

AMBULATORY COMPUTERIZED PROVIDER ORDER ENTRY AND PDA-BASED  
CLINICAL DECISION SUPPORT SYSTEMS: AN INVESTIGATION OF THEIR  
PATIENT SAFETY EFFECTIVENESS VIA AN INTEGRATIVE AND  
SYSTEMATIC REVIEW

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Dedicated to my parents: Sheila and Bruce Taffel

AND

grandparents: Millie and Martin Cohen; Bernice and Frank Taffel

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**Definitions:**

Medication Errors \* - “Errors in the process of ordering, transcribing, dispensing, administering, or monitoring medication” (Kaushal, Shojania & Bates, 2003, p. 1410)

Adverse Drug Event\* - “An appreciably harmful or unpleasant reaction resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product” (Frankel, 2000, p. 1212)

Ambulatory Computerized Provider Order Entry (ACPOE) - “A software application that supports the ordering of medications, diagnostic tests, interventions, and referrals by providers in ambulatory clinics and physician offices in both hospital and community settings” (Johnston, Pan, & Walker, 2004)

Electronic Prescribing Systems (EP) - “Computerized systems that clinicians use to prescribe medications” (Bell et al., 2004, pp. W4–305)

(\*). Although this study mentions both medication errors and adverse drug events (ADEs), it is important to know the difference between them. Medication errors do not necessarily harm or injure patients, and are preventable. ADEs, on the other hand, do cause some form of harm or injury and are not always preventable. ADEs associated with medication errors are preventable.



## ABSTRACT

Jared Ross Taffel

### AMBULATORY COMPUTERIZED PROVIDER ORDER ENTRY AND PDA-BASED CLINICAL DECISION SUPPORT SYSTEMS: AN INVESTIGATION OF THEIR PATIENT SAFETY EFFECTIVENESS VIA AN INTEGRATED AND SYSTEMATIC REVIEW

Substantial research has been done on inpatient provider order entry systems with varying degrees of clinical decision support. Such studies have examined how these technologies impact patient safety as well as the quality and cost of care. However, given that most medical care and prescriptions are administered in an ambulatory setting, the dearth of research on ACPOE systems is quite astonishing. This knowledge gap demonstrates the need for an integrative and systematic literature review that attempts to assess the research done on computerized patient safety interventions in ambulatory care.

This review's findings provided adequate evidence that ACPOE systems are effective interventions for reducing medication errors. Other evidence further indicated that, in terms of functional capabilities, commercial ACPOE and e-prescribing systems may be catching up with their homegrown counterparts. PDA-based CDSSs were depicted as useful tools for raising adherence to guidelines and inducing safer prescribing. These findings suggest that ACPOE and PDA-based CDS systems show promise for improving safety and healthcare quality in ambulatory settings. ACPOE specifically, tended to have more advanced CDS attributes but, nonetheless, showed more negative results compared to the e-prescribing systems. Close scrutiny should therefore be given to the elements of decision support that ambulatory physicians find most useful.

## CHAPTER ONE: INTRODUCTION AND BACKGROUND

The presence of medication errors and adverse drug events (ADEs) in the healthcare arena is both eminent and problematic. An estimated 7000 people die annually from medication errors, which are the fourth- to sixth-leading cause of death in the United States (Van de Velde & Degoulet, 2003). An Institute of Medicine (IOM) study has reported similar estimates, declaring that more individuals die per year from medical errors than from car accidents, breast cancer or AIDS (Kohn, Corrigan & Donaldson, 1999). Moreover, these errors generate steep expenses, which can cost the U.S. health care system up to \$77 billion annually (Grissinger, Globus, & Fricker, 2003). Underscoring the impact of prescription dispensing, Kilbridge (2001) argues that “[p]rescribing medication is the physician’s most frequently used, efficacious and potentially dangerous therapeutic tool, outside of surgical intervention” (p. 7). Although efforts have been made to address this issue by using CPOE technology, outcomes remain mixed.

Likewise, Koshy asserts that extant error prevention techniques do not adequately reduce errors or guarantee safer healthcare delivery (Koshy, 2005). For example, reminders and alerts built into (CPOE) systems with decision support capabilities aiming for error prevention can elicit “alert fatigue” in the physician. When some reminders are of a trivial nature and others are critical for patient safety, doctors can be overloaded with too many alerts and, thus, run the risk of missing the critical ones. “Alert fatigue” may prompt physicians to override both crucial and frivolous alerts, thereby undermining safety mechanisms in certain CPOE systems (van der Sijs, Aarts, Vulto, & Berg, 2006).

Nevertheless, most claims regarding CPOE technology's impact on medication errors are based on inpatient findings. As Johnston, Pan and Walker (2004) have argued,

the “majority of this existing evidence demonstrating the value of CPOE comes from hospital settings, and thus much less is known about the value of ambulatory CPOE” (p. 5). To put this into perspective, consider the fact that an increasing proportion of healthcare is being rendered in outpatient settings. This alone emphasizes the need for further research and understanding of CPOE technology and its influence in that particular environment (Thomsen, Winterstein, Sondergaard, Haugbolle, & Melander, 2007). The high variability of outpatient data supports this notion; annual estimates of the rate of drug errors as they relate to outpatients have fluctuated between 5% and 35%, thereby suggesting significant disagreement (Gandhi et al., 2000). As Gandhi et al. (2003) have emphasized, “[e]ven though most prescribing occurs in outpatient settings, much less is known about outpatient adverse drug events than about inpatient events” (p. 1557). Adding to the puzzle of why technologies aimed at improving medication safety in ambulatory care are under studied is the greater complexity of the ambulatory setting when compared to that of the inpatient setting, especially when it comes to ordering and dispensing prescriptions (Tamblyn et al., 2006). Patients in ambulatory care are (up to 40%) more likely than inpatients to obtain their prescriptions from multiple pharmacies, and they are much more likely (60–80%) than inpatients to have prescriptions from multiple physicians (Tamblyn et al., 2006). Such statistics call for an IT infrastructure that easily allows for a smooth integration of ACPOE systems into outpatient settings.

