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Impact of an Electronic Medical Record Implementation on Drug Allergy Overrides in a Large Southeastern HMO Setting

Renny Varghese

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Impact of Electronic Medical Records on Drug Allergy Overrides

In a

Large Southeastern HMO setting

By

Renny Varghese

B.S., Georgia State University

**A Thesis Submitted to the Graduate Faculty
Of Georgia State University in Partial Fulfillment
Of the
Requirements for the Degree**

MASTER OF PUBLIC HEALTH

ATLANTA, GA

30303

**Impact of Electronic Medical Records on Drug Allergy Overrides
In a
Large Southeastern HMO setting**

**By
Renny Varghese**

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July 24, 2007

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Renny Varghese

Impact of an Electronic Medical Record Implementation on Drug Allergy Overrides in a Large Southeastern HMO Setting

(Under the direction of Russell Toal, Associate Professor)

Electronic medical records (EMRs) have become recognized as an important tool for improving patient safety and quality of care. Decision support tools such as alerting functions for patient medication allergies are a key part of reducing the frequency of serious medication problems.

Kaiser Permanente Georgia (KPGA) implemented its EMR system in the primary care departments at Kaiser's twelve facilities in the greater metro Atlanta area over a six month period beginning in June 2005 and ending December 2005.

The aim of this study is to analyze the impact of the EMR implementation on the number of drug allergy overrides within this large HMO outpatient setting. Research was conducted by comparing the rate of drug allergy overrides during pre and post EMR implementation. The timeline will be six months pre and post implementation. Observing the impact of the incidence rate of drug allergy alerts after the implementation provided insight into the effectiveness of EMRs in reducing contraindicated drug allergies.

Results show that the incidence rate of drug allergy overrides per 1,000 filled prescriptions rose by a statistically significant 5.9% ($p > 0.0002$; 95% CI [-1.531, -0.767]) following the implementation. Although results were unexpected, several factors are discussed as to the reason for the increase.

Further research is recommended to explore trends in provider behavior, KPGA specific facilities and departments, and in other KP regions and non-KP healthcare settings.

INDEX WORDS: electronic medical records, drug allergy overrides, patient safety, medication errors, decision support tools, outpatient setting, primary care, computerized provider order entry

CHAPTER I INTRODUCTION

Computerized order entry systems used within electronic medical records have the potential to prevent medication errors and decrease adverse drug events with the use of clinical decision support systems which present alerts to providers. Despite the large volume of medications prescribed in the outpatient setting, few studies have assessed the impact of computerized alerts, particularly drug allergy alerts, on medication errors in an outpatient primary care setting. A drug allergy alert warns providers when the patient has had a prior reaction to a medication ordered in an electronic medical record (EMR). A provider can override an alert when, for example, a patient has already shown a tolerance to the medication or if the alert is inappropriate.

The Institute of Medicine (IOM) included computer-assisted decision making among the technologies that could improve medication safety in its call for the development of a Center for Patient Safety within the Agency for Healthcare Research and Quality (IOM, 1999). EMRs, computerized provider order entry (CPOE), and drug allergy alerts are included in these computer-assisted decision making tools.

Simply defined, an EMR is a longitudinal medical record in a digital format. EMRs support physicians by providing accessibility to complete and accurate medical data, alerts, reminders, clinical decision support systems, links to medical knowledge, and other aids. EMRs integrate systems to communicate with all facets of a patient visit; one of these critical systems is CPOE. CPOE is a prescription ordering system in which the provider enters medication orders directly into a computer. Medication orders are sent immediately to the pharmacy, where patients may pick up their medications without a paper prescription. When a prescription is ordered in CPOE and the patient has an

existing drug allergy to the medication ordered, a drug allergy alert appears to the provider in a pop-up window, as well as to the pharmacist in an external pharmacy system. The provider or pharmacist has the option to change, cancel or continue with the order. A drug allergy override occurs when the provider or pharmacist decide to continue with the original order and disregard the drug allergy alert.

One of the acknowledged benefits of EMRs, CPOE, and drug allergy alerts is their ability to provide clinicians with useful information to help with decision-making and decreasing errors. Improved quality, cost effectiveness and a decrease in undesirable medical practice variation are other anticipated outcomes in having EMR and CPOE systems. The usefulness of electronic alerts has been demonstrated in numerous studies (Krall et al., 2001, Shah et al., 2006, van der Sijs et al., 2006). Given their potential benefits, there is great incentive for system implementers to rapidly increase the number and coverage of alerts. However, evidence exists that the effect of alerts may degrade over time and that users may ignore or override alerts (Abookire et al., 2000, Demakis et al., 2000). Also, a number of related usability issues remain, including whether alerting systems should err on the side of sensitivity and error detection or specificity and fewer false positives (Kuperman et al., 2003). In fact, there is very little known about the limits of alerting in the outpatient setting.

At least 44,000 people, and perhaps as many as 98,000 people, die in hospitals each year as a result of medical errors that could have been prevented, according to estimates from two major Institute of Medicine reports: *To Err is Human: Building a Safer Health System* and *Crossing the Quality Chasm: A New Health System for the 21st Century* (IOM 1999; 2001). Even using the lower estimate, preventable medical errors

exceed deaths attributable to motor-vehicle accidents, breast cancer, and AIDS. The two IOM reports identified computerization of medication prescribing as an important patient safety strategy care in the United States.

In 2003, Kaiser Permanente launched a national \$3 billion EMR initiative known as KP HealthConnect which was a large-scale effort to integrate all patient information linking medical, billing, scheduling and registration data for any provider to connect to the system nationally. The hallmark of KP HealthConnect is that it contains an integrated patient database including primary care, pharmacy, laboratory, surgery, and radiology data. Providers are able to send prescriptions to pharmacies electronically, refer patients to specialists, and share information with other providers on a real time basis. Kaiser Permanente of Georgia (KPGA) implemented the KP HealthConnect system over a six month period in 2005 for 12 facilities in the greater Atlanta area. Each of the 12 facilities has primary care and specialty departments available for patient care. The primary care departments were outfitted with the KP HealthConnect system during 2005, and the specialty departments implemented KP HealthConnect in 2006 (KP, 2005). The focus of this research study only pertained to primary care department data because specialty data was not available.

The purpose of this study was to evaluate the impact of an EMR system implementation on drug allergy overrides in a large Southeastern health maintenance organization (HMO) outpatient setting. The overarching purpose of the study was to determine the impact of using computerized alerts to improve medication prescribing in the outpatient setting, focusing mainly on allergy interactions related to medication orders.

The research question being addressed for this study was as follows: Is there a significant impact on the incidence of drug allergy overrides after an EMR implementation. The research hypothesis was: There is a decrease in the incidence rate of drug allergy overrides following the implementation of the EMR system. The null hypothesis (H_0) was: There is no significant difference in the incidence rate of drug allergy overrides when pre and post implementation periods are compared.

A literature review was conducted in Chapter II on the current issues of medication safety, possible solutions for medication safety, and evaluation of those solutions. Chapter III presents the methodology, study design, and study setting. Chapter IV describes the results, drug allergy override incidence rates, and significance tests. Chapter V contains observations, applicable theories, recommendations, proposed further research, and conclusion.

CHAPTER II LITERATURE REVIEW

The IOM report *Patient Safety: Achieving a New Standard of Care* states that medical errors can be caused by an act of commission or omission (IOM, 2004). **Table 1** defines commission and omission in more detail, as well other key terms. The focus of this research concentrates on acts of commission in regards to medication errors and drug allergy overrides.

The literature summarized in this paper focuses on the current state of medication safety, the potential solutions for medication safety, and an evaluation of these solutions.

Table 1: Key Terms and Definitions

Adverse drug event (ADE)	Any injury due to medication. Examples include an allergic reaction occurring in a patient not known to be allergic to a given medication or a wrong dosage leading to injury (e.g., rash, confusion, or loss of function) (Bates et al., 1995a).
Clinical Decision Support System (CDSS)	Active knowledge systems which use two or more items of patient data to generate case-specific advice (Osheroﬀ, 2005).
Clinical Provider Order Entry (CPOE)	A portion of a clinical information system where the provider enters orders for medications, procedures, laboratory or radiology tests directly into the computer. The system then transmits the order to the appropriate department to be carried out. The most advanced implementations of such systems also provide real-time clinical decision support such as drug-allergy and drug-drug interaction checking dosage and alternative medication suggestions, and duplicate therapy warnings (Osheroﬀ, 2005).
Commission	An act of prescribing a medication that has a potentially fatal interaction with an allergy or another drug the patient is taking (IOM, 2004). These errors are the focus of this study.
Electronic Medical Record (EMR)	A longitudinal electronic patient record that resides in a system specifically designed to support users by providing accessibility to complete and accurate data, alerts, reminders, clinical decision support systems, links to medical knowledge, and other aids (IOM, 2004).
Health Level 7 (HL7)	A standard interface for exchanging and translating data between computer systems. HL7 facilitates the transfer of pharmacy data,

	laboratory results, and other information between different computer systems (Bond et al., 1999).
Medication error	The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Examples include drug prescription to which the patient has an allergy to, wrong dosage prescribed, wrong dosage administered for a prescribed medication, or failure to give (by the provider) or take (by the patient) a medication. (IOM, 2000)
Near miss	An act of commission or omission that could have harmed a patient but did not do so as a result of chance (e.g., the patient received a contraindicated drug but did not experience an ADE, prevention (e.g., a potentially lethal overdose was prescribed, but it was identified before administration), or mitigation (e.g., a lethal overdose was administered but discovered and offset with an antidote) (IOM, 2004).
Omission	The failure to prescribe medications for which there is an evidence base for the ability to reduce morbidity and mortality (IOM, 2004).
Patient Safety	The freedom from accidental injury due to medical care or medical errors (IOM, 1999)
Pharmacy Information Management System (PIMS)	An external application used by healthcare setting pharmacy departments to record dispensing, inventory control, and clinical decision support in the department. EMRs typically integrate with PIMS by creating and storing medication order details, dispensed medication details, current medications, and drug administration details in the EMR then sending them via HL7 code to the PIMS (Osheroff, 2005).

Current State of Medication Safety

Since the release of the IOM's aforementioned reports, national attention has been focused to reduce medication errors and preventable adverse drug events. Hundreds of thousands of errors occur in the U.S health care system everyday. Fortunately, most of these errors result not in serious harm but in "near misses" (see Table 1). However, a small percentage of errors do result in adverse drug events, exacting a substantial toll in terms of unnecessary injury, disability, and death (IOM, 2004).

Comprehending the full magnitude of the medication safety challenge with complete certainty is difficult. The health care industry does not routinely conduct an

evaluation of medical errors. Studies have challenged the estimates of patient harm attributable to errors, as well as the methodologies used to develop them (Brennan, 2000; Hayward et al., 2001; McDonald et al., 2000). It is complicated to create an overview of error rates and costs because research designs have employed a wide variety of definitions, institutions, locations, time periods, and sample sizes and error rate formulas are not standard.

Historically, providers have documented and delivered care using paper records because of their simplicity, low implementation cost, and widespread acceptance. However, paper records have significant disadvantages: availability to only one person at a time; frequent illegibility; inability to be accessed remotely or at the time and place needed; growing so thick as to be unwieldy; low utility and large overhead as vehicles to evaluate quality; and segmentation with multiple volumes and multiple storage sites (Bates et al., 2003a). The most serious problem with paper records is that they impede clinical decision support; data stored in inaccessible formats cannot incorporate or trigger decision support tools.

George Halvorson, CEO of Kaiser Permanente since 2002, also states in his book *Epidemic of Care: A Call for Safer, Better, and More Accountable Health Care* that paper medical records are critical obstacle to increase medication safety. Halvorson et al. agrees that paper medical records are inadequate, inaccessible, sometimes inaccurate, and invariably inert. Prescriptions and work orders are too often illegible and misread. There are few follow-up care reminders or tracking systems for individual patients or providers. Halvorson et al. determines paper medical records lack in feedback, quality control, patient-focused overview, and information strategy. Paper medical records are kept

physically in each provider's offices for the same patient and can not be integrated with each other. This lack of coordination creates dangerous health situations when patients have unknown contraindicated medications from multiple providers (Halverson et al., 2003).

A study of a large Florida hospital evaluated errors in the EMR and traditional paper medical records for vital sign documentation. The results demonstrated that use of an EMR can reduce vital sign documentation errors by more than half compared with traditional manual documentation in paper charts. Researchers found the error rate for electronic vital signs documentation to be less than 5 percent, compared with the paper chart error rate of 10 percent (Gearing et al., 2006).

A study in Germany compared paper records with the EMR system to research procedure coding documentation. The EMR documentation showed potential advantages in both quality and quantity of procedure coding: a lower number of imprecise codes and a higher number of appropriate codes pertaining to operations (Stausberg et al., 2003).

Tang et al. investigated whether using an EMR affected the completeness of documentation and appropriateness of documented clinical decisions by evaluating 50 progress notes where physicians used either the EMR or the traditional paper record. Physicians in the study who used the EMR produced more complete documentation and documented more appropriate clinical decisions. The expert reviewers rated the problem lists and medication lists in the EMR progress notes as significantly more complete than those in the progress notes in the paper record (1.79/2.00 vs. 0.93/2.00, $P < 0.001$, and 1.75/2.00 vs. 0.91/2.00; $P < 0.001$, respectively). Physicians who used an EMR provided more evidence in their documented assessment that they had considered relevant patient

factors in making their decisions and documented more appropriate decisions than did those who used traditional paper patient records (Tang et al., 1999).

