist](#)

Off

Principle: Complete/Correct EHR UseRationale for Practice or Risk Assessment

Appropriate testing reduces the risk of errors associated with inappropriate CDS or CPOE system behavior.

Suggested Sources of InputClinicians, support staff,
and/or clinical
administrationEHR developer
Health IT support staffExamples of Potentially Useful Practices/Scenarios

- The Leap Frog test is taken to ensure the safety of CDS.²²⁻²⁴
- CDS Interventions are evaluated to ensure correct firing of alerts and reminders.²⁵

Assessment NotesFollow-up ActionsPerson Responsible for Follow-up Action[reset page](#)

Click on a link below to view the topic online:

[» References](#)[» Phases & Principles](#)[» Meaningful Use](#)[» HIPAA](#)

SAFE PRACTICE 16: SAFE ADOPTION OF COMPUTERIZED PRESCRIBER ORDER ENTRY

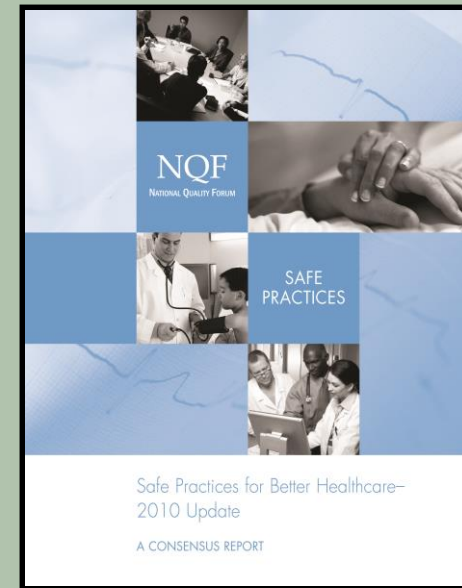
The Objective

Promote the safe use of medications, tests, and procedures through the successful implementation of integrated clinical information technologies that reduce preventable harm to patients.

The Problem

Medical errors related to medication and other clinical ordering errors are common. The majority of such events are preventable. In 2006, the Institute of Medicine (IOM) estimated that 400,000 preventable drug-related injuries occur in hospitals and that an additional 800,000 injuries occur in long-term care settings each year. [IOM, 2007]

The frequency of such errors is alarming: More than 500,000 Medicare recipients experience a medication-related injury during visits to outpatient clinics each year. A recent study estimated that 1 of every 10 adult patients suffers a serious medication-related adverse event. [Adams, 2008] The rate for pediatric patients is estimated to be three times higher than the rate for adults. [Kaushal, 2001]



Information Transfer and Clear Communication

CPOE may be adopted with a stage approach once integrated information systems are in place to support safety and effective CPOE systems...

The CPOE system is tested against The AHRQ/NQF Inpatient CPOE Testing Standards...developed to provide organizations that are implementing CPOE with appropriate decision support about...

Example Implementation Approaches

- Providing training early in the development of a CPOE system will increase user familiarity and enhance safety and efficiency. [Ghahramani, 2009; Niazkhani, 2009]
- During the pre-implementation phase, address concerns of staff to ensure better user receptivity and effectiveness with the CPOE system. [Georgiou, 2009]
- CPOE may be adopted with a staged approach once integrated information systems are in place to support safe and effective CPOE systems. At least 75 percent of all inpatient medication orders should be entered directly by a licensed prescriber:
 - Stage 1: CPOE is in place on at least one ward/unit in the hospital.
 - Stage 2: CPOE is in place on three or more wards/units in the hospital.
 - Stage 3: CPOE is in place on more than 50 percent of the wards in the hospital.
 - Stage 4: Full compliance with at least 75 percent of all medications entered through the CPOE system by the prescriber.
- The CPOE system is tested against The Leapfrog Group Inpatient CPOE Testing Standards. These standards were developed to provide organizations that are implementing CPOE with appropriate decision support about alerting levels; these alerting levels need to be carefully set to avoid overalerting and underalerting. [Anderson, 2009] One way to ensure effective alerting is through

AHRQ EHR Flight Simulator



Principles Behind the Evaluation Methodology

■ Principle #1: Target the Harm

- Common sources of ADE's (not errors)
- Sources of severe harm (existing literature and expert consensus)

■ Principle #2: Encourage Quality Improvement

- Categorize test set by type of error
- Provide feedback to the provider organization for each category
- Provide advice about nuisance alerting

■ Principle #3: Accentuate the positive

- Encourage quality, as well as harm reduction (ADE's)
 - ▶ Address errors of commission and omission
 - ▶ Include corollary orders and duplicate interventions

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 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.^{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.