Likewise, the knowledge gap between inpatient and outpatient settings with regard to CPOE technology and patient safety forms an ironic situation. Many of the drug errors that occur in ambulatory care have the potential to lead to hospitalization, and such errors could be prevented if outpatient providers were equipped with the comprehensive

information and close control found in hospital inpatient care (Thomsen et al., 2007).

After all, the ordering stage has important implications for clinical decision making and subsequent health outcomes. As Eslami, Abu-Hanna and Keizer (2007) have explained, the “ordering step is crucial in the process: it is the point at which the physician’s thoughts are transformed to decisions which trigger a series of actions, ultimately resulting in the patient receiving the medication” (p. 400).

### *Purpose Statement*

This research paper examines the effects of outpatient CPOE systems (including handheld e-prescribing devices) on medication and patient safety by means of an integrated literature review, a widely accepted research method for fusing prior research efforts on a related topic (Cooper, 1989). Integrating research should help assess both what previous studies have concluded and the questions such studies have left unanswered. This analysis, moreover, can generate future research by reconciling efforts to open avenues for comparing and contrasting the impact of CPOE technology on inpatient and outpatient settings, respectively. Such comparative studies will help to form a clear understanding both of the way that CPOE systems function in the ambulatory environment and of the technology itself.

This study's objective is to shed light on the state of affairs with regard to ambulatory CPOE systems' impact on patient safety. Integrating research will facilitate efforts to elucidate the role of ambulatory order entry systems in patient safety, cost reduction, and health care quality improvement. This approach will also help bridge the gaps in research left by the meager attempts made thus far to study CPOE in the medical

care environment that is characterized by a heavy intake of patients and a rapidly paced atmosphere and where most health care is provided: Outpatient settings.

## CHAPTER TWO: LITERATURE REVIEW

### **Overview of CPOE system Impact on Patient Safety**

Comprehensive studies have sought to analyze the effects of CPOE systems on medication safety primarily for inpatient care. For instance, one thorough study concluded that CPOE systems with clinical decision support are effective at substantially lowering medication error rates (up to 55%) in selected hospital settings (Kaushal, Shojania, & Bates, 2003). On the other hand, most prescriptions are written in outpatient settings and yet little is known about the effect of CPOE on medication errors in this venue. Certain explanations have been proposed as to why such a knowledge gap exists. Foremost among these explanations is the claim that the greater accountability to which ambulatory patients are generally held for acquiring, managing, and adhering to their medication regimens creates more variability in this process, which could lead to medication errors. Other possible factors include a lesser degree of doctor-patient communication and chart reviews which are expensive and contain deficient or missing documentation regarding medication errors, thereby leading to less accurate reporting of such errors in the ambulatory setting (Gandhi et al., 2000). As can be deduced from Kuperman et al. (2007), ACPOE systems tend to be inferior to their inpatient counterparts in terms of the availability of relevant clinical information. Specifically, Kuperman et al. (2007) state that “[a]mbulatory medication lists are often incomplete, lacking over-the-counter medications, herbal drugs, various supplements and medications prescribed at other sites” (p. 33). Despite the relatively positive findings regarding the

reduction of medication errors among studies looking at inpatient settings, certain studies concluded that insufficient evidence exists to say the same for CPOE systems in the outpatient setting, suggesting the need for further analysis (Eslami et al., 2007). Nonetheless, such studies did find sufficient evidence of the potential for ambulatory CPOE systems to improve adherence to medical treatment guidelines possibly to a greater degree than in hospitals (Eslami et al., 2007). Such adherence is extremely important in the ambulatory environment, where communication between patients and their physicians is limited as a result of infrequent face to face visits (Gandhi et al., 2003).

Another a major problem within ambulatory care is the ordering of duplicate, redundant, and unnecessary tests, which naturally increases the risk of errors and patient harm. One study performed a before-and-after cohort controlled trial of CPOE on the impact of outpatient testing, including full blood count, urea and electrolytes and urine culture tests (Collin et al., 2008). Based on the findings that the intervention group saw a reduction in testing while the control group saw increases in testing (mean change as percentage between groups: full blood count: -1.9% vs. 4.6%; urea and electrolytes: -0.6 vs. 3.6%; urine culture: -0.5 vs. 1.5%), the study concluded that such systems can potentially increase efficiency of care by instigating a reduction in outpatient tests (Collin et al., 2008).

### **The Benefits**

Providers remain reluctant to adopt outpatient order entry technology despite evidence of its potential benefits for both patients and health care professionals. A study done at the Center for Information Technology Leadership concluded that ACPOE has a

significant value proposition to offer on a multitude of levels. Outpatient order entry systems could facilitate the reduction of medication errors and raise acquiescence to treatment protocols (Johnston, et al., 2004). As was shown in their study, Johnston et al. (2004) estimate that “[e]ach outpatient provider using an advanced ACPOE system would eliminate nine ADEs, six visits per year, four admissions and three life-threatening ADEs in five years of practice” (p. 6). Other studies have had similar findings. With the amount of ambulatory medication errors rising, it is likely that primary care e-prescribing has great potential for beneficial outcomes on patient safety (Bodenheimer & Grumbach, 2003). There is also reason to believe that ACPOE systems will decrease the threat of medical malpractice for physicians and reduce malpractice insurance premiums as a result of the technology’s ability to enhance the quality and safety of patient care (Johnston et al., 2004).