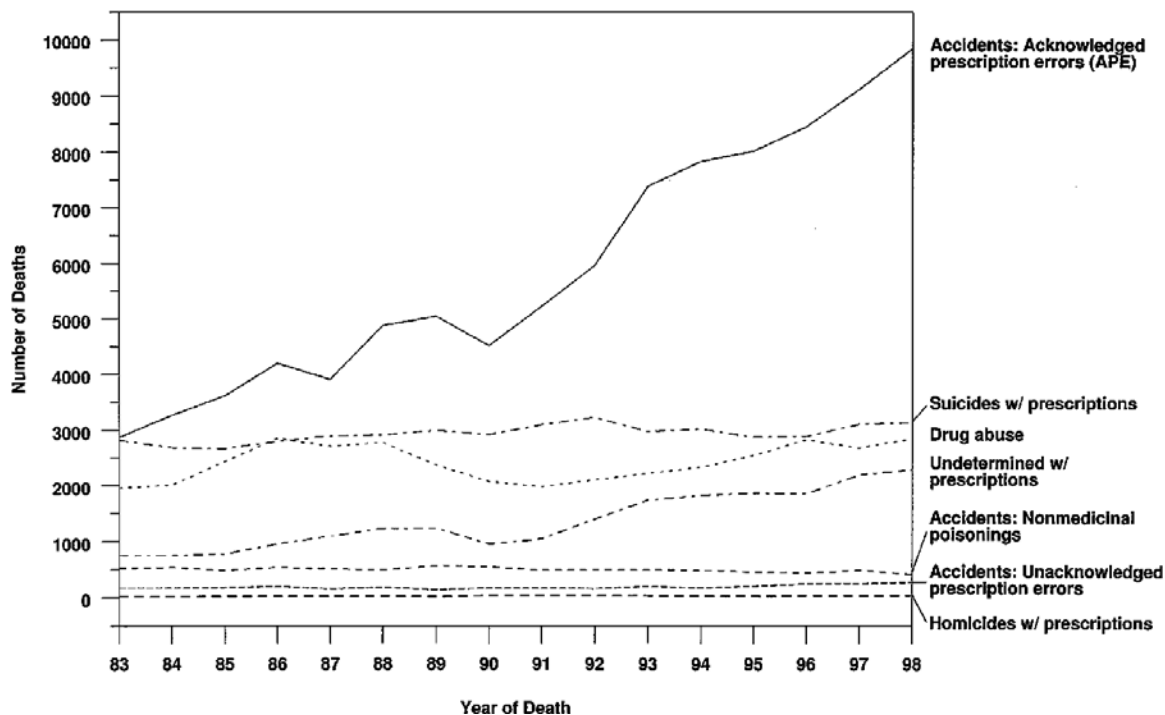
A major study conducted by RAND Health, the nation's largest independent health policy research organization, illustrated the need for medication safety solutions regarding recommended health care. The study established that nearly half of all adults in the United States fail to receive recommended health care in all settings. More specifically, the study found that providing the recommended care to diabetic, hypertensive, and heart attack patients would result in thousands of preventable deaths (McGlynn et al., 2003). For many of these conditions, medications are the recommended treatment option, and monitoring the prescription of these medications becomes an even more vital issue.

However, compared with the inpatient setting, there is a substantial lack of information regarding medication errors in the outpatient setting. Several reasons exist for the relative deficiency of medication error data in the ambulatory setting. In contrast to inpatients, outpatients are responsible for both obtaining and administering their medications. Therefore, the process for medication administration is much less controlled (Feldstein et al., 2005). Providers also have less regular contact with outpatients and are less likely to hear about all of the patient's problems. Chart review also has limitations related to high costs and inadequate documentation. Therefore, previous studies of outpatients have relied heavily on patient report, which can be limited by patient recall bias (Bates et al., 2003a).

The amount of medical errors has increased dramatically. Phillips et al. found that the number of deaths reportedly caused from medication errors increased by 2.5 fold

from 1983 to 1993 (Phillips et al., 1998). This percentage increase was greater than for almost any other cause of death, and far outpaced the increase in the number of prescriptions. Since this study appeared, more recent mortality data have become available, which indicate a continued, upward trend in deaths from prescription medicines (**Figure 1**). From 1983 to 1998 all mortality from medication errors increased by 243% (9856/2876), while outpatient mortality from medication errors increased by 907% (1733/172). This 907% increase is much greater than would be expected from the overall increase in outpatient visits and from the increase in outpatient deaths from other causes (Phillips et al., 2002).

Figure 1: Trends in U.S. deaths from prescriptions and related causes, 1983–1998*



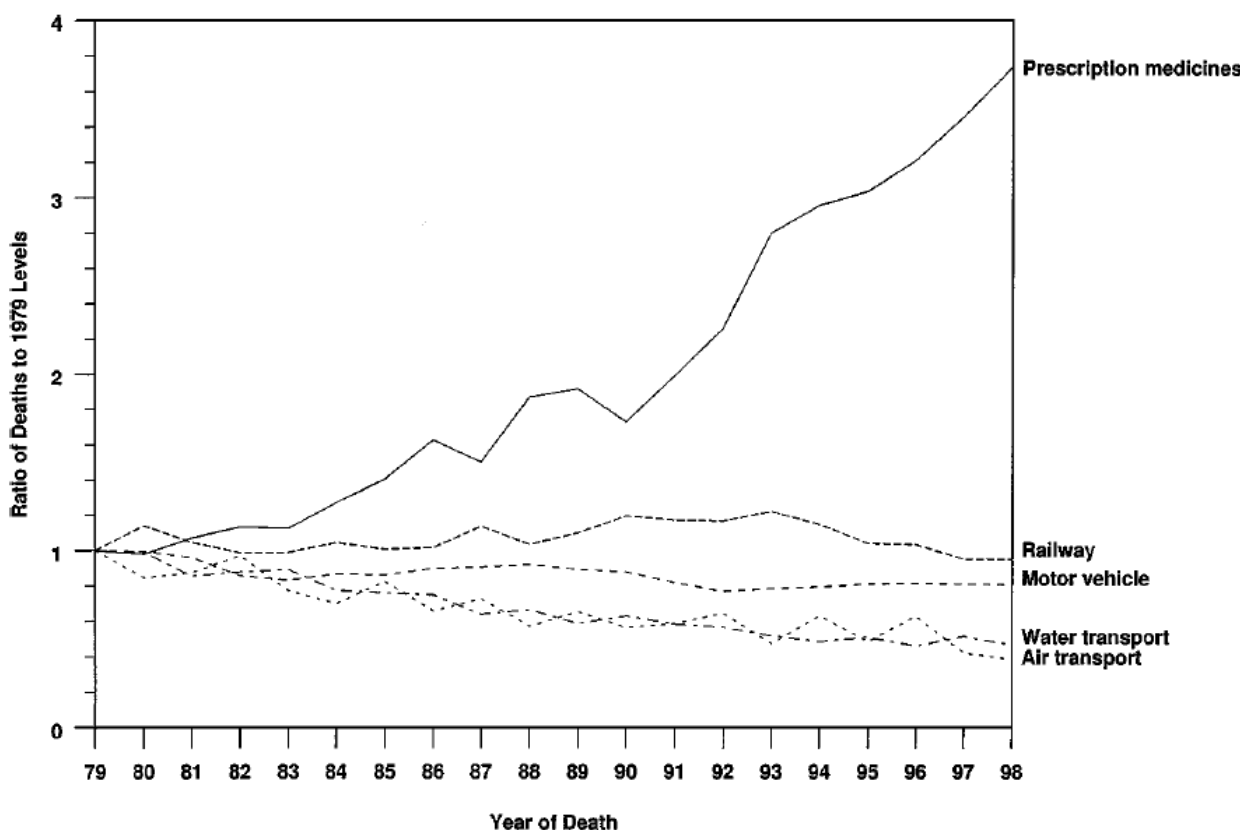
Phillips DP, Breder CC.(2002). *Morbidity and Mortality from Medical Errors: An Increasingly Serious Public Health Problem* *Annu.Rev.Public Health.* 23: 135-50

*This figure is a modified and updated version of one originally presented by Phillips et al. 1998, which covered 1983–1993. The causes plotted are accidents from prescriptions for which error is acknowledged; suicides with prescription medicines; dependent and nondependent drug abuse; prescription medicines, for which it is undetermined whether death resulted from purposeful or accidental acts; accidental poisonings by non-medicinal solid and liquid substances; accidents from prescriptions for which errors not acknowledged; and homicides with prescription medicines.

Figure 1 indicates that medication error deaths increased more steeply than did other deaths resulting from the misuse of solid and liquid substances. At the beginning of the study period the number of medication error deaths was about the same as the number of deaths from suicides using prescriptions. However, at the end of the study period, fatal accidents from medication errors far outnumbered suicides from prescriptions. In fact, medication error deaths outnumbered all other plotted deaths from solid and liquid poisoning combined (9856 versus 8924 in 1998) (Phillips et al., 2002). Aside from medication error deaths, only one other category markedly increased: deaths from prescription medicines for which it is undetermined whether the misuse is purposeful (in the form of suicide or homicide) or accidental. These undetermined prescription deaths increased by 207%.

Figure 2 compares 20-year trends in accidental deaths from prescription medicines with trends in accidental deaths from aircraft, watercraft, trains, and motor vehicles. In 1998, the latest data-year available, the number of accidental deaths from prescriptions was five times the number of accidental deaths from aircraft, watercraft, and trains combined ($10,133/1,887 = 5.37$) (Phillips et al., 2002). Fatal transport accidents in each sector have either decreased or remained approximately level; in contrast, fatal prescription accidents have increased markedly.

Figure 2: Trends in U.S. deaths from prescriptions and from different types of transportation accidents, 1979–1998*



Phillips DP, Breder CC.(2002). *Morbidity and Mortality from Medical Errors: An Increasingly Serious Public Health Problem* *Annu.Rev.Public Health*. 23: 135-50

*To facilitate comparison of trends, mortality levels have been expressed in terms of a ratio: deaths in a given year/deaths in 1979. Thus, for example, the number of accidental deaths from prescription medicines in 1998 is nearly four times the number in 1979. The causes plotted comprise prescription and transportation accidents: prescriptions with acknowledged and unacknowledged error; railway; motor vehicle traffic; water transport; and powered aircraft.

The IOM Committee on Identifying and Preventing Medication Errors estimates that at least 1.5 million preventable ADEs occur each year in the United States (IOM, 2006). Approximately 35% of these preventable ADEs occur in the ambulatory care setting. Among outpatient Medicare patients alone, Gurwitz et al. projected 530,000 preventable ADEs and 50 ADEs per 1,000 person-years (Gurwitz et al., 2003). However, their approach was conservative since it did not involve direct patient contact, which

yields much higher rates (Gandhi et al., 2003). The number of outpatient encounters exceeds the number of inpatient admissions, the consequences of medical errors and the opportunities to improve in the outpatient setting may dwarf those in hospitals (Gurwitz et al., 2003).

Most medication errors are minor, however a small portion result in an injury or adverse drug event (ADE). Even though only about 20% of patients react when they receive medications to which they have “known allergies”, the reactions can be devastating when they occur (Bates et al., 2000). Prescribing errors are a significant cause of injuries. For example, in one study of the impact of computerized physician order entry (CPOE, including allergy alerts), the rate of known allergy errors decreased by 56% ($p > 0.009$) (Bates et al., 1995). Lazarou et al. conducted a meta-analysis which suggested more than 1 million outpatients in the United States experienced an ADE that required hospital admission in 1994, and 4.7% of admissions were caused by drugs (Lazarou et al, 1998).

Medication errors are common in hospitals during all steps of the medication-use process—procuring the drug, prescribing, dispensing, administering, and monitoring the patient’s response. In hospitals, they occur most frequently at the prescribing and administration stages (IOM, 2006). Substantial variations in error rates are found. Detection methods addressing all stages but not including direct observation of administration found a rate of 0.1 prescribing errors per patient per day in a study of hospital pediatric units (Kaushal et al., 2003) and a rate of 0.3 prescribing errors per patient per day in a study of hospital medical units (Bates et al., 1995b). A major study using direct observation of administration carried out at 36 different health care facilities

found an administration error rate of 11 percent. Since a hospital patient receives an average of at least ten medication doses per day, this figure suggests that on average, a hospital patient is subject to one administration error per day (Barker et al., 2002). Further, since prescribing and administration errors account for about 75 percent of medication errors (Leape et al., 1995), the IOM Committee on Identifying and Preventing Medication Errors conservatively estimates that a hospital patient is subject to at least one medication error per day on average (IOM, 2006).

Beyond their cost in human lives, preventable medical errors exact other significant tolls such as financial expenses and loss of trust in the alert system. Current understanding of the costs of medication errors is highly incomplete. Most of what is known relates to additional health care costs associated with preventable ADEs.

For hospital care, the estimated additional cost of inpatient care for a preventable ADE incurred while in the hospital is \$5,857 using 1993 cost data (Bates et al., 1997). Using this estimate, the IOM Committee on Identifying and Preventing Medication Errors calculated an annual cost of \$2.3 billion in 1993 dollars or \$3.5 billion in 2006 dollars due to medication errors (IOM, 2006). For ambulatory care, the best estimate derives from a study conducted by Field et al. in 2005 that calculated the annual cost of preventable ADEs for all Medicare enrollees aged 65 and older. The cost in 2000 per preventable ADE was estimated at \$1,983, while national annual costs were estimated at \$887 million in 2000 dollars or \$1.03 billion in 2006 dollars (Field et al., 2004).