Many Research Databases Used

Research background, combined with the practical experience of the EHR pioneers, was first used to define the focus.

Preventable ADEs in 10.4/100 admissions to six community hospitals

Types of CPOE-preventable ADEs	Percentage*
Patient Diagnosis	1
Duplicate Med Check	1
Drug-drug	2
Drug Frequency	3
Drug Allergy	4
Drug-specific Guidelines+	7
Drug-age	9
Drug dose Suggestion (typical)	9
Renal Check	19
Drug-lab Check	27

* All sites

+ Ondansetron

Source: Bates et al. "Saving lives, Saving money: The Imperative for Computerized Physician Order Entry in Massachusetts Hospitals." The Clinical Baseline and Financial Impact Study. MTC and NEHI. February 2008.

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 ...

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).



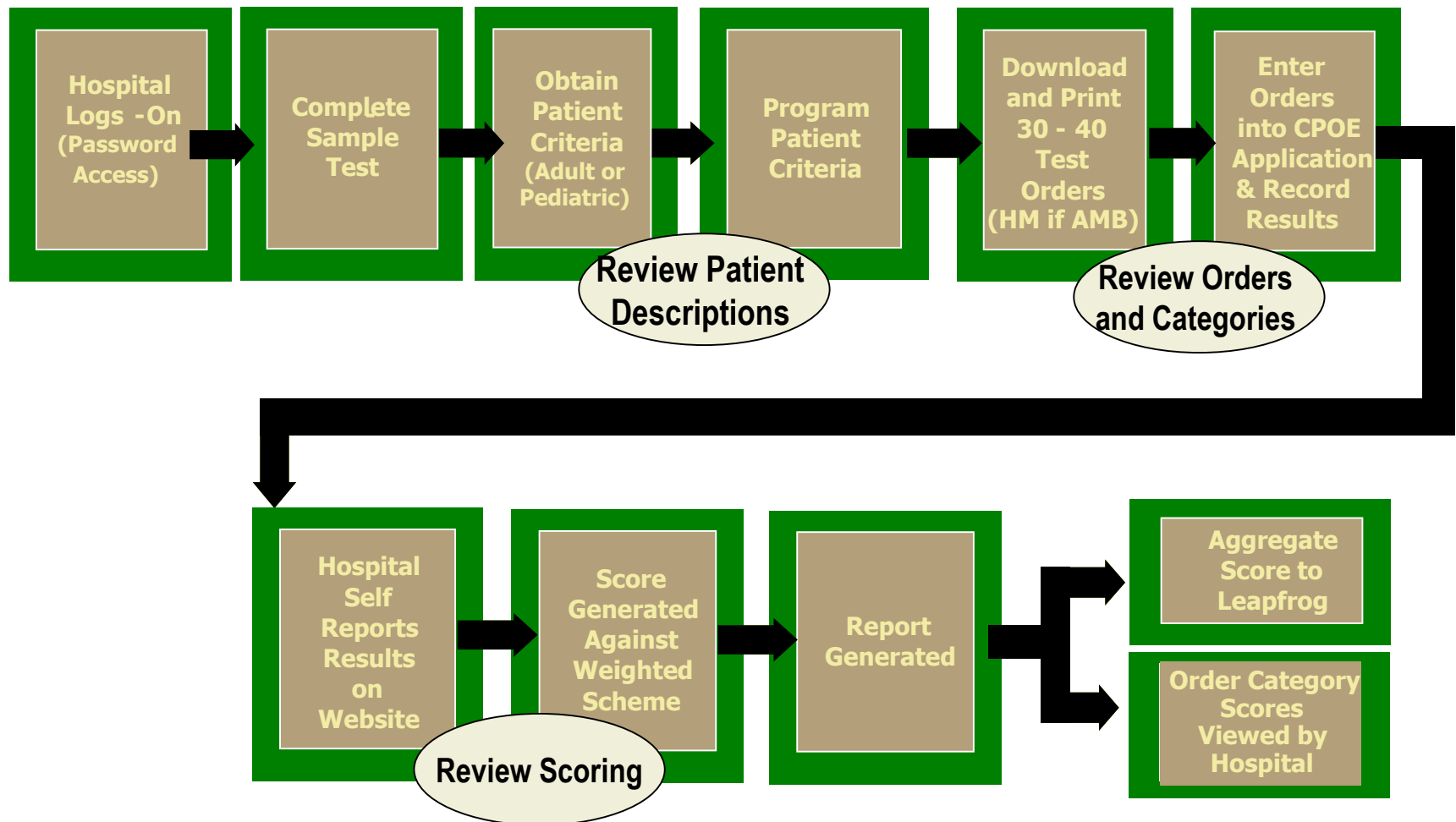
Coumadin (Warfarin) 5 mg po three times a day.