The CITL study also estimated substantial financial savings if extensive adoption of ACPOE systems were to take place. Such estimates in annual cost savings are comparable to other projections and range from \$3.5 billion just for basic electronic prescribing to \$44.2 billion for advanced outpatient order entry systems with sophisticated clinical decision support (Johnston et al., 2004). Other stakeholders such as third party payers also stand to gain financially from the use of ACPOE systems in medical care delivery. Thus, it is perplexing to many that, despite the potential of this technology to positively impact the quality of patient care and result in third party payer financial gain, payers have not put programs into place to incentivize provider use of ACPOE (Johnston et al., 2004). Of course, these payers could be responding to the negative results of the majority of studies which have focused on EHR use and improved

quality of care. Nonetheless, they would do well to note that most use of such systems in those studies does not include ACPOE specifically. From a common sense perspective, if healthcare expenditures are greatly reduced, more resources become available for allocation toward providing better patient care. With more than 70% of healthcare expenditures attributed to what physicians order in the patient care process, the positive impact that order entry systems stand to provide is quite considerable (Van de Velde & Degoulet, 2003).

Similarly, in the specific case of prescription ordering in the ambulatory setting, primary care physicians order more medications per patient and visit with more patients on a per diem basis than do specialty care physicians, which suggests that the potential for errors is considerable in such a setting (Menachemi, Ford, Chukmaitov, & Brooks, 2006). It has been shown that 62% of medication errors happen at the ordering phase of the medication process in the inpatient setting (Bates et al., 1995). However, little information exists on the prevalence of medication errors and ADEs in the ambulatory setting (Gandhi et al., 2003). The results of one study suggest not only that such errors are widespread among ambulatory patients and carry substantial ramifications, but also that more than one-third of them are avoidable (Gandhi et al., 2003). Primary care physicians can garner benefits from the use of ACPOE systems to make their practices more timely, efficient, and safe (Menachemi et al., 2006).

ACPOE systems would improve the quality of care primarily by reducing medication errors and ADEs as well as by delivering more organized, efficient, and less costly care (Johnston et al., 2004). The projections of one study reveal the great potential of ACPOE systems to improve the quality of care through significant lowering of



medical errors. As Johnston et al. (2004) estimate, “nationwide adoption of advanced ACPOE would eliminate nearly 2.1 million ADEs, more than 136,000 life-threatening ADEs, nearly 1.3 million visits and more than 190,000 hospitalizations per year” (p. 8). It was also projected that intermediate ACPOE systems, which contain order-specific decision support but lack detailed information regarding patients, would have similar effects on medication safety and quality of care (Johnston et al., 2004). One standard feature of all ACPOE systems is their ability to generate complete orders. This feature alone yields numerous benefits for the quality and cost of care: it decreases the amount of clinical recalls, which saves time and lessens the number of rejected claims by third party payers (Johnston et al., 2004). Complete medication orders include the drug name, route, frequency, dose, and indication (Winslow, Nestor, Davidoff, Thompson, & Borum, 1997). If any part of this information is omitted when an order is written, false suppositions can be made by other clinical and pharmaceutical personnel, which, in turn, raise the chances of medication errors (Winslow et al., 1997).

### **The Barriers**

Though ACPOE technologies are widely available and can provide numerous benefits, a very low proportion of hospitals and physician’s offices have such systems installed. A national survey of ambulatory care physicians revealed that 13% recounted having a basic electronic records system and 4% reported having a fully functional system installed in their offices (DesRoches et al., 2008). The key difference between basic and fully functional electronic record systems is the level of order entry capacities and clinical decision support (DesRoches et al., 2008). More specifically, the broader range of ACPOE functionalities are part of a fully functional system whereas only

prescription ordering comprises part of a basic system (DesRoches et al., 2008). The cost of implementing both basic and especially fully functional systems is certainly not cheap. It would seem quite evident from low adoption rates of this technology that most medical providers do not yet view order entry systems as compelling enough investment opportunities. In support of the foregoing, the study by DesRoches et al. (2008) concluded that for ambulatory physicians “[t]he most commonly cited barriers to adoption were capital costs (66%), not finding a system that met their needs (54%), uncertainty about their return on the investment (50%), and concern that a system would become obsolete (44%) (Table 5)” (pp. 54-56). The average physician seemingly falls somewhere in the middle to right end of the adoption curve when it comes to the use of computerized tools, including CPOE, in medical practice. Their placement on the adoption curve parallels the general, mainstream population’s tendency to be conservative and cautious when investing in new ideas, technologies, and services (Rogers, 1962). As one study suggests, physicians will tend to be more likely to adopt computerized tools in medicine only when such adoption is considered to be the “standard of practice” (Berwick, 2003).

The expenses generated from installing CPOE reinforce the reluctance of hospitals and other healthcare institutions to adopt such systems (Wolf, 2007). The perceived prohibitive cost of installing CPOE systems coupled with a lack of assurance that these systems will fulfill their potential for reducing error and improving quality of care is a real barrier (Solovy, 2001). One study found evidence that the infiltration of managed care into medical communities can negatively influence physician use of ACPOE systems (Menachemi et al., 2006). It was hypothesized that having less financial

freedom as a result of time constraints, reduced physician reimbursement, and regular operating costs imposed by managed care organizations (MCO) was a likely culprit of the reluctance by physicians to use and integrate ACPOE technology (Manachemi et al., 2006). But while large group practices and hospitals are clearly in a better position to afford ACPOE systems, they remain hesitant about adopting and using the technology (Bigelow et al., 2005).