However, these studies neglected to examine costly medication errors in terms of loss of trust in the health care system by patients and diminished satisfaction by both patients and health professionals. Patients who experience a long hospital stay or

disability as a result of errors pay with physical and psychological discomfort. Health professionals pay with loss of morale and frustration at not being able to provide the best care possible. Society bears the cost of errors as well, in terms of lost worker productivity, reduced school attendance by children, and lower levels of population health status (IOM, 2004).

Potential Solutions for Medication safety

Computerized support tools are the key to solving each of the problems mentioned above. Along with improving the provider-patient relationship and improving drug information resources, electronic medication prescribing is a critical component to reducing errors. New computerized systems for prescribing drugs and other applications of information technology, such as EMRs, CPOE, and CDSS (which use drug allergy alerts) show promise for reducing the number of drug-related mistakes. Studies indicate that paper-based prescribing is associated with high error rates (Kaushal et al., 2003). Electronic prescribing is safer because it eliminates problems with handwriting legibility and, when combined with decision-support tools can automatically alert providers to possible allergies, interactions and other potential problems (IOM, 2006).

In parallel accord, Halvorson et al. states the solution to medication safety issue is electronic. An automated, computerized, all-inclusive electronic medical record that includes medical best practice protocols, interactive programming, patient-friendly explanations, clear communications, and standardized, automatic reminder systems is a critical element to reduce medication errors (Halvorson et al., 2003).

Converting healthcare systems from paper to electronic medical records is more feasible in recent years due to high speed internet connections, increasing capabilities of computers, and increasing use of mobile devices. Given the widely dispersed nature of primary care services, the Internet can now play a critical role in this transformation. High-speed connections from physician offices can provide web-based clinical tools. The speed and power of readily available computers are increasing and their costs decreasing. Computers and software are evolving rapidly, so mobile devices can be easily linked to wireless medical networks. Handheld computers can be useful sources of drug guidelines and other information and in the near future will likely help to extend desktop networks (Miller et al., 2004).

Medication Error Solutions

EMR: An EMR encompasses a “longitudinal collection of electronic health information for and about persons, immediate electronic access to person- and population-level information by authorized users, provision of knowledge and decision-support systems that enhance the quality, safety, and efficiency of patient care and support for efficient processes for health care delivery” (IOM, 2004). EMRs have the ability to provide instant access to critical patient information, automatic access to best-care practices and current science through embedded protocols and tutorials, tracking data and automatic reminders for follow-up care, automatic tracking of care and measuring of results to know what works and to build quality and efficiency improvements on that knowledge (IOM, 2006).

CPOE: CPOE is a tool available in an EMR where providers can electronically enter instructions for the treatment of patients under his or her care. These orders are communicated over a computer network to the medical staff (nurses, therapists or other physicians) or to the departments (pharmacy, laboratory or radiology) responsible for fulfilling the order (Ash et al., 2004a). Orders are not lost, legible, and immediately available to ancillary groups such as the pharmacy. CPOE has been promoted by groups such as Leapfrog, the Joint Commission on Accreditation of Healthcare Organizations, and the IOM as a mechanism to realize the objective of improving patient care quality, lowering health care costs, and reducing clinical errors (Mekhjian et al., 2002).

CDSS: Clinician Decision Support Systems are utilized within CPOE and serve several purposes. CDSS allows real-time patient identification, checks on allergies and treatment conflicts, drug dose recommendations, and reviews of ADEs. A critical function of CDSS is the automated application of medications being checked against patient allergies for potential inappropriate prescribing. Physicians and nurses can review orders immediately for confirmation (Ash et al., 2004a).

Drug Allergy Alert: A drug allergy alert warns providers when the patient has had a prior reaction, whether an allergy or a sensitivity, to a medication recorded in the EMR. An allergy is defined as a hypersensitive reaction to medications by the body's immune system. The immune system mistakes medication as harmful and creates antibodies to fight it. Allergy symptoms develop when the antibodies are battling the "invading" medication. An allergic reaction can also arise from antibodies that been created to combat earlier medications. A sensitivity is a drug reaction that is non-immune-mediated. Sensitivities (e.g., may lead to nausea or diarrhea) are less severe than allergies

(e.g., chest pain, anaphylaxis, death) (Bonds et al, 1999). In CPOE applications that maintain patients' medication and allergy lists (e.g., KP HealthConnect), ordered drugs can be checked against the patient's allergy list, and decision support can generate alerts that warn the physician of a possible allergy to the ordered drug. Physicians can either accept or override these alerts. Overriding alerts occurs when, for example, a patient has already shown tolerance to the medication or if the alert is inappropriate.

PIMS: EMRs are repositories of patient data either entered directly or interfaced from external applications. One such application is a Pharmacy Information Management System (PIMS) that is typically used by pharmacy departments to record activity. Typical PIMS modules include script registration, dispensing, clinical decision support including interaction checking, inventory control, and management reporting. EMRs typically integrate with PIMS by creating and storing script details and current medications in the EMR then sending them via HL7 to PIMS, and by storing dispensed medication and drug administration details in the EMR (Bond et al., 1999).

Potential benefits of solutions

Although the full range of EMR benefits will not become clear until more systems are implemented and more processes computerized, EMR systems can improve efficiency and quality. The EMR is available 24 hours daily, 7 days a week; can be viewed by more than one user at a time; is available from remote locations; can nearly always be found; and is legible. A covering physician can rapidly get a sense of a patient's problems by quickly reviewing those problems, medications, and recent notes in the EMR (**Figure 3**).

Figure 3: Snapshot of EMR*

REMINDERS

- Patient is overdue for Mammogram (rec q 1 year).
- Patient is overdue for Optho exam (rec q 1 year).
- Patient is overdue for Cholesterol test (rec q 1 year).
- Diabetic not on ACE-Inhibitor overdue for urine protein measurement (rec: q 1 year).
- Elevated HbA1C (10.4). Suggest nursing education visit.
- Patient is on famotidine. Cimetidine and ranitidine are lower cost alternatives.
- Current smoker. Suggest counseling.

<u>Medications</u>	<u>Problems</u>	<u>Health Maintenance Items</u>	<u>Allergies</u>
Beconase 2 puff na BID	AODM	Mammogram - 12/17/96: See report	Penicillins: Anaphylaxis
Albuterol 2 puff inh QID	Asthma	Breast Exam	
Atrovent 2 puff inh QID	PAF	Pap smear - 01/06/97: Primary dx: no malignant cells	
Azmacort 8 puff inh BID	Obesity	Cholesterol - 03/13/98: 192	
Metformin 500 mg po TID	Tobacco Use	Stool guaiac	
Glyburide 10 mg po BID	Vocal Cord Polyp	Flu shot - 01/21/99	
Flexeril 10 mg po PRN	Lumbar Disc Disease	Pneumovax - 10/12/95	
Verapamil 80 mg po QD	Right Breast Cyst	HgA1C - 01/21/99: 10.4*	
		Podiatry Exam - 11/06/97: Smith.	

Bates et al. (2003b). J Am Med Inform Assoc. 2003 Jan–Feb; 10(1): 1–10

*Snapshot for a typical patient. When a primary care provider sees a patient, the EMR typically provides a snapshot of key information, including but not limited to the patient's demographics, problem list, medications, and health maintenance information. These and other data can be used to generate a set of reminders, which improve the likelihood that a patient will actually receive needed care. Without such decision support, it is extremely hard to rapidly determine what actions are due.

Even more than improving efficiency, quality may be the greatest benefit of computerization. The current volume of clinical data required for practice is difficult for providers to retain given the broad scope of primary care (Miller et al., 2004). As information becomes obsolete, it is not refreshed, and new knowledge cannot be integrated. Thus, physicians take “short cuts,” using clinical experience and heuristics

rather than pursuing organized investigations (Bates et al., 2003b). Therefore, computerization of alerts, reminders, and prevention guidelines benefits patients.

Computerization of medication prescribing improves safety; in one study of inpatients, the medication error rate was reduced by more than 80% (Bates et al., 1999a). Communication between patients and providers represents a particular problem in outpatient care (Gandhi et al., 1998) and computerization may be helpful in this domain. Another quality improvement benefit of computerized prescribing comes from the monitoring and tracking of ADEs, abnormal laboratory results, and ensuring that appropriate patient follow-up occurs. Moreover, EMRs can be linked with public health surveillance, which may be extremely important in emergencies such as a bioterrorism attack or an epidemic (Kuperman et al., 2003). EMRs have important benefits for specialty care as well. For example, poor communication plagues the current referral process (Feldstein et al., 2005) and could be ameliorated through computerization. Poorly coordinated care can lead to ADEs, unnecessary tests and treatments, and higher costs.

Legislation

The 2001 IOM report called for major federal investment in information technology as crucial to achieving necessary changes, such as “elimination of most handwritten clinical data by the end of the decade.” Better use of information technology is essential to providing better care at lower cost (IOM, 2001).

The President, by Executive Order, established the position of National Coordinator for Health Information Technology (HIT). The National Coordinator for HIT is the chief advisor to the Secretary of Health and Human Services (Mike Leavitt) to lead

the actions needed to meet the President's call for widespread availability of secure, interoperable health IT. In November 2004, the National Coordinator issued a request for information to gather public input on the development of a Nationwide Health Information Network (NHIN). In analyzing the more than 500 responses in early 2005, the Office of the National Coordinators for Health IT (ONC) found that a lack of uniform standard was a key obstacle to the success of a NHIN (HHS, 2007).

In 2005, Secretary Leavitt announced the formation of the American Health Information Community (AHIC), a federal advisory committee made up of public and private sector leaders who represent a broad spectrum of healthcare stakeholders. The AHIC was established to make recommendations to the Secretary on how to accelerate adoption of interoperable electronic health IT in a smooth, market-led way (HHS, 2007).

Also in 2005, the ONC awarded nine contracts to conduct work in several key areas of the health IT initiative. Included in these contracts are the Health Information Technology Standards Panel, Certification Commission for Healthcare Information Technology, Anti-Fraud for Electronic Health Records, NHIN, Adoption of Electronic Health Records, and Clinical Decision Support (HHS, 2007).

The Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41) was signed into law by President Bush on July 29, 2005. It encourages healthcare providers to promote a "culture of safety" through their voluntary submission of medical errors data. The data would be used for educational and research initiatives and analyses supported by the Agency for Healthcare Research and Quality (AHRQ). The law promotes voluntary provider participation by creating a network of HHS-certified

"patient safety organizations" (PSOs) that would collect and evaluate medical errors data (P.L. 109-41, Patient Safety and Quality Improvement Act of 2005).

In 2006, AHIC delivered its first set of recommendations to Secretary Leavitt. EMRs were included in the recommendations as a work group area that the Secretary officially accepted. AHIC recommends creating standardized, secure records of past and current laboratory test results that is accessible by health professionals. He also accepted the AHIC's recommendation for federal healthcare delivery systems, which provide direct patient care, to develop an adoption plan to integrate the interoperability standards into their software systems by December, 2007. The President issued another Executive Order in 2006 committing federal departments and agencies that purchase and deliver health care to require the use of health IT that is based on interoperability standards recognized by the Secretary of HHS (HHS, 2007).

Four prototype architectures for a NHIN were delivered in January, 2007. These prototypes were developed with functional requirements and security and business models for health information exchange. Also in 2007, the AHIC formed workgroups (The Confidentiality, Privacy and Security Workgroup, The Quality Workgroup, The Personalized Health Care Workgroup) to make recommendations to the Secretary (HHS, 2007).

In June 2007, JCAHO announced the 2008 National Patient Safety Goals and related requirements for each of its accreditation programs. The goals and requirements, recently approved by the Joint Commission's Board of Commissioners, apply to the nearly 15,000 Joint Commission-accredited and certified health care organizations and programs, including Kaiser Permanente (JCAHO, 2007).

Major changes in this sixth annual issuance of National Patient Safety Goals include a new requirement to take specific actions to reduce the risks of patient harm associated with the use of anticoagulant therapy (the use of certain drugs to prevent formation of harmful blood clots). The new anticoagulant therapy requirement addresses the widely-acknowledged patient safety problem and becomes a key element of the goal: Improve the safety of using medications. It is applicable to hospitals, critical access hospitals, ambulatory care and office-based surgery settings, and home care and long term care organizations. The foregoing new requirements have a one-year phase-in period that includes defined milestones. Full implementation is targeted for January 2009 (JCAHO, 2007).

Evaluation of solutions

EMRs, CPOE, CDSS, and PIMS are integral components to make the medication safety strategy a realization (Bates et al., 1998; Raschke et al., 1998). EMRs have been shown to integrate data, save time, increase compliance, reduce medical errors, and improve the quality of health care delivery (Bates et al 1998; 1999; Evans et al 1998).

Several EMR systems are available in the healthcare market (**Table 2**). To gauge the extent of health IT use among U.S. hospitals and to better understand the barriers to further adoption, the American Hospital Association (AHA) surveyed hospitals in fall 2006. More than 1,500 community hospitals- about 31 percent of all U.S. community hospitals- responded to the survey. Over two-thirds of hospitals (68 percent) had either fully or partially implemented EMRs in 2006. Hospitals reported dramatic increases in the use of computerized alerts to prevent negative drug interactions. In 2006, 51 percent

of hospitals were using real-time drug interaction alerts, up from 23 percent in 2005 (AHA, 2007).