Web-Based Evaluation Tool (cont.)

- For ambulatory test: additional capability to test basic health maintenance prompting

- Outputs received immediately after submitting results
 - Individual site performance feedback
 - ▶ Indicating performance in each medication order category
 - ▶ Indicating performance for health maintenance (ambulatory only)
 - Sensitivity = the ones that you got right (percentage)
 - Specificity = how many did you get that you should not have (percentage)
 - Aggregate score for public reporting - similar to the Leapfrog Hospital Quality and Safety Survey

Web-Based Evaluation Tool



The team of advisors helped to define the order categories in the assessment to reflect the sources of common, preventable ADEs identified in research.

Order Category	Description	Example
Therapeutic duplication	Medication with therapeutic overlap with another new or active order; may be same drug, within drug class, or involve components of combination products	Codeine AND Tylenol #3
Single and cumulative dose limits	Medication with a specified dose that exceeds recommended dose ranges or cumulative dose	Ten-fold excess dose of methotrexate
Allergies and cross-allergies	Medication (or medication class) for which patient allergy has been documented	Penicillin prescribed for patient with documented penicillin allergy
Contraindicated route of administration	Order specifying an inappropriate route of administration (e.g., oral, intramuscular, intravenous)	Tylenol to be administered intravenously
Drug-drug interaction	Medication that results in known, dangerous interaction when used in combination with a different medication in a new or existing order for the patient	Digoxin AND Quinidine

The team of advisors helped to define the order categories in the assessment to reflect the sources of common, preventable ADEs identified in research. cont.

Order Category	Description	Example
Contraindication/dose limits based on patient diagnosis	Medication either contraindicated based on patient diagnosis or diagnosis affects appropriate dosing	Nonspecific beta blocker in patient with asthma
Contraindication dose limits based on patient age and weight	Medication either contraindicated for this patient based on age and weight or for which age and weight must be considered in appropriate dosing	Adult dose of antibiotic in a newborn
Contraindication/dose limits based on laboratory studies	Medication either contraindicated for this patient based on laboratory studies or for which relevant laboratory results must be considered in appropriate dosing	Normal adult dose regimen of renally eliminated medication in patient with elevated creatinine
Corollary	Intervention that requires an associated or secondary order to meet the standard of care	Prompt to order drug levels when ordering Dilantin
Cost of care	Test that duplicates a service within a timeframe in which there is typically minimal benefit from repeating the test	Repeat test for Digoxin level within 2 hours

Print your results and sign-out.

CPOE Evaluation Application - Windows Internet Explorer

http://research.cpoesimulator.org:8888/user/Submitresults.asp

File Edit View Favorites Tools Help

Convert Select

Favorites VitalChek Express - Birth Ce... Suggested Sites Free Hotmail Web Slice Gallery


CPOE Evaluation Application

Home RSS Print Page Safety Tools






Adult inpatient

Category	Score(in percent)
Therapeutic duplication	100.00
Drug-allergy	100.00
Drug-route	100.00
Drug:drug	100.00
Drug:diagnosis	100.00
Drug-labs	100.00
Monitoring	100.00
Deception	100.00
Nuisance	100.00
Drug-renal	100.00
Drug-age	100.00
Drug-dose (single)	100.00
Drug-dose (daily)	100.00

Your TOTAL Medication Checking score reflects:

 Fully implemented recommended safety practice

Note: Medication checking Total score does not include Nuisance and Deception Analysis categories

Legend	Description
	Did not meet criteria for a good early stage effort
	Good early stage effort in implementing recommended safety practice
	Good progress in implementing recommended safety practice
	Fully implemented recommended safety practice
	Did not complete the evaluation or did not report results

Done

Start status: Disconnected | V... Gmail - CPOE Checklist - ... CPOE Evaluation Appli... Microsoft PowerPoint - [c...]

Internet 100% 2:15 PM

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
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The People-to-People Health
Foundation, Inc.

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.