Another major concern is an ACPOE system's potential to initiate a change in physician workflow. Contributing to the reluctance of healthcare providers to invest in ACPOE is a fear that the technology will interfere with or disrupt the work cycle to which they are accustomed. The compulsory changes in customary work routines can galvanize resistance to the technology (Van der Meijden, Tange, Troost, & Hasman, 2003). Devoting time to training and learning more about the technology all feeds into workflow disruption (Bodenheimer & Grumbach, 2003). Furthermore, physicians do not relish the idea of taking away valuable time they could be spending with their patients to deal with the overall electronic ordering process (Ash, Stavri, Dykstra, & Fournier, 2003). Thus, the key for a smooth transition is for such systems to possess the ability to promote effectual workflows without harmfully impacting the doctor-patient relationship (Gadd & Penrod, 2001).

Some providers are concerned that ACPOE systems may facilitate or even cause medication errors, although this issue has not been thoroughly researched and existing evidence has suggested arguments to the contrary (Johnston et al., 2004). A more recent study, however, identified unintended consequences of CPOE systems using a mixed methods approach (Ash, Sittig, Dykstra, Campbell, & Guappone, 2009). Such unintended

consequences, for example, included extra time requirements, workflow issues, changes in power structure, mistakenly entering orders for the wrong patients from the “juxtaposition” of adjacent patient records, and the potential for overdependence on the technology (Ash et al., 2009). Identifying and examining the aspects that lead to successful CPOE implementation is critical for avoiding its error-causing potential (Ash et al., 2009). Any evaluation of electronic order entry systems will require researchers to determine whether they prevent more errors than they cause or vice versa.

Inadequate customization capabilities to meet the specific needs of healthcare providers may also hinder implementation of the technology. This unfortunate fact holds true especially in the case of commercial order entry systems, which have a tendency to be more generalized in their functionality than homegrown systems but are still nonetheless helpful and useful. Additionally, as can be gleaned from Johnston et al. (2004), there are several types of commercial off-the-shelf ACPOE vendors who appear to be offering more comprehensive products. Typical standard features include electronic prescribing with refills, checks for drug-drug interactions, drug-diagnosis, and drug-laboratory, as well as patient healthcare databases and drug related medical knowledge bases (Johnston et al., 2004).

Close analysis of the aforementioned existing barriers exposes their root causes. Understanding the causes that impact the use of ACPOE systems by providers will help key stakeholders in the healthcare arena to both recognize these barriers and identify the ways in which they shape the adoption of order entry systems in the ambulatory setting (Menachemi et al., 2006). Such knowledge can then be used in an effort to enhance patient safety and the quality of care rendered (Menachemi et al., 2006).

## **The Quality and Continuity of Care**

Given the information-rich nature of medical care, ease of access to such information by physicians is critical for the quality and continuity of care. An issue of particular concern in the ambulatory setting is that, according to Bodenheimer and Grumbach (2003), “[o]n average, each ambulatory visit generates one clinical question that the physician is unable to answer” (p. 261). This fact alone emphasizes the necessity of ACPOE systems to aid in the decision making process through the retrieval of patient information and available clinical decision support at the point of care. However, these systems should not be substituted for a literature search, nor should they be used in that regard because the information found in alerts is institution-specific and may not be up to date. The concept of evidence-based data that is applicable across all clinics should be a regular element of any ambulatory practice whether it is via computer or handheld PDA devices (Bodenheimer & Grumbach, 2003). ACPOE systems have been endorsed as a promising technology that should help tackle healthcare quality issues of national importance like medication safety (Johnston et al., 2004). Of particular pertinence to outpatient care is inadequate or no dedication to standard protocols for preventative measures, long-term disease management, and the transcription of test outcomes (Gandhi et al., 2005). The use of ACPOE systems has been recognized as a plausible strategy to tackle such quality of care issues (Gandhi et al., 2005). The CITL has projected that ACPOE has significant potential to prevent ADEs and reduce unnecessary visits and admissions, although the estimates differ substantially depending on the degree of technological sophistication in any given ACPOE (Johnston et al., 2004).

It is also important to understand the role that ACPOE systems can play in the continuity of patient care. One area that has been under studied, and adds to the myriad conundrums regarding patient safety in ambulatory care, is the insufficient communication between inpatient and outpatient physicians about a patient's plan of care (Moore, Wisnivesky, Williams, & McGinn, 2003). Evidence suggests that less than half of all ambulatory physicians are equipped with important information regarding their patient's discharge plans and medication regimens from inpatient visits (Moore et al., 2003). It can thus be inferred that such disengaged communication and a lack of complete information transmitted between the two clinical settings would be likely to facilitate the occurrence of medical errors and adverse drug events.

ACPOE systems should correspond with their inpatient counterparts to create an efficient, streamlined flow of critical patient information that is readily available at the point of care. From a common sense view, instituting these systems would save time, reduce costs, sustain continuity of care from inpatient to outpatient settings and improve the overall quality and consistency of care. It was concluded in one study that a patient's risk of being readmitted to the hospital could be reduced if a primary care physician or post-discharge provider simply had the discharge summary at hand (Van Walraven et al., 2002). As can be deduced from this study, the generation of a more comprehensive patient outlook by enabling communication between inpatient and outpatient order entry systems holds numerous possible benefits for patient care at multiple points of the process. The research in this area is insufficient and, thus, more efforts are needed to address the current concerns of medication discontinuity and medical test errors, stemming from the discontinuity of care problem (Moore et al., 2003).