Table 2: Twenty-six Outpatient EMR Systems

Charting Plus	NextGen
ChartWare	O-HEAP
Clinical Works Module (ASP)	Partner
ComChart	PEARL
DOCU*MENTOR Dossier	Physician Practice Solution
Dr. Notes Program	Physician Practice Solution (ASP)
ENTITY	PowerMed EMR
EpicCare	Practice Partner Patient Records
HealthMatics	QDClinical
Health Probe Patient Information Manager	SOAPware
Logician	TopsChart (ASP)
Logician Internet (ASP)	VersaForm CPR
MedicWare EMR	Welford Chart Notes

Bates, DW et al. (2003b). A Proposal for Electronic Medical Records in U.S. Primary Care. J Am Med Inform Assoc, 10(1), 1-10.

The estimated net benefit from using an EMR for a 5-year period was \$86,400 per provider. Benefits accrue primarily from savings in drug expenditures, improved utilization of radiology tests, better capture of charges, and decreased billing errors (Wang et al, 2003). Even though U.S. medical care is the world's most costly, its outcomes are mediocre compared with other industrialized nations. The World Health Organization (WHO) report ranking the world's health systems placed the United States 37th in 2000 (WHO, 2000).

Both Australia and England have implemented highly successful national programs to promote the use of EMRs in primary care (Kidd et al., 2000; Purves et al., 1999). Other countries, including New Zealand and the Netherlands, have also achieved substantial success (Thakurdas et al., 1996).

In terms of speed, Australia's results have been most dramatic. In May 2000, 70 percent of primary care practices stated that the majority of their physicians were using a computer in their examination rooms to order most of their prescriptions, compared with only 15 percent of primary care providers reporting computer use for any purpose in October 1997. Australia achieved this transition by providing primary care providers with financial support to help purchase a computer, supporting system implementation for those who needed it, and offering incentives for providers to submit claims electronically (Kidd et al., 2000).

England has made greater progress, albeit more slowly. Ninety-eight percent of primary care providers have access to an EMR on their desktop. Nearly all use it for prescription refills, and 30 percent report that their practices are paperless. Only three vendors supply these EMR systems and accreditation is required for the sale of systems. An application called Prodigy interacts with these applications and provides evidence-based decision support (Purves et al., 1999).

Each of these countries made a national investment in a coordinating group to develop a strategic framework and identify standards. Development of the actual EMRs has been carried out by private vendors, who have benefited from having a common set of goals and standards. In addition, each country developed incentives for providers to make the transition from paper to electronic records.

Many effective error prevention strategies are available, especially for hospital care. In the hospital setting, there is evidence for the effectiveness of computerized order entry with clinical decision-support systems (Bates et al., 1998), for clinical decision-support systems themselves (Evans et al., 1998), and for pharmacist participation on

hospital rounds (Leape et al., 1999). Involving pharmacists in the management of medications in nursing homes and ambulatory care also shows promise (IOM, 2006), but requires additional study.

While computerized prescribing applications are commercially available, these systems may not be as effective for improving safety if providers override clinically important alerts. Recent findings show that CPOE used in conjunction with basic CDSS, such as drug allergy alerts decreases the likelihood of serious medication errors (Bond et al., 2001). CPOE has been shown to be an effective technique for reducing potential medication errors. Two studies found that CPOE reduced medication errors from by 55 percent and 81 percent in an inpatient setting (Bates et al., 1998; 1999). In 1998, Bates et al. studied a large tertiary care hospital, comparing a baseline to after a CPOE implementation. The study found that serious medication errors decreased 55 percent, from 10.7 events per 1000 patient-days to 4.86 events per 1000 ($P=.01$) (Bates et al., 1998). In 1999, Bates et al. studied three medical units for seven to ten-week periods in four different years. The study found medication error rate fell 81 percent, from 142 per 1,000 patient-days in the baseline period to 26.6 per 1,000 patient-days in the final period ($P < 0.0001$) (Bates et al., 1999).

A common issue that comes along with implementing CDSS and drug allergy alerting is overrides. Drug allergy alerts can provide substantial aid to providers when given at the appropriate time and displaying an accurate alert message. These alerts can modify ordering behavior especially when presented at key times such as when physicians are writing orders (Bates et al., 1998, Bates et al., 1999, Overhage et al., 1997).

However, drug alert overriding is a common phenomenon. Overriding alerts occurs when, for example, a patient has already shown tolerance to the medication or if the alert is inappropriate.

A study reviewing the literature on physician response to drug alerts found drug alerts are overridden in 49% to 96% of cases (van de Sijs et al., 2006). Low-level (non-critical) alerts appear to be overridden more often than high-level alerts (serious alerts), but this could not be completely confirmed in a study with three severity levels of alerts (Abookire et al., 2000). However, alert levels can not be compared between studies because standardization of alert levels is absent. None of these quantitative studies discusses the relationship between different levels of alerts and override rates.

These studies illustrate that drug allergy overrides have become increasingly widespread. However, several factors give rise to the explanation of the high rates of overriding: incomplete or inaccurate clinical data, lack of standardization, alert fatigue, and unclear alerts.

Data shows that currently there is a great deal of missing information in primary care settings (Smith et al., 2005). Incomplete and inaccurate clinical information may lead to redundant or conflicting alerts, and subsequent drug allergy alert overrides. Besides human error (e.g., the admitting provider not entering any or the correct drug allergy information), a patient's complete drug use and allergy profiles may be incomplete due to discontinuous enrollment of members or patient confidentiality protections. When health plan members disenroll, their prescription drug and medical claims history may not be transferred to the new health plan. Disenrollment in managed care plans can lead to precarious gaps in prescription drug claims and drug use history.

Patients with sensitive diseases (e.g., AIDS, behavioral health issues) may have confidentiality protections on their records that may restrict access to what is deemed ‘sensitive information’. These confidentiality protections may fragment pharmacy data from other relevant data required for an effective pharmacy system. This disintegration of pharmacy claims data raises the possibility of potentially preventable adverse outcomes (Fulda et al., 2004).

Maintaining accurate allergy lists can be difficult because there may not be clear distinctions between allergies and sensitivities, and there is no general consensus on whether both should be included in allergy lists. In addition, neither the specificity of alerting algorithms nor the relative effectiveness of different methods of alerting (e.g., alerts that interrupt workflow vs. those that display information, but do not interrupt) has been elucidated fully. Hsieh et al. cited the reason for increased override rates was highly inclusive drug-class and drug cross-reactivity mapping, which generates a large number of allergy alerts for drugs with only slight potential to cause an allergic reaction. Hsieh et al. suggests a drug allergy checking process with more rigorous constructs which that concentrate on the difference between high potential for an allergic reaction versus only a slight potential is needed. Policies requiring physicians to renew certain drugs for the same patient multiple times, causing many redundant alerts to be generated, were also cited (Hsieh et al., 2004).

The most common reason for overriding was alert fatigue. Alert fatigue is caused when providers believe that an alert is not serious, irrelevant, or shown repeatedly (Magnus et al., 2002; Feldstein et al., 2004). Alert fatigue has not been thoroughly studied, but is described as the mental state that is the result of too many alerts

consuming time and mental energy. Alert fatigue can cause important alerts to be ignored along with clinically unimportant ones (Peterson et al., 2001). Both inaccurate data and highly inclusive drug allergy reactivity lexicons can lead to superfluous alerts. Numerous alerts arising from trivial or false positives add to an already heavy workload. Receiving too many alerts can result in slowing the provider down rendering the alert ineffectual (Feldstein et al., 2004).

Alerts that are unclear, too extensive, complicated to interpret, and where medical consequences are not apparent are overridden frequently (Magnus et al., 2002, Feldstein et al., 2004). Twenty-two percent of general practitioners admitted to overriding drug alerts without checking the validity of the alert (Magnus et al., 2002). In a study on corollary orders, the rationale not to accept reminders included inappropriate orders, disagreement with the guidelines, and lack of time (Overhage et al., 1997). Lack of comprehension about significance of the warnings also hinders accurate and efficient management of drug alerts (Hsieh et al., 2004).

Weingart et al. assessed the appropriateness of alerts and uncovered that 39% of the alerts were false positives. Reviewers concurred with providers' decisions in 95.6% of cases where providers overrode a legitimate alert (Weingart et al., 2003). Oppenheim et al. conducted a study to determine the error frequency made by trainees for patients with renal impairment and the frequency of alerts to correct these orders to providers. Oppenheim et al. found that 48% of the true positive alerts were overridden by providers (Oppenheim et al., 2002).

Overriding drug allergy alerts may result in the direct effect of ADEs or the indirect effect of decreased user acceptance. The direct effect of overridden alerts on

safety is mentioned in three publications. Adverse events were observed in 2.3%, 2.5%, and 6% of the overridden alerts, respectively, in studies with override rates of 57%, 90%, and 80% (Peterson et al., 2001; Weingart et al., 2003; Hsieh et al., 2004). ADEs were preventable in 0.8% for the Weingart et al. study and none of the overrides for the Hsieh et al. study (Weingart et al., 2003; Hsieh et al., 2004).

Overriding drug allergy alerts may also indirectly weaken medication safety. Too many alerts with low credibility may cause physicians to override important alerts along with unimportant ones. Hospitals, in turn, have been shown to turn off an entire collection of alerts, including relevant ones which decrease user acceptance and trust in the alerting system (Payne et al., 2002; Magnus et al., 2002; Ash et al., 2004b).

One study found that errors and lost improvement opportunities result from the failure of clinical laboratory and pharmacy information systems to effectively communicate (Schiff et al., 2003) with one another. Evans et al. found ADE rates were reduced with the implementation of ADE surveillance, alerts to pharmacists about drug allergies, standardization of antibiotic administration rates, and physician notification about ADEs (Evans et al, 1998). Another study found that involving clinical pharmacists in reviewing drug orders significantly reduced the potential harm resulting from errant medication orders (Folli et al., 1987). Greater improvement in reducing medication errors is possible through implementation of CPOE with real time decision support incorporating linked laboratory and pharmacy data.

It should be noted that recent studies have identified implementation problems and the unintended occurrence of new types of errors with these computerized approaches (e.g., pharmacy inventory displays of available drug doses being mistaken for

the usual or minimally effective doses). Avoiding these problems requires addressing business and cultural issues before such strategies are implemented and aggressively solving technological problems during the implementation process. Regulatory issues must also be addressed for electronic transmission of prescriptions to be practical (IOM, 2006).

The following chapter will discuss the methodology and procedures of this research study to determine the impact of an EMR implementation on drug allergy overrides in an HMO setting.

CHAPTER III METHODS AND PROCEDURES

The purpose of this study was to evaluate the impact of an EMR system implementation on drug allergy overrides in a large Southeastern HMO outpatient setting. The overarching purpose of the study was to determine the impact of using computerized alerts to improve the prescribing of medications in the outpatient setting. The study focused on allergy interactions related to medication orders.

The research question being addressed for this study was: Is there a significant impact in the incidence of drug allergy overrides after an EMR implementation? The research hypothesis was: There is a decrease in the incidence rate of drug allergy overrides following the implementation of the EMR system. The null hypothesis (H_0) was: There is no significant difference in the incidence rate of drug allergy overrides when pre and post implementation periods are compared.

Research Design

A retrospective cross-sectional study was conducted to determine the impact of an EMR implementation on drug allergy overrides at KPGA. The impact of an EMR implementation on drug allergy overrides was measured by calculating an incidence rate of drug allergy overrides per 1,000 prescriptions. The incidence rate was assessed using the total number of drug allergy overrides and prescriptions filled. Comparing the rates of drug allergy overrides per 1,000 prescriptions pre and post intervention (defined in Study Setting) provided a measure of the efficacy of the EMR intervention.

The research variables included:

1. Total count of drug allergy overrides prior to the KP HealthConnect implementation,
2. Total count of drug allergy overrides following the KP HealthConnect implementation,
3. Total count of prescriptions prior to the KP HealthConnect implementation,
4. Total count of prescriptions following the KP HealthConnect implementation,
5. Incidence of drug allergy overrides per 1000 prescriptions prior to KP HealthConnect, implementation and,
6. Incidence of drug allergy overrides per 1000 visits following the KP HealthConnect implementation.

The comparative incidence rates were calculated by dividing the total number of drug allergy overrides by the total number of prescriptions filled. This calculation garnered an incidence rate for both the pre and post implementation periods in the format of drug allergy overrides per 1,000 prescriptions.

For the purposes of this research study, “prescription” was defined as a written medical order by a provider to a pharmacist for treatment to be provided to the patient. “Total prescriptions” was defined as total prescriptions that were filled within the KPGA Pharmacy department within either the pre or post implementation period (not including prescription refills). The same definition of total prescription was used for both the pre and post periods.

A “drug allergy override” was defined as a provider’s or pharmacist’s action to override a drug allergy alert. In this research study, provider drug allergy overrides (from KP HealthConnect) were not available, therefore only pharmacist drug allergy override data was accessible and utilized (from PIMS). Drug allergy overrides are discussed in

further detail in Chapter IV. The definitional rules of what constituted an override were confirmed as identical for the pre and post implementation in discussions with the KPGA Pharmacy Drug Informatics Specialist.