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

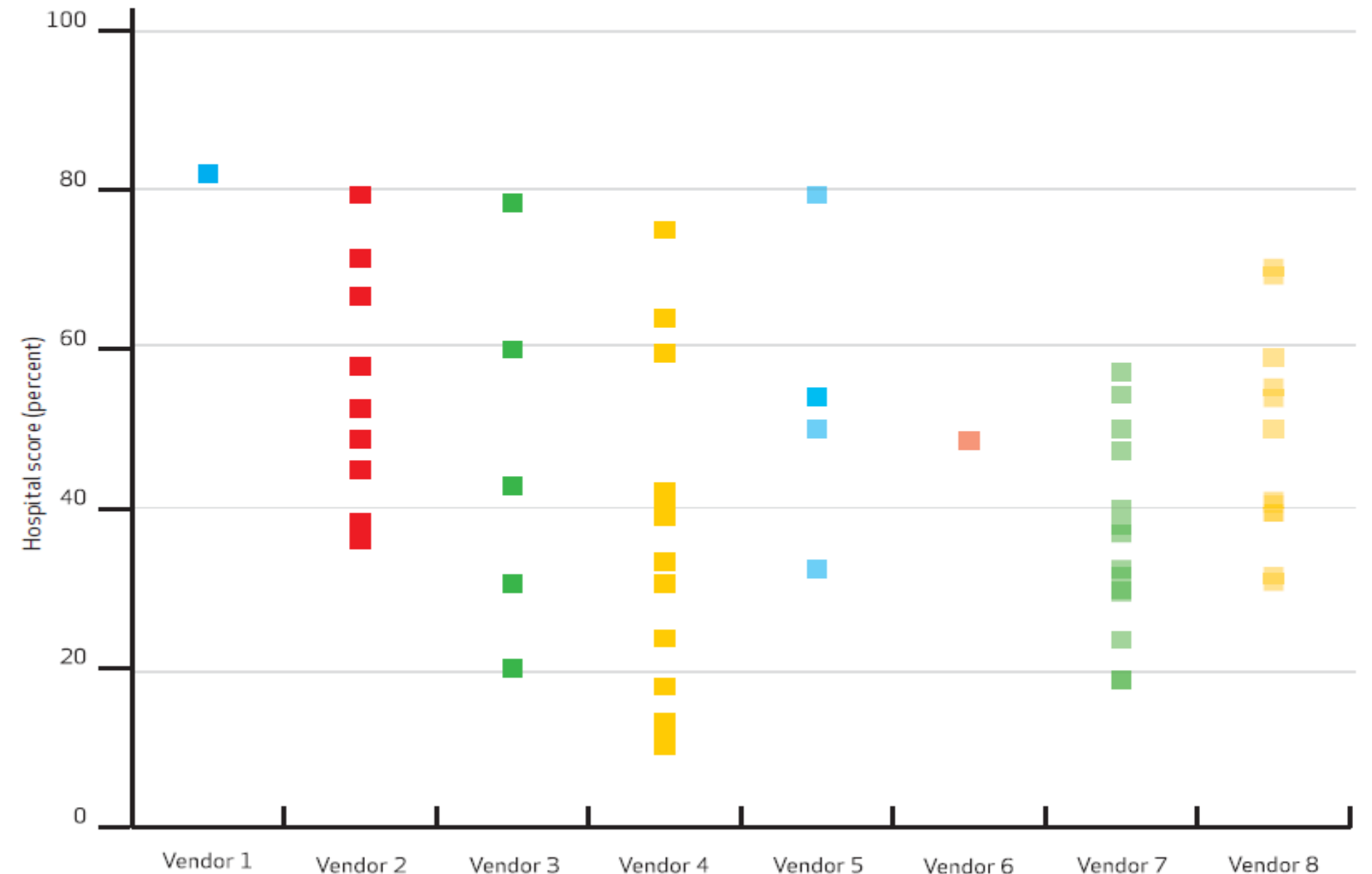
David C. Classen is an associate professor of medicine at the University of Utah in Salt Lake City, and is also with CSC Healthcare.