## **Perceptions and Attitudes**

The implementation of CPOE systems involves many stakeholders and, therefore, elicits a multitude of perceptions and attitudes. Within the clinical and organizational environment, Ash et al. (2003) asserted that “[e]ach has a view of CPOE that is colored by his or her role or combination of roles” (p. 240). However, because physicians are the primary users of the technology, and patients are the recipients of the care that is influenced by use of the technology, the perceptions and attitudes of these two groups toward ambulatory order entry are of utmost significance. Generally, physicians will be skeptical of computer applications in medicine unless it is clearly illustrated to them that there is substantial added value in exchange for the time and effort they have to spend to incorporate such systems into their practice (Gadd & Penrod, 2001). One qualitative study evaluated physician attitudes as they relate to ACPOE and its range of functions by surveying a sample of 262 primary care physicians with a response rate of 55% (n=144) (Gandhi et al., 2005). Those who responded were primarily concerned that using ACPOE would take up too much time, which they feared would both detract from the time that could have been spent with patients and retard the overall clinician work process (Gandhi et al., 2005). Such concerns should be dealt with to promote extensive provider approval of the technology; it is not enough to reiterate some of the more positive effects of the technology, such as improving the trail of tests administered and the warnings given regarding omitted tests (Gandhi et al., 2005).

In this digital age, patients are able to obtain their medical information, manage their own healthcare, and actively participate in the decision-making process more easily (Fieschi, 2002). The increasing amount of patient involvement can work to both their own and

their healthcare provider's advantage. The doctor-patient relationship would be enhanced as a result of better controlled and documented interactions (Fieschi, 2002). Therefore, it can be inferred, in the case of medication and patient safety, that physician access to ACPOE systems and patient access to their electronic medical records would form a symbiotic relationship; both parties would be well-informed regarding relevant history and medication use and, consequently, the risk of medication errors or adverse drug events would decrease. Moreover, interventions addressing the critical issue of outpatient drug safety need to acknowledge both the patient-centeredness of the management of medication regimens and the environmental aspects unique to outpatient settings (Budnitz & Layde, 2007). Patients, whose aspirations and expectations have kept pace with the digital age, generally view computerized tools in medicine enthusiastically and with a sense of empowerment (Fieschi, 2002).

### **Literature Review Summary**

In summary, the literature suggests that the knowledge pertaining to ACPOE and outpatient electronic prescribing systems regarding their influence on patient safety is scant. The benefits of, barriers to and other elements relevant to the role of ACPOE in the quality, safety, consistency and continuity of care were explained. Moreover, perceptions of the technology from both a provider and patient standpoint were identified. While certain theories have been presented and estimates have been made in regards to such factors, the question of interest has not been sufficiently answered. The knowledge gap evident within the literature brings forth the issue of whether ACPOE and ambulatory e-prescribing systems are effective patient safety interventions in preventing medication errors and ADEs. Such a knowledge gap also serves as a benchmark for the introduction



of this systematic research review which will attempt to fill in what has been left unanswered based on what is known and unknown.

### **Study's Significance**

As previously demonstrated, a lack of knowledge exists regarding the effects of CPOE on medication safety in the ambulatory setting. This study has attempted to clarify and reconcile the way in which CPOE systems impact medication safety in the ambulatory setting because research on this question is clearly underdeveloped when compared with the research that has been undertaken to study these systems' inpatient counterparts. In fact, inpatient CPOE systems have been studied in depth over the years and yet most medical care is not rendered in that setting. Thus, this study has endeavored to provide a comprehensive and integrative literature review of outpatient CPOE systems and their influence on medication safety. The study also has provided an overall picture of the state of knowledge in this growing area, the direction in which it is heading, and the information that will be necessary to help determine not only the most appropriate focus of future research, but also how to improve the technology for greater patient safety and quality of care. In the process, this study highlighted the differences of the way these interventions function in each healthcare environment, thereby deeming them incomparable.

This study produces evidence of importance to researchers, funders of research, policymakers, and ambulatory physicians. The upfront and maintenance costs of the systems serve as a true hindrance to widespread adoption. Nevertheless, the results of this review may help to support the legislation that has already been crafted around e-prescribing. To authenticate this point, Menachemi et al. (2006) states that the "national

strategic plan for the adoption of HIT has included A-CPOE, and the Medicare Modernization Act of 2003 has sought to promote the use of A-CPOE systems” (p. 738). In addition, the more recent American Recovery and Reinvestment Act of 2009 contains provisions that strongly encourage and incentivize the use of Health Information Technology, including ambulatory computerized physician order entry to build a solid IT infrastructure for the U.S. healthcare system. Such government sponsored encouragement underscores the realized potential benefits that A-CPOE systems can offer the medical community and its key stakeholders. The significance of contributing to the sparse amount of literature regarding the influence of ACPOE systems on medication and patient safety should overshadow any limitations in the analysis.

### **Research Questions**

- a. Are ACPOE, electronic prescribing, and handheld-based CDS systems effective tools for improving medication and patient safety in the ambulatory setting?
- b. How do they compare to inpatient CPOE and CDS systems in terms of their impact on medication safety? Are the effects on medication safety similar or substantially different and why?
- c. What is the impact, if any, of the findings, given the increasing shift in healthcare toward delivery in the outpatient setting coupled with changes and greater technological sophistication in the CPOE and CDS systems themselves?
- d. Are there any notable differences or identifiable trends in medication safety impact as a result of the type of ambulatory systems used? What factors might explain such differences or trends?

### CHAPTER THREE: RESEARCH DESIGN AND METHODOLOGY

The approach taken for this research was to conduct a systematic and integrative literature review. Integrative research reviews are useful and instrumental in summarizing previous research by drawing general conclusions from a multitude of other studies that focus on the same or similar premise (Cooper, 1989). The integrative reviewer aims to represent the state of knowledge regarding the relevant findings and unsolved questions of prior research. (Cooper, 1989). Because research efforts concerning ACPOE system impact on medication safety have been so meager, it was logical and necessary to conduct an integrative literature review in this study to arrive at the “state of knowledge” on this topic.