A Z-test was used to calculate the significance of the pre and post implementation incidence rates. The pre and post implementation incidence rates were independent proportions. The Z-test compared the significance of the difference between the two independent proportions to find if the difference between the two proportions was large enough to be statistically significant. The Z-test calculation was as follows:

$$z_1 = \frac{\hat{p}_1 - \hat{p}_2}{\sqrt{\frac{\hat{p}_1(1-\hat{p}_1)}{n_1} + \frac{\hat{p}_2(1-\hat{p}_2)}{n_2}}}$$

where proportions \hat{p}_1 and \hat{p}_2 were the incidence rates for the pre and post implementation periods, respectively and n_1 and n_2 were the total prescriptions for the pre and post implementation periods, respectively. A confidence level of 95% ($\alpha = .05$) and a two-tail probability were used for this study. The confidence interval (CI) was calculated using the following formula for the 95% significance level:

$$(\hat{p}_1 - \hat{p}_2) \pm 1.96 \sqrt{\frac{\hat{p}_1(1-\hat{p}_1)}{n_1} + \frac{\hat{p}_2(1-\hat{p}_2)}{n_2}}$$

The null hypothesis (H_0) can only be rejected at level α if and only if the $100(1-\alpha)\%$ confidence interval does not contain 0.

The data used in this research qualified as a de-identified data set. None of the 18 HIPAA Privacy Rule identifiers were included. The study used secondary data collection to create a de-identified data set, which used the total amount of both drug allergy alerts and prescriptions. Using total amounts for analysis purposes limited any risk for patient

identification. There were not any physical, psychological, social, or legal risks to participants during the course of this research study. This study was approved by the Institutional Review Boards at Kaiser Permanente of Georgia and Georgia State University.

The setting for the study and data collection methods undertaken at KPGA is discussed in the remainder of this chapter.

Study Setting

Kaiser Permanente (KP) is a national nonprofit multi-specialty HMO that provides care to 8.4 million members in nine states and the District of Columbia. KP is accredited by the National Committee for Quality Assurance (NCQA), which has been recognized as the gold standard in accreditation (NCQA, 2005).

Kaiser Permanente of Georgia (KPGA) owns and operates twelve medical facilities throughout the 21-county Atlanta area, serving more than a quarter of a million members. The research data utilized in this study was included data from all twelve medical facilities.

A retrospective cross-sectional study was conducted using pre and post periods for the KP HealthConnect implementation. Twelve facilities which implemented KP HealthConnect in their primary care departments did so over a six month period (**Table 3**). The TownPark office was the first facility to implement the system June 2005. The Forsyth, Brookwood, and Alpharetta offices were the final facilities to implement the system in December 2005.

Table 3: Facility Timeline (Pre, Implementation, and Post)

FACILITY	PRE PERIOD START*	PRE PERIOD END	IMPLEMENTATION DATE**	POST PERIOD START***	POST PERIOD END
TownPark	12/1/2004	5/31/2005	6/26/2005	3/1/2006	8/31/2006
Southwood/ Southwood Specialty	12/1/2004	5/31/2005	8/7/2005	3/1/2006	8/31/2006
Panola	12/1/2004	5/31/2005	9/25/2005	3/1/2006	8/31/2006
Glenlake	12/1/2004	5/31/2005	9/25/2005	3/1/2006	8/31/2006
Henry	12/1/2004	5/31/2005	10/16/2005	3/1/2006	8/31/2006
Crescent	12/1/2004	5/31/2005	10/16/2005	3/1/2006	8/31/2006
Cascade	12/1/2004	5/31/2005	11/6/2005	3/1/2006	8/31/2006
Gwinnett	12/1/2004	5/31/2005	11/27/2005	3/1/2006	8/31/2006
Cumberland	12/1/2004	5/31/2005	11/27/2005	3/1/2006	8/31/2006
Forsyth	12/1/2004	5/31/2005	12/18/2005	3/1/2006	8/31/2006
Brookwood	12/1/2004	5/31/2005	12/18/2005	3/1/2006	8/31/2006
Alpharetta	12/1/2004	5/31/2005	12/18/2005	3/1/2006	8/31/2006

*The Pre Period includes the six months prior to the first facility's (TownPark) implementation of the KP HealthConnect system

**The Implementation date was the date that KP HealthConnect was implemented at that facility

***The Post Period includes the six months after the final facilities were implemented with KP HealthConnect. The six month post period begins after a two month period to account for the learning curve.

For the purposes of this research study, the pre implementation period was defined to be the six months prior to the first facility's implementation date (12/1/04 – 5/31/05). The actual implementation of KP HealthConnect for all primary care departments took place over the six months (6/1/05 – 12/31/05). The post implementation period was defined as six months following the final facility's implementation (3/1/06 – 8/31/06). The post implementation period began two months following the final facility's implementation date. Based on discussions with KPGA personnel, the decision was made to begin the post implementation period two months following the final facility's implementation to account for a learning curve of providers and staff.

KPGA specialty departments (e.g., OB/GYN, Podiatry, Behavioral Health, etc.) implemented KP HealthConnect in 2006. However, specialty department data was not available during the course of this research study. Therefore, for the purposes of this study, only primary care department data was utilized. Also, the total drug allergy overrides and the total prescriptions filled data was not facility specific; instead the data was only available as an aggregate number for the twelve facilities.

The target population included the total number of prescriptions and drug allergy overrides during the pre and post periods. Therefore, the inclusion criteria for this study were the total number of drug allergy overrides and the total number of prescriptions during the pre and the post implementation periods for all primary care departments. Exclusion criteria included the drug allergy overrides and prescriptions which fell outside of pre and post implementation periods.

Data Collection

The following procedures were used to collect data immediately described in the preceding paragraphs.

All data used in this study came from two databases, PIMS and a Paradox relational database, that were housed within KPGA. PIMS is a system that records all pharmacy related data (e.g., prescription orders, dispensing information, inventory control, clinical decision support information including drug allergy override data).

Prescription data was housed on a national repository server, along with all patient visit data, which was not available for the authors use. Therefore, a Paradox

relational database housed at KPGA was created for the purposes of this study by a KPGA data technician, containing only pre and post prescription implementation data.

Drug allergy override data was housed in the PIMS. Data used in this study was abstracted by the KPGA Pharmacy Drug Informatics Specialist, based on the following two criteria:

1. Drug allergy overrides that occurred within the pre and post implementation date parameters
2. Drug allergy overrides that occurred within the primary care departments of the 12 KPGA facilities

For the purposes of this study, drug allergy data was available in the format of two text files, one for pre and post implementation date parameters. The text files were then converted into two de-identified Access databases by a KPGA data technician. Included in the de-identified Access files were two fields: a generic label of “Per Pharmacist ID” and “Drug Allergy Overrides”. The actual pharmacist ID was not included in the Access file, only the number of drug allergy overrides per day. The “Drug Allergy Overrides” field was the count of drug allergy alerts per day. Each line of the pre and post Access files were defined as the number of drug allergy overrides per pharmacist ID per day. To obtain the total amount of drug allergy overrides, two queries were run on both the pre and post implementation files. The total number of drug allergy overrides that met the criteria from PIMS was 41,411 records, pre and post implementation.

Prescription data was housed in a stand-alone internal Paradox relational database created for the purposes of this study. Data used in this study were abstracted by the KPGA data technician, based on the following two criteria:

1. Total prescriptions filled within the pre and post implementation date parameters.
2. Total prescriptions prescribed through primary care departments and filled at KPGA facility pharmacies.

For the purposes of this research study, a de-identified data set was created in two Paradox relational databases including only drug prescriptions filled within the pre and post implementation date parameters. Included in the de-identified Paradox database was the “Presc_Fill_Com” field, which was created by the KPGA data technician to capture the number of prescriptions per patient per day. Patient names or HRNs were not included, only the number of prescriptions per patient per day. To obtain the total number of prescriptions filled at KPGA pharmacies during the pre and post implementation period, two queries were run on both the pre and post implementation databases. The total number of prescriptions filled pre and post implementation that met the criteria from the Paradox relational database was 2.07 million.

Incidence rates were calculated by dividing the total number of drug allergy overrides by the total number of prescriptions filled. This calculation garnered an incidence rate for both the pre and post implementation periods in the format of drug allergy overrides per 1,000 prescriptions. The incidence rates were then compared between the pre and post implementation periods to measure the impact of the EMR implementation. If the incidence rate was higher for pre period verses the post period, then the EMR implementation on drug allergy overrides would be considered a positive impact. If the incidence rate was lower for the pre period verses the post period, then the EMR implementation on drug allergy overrides would be considered a negative impact.

The significance of the difference between the two incidence rates was established using a Z-test. Microsoft Excel was used to calculate the Z-test formula and the Confidence Interval at the 95% significance level (see Chapter III, Research Design).

All data files were available only on the I drive (KP employees accessible only), de-identified, and password protected. Only the investigators had access to the password. Recognizing the policy against using any media to copy sensitive PHI for use outside of Kaiser Permanente grounds, data analysis and research was conducted on a KP workstation.

The following chapter reports the findings of this research study using the methodology and procedures detailed above.

CHAPTER IV RESULTS

This chapter will detail the KPGA drug allergy override workflow pre and post KP HealthConnect implementation, followed by the final results garnered from this research study.

Pre Implementation Workflow

Prior to the KP HealthConnect implementation, drug allergy overrides were only managed by the clinical pharmacists when prescriptions were manually ordered by providers on paper medical records. PIMS was implemented prior to KP HealthConnect and was used to capture all medication orders by manual data entry.

For example, a provider ordered a medication for a patient manually and misses a drug allergy contraindication with the ordered prescription. The prescription would be manually entered into PIMS. The pharmacist would receive a drug allergy alert for the patient's medication order in PIMS, but an action would be required to fill the prescription. The pharmacist had three options: cancel the order, choose another option to fill the prescription, or override the drug allergy alert and continue with the original order. The pharmacist may contact the provider to decide to cancel or change the order and then the pharmacist may make the appropriate changes to the medication order. If the provider and pharmacist decide to override the drug allergy, an override reason, which is typed in a free text field, would be required to continue with the order.

Except override reasons, the remainder of the drug allergy override data (e.g., patient data, provider and pharmacist ID, medication ordered) would be recorded within

PIMS. Thus, drug allergy override reasons were not obtainable for analysis within this study. A total of the de-identified drug allergy overrides was available to be used during the course of this study.

Drug renewals were not included in the data utilized for this study. The study did not have access to complete prescription data. Eight percent of prescriptions were filled outside of KPGA pharmacies and these were not included as in the total prescriptions filled.

Post Implementation Workflow

Once KP HealthConnect implemented its computer based order entry system (CPOE), providers had a decision support system (CDSS) to aid in the detection of drug allergy contraindicated prescriptions. In this post period, the patient's medication order was reviewed by two systems (CPOE and PIMS) compared to the one system (PIMS) in the pre period.

The CPOE tool provided clinical-decision support to providers by means of alerts driven by CDSS. CDSS relied on multiple sources of routinely collected data such as patient demographic characteristics, medical problem lists, previous diagnoses, vital signs, active inpatient orders, previous pharmacy records, and coded radiology results. Every patient must have drug allergies entered by the admitting providers in order entry; this entry was coded into an allergy table. The allergy table contained the drug ingredients, which are activated as possible allergens. For a drug-allergy checking system to function, patient allergy data must have been stored prior to medication ordering. The important attributes of a patient allergy record were the medication or ingredient to which

the patient is allergic, as well as the reaction that the patient experiences when exposed to the allergen (e.g., rash, nausea, anaphylaxis, etc.). **Figure 4** shows an example of an allergy documentation screen.

Figure 4: Allergy documentation screenshot

Clinical Application Suite (4.3.29) Tuesday Feb 26, 2002 5:23 PM You are logged in as: Gilad Joseph Kuperman, M.D., P... Pt Details

Select pt TEST, TEST MGH 3651718 3y M UNKNOWN, PHYSICIAN BLUE CHOICE NE- MGH PCP

Status	Allergy	Entry Date
Active; Pend	*Allergy to: Ragweed Reaction: Rash	02/26/02 12:37 PM
Active; Pend	Allergy to: Demerol Reaction: Irritability	02/26/02 12:37 PM
Active; Pend	Allergy to: Morphine Reaction: Rash	02/26/02 12:37 PM
Active; Pend	Allergy to: Sulfa Reaction: Irritability	02/26/02 12:37 PM
Active; Pend	Allergy to: Erythromycins Reaction: Hypotension	02/26/02 12:37 PM

Allergen: Aspirin
Bactrim
Cephalosporins
Codeine
Demerol
Erythromycins
IV Contrast
Morphine
NSAID's
Penicillins
Sulfa
Tetracyclines
G6PD Deficiency
Other

Reaction: Anaphylaxis
Angiodema
Dystonia
GI upset
Heme Positive Stools
Hives
Hypotension
Irritability
Itching
Mental Status Change
Rash
SOB

Drugs Foods Environmentals

Select an Allergen and a Reaction, then press OK.