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

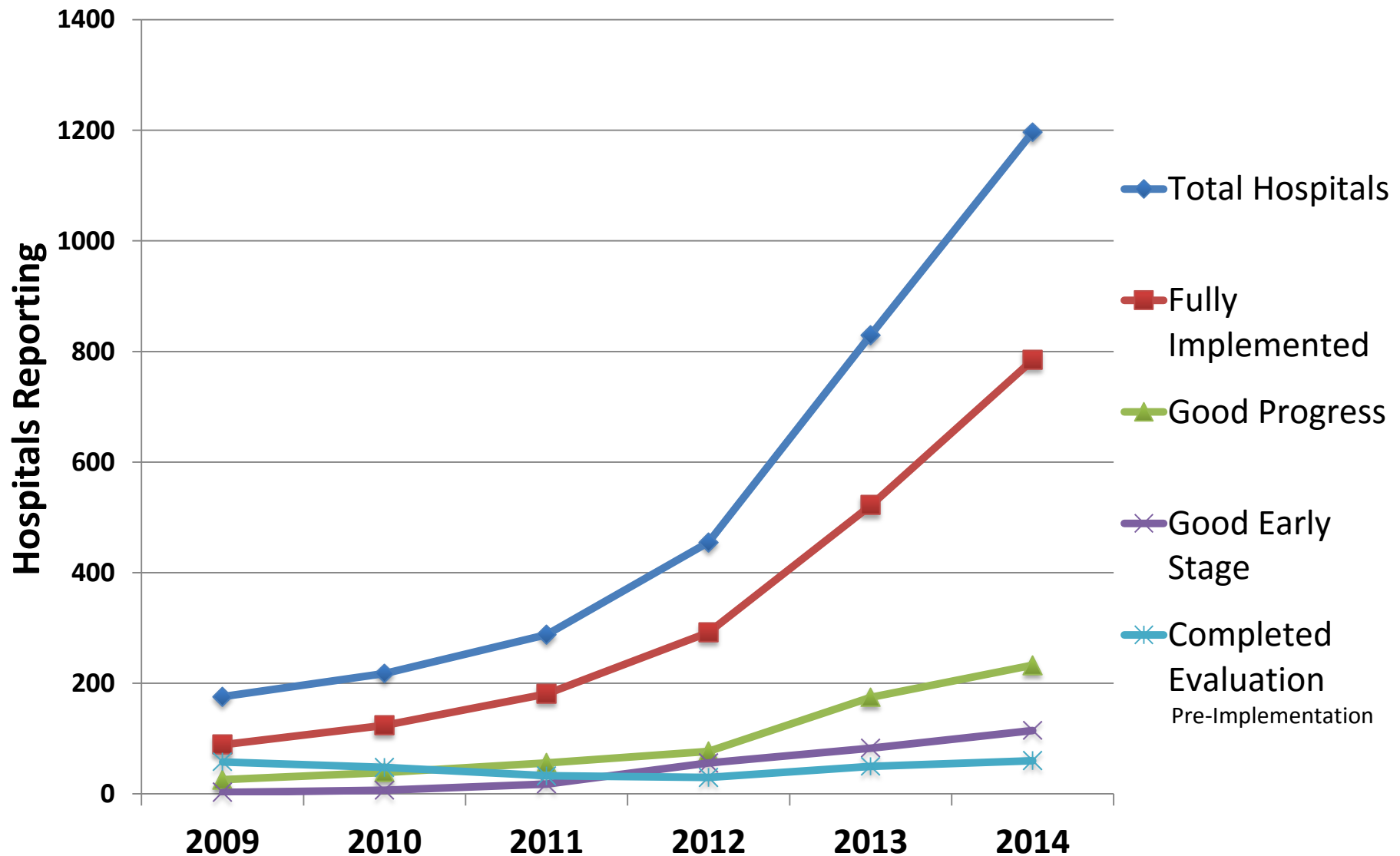
In this application of clinical decision support, physicians are made aware of potential safety issues that can result—for example, when ampicillin is given to a patient with a known allergy to penicillin, or the dose being ordered for a pediatric patient is much higher than the therapeutic range for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