Another advantage of having taken this approach was to identify holes in the research which helps to guide and inform future research endeavors, ultimately paving the way for a more comprehensive outlook and solid understanding of the effects of order entry systems in the outpatient setting. From the standpoint of the reader, Cooper (1989) notes that “an integrative research review is intended to replace those earlier papers that have been lost from sight behind the research front and to direct future research so that it yields a maximum amount of new information” (p. 13). As Cooper (1989) further illustrates, the integrative research review process can be broken down into five stages:

- Problem formulation
- Data collection
- Evaluation of data points
- Analysis and interpretation
- Presentation of results

I have replicated the procedures used in a study by Kaushal, Shojania and Bates (2003) entitled “Effects of Computerized Physician Order Entry and Clinical Decision Support Systems on Medication Safety,” in which a systematic literature review was conducted. The inclusion criteria developed for that review comprised studies in which the design was either a “randomized controlled trial, a non-randomized controlled trial, or an observational study with controls and if the measured outcomes were clinical (eg, adverse drug events) or surrogate (eg, medication errors) markers” (Kaushal et al., 2003, p. 1409).

Conversely, my study differs from the review done by Kaushal, Shojania and Bates (2003) in both relatively incidental and comprehensive ways. One somewhat minor difference is that, although my research used the same procedures performed in the aforementioned study, it consisted of more current and updated data on studies done from 1998 to the present. It therefore covered a broader time frame. Also, their systematic review was performed by two reviewers whereas I was the only reviewer for this study.

My review departs, perhaps more crucially, from that of Kaushal, Shojania and Bates (2003) in terms of the scope of technologies analyzed. Their review examined several isolated clinical decision support systems in addition to CPOE systems with clinical decision support functionality in the inpatient setting. By contrast, I have focused on CPOE systems with varying degrees of clinical decision support integrated into such systems or standalone CPOE interventions in the ambulatory environment. Electronic order entry systems can be independent of the type of technology used. Therefore, technologies other than the traditional desktop computer workstations such as laptops or handheld devices were included as well.

Due to the increasingly popular use of handheld computers among practitioners, an analysis of the contributions these devices have made to medication safety was valuable. Handheld devices in primary care are primarily used for easy access to online drug referencing information and knowledge bases (Bates & Gawande, 2003). The use of PDA devices in the ambulatory setting for medication management and electronic prescribing indeed shows promise. The incorporation of PDAs into clinical settings has demonstrated the ability to facilitate the retrieval of drug and patient information by healthcare providers and to reduce the rate of medication errors (Fischer et al., 2003). Consequently, it was acceptable for this review to include an analysis of studies evaluating standalone PDA or palmtop-based clinical decision support systems that often serve as an extension or complement to the electronic prescribing process.

Finally, the key difference between my review and that of Kaushal, Shojania and Bates (2003) is the healthcare setting in which the studies for review take place. This review has focused on the evaluation of various electronic order entry systems in the ambulatory setting. Such an integrated review not only added another meaningful and useful dimension to the study by accounting for a different healthcare setting but also attempted to provide a more complete view of the implications of CPOE technology on medication safety. Thus, although my review departs substantively from that of Kaushal et al. (2003), this departure does not detract from its validity.

In fact, my review preserved some of the elements of the replicated study as well. One similarity it shares is in its incorporation of the same frameworks used for the assessment of study design and projected results of interest (Kaushal et al., 2003). Such frameworks arose through the University of California San Francisco – Stanford

Evidence-Based Practice Center (**Tables 1 and 2**) for the assessment of research design and metrics, which includes previously available frameworks and advice for the appraisal and fusion of existing literature (Kaushal et al., 2003). These tables served as a guide for study selection in which the hierarchical breakdown of study design and outcome measure levels helped to organize and pinpoint studies that give credence to practical measurement of medication safety that is influenced by ACPOE systems with any level of clinical decision support functionality. Consequently, the use of these hierarchies helped to avoid the pitfalls of subjective evaluation of studies. The applied frameworks are specifically designed to account for the diverse characteristics of studies involving CPOE systems with or without clinical decision support (Kaushal et al., 2003).

In addition, this study attempted to include commercial order entry systems, which are widely available but poorly adopted by providers. As postulated by Kaushal et al. (2003), “a need exists for research evaluating commercial systems” (p.1415). However, considering that most of the research and supporting literature stems from homegrown systems, and that it is more cost-effective to implement such in-house developments, the inclusion of studies evaluating commercial systems was expectedly limited. Still, this limited inclusion was of value to the overall analysis, as will later be seen.

Having conducted an integrated literature review proved to be a valuable tool in representing the state of knowledge concerning ACPOE systems as patient and medication safety interventions and in exposing areas in the research which have been left unanswered, thereby helping to direct future research and developments. To achieve such a goal, relevant data was extrapolated and analyzed from systematically selected

studies that met the inclusion criteria involving outpatient settings, clinical trials, and metrics. Thus, my inclusion criteria constituted studies done on ACPOE systems and ambulatory handheld computer CDSS interventions from 1998 to the present. The design of the studies consisted of a randomized controlled trial, a non-randomized controlled trial, or observational studies with controls (Kaushal et al., 2003). In other words, they reflected minimum level 3 studies from the research design framework (**Table 2**).