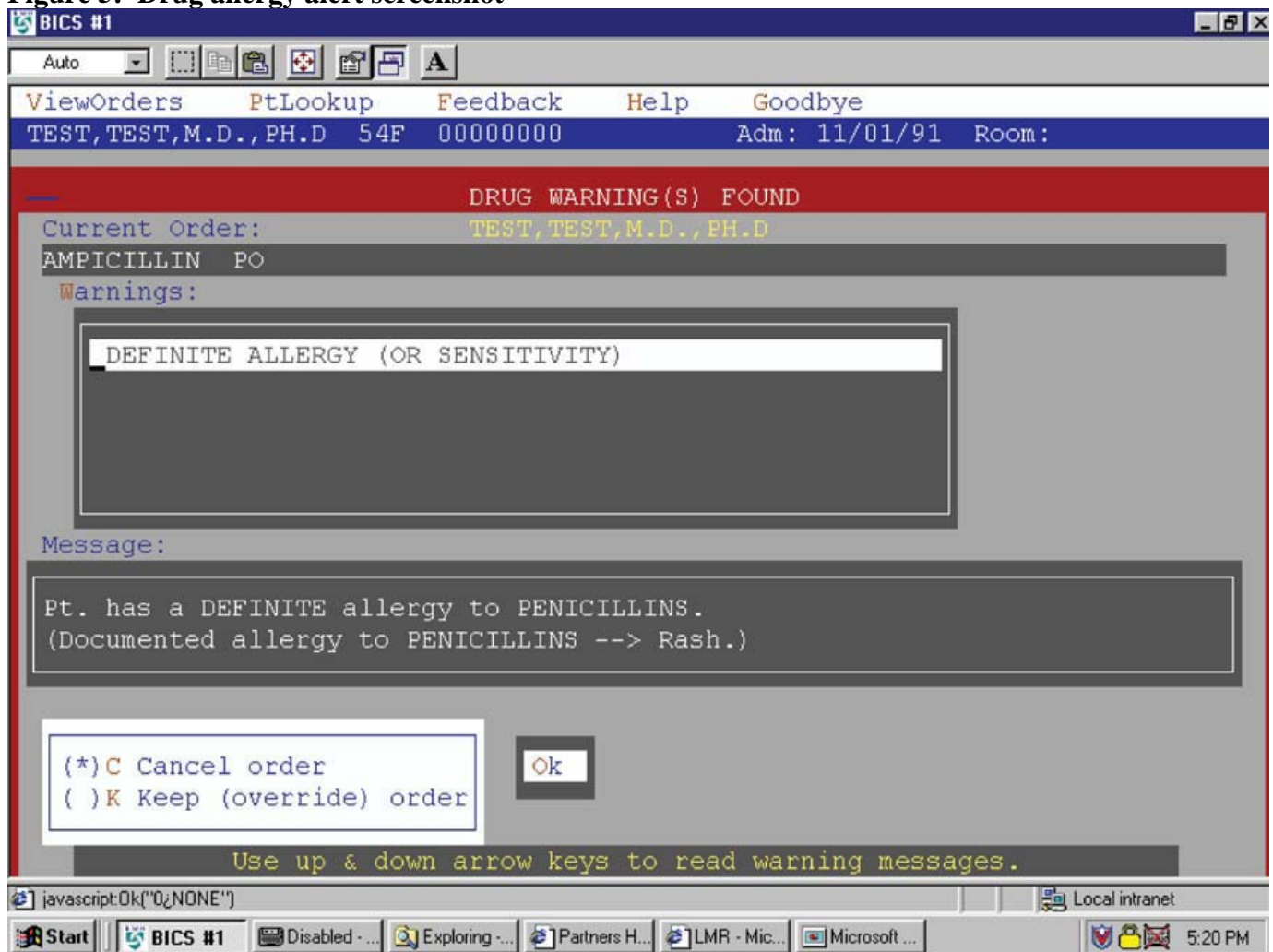
OK Cancel

Kuperman GJ et al. (2003). *Effective drug-allergy checking: methodological and operational issues*. *J Bio Inform*(36), 70-79.

Every subsequent medication ordered during the admission is crosschecked against the allergen tables for potential allergy. Allergies are best represented as

ingredients. Most medications contain only one active ingredient (e.g., penicillin) so documenting that the patient is allergic to the medication penicillin is the same as stating that the patient is allergic to the ingredient penicillin. Some medications contain more than one active ingredient (e.g., Bactrim contains trimethoprim and sulfmethoxazole). If the patient is stated to be allergic to “Bactrim,” many applications will represent that as an allergy to the ingredient sulfmethoxazole and an allergy to the ingredient trimethoprim (Morimoto et al., 2004). If there is a documented allergy to a specified medication and a medication with a known allergy is ordered, an alert is generated on the CPOE screen. An example of a drug-allergy alert screen is shown in **Figure 5**.

A drug-allergy alert screen displayed details of the alert (i.e., the drug being ordered, the drug to which the patient is allergic, and the patient’s documented reaction that occurred when the patient was exposed to this drug in the past) and offered two options: cancel the medication being ordered (i.e., “accept” the alert), or continue with the prescription despite the alert (i.e., keep the medication, or “override” the alert). Figure 5 displays a drug-allergy interaction from the Brigham and Women’s Hospital CPOE application. However, KP HealthConnect has a third option available to change the order included in the CPOE application.

Figure 5: Drug allergy alert screenshot*

Kaushal et al. (2003). Effects of Computerized Physician Order Entry and Clinical Decision Support Systems on Medication Safety: A Systematic Review. *Arch Intern Med*, 163(12), 1409-1416.

*The patient has a documented allergy to “penicillins” and the medication being ordered is ampicillin. If the physician chooses to “keep” the order, he will be presented with a free text field in which to enter the reason for the override.

If the provider decided to cancel the order, the prescription will not route to PIMS or become part of the patient’s EMR. If the provider decided to change the order, they can make the appropriate changes and only the altered prescription will route to PIMS (see **Figure 6**). If the provider decided to override the drug allergy alert, a reason must be typed in a free text field to continue with the order. The providers’ reasons for overriding allergy alerts were attached to medication orders so that pharmacists and nurses could

consider them when double-checking the orders for drug allergy interactions before dispensing and administration. Before the prescription was filled by the pharmacy, the order would still process through PIMS and the pharmacist would have the same options as detailed during the pre implementation period.

Figure 6: Alternative medication alert in CPOE screenshot *

The screenshot displays a CPOE interface with a patient record for 'KPNW, FIFTEEN' (DOB: 12/15/1937, Age: 65, Sex: M). The 'Prescriptions' section shows an allergy/intolerance for 'elderly'. A search for 'elderly' returns a list of matches, including 'ELDERLY/ANXIETY'. A 'Medication Alternatives' window is open, showing a table of alternatives for 'ELDERLY/ANXIETY'.

Medication	Sig	Quantity	Refill
LORAZEPAM 0.5MG TABS [10539]	1T PO B-TID PRN FOR 'ANXIETY'	30	1
LORAZEPAM 1MG TABS [6423]	1T PO B-TID PRN FOR 'ANXIETY'	30	1
OXAZEPAM 10MG CAPSULE [8540]	1C PO B-TID PRN FOR 'ANXIETY'	30	1
OXAZEPAM 15MG CAPSULE [8317]	1C PO B-TID PRN FOR 'ANXIETY'	30	1
PNL PAROXETINE 10MG TITRATION [***PANEL***]			
BUSPAR 5MG TABLET [4829]	1T PO B-TID	90	5
BUSPAR 10MG TABLET [5257]	1T PO B-TID	90	5

Feldstein et al., (2005). Decision Support System Design and Implementation for Outpatient Prescribing: The Safety in Prescribing Study. AHRQ Publication 050021, 1-4. 55

*Allergy documentation screen from Massachusetts General Hospital order entry application. Note coded pick lists of common allergies and reactions. Allergies not appearing on the list can be selected by choosing "other." A selector function appears that lets user select from a much larger coded list.

Data was not available on the provider's response to the CPOE drug allergy alerts (e.g., whether the provider cancelled, changed, or overrode the orders and override reasons). Thus, PIMS drug allergy override data was used as the numerator in the calculation of the comparative incidence rates for the pre and post implementation periods. Drug renewals were not included in the data utilized for this study. The study did not have access to complete prescription data. Eight percent of prescriptions were filled outside of KPGA pharmacies and these were not included as in the total prescriptions filled.

Findings

The review of the Paradox database (prescription data) from the pre implementation period revealed a total of 1,011,722 filled prescriptions. The review of the PIMS database (drug allergy override data) revealed that there were 19,652 instances of drug allergy overrides from the pre implementation period. The incidence rate for the pre implementation period was obtained by dividing the total number of drug allergy overrides by the total number of prescriptions filled. Therefore, the pre implementation period incidence rate was 19.42 drug allergy overrides per 1,000 prescriptions (**Table 4**).

The review of the Paradox database from the post implementation period revealed a total of 1,057,849 filled prescriptions. The review of the PIMS database revealed that there were 21,759 instances of drug allergy overrides for the post implementation period. Utilizing the same incidence rate calculation as above, the post implementation period incidence rate was 20.57 drug allergy overrides per 1,000 prescriptions.

TABLE 4: Pre and Post KP HealthConnect Implementation Data

	Pre Period	Post Period
Date Parameters	12/1/04-5/31/05	3/1/06-8/31/06
Total drug allergy overrides	19,652	21,759
Total prescriptions filled	1,011,722	1,057,849
Incidence rate of overrides per 1,000 prescriptions filled	19.42	20.57

As seen in Table 2 above, the incidence rate of drug allergy overrides per 1,000 filled prescriptions rose from 19.42 to 20.57, a percentage increase of 5.9% from the pre period to the post period. The amount of total drug allergy overrides following the KP HealthConnect implementation increased by 10.7%. The amount of total prescriptions filled following the KP HealthConnect implementation increased by 4.6%.

A Z-test was calculated in Microsoft Excel at the 95% significance level. The formula was as follows:

$$z_1 = \frac{\hat{p}_1 - \hat{p}_2}{\sqrt{\frac{\hat{p}_1(1-\hat{p}_1)}{n_1} + \frac{\hat{p}_2(1-\hat{p}_2)}{n_2}}},$$

where proportions \hat{p}_1 and \hat{p}_2 were the incidence rates for the pre and post implementation periods, respectively and n_1 and n_2 were the total prescriptions for the pre and post implementation periods, respectively. Therefore $\hat{p}_1 = 19.42$, $\hat{p}_2 = 20.6$, $n_1 = 1,011,722$, $n_2 = 1,057,849$. The Z-score is then -5.879, with a two-tailed probability of $p = 0.0002$. The 95% confidence interval formula was as follows:

$$(\hat{p}_1 - \hat{p}_2) \pm 1.96 \sqrt{\frac{\hat{p}_1(1-\hat{p}_1)}{n_1} + \frac{\hat{p}_2(1-\hat{p}_2)}{n_2}}$$

Using Microsoft Excel to calculate, the 95% confidence interval was found to be [-1.531, -0.767].

The 95% CI [-1.531, -0.767] does not contain zero. Therefore, there is sufficient evidence at the 95% confidence level ($p = 0.0002$) to reject the null hypothesis (H_0), which states that there is no significant difference between the incidence rate of drug allergy overrides when pre and post implementation periods are compared. Since the values included in the 95% CI are negative, the direction of the significant effect can be inferred as the pre period incidence rate being less than the post period incidence rate ($\hat{P}_1 < \hat{P}_2$).

The following chapter will discuss the findings described in the research study designed herein, provide recommendations, detail the study's limitations, discuss opportunities for further research, and conclude the study.

CHAPTER V DISCUSSION

The incidence rate of drug allergy overrides per 1,000 filled prescriptions rose by a statistically significant 5.9% ($p > 0.0002$; 95% CI [-1.53, -.77]) following the implementation of KP HealthConnect. The results are surprising. KPGA researchers expected a decrease in drug allergy overrides once the EMR was fully implemented. The negative values of the 95% CI signified the incidence rate increased post implementation, which was the contradictory of the research hypothesis stating the incidence rate of drug allergy alerts would decrease following the EMR implementation. Unfortunately, the experience at KPGA may not be comparable or translatable to other KP national facilities or non-KP HMO settings in Atlanta.

Other studies have found drug alert overriding to be a common phenomenon. One study showed an increase in override rates from about 50% to 75% during a five-year period at Brigham and Women's Hospital, indicating a declining compliance to safety alerts (Abookire et al., 2000). High override rates were observed in drug refills and in poorly defined drug allergies (Abookire et al., 2000; Payne et al., 2002; Weingart et al., 2003; Hsieh et al., 2004). Another recent study found a 69% override drug allergy rate and an 88% override rate for drug-drug interaction alerts at the Veterans Administration Puget Sound Health Care System in Seattle, WA (Payne et al., 2002). Similarly, Weingart et al. found ambulatory providers at five primary care practices overrode 91% of drug-allergy alerts, and 89% of high-severity drug-drug interaction alerts (Weingart et al., 2003). Weingart et al. suggested that the threshold for alerting was set too low and that CPOE should suppress alerts for drug refills for medications that patients currently tolerate. Heish et al. found 80% drug allergy alerts were overridden in 1,150 patients.

Overrides of drug-allergy alerts were common and about 1 in 20 resulted in ADEs, but all of the overrides resulting in ADEs appeared clinically justifiable (Heish et al., 2004).

Although the research design of these studies differed from this current study, the results of all suggest that alert overriding was a frequent occurrence and the provider reasons behind overriding needed further research.

In other studies, decision support has improved care with some success (Bates et al., 1994; Bates et al., 1999a). Although the following two studies did not specifically measure drug allergy alert overrides, it is important to note that decision support has had an impact on medication errors and medication safety. Bates et al. (1994) a 55% decrease in non-intercepted serious medication errors ($p = .01$). As a secondary outcome, this study found a 17% decrease in the preventable ADE rate, which was not statistically significant ($p = .37$). Bates et al. (1999a) demonstrated an 81% decrease in medication errors and an 86% decrease in non-intercepted serious medication errors ($p < .001$ for both). This study found a decrease in the rate of ADEs per 1000 patient-days from 14.7 to 9.6 during the study ($p = .09$) and a decrease in the number of preventable ADEs from 5 to 2 ($p = .05$).