EXHIBIT 2

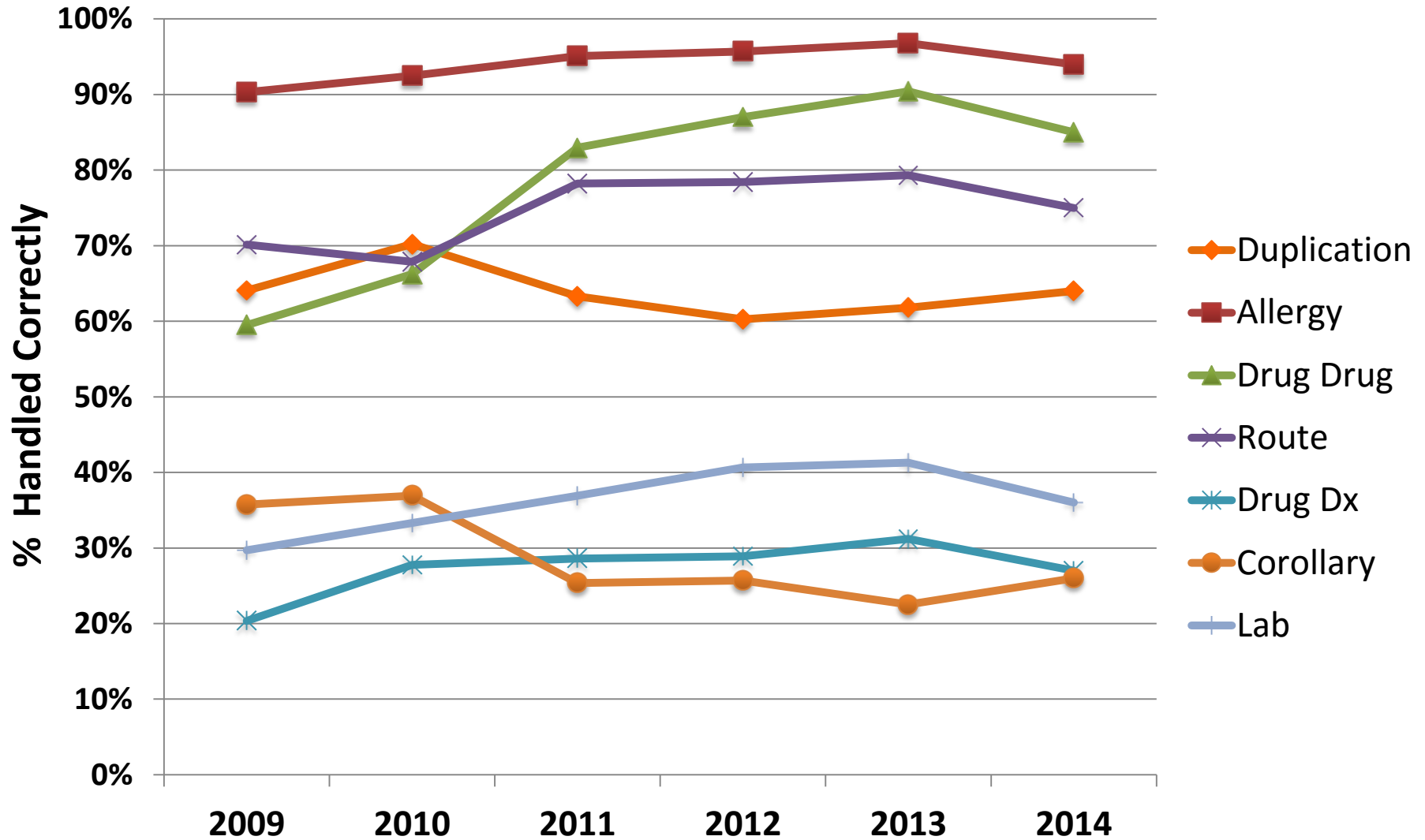
Hospital Scores For Detection Of Test Orders That Would Cause An Adverse Drug Event In An Adult Patient According To The Software Product (Vendor) Implemented



Growth in Participation and Performance



Handled Correctly by Checking Category - 1



NEW CATEGORIES

Order Category	Description	Example
CHOOSING WISELY	INAPPROPRIATE ORDERING OF MEDICATIONS, LABORATORY TEST, RADIOLOGIC TESTS	ORDERING OF VIT D LEVELS IN LOW RISK PATIENTS
PREVENTION OF COMMON HOSPITAL COMPLICATIONS	APPROPRIATE ORDERING OF INTERVENETIONS TO PREVENT HOSPITAL COMPLICATIONS -- CLABSI OR DVT	ORDERING OF APPROPRIATE INTERVENTIONS FOR PATIENTS WITH CENTRAL LINES IN PLACE
USABILITY OF CLINICAL DECISION SUPPORT	EVALUATION OF USABILITY OF COMMON DECISION SUPPORT CAPABILITY	USE OF THE IMEDESA TOOL
EHR ERROR DETECTION	EVALUATION OF COMMON EHR ERRORS	USE OF THE ORDER REORDER RETRACT TOOL

Questions?

Comments