Acceptable study designs for observational studies were before-and-after interventions, case control, cohorts and cross sectional, retrospective or interrupted time series analyses (Kaushal et al., 2003). Systematic reviews were also eligible for inclusion provided that they addressed the elements under study in my own research. The metrics of interest consisted of levels 1 through 3 or any combination thereof from the outcome measure framework (**Table 2**). The concrete differences between level 1 and 2 measures (see Definitions section) affect the outcome. In the case of ADEs, the result was patient morbidity or mortality and thus, “clinical” (Kaushal et al., 2003). Conversely, medication errors are of potential risk to the patient but do not necessarily cause any harm and therefore are “surrogate” outcomes (Kaushal et al., 2003). In correspondence with **Table 2**, level 1, 2 and 3 measures were preferable for the analysis (Kaushal et al., 2003). While studies consisting of level 3 measures have an oblique connection to the target safety outcomes, it did not preclude them from eligibility for inclusion in the analysis. I have excluded studies that either fail to account or adjust for inherent biases and confounders, have no experimental controls (level 4 study designs) and outcome measures that are irrelevant to a reduction in medical errors or adverse events (level 4 outcome measures),

or fall outside of the proposed time frame. The following points can be addressed empirically from this study:

- Medication errors and ADEs are abundant and problematic in ambulatory care.
- ACPOE, electronic prescribing with any level of clinical decision support as well as PDA-based CDS systems are an effective means of significantly reducing medication errors and ADEs in the ambulatory setting.
- Much has changed in regards to the development and safety of such systems within the time frame that will be used in my study: 1998 – present.
- ACPOE systems are at or below the level of safety as their inpatient counterparts.
- The biomedical literature pertaining to ACPOE systems and analysis of their effect on medication safety is going to be a little more profuse for each consecutive year within the study period.
- The body of research on ACPOE technologies primarily stems from homegrown systems at academic research institutions.
- The impacts on medication and patient safety are commensurate with the level of sophistication of technologies as well as the extent and practicality of clinical decision support integrated into such systems.
- Level 2 and 3 outcome measures will be more predominant within the specific body of literature.



**Table 1. Hierarchy of Study Designs\***

<b>Level</b>	<b>Study Design</b>	<b>Description</b>
1	Randomized controlled trials	Includes quasi-randomized processes such as alternate allocation
2	Nonrandomized controlled trials	Includes prospectively planned studies with predetermined eligibility criteria and outcome measures or prospective cohort studies that include intervention and control groups
3	Observational studies with controls	Includes retrospective, interrupted time series (a change in trend attributable to the intervention), case-control studies, cohort studies with controls, and health services research that includes adjustment for likely confounding variables
4	Observational studies without controls	Includes cohort studies without controls and case series

**Table 2. Hierarchy of Outcome Measures**

<b>Level</b>	<b>Outcome Measure</b>	<b>Description</b>
1	Clinical outcome	Any measure of morbidity or mortality including adverse drug events as defined in the "Outcome Definitions" subsection of the text.
2	Surrogate outcome	Observed errors, intermediate outcomes (eg, laboratory test results) with a well-established connection to the clinical outcomes of interest (usually adverse events)
3	Other	Other measurable variables with an indirect or unestablished connection to the target safety outcome (eg, pretest/post test after an educational intervention and compliance with "optimal" or "recommended" prescribing practice)
4	None	No outcomes relevant to decreasing medical errors or adverse events (eg, the study describes an approach to detecting errors but reports no measured outcomes)

## **Study Identification and Selection**

The study selection and data collection stage is critical for addressing the topic of interest. The art of searching is contingent upon applying certain methods where appropriate, as there are several channels through which the pertinent research may be found (Cooper, 1989). Relevant studies were identified and retrieved using the following database applications: Ovid SP, PubMed and Web of Science, all of which are geared toward searches within the biomedical literature. I also performed advanced searches in Google Scholar to evaluate and retrieve relevant citations. The platform of Ovid SP allows for searches across multiple bibliographic databases. The databases selected throughout my search process were Medline, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Health Star, and Health Technology Assessment. I specifically searched for studies evaluating computerized outpatient order entry systems either lacking clinical decision support or containing varying levels of clinical decision support with data about the degree of efficacy such systems had on medication safety. For purposes of clarification, an integrated CDS system that offers guidance on drug dosage, selection, and duration are considered basic, while those which provide drug references, knowledge bases, drug-drug and drug-allergy interactions, and alerts of potentially dangerous or inappropriate orders are considered to be more advanced systems (Kaushal et al., 2003).

As a graduate student in the Indiana University School of Informatics, I had access to these online databases through the Ruth Lily Medical Research Library at the Indiana University School of Medicine. Consulting with a medical librarian, moreover, was useful and informative. I was made aware of various search and citation features within



The conglomeration of studies gathered were then scrutinized to determine whether they met the inclusion criteria set forth previously.

The topic of ACPOE and its effect on patient safety has developed its own “invisible college” or, in other words, a group of prominent researchers who study and report on this or similar topics and make an effort to pool their respective research endeavors (Cooper, 1989). This phenomenon stems from the under-studied and underdeveloped nature of this particular area of research. Cooper (1989) asserts that “[i]nvisible colleges are temporary units that deal with special problems and then vanish when the problem is solved or the focus of the discipline shifts” (p. 41). I became aware of the invisible college by a combination of the search process, information gathered from my committee members, and the known fact that this area of study is sparse and leaves many unanswered questions. This process helped me in narrowing down a list of authors to look for during study selection.

Publication issues also limited the literature I was able to include in my review. There were two studies I came across on the [clinicaltrials.gov](http://clinicaltrials.gov) website that met my inclusion criteria stated above. After having contacted the principal investigators for those projects, I was informed that the data were in but the studies have not been published yet. Therefore, I was unable to include those studies in my analysis. They did however provide me published data that was eligible for incorporation into the research review. The principal investigators within the context of my research review were considered to be “invisible college contacts” or scholars that are known to be heavily involved in a particular area of research (Cooper, 1989). Such an effort was an attempt to reduce publication bias in the research review. Publication bias is the tendency to publish

only those results that are significant; this tendency can lead to an inflated portrayal of a relation (Cooper, 1989). According to Hopewell, McDonald, Clarke and Egger (2007), the inclusion of studies that have not been officially published, or what they refer to as “grey literature,” is advisable. It can help to conquer some of the issues publication bias can present, which may come about as a result of the discriminatory nature of the data that is publicly available (Hopewell et al., 2007). However, given that my attempts to include some “grey literature” into the review were futile, it was accounted for as a potential limitation in this study. The subsequent decision to rely solely on published data therefore deemed this study exempt from Institutional Review Board approval.