Possible reasons for increased incidence rate

It was not clear from the aggregate data of this study why the incidence rate of drug allergy overrides increased following implementation; however, there may be several reasons for the increase. The challenge of ensuring allergy alerts stemmed from a number of factors which may include inaccurate data, highly inclusive alert databases, and lack of monitoring of alerts and overrides.

Inaccurate data: First, KP HealthConnect, in its infancy, may not contain all the possible and available, relevant, and accurate patient information. For example, inpatient diagnoses, inpatient medications, and diagnoses from claims databases obtained from members who obtain a portion of their care in non-Kaiser Permanente facilities would be missed by a drug allergy alert within KP HealthConnect since there was not a system in place currently to enter these external data into the patients EMR. Human error including improper allergy data entry may trigger redundant, inappropriate, or conflicting drug allergy alerts, and subsequent overrides would ensue. Heish et al found that “Patient does not have this allergy/Tolerates” was a common reason given for overrides and accounted for nearly a third of drug allergy overrides (Heish et al.,2004). The high incidence of this override reason suggests that physicians may often be using the patient's self-report or other information at the time of visit to determine if a patient will tolerate the medication. Other contributing factors to the use of the override option may be the infrequent updating of patients' allergy lists, resulting in many patient records being out of date or inaccurate, and the numerous locations where allergies are documented in the chart, often with little agreement. Presenting clinicians with inaccurate alerts may erode their faith in the system and make it more likely for them to ignore subsequent alerts.

Highly inclusive alert databases: Highly inclusive drug-classes and cross sensitivity knowledge bases can generate a large number of alerts for drugs that only have a slight potential to trigger an allergic reaction, causing numerous but justified overrides. Abookire et al. and Weingart et al. both found that high override rates were partly attributed to alerting protocols that generated alerts as long as the ordered drug was in the same family as a drug on the patient's allergy list (Abookire et al., 2000; Weingart et al.,

2004). Hsieh et al. also found that the majority (90%) of overrides occurred when the two drugs belonged to the same family but were not identical (for example, codeine and hydromorphone) (Hsieh et al., 2004).

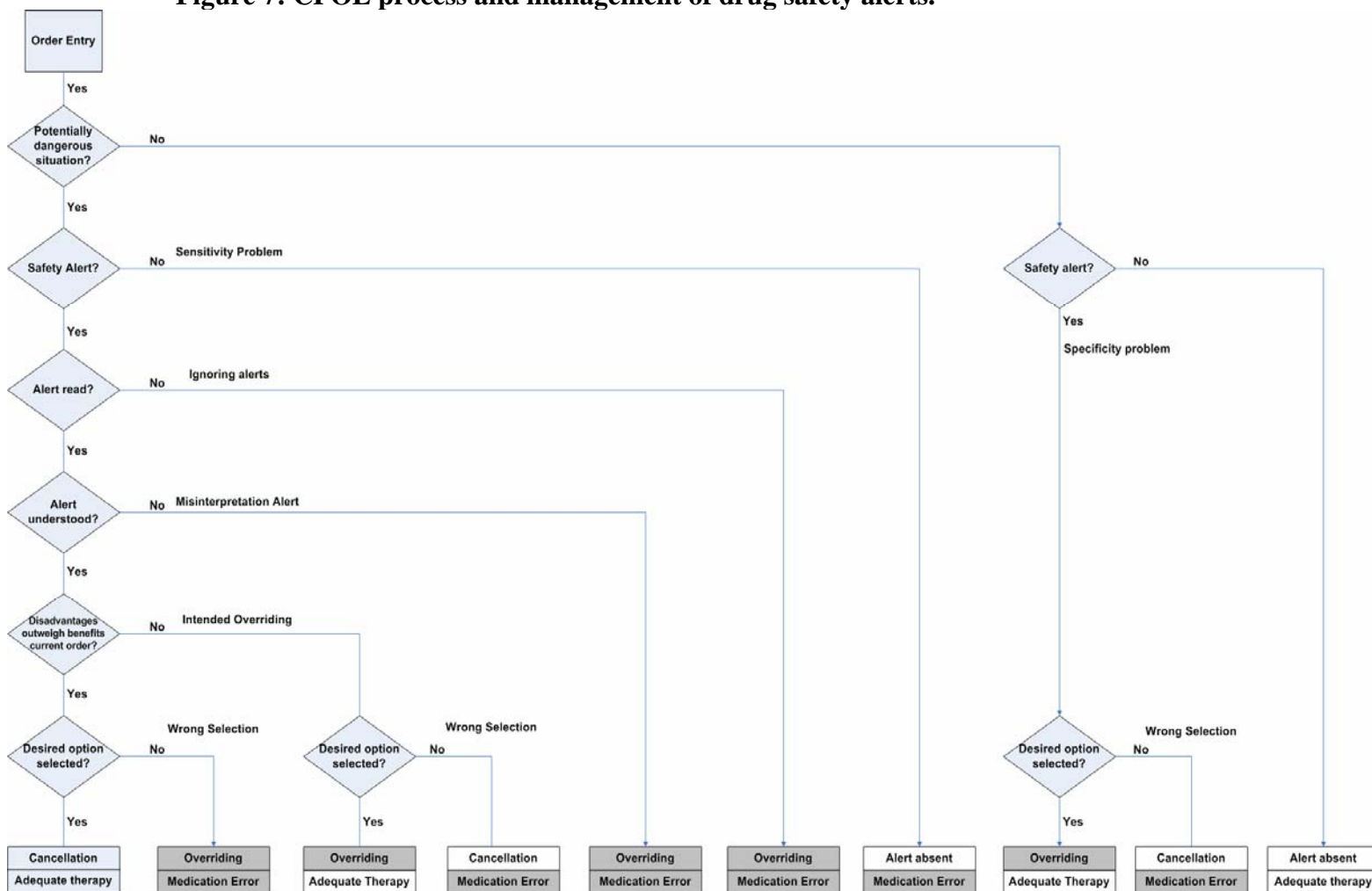
When the threshold for alerting was set too low, clinicians were inundated with alerts of low clinical significance, leading to alert fatigue, high override rates and the potential to override even important alerts. Weingart et al. found that providers were more likely to override alerts for renewals compared with new prescriptions (Weingart et al., 2003). However, renewals were not included in the data utilized for this study. In addition, alert fatigue (described in Chapter II) has been shown to be a critical factor in high override rates (Peterson et al., 2001, Magnus et al., 2002). Redundant, conflicting, seemingly unimportant drug allergy alerts can drain the provider's time and energy, and subsequently these alerts will be overridden and ignored. Unfortunately this may lead to ignoring critical alerts along with negligible ones.

In addition, there is no clear distinction between allergies and sensitivities. Allergies are body reactions which involve the entire immune system. Sensitivities are somewhat different body reactions which do not involve parts of the immune system. Allergies and sensitivities are very similar in their effects. Either or both can cause any symptom ranging from itches, rashes, and minor pains to more complex problems such as schizophrenia, depression, ADD/ADHD, obesity and arthritis. Therefore, the difference between allergies and sensitivities is unclear and sustaining a standardized allergy list becomes difficult. The balance of critical and superfluous alerts has yet to be standardized.

Lack of monitoring: There was a lack of continuous quality improvement system, since clinically appropriate and inappropriate overrides were not monitored. Drug allergy alerts and override reasons were not examined if decisions by providers and pharmacists were deemed appropriate. In the study by Weingart et al., physician reviewers judged one-third of generated alerts to be inappropriate (Weingart et al., 2003). Similarly, Heish et al. with drug-allergy alerts highlighted that the vast majority of allergy alert overrides were clinically appropriate and did not lead to adverse drug events (Heish et al., 2004). For example, there were cases where the clinician stated new evidence existed for use of the medication despite the displayed contraindication (Heish et al., 2004). More broadly, these findings of inaccurate alerts underscore the need to keep drug alert knowledge bases up-to-date with current clinical literature to achieve more credible alerts.

Decision support should prevent patients from receiving the wrong drug or the wrong dose when prescription errors are made. However, not all errors are caught because alerts are not read, are misinterpreted, or are wrongly overridden. In **Figure 7**, van de Sijs et al. schematically elucidates the CPOE process, the management of drug safety alerts, and the emergence of medication errors.

Figure 7: CPOE process and management of drug safety alerts.



Van de Sijs et al., (2006). J Am Med Inform Assoc. 13(2): 138–147.

Shah et al. found in many instances that although the clinician continued ordering an alerted medication, he or she also eliminated the potential contraindication (facilitated by the CDSS) by discontinuing the preexisting medication or removing an inaccurate diagnosis. Other times, although the contraindication persisted, the alert achieved its intended effect by altering clinician behavior (i.e., ordering extra monitoring) (Shah et al., 2006). Thus, even when a clinician continued ordering an alerted prescription, the alert may have appropriately modified subsequent actions, which is important to assess when

fully evaluating the impact of a CDSS. Van de Sijs et al. termed this action as “justified overriding” (van de Sijs et al., 2006).

Figure 7 clarifies reasons for “justified overriding” (e.g., when the benefits of the drug outweigh the disadvantages of a drug allergy interaction and where the provider can knowingly monitor potential ADEs) (Weingart et al., 2003). According to the figure, the contrary is true as well; a cancellation or change of a drug order due to a drug allergy alert can cause a medication error. Overriding a drug allergy alert is often seen as a problem, but it should be emphasized that only unjustified overriding (ignoring alerts, misinterpretation, and incorrect selection) poses the problem (van de Sijs et al, 2006).

Justified overriding may be patient-related or can occur when an alert is based on erroneous patient information. Patient-related reasons include, for example, clinically insignificant alerts, a limited treatment course, patient tolerance of the medication or dose in the past, discussion of potential adverse events with the patient or monitoring thereof, absence of a good alternative, and the benefits of the drug outweighing the disadvantages (Weingart et al., 2003). Examples of erroneous patient information include inaccurate allergy information or medication lists that are out of date, which justify overriding (Weingart et al., 2005; Spina et al., 2005). Appropriate alerts can be defined as true positive alerts, alerts that are correct and current for the patient at hand. It does not imply that appropriate alerts are always perceived as useful.

Theory

The Social Cognitive Theory was applied and used as a framework for this study. The Social Cognitive Theory provides a structure for understanding, predicting, and

changing human behavior. The theory identifies human behavior as an interaction of personal factors, behavior, and the environment (Bandura, 1986).

The interaction between the person and behavior involves the influences of a person's thoughts and actions in the theory. The interaction between the person and the environment involves human beliefs and cognitive competencies that are developed and modified by social influences and structures within the environment. The interaction between the environment and behavior involves a person's behavior determining the aspects of their environment and in turn their behavior is modified by that environment. The Social Cognitive Theory influenced this study by examining how the newly implemented EMR environment influenced the behavior of pharmacists and providers by measuring the use of drug allergy overrides.

Issues of drug allergy alert overriding can be explained with the help of Reason's model of accident causation. This model is applicable to complex sociotechnical systems that require coordination of a large number of human and technologic elements and focuses on person, team, task, workplace, and organization (Reason, 1990; 2000). Alerting systems in CPOE are an example of such a complex sociotechnical system.

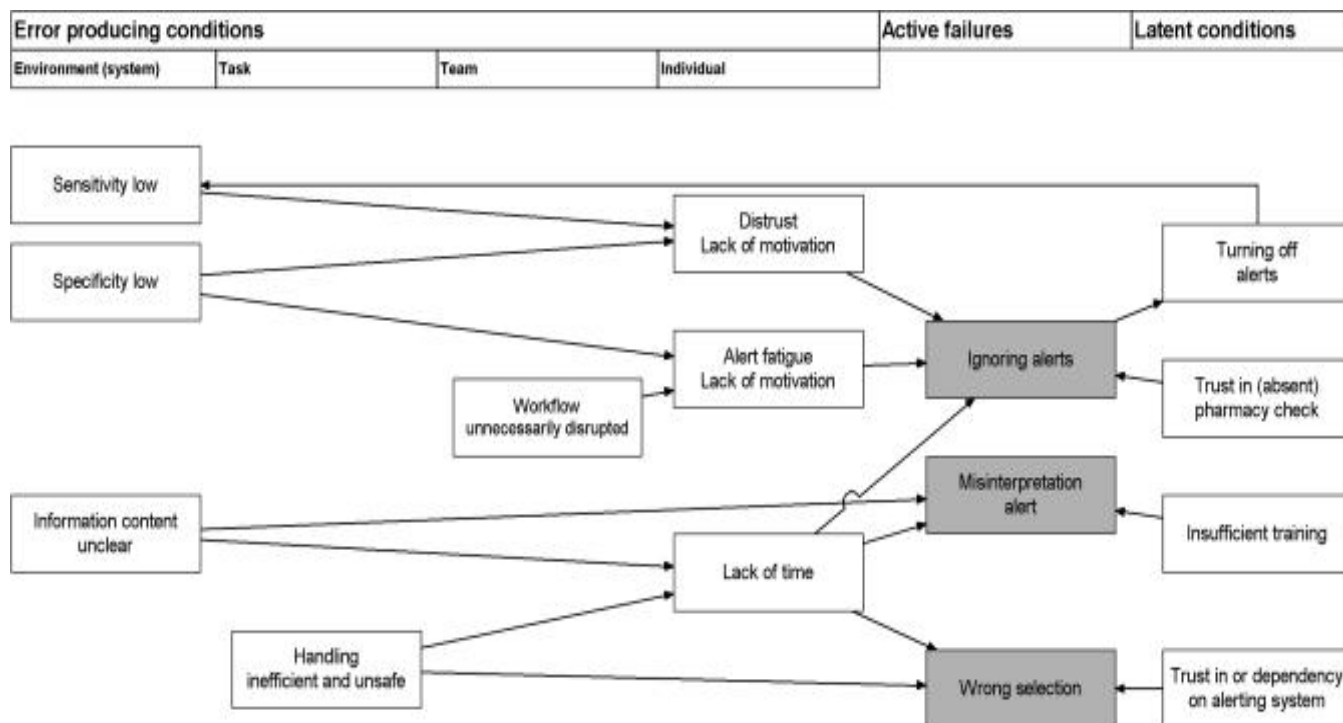
Reason differentiates between active failures, error-producing conditions, and latent conditions (Reason et al., 1998; Reason 1990; 2000; 2004). Active failures are errors (slips, lapses, and mistakes) and violations of an individual having an immediate adverse effect. Error-producing conditions are factors that affect performance of individuals, thus provoking active failures. These factors can originate in the environment, team of care providers, individual, or task at hand. Latent conditions are defensive gaps, weaknesses, and absences that are unwittingly created as the result of

earlier decisions made by system designers, builders, regulators, and managers. Latent conditions can originate from organizational processes or management decisions.

Reason's model shows that accidents result from a chain of numerous contributing factors at different levels: active failures, error-producing conditions, and latent conditions, individual and organizational factors. Accidents, medication errors, result when there is a simultaneous alignment of gaps (Reason et al., 1998; Reason 1990; 2000; 2004)

Figure 8 illustrates how suboptimal decision support can reduce physicians' motivation, thus provoking active failures in alert handling.

Figure 8: Reason's model applied to drug safety alerts in computerized physician order entry.



Van de Sijs et al., (2006). *J Am Med Inform Assoc.* 2006 Mar-Apr; 13(2): 138-147.

Recommendations

The author believes that effective EMR systems can improve practitioner prescribing and reduce medication errors. The study highlighted a number of possible improvements to reduce errors.

Increase usability and decrease workflow interruptions: Developers must make it easy for a provider to “do the right thing” and increase the usability of the system. Alerts need to be clear, concise, and easy to navigate. Feldstein et al. found that decision support alerts are followed less often when they appear at inappropriate times in workflow, are difficult to read, add to time pressure, and are canceled before being fully read (Feldstein et al., 2005). Alerts should include the automatic generation of dialog boxes or other means to facilitate clinician actions that will eliminate drug contraindications (e.g., discontinuing pre-existing medications or inappropriate diagnoses) or will implement recommended monitoring (e.g., ordering laboratory tests). In addition, improving the maintenance of patients' allergy lists could be accomplished by having clinicians select override reasons from a menu of choices; selection of reasons such as “Patient does not have this allergy/Tolerates” or “Patient taking already” from the menu would automatically prompt the clinician to remove the drug from the allergy list.

The alert burden should be reduced by presenting providers with only the most clinically relevant contraindications, and providers should only be interrupted for contraindications with high clinical severity. Shah et al. found high user acceptance of ambulatory computerized prescribing alerts when using a selective knowledge base and minimizing workflow interruptions. By implementing tiered alerts (levels of severity), the alert burden was limited by assigning 71% of alerts to a non-interruptive display mode.

Clinicians accepted the more selective interruptive alerts two-thirds of the time (Shah et al., 2006).

Minimize false positive alerts: Many CDSS use commercial knowledge bases to drive their alerting. These knowledge bases are often highly inclusive, placing more emphasis on breadth of coverage than on clinical relevancy or severity of adverse events (Reichley et al., 2005). However, this approach can have serious consequences. If too many alerts are delivered, in addition to missing important alerts, clinicians may refuse the application altogether due to disruptions in workflow. When designing knowledge bases for CDSS, care must be taken to display alerts judiciously and to maintain the right balance between useful alerting and over-alerting (Ash et al, 2004b). Therefore, testing the sensitivity of the drug allergy alerts by verifying that the drug allergy alert is firing appropriately and has high clinical severity and relevance is critical to reducing false positive alerts. Inaccurate alerts should be reduced by keeping drug alert knowledge bases up-to-date with current clinical literature, maintaining accurate clinical documentation in electronic medical records, and creating optimal linkage to all repositories of patient information.

National standardization: Two levels of standardization need to exist: a standardized national knowledge base and standardized pharmacist and provider input.

To address the issue of alert fatigue and failure to recognize potentially important alerts, organizations can customize alerts for their local sites. However, this customization process is complex and time-consuming and requires obtaining consensus from the medical staff and the pharmacy. As a consequence, alerts might not be standardized across the country or even across health care enterprises. The creation of a

customized knowledge base that all alert databases derive from requires substantial institutional resources. Since not all organizations can devote needed resources, a central repository of knowledge base information should be created for public sharing. Without a national plan or standards, each insurer could promote its own EMR that is incompatible with others.

There is currently also a lack of standardization of actions from providers and pharmacists for drug allergy alert overrides. A set menu of options facilitating appropriate prescribing (e.g., correcting an error in the patient's allergy list) and a standardized list of override reasons should be available to providers and pharmacists. These menu options should encourage that best practices are followed in every drug allergy alert and that all override reasons are captured for future research.

For each organization included in NCQA's various report cards, a certain number of stars appear in each category which that organization was evaluated. These stars reflect how well an organization performed against the standards and/or measures in that category. HMOs are evaluated in the five categories of Access and Service, Qualified Providers, Staying Healthy, Getting Better and Living with Illness. For HMO/POS plans, 4 stars indicated the highest level of performance in a category. Currently KPGA has obtained an "Excellent" accreditation standing from NCQA (NCQA, 2005). However, there are no specific requirements that regard the monitoring of drug allergy alerts or overrides. Adding drug allergy alerts and override monitoring to the NCQA's standard requirements will only strengthen the struggle to reduce medication errors.

Resistance to change is ubiquitous in health care. Incentives by the federal government to providers and pharmacists alike, which are essential human components of

the EMR system, are necessary. Provider and pharmacist performance may be suboptimal due to heavy workloads and incorrect or lack of identification of only clinically significant preventable drug allergy alerts. Any electronic alert system will only be effective if both the providers and pharmacists both collaborate to respond to drug allergy alerts. Therefore, incentive based performance can provide the impetus to manage drug allergy alerts well. These potential incentives include:

1. Pay for performance: Rather than paying for care by the piecework method (fee-for-service) or using administered price arrangements (for example, daily rates, fee schedules and capitation), reimbursement should be linked at least in part to adherence to safety and quality measures. (e.g., the percentage of patients questioned about allergic drug reactions would result in a fiduciary reward, or a certain percentage of inappropriate overrides would result in disciplinary action)
2. Specific consideration and compensation for the extra time and effort involved in managing drug allergy alerts.

Continuous improvement and monitoring: Maintaining the knowledge within the system and managing the individual pieces of the system are critical to successful delivery of decision support. Continuous monitoring by tracking the frequency of alerts and user responses and evaluating the resulting reports on a regular basis is a necessary step to improving medication safety. Thus, if it becomes clear that a drug-drug or drug-allergy interaction is appearing suddenly tens of times per day yet is always being overridden, an appropriate corrective action can be taken.

An override reason should be required input, enabling pharmacists and nurses downstream in the medication order process to see not only that the ordering physician

has considered the risk of drug allergy but also understand the reason why the physician felt it was safe to override the alert. Furthermore, modifying the override reason field so that physicians pick from a menu of choices enables automatic updating of the patient's allergy history—if the reason chosen is, for example, that the patient tolerates the drug well or is already taking the medication at home. The override reasons provide information that help us better understand why certain alerts are not accepted, and therefore to potentially modify the alerting strategy. This study shows the importance of analyzing override reasons as a quality improvement tool to improve alerting strategies, and organizations should consider making this part of their routine improvement processes after implementing CPOE.

Clinician override reasons should be validated before changes to an alert knowledge base are made. There are occurrences where clinicians override the alerts without providing a reason. While these instances are a lost opportunity to understand the clinician's reason for override, we recognize that these omissions may occasionally be necessary for clinical expediency. Given the potential value of this information for future alert improvement, CDSS should be designed to most effortlessly capture the reason for clinician overrides and minimize omissions of override reasons.

Although clinicians may not cancel an order for an alerted medication order, their subsequent actions may eliminate the potential contraindication. These actions represent an acceptance of alert recommendations and should be assessed when evaluating the impact of a CDSS.

It is also critical to keep up with the pace of change of medical knowledge. A possible solution could be to assign each area of decision support (e.g., drug-drug, drug-

allergy, preventative reminders) to an individual, and requiring an assessment periodically to ensure that the knowledge base remains applicable. However, the effort required to monitor and address issues in EMR systems is considerable and is easy to underestimate.

Because a CDSS system can mitigate most but not all prescribing errors, the clinical pharmacist involvement in the medication use process, as well as a CPOE system with advanced clinical decision support, is vital for improving medication safety. A well trained and capable provider can manage drug allergy alerts within the CPOE tool and can act accordingly. Pharmacists are the last line of defense against inappropriate prescribing and drug use in the ambulatory setting.

In addition, the federal government should conduct safety studies to evaluate the effectiveness of its recommendations and of medical procedures in general. Continuous quality improvement to ensure appropriate alerting is critical for continued efficacy and acceptance of CPOE decision support. Evaluation is necessary through KP, federal government agencies, and other research entities to verify that these alerts are firing appropriately.

Limitations and Further Research

This study design includes limitations that merit discussion. Because our data was limited to the aggregate number of drug allergy overrides and prescriptions filled, it was only able to provide a generic snapshot of the incidence rates of drug allergy overrides. Justified overriding could not be established as a possible reason of the increase of the incidence rate post implementation. Also, the study was not able to consider alert effectiveness based on the role of the provider. Data was not available on the provider's

response to the CPOE drug allergy alerts (e.g., whether the provider cancelled, changed, or overrode the orders and override reasons). Thus, PIMS drug allergy override data was used as the numerator in the calculation of the comparative incidence rates for the pre and post implementation periods. More detailed data may have discovered provider ordering behavior, specific facility tendencies, patient demographic trends, and a specialty department comparison. Further research is needed to explore the potential patterns in these groups of drug allergy overriding behavior.

Another limitation is that the definitional logic or rules that triggered allergy alerts in PIMS or KP HealthConnect were not available for comparison of the pre and post periods. Further research is needed to verify the logic or rules were the consistent for both periods.

Also, the study took place within an HMO primary care setting, thus the results may not be generalizable to other medical practice settings (e.g., nursing homes, hospitals, private practices) or specialty ambulatory care. Specifics will vary depending upon the type of EMR utilized and the provider culture and organizational structure. Also these results may not be generalizable to other outpatient settings where pharmacists do not play such an active role in medication safety.

Finally, the data utilized in this research study was specific only to the KPGA region. Including Georgia, KP facilities include 431 medical offices in California (Northern and Southern regions), Colorado, Hawaii, Mid-Atlantic States (Washington D.C., suburban Maryland, northern Virginia, and Baltimore), Ohio, Oregon, and Washington. Data from these other regions were not available to compare the findings from this research study. Further research is needed to investigate if the results are similar

to other KP facilities across the United States. Along the same lines, similar HMO settings or settings with comparable EMR systems within the Atlanta area were not available for assessment for this study. Further research is needed to evaluate these other settings to verify regional trends within other outpatient, inpatient, and long term care settings. Other KP national regions and non-KP, local settings can utilize this study design outlined herein to compare the impact of EMR implementations on drug allergy overrides.

While electronically generated clinician reminders have proved effective in multiple clinical settings, only limited information exists about why clinicians often fail to follow computer-generated advice. Questions exist regarding the most effective ways to deliver reminders and decision support advice. Additional research is needed to begin to consider how information should be organized and delivered, how patients can become involved, what role patient-managed records should play, and how communication between providers and patients can be improved. Research investment is essential if we want to improve the way evidence is provided at the point of care.

Conclusion

Electronic medical records provide many benefits. Decision support in CPOE has been shown to improve medication safety by providing alerts to physicians of potentially dangerous drug allergy interactions. This study evaluated the impact of an EMR implementation on drug allergy overrides and found an increased incidence of alert overrides following the implementation. As a result, healthcare settings (ambulatory, hospital, long term care, etc.) should use caution when designing decision support

systems and should include continuous monitoring of drug allergy alerts to contribute to a successful implementation. Also, evaluation of drug allergy override reasons could aid in alerting systems gaining their full potential and improvement of medication errors.

Implementing an EMR system with an integrated CDSS is a difficult undertaking, and while it does not solve the entire medication safety problem, it is an important piece of the puzzle, and real improvements in the medication use and drug allergy process can be realized.

The question still remains as to where the optimal specificity for alerts lies. A safe alerting system has high specificity and sensitivity, presents clear information, does not unnecessarily disrupt workflow, and facilitates safe and efficient handling. More research is needed to find the optimal balance between over and under alerting. Also future larger, more prolonged studies can help to determine the full relationship between automated alerts for drug allergy interactions and the related outcomes of ADEs.

In summary, more study is needed to understand which healthcare quality problems are best suited to remedy by computerized intervention and which system designs are most successful in achieving behavioral change.

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