After collecting relevant research, I was then able to use the “ancestry approach” to further refine the search process. Cooper (1989) explains that in using this approach, “the reviewer retrieves information by tracking the research cited in already-obtained relevant research” (p. 43). Scrutinizing the bibliographies from a handful of pertinent articles enabled me to capture studies I may not have otherwise found. Initial selection was based on the titles of the cited research and how well they seemed to address the topic of interest. The final decision regarding whether or not to include a given study in the integrative review hinged on the unit of analysis or outcome measure used and the study’s design. Units of analysis in scientific research are, according to Babbie, (2004) “those things we examine in order to create summary descriptions of all such units and to explain differences among them” (p.96). Given the heterogeneous nature of the research in this area, it was unavoidable that some of the studies selected for inclusion did not specifically measure the rate of serious medication errors and preventable ADEs. Upon

further review, a study was excluded if its unit of analysis was a level 4 outcome measure, because that measure is irrelevant to reducing medical errors or adverse events.

### **Study and Data Evaluation**

There is, however, far more to the process of deciding which studies to include than just selecting studies that match the inclusion criteria. The data therein must be evaluated on a deeper level to ascertain the quality of the research and data validity. As Cooper (1989) points out, “[d]ata evaluation requires the establishment of criteria for judging the procedural adequacy of how the data were generated” (p. 63). It is important in the data evaluation phase to consider possible confounding factors that may render the data extraneous to the issue of interest (Cooper, 1989). For example, an ACPOE system may not be completely responsible for a significantly positive impact on medication safety. The bulk of this finding may be attributed to a confounder such as having pharmacists present in an outpatient center to manage the prescribing process and serve as consultants when needed. Studies were evaluated to ensure that confounding factors were either avoided or at least adjusted for (levels 1-3 study designs).

I used the frameworks in **Tables 1 and 2**, designed by the University of California San Francisco-Stanford Evidence-Based Practice Center for the evaluation of study design and measured outcomes, as a guide for the assessment and integration of existing research. The studies, which were initially identified and selected by title and abstract, were further scrutinized for characteristics of methodological quality using guidelines for systematic reviews from the Potsdam Institute of Pharmaco-epidemiology and Technology Assessment (Cook, Sackett & Spitzer, 1995) and critiques of patient safety interventions from the Agency for Healthcare Research and Quality (Shojania, Duncan,

McDonald, Wachter, & Markowitz, 2001). This method of assessing study quality became preferable to the quantitative scoring of study quality because of the inherent problems found in quality scoring, such as a wide variation in scales used for the same purpose (Juni, Witschi, Bloch, & Egger, 1999). Furthermore, given the diverse nature of studies included in this review, quantitative scoring was deemed inappropriate.

### **Data Extraction and Analysis**

Due to the degree of heterogeneity detected in the studies included for review, I could not justify performing a quantitative or meta-analysis. Heterogeneity was found on multiple levels including study design, clinical outcome measures, statistics used for analysis (which made actual results vary), and type of technology used for electronic order entry (which ranged from basic to more sophisticated clinical decision support on ACPOE and e-prescribing systems). Consequently, a qualitative approach was undertaken to analyze the results across multiple studies. The heterogeneous nature of the included studies, however, enabled me to organize and perform qualitative sub-group analyses by searching for patterns and trends in the data based on each sub-group. Taking such an approach can facilitate a better understanding of the heterogeneity that exists across the studies and how it fits into the larger scheme of the research review (Cook et al., 1995). The sub-groups consist of study design, setting, outcome measures, patient demographics and the type of technology used. I additionally presented overall patterns of study designs, their corresponding outcome measures, and commercial-versus-homegrown systems, and I elaborated on the potential implications of such patterns for the research review as a whole.

## CHAPTER FOUR: RESULTS

A total of twenty-one studies met the inclusion criteria. Six potential studies from the initial selection were discarded for the following reasons. Two had a relatively weak and uncontrolled sampling design (Lapane, Waring, Schneider, Dube, & Quilliam, 2008; Galt et al., 2005); two introduced non-computerized prescription safety interventions into the observation of patient care (Frances, Alperin, Adler, & Grady, 2001; Samore et al., 2005); one evaluated the effect of computerized reminders integrated into hospital information systems at twelve ambulatory Veterans Affairs (VA) clinics on provider adherence to standards of care, which was too broad to yield meaningful data on medication ordering in particular (Demakis et al., 2000); and one was a meta-analysis of randomized controlled trials, which showed a positive effect on improving anticoagulation therapy and rates of hemorrhaging but, nonetheless, focused on isolated CDSSs and also incorporated results from inpatient settings (Chatellier, Colombet, & Degoulet, 1998). Studies were broken down into three groups: Electronic prescribing systems, ACPOE systems and clinical decision support on handheld computers. For clarification within the scope of this review, ACPOE systems are multi-functional technologies used for more than just ordering medications such as laboratory tests. Electronic prescribing systems, on the other hand, are used solely for the transmission of medication orders. Both types of systems can have any level of clinical decision support and be interfaced with or linked to a broader, more comprehensive system such as an electronic health record (EHR), clinical information system, or electronic patient flow manager. Such systems can also be independent of the type of technology used.



### **Explanation of Study Designs, Backgrounds and Outcome Measures**

The ten studies listed in **Table 4** assessed basic electronic prescribing systems as well as those electronic prescribing systems with some level of clinical decision support. Four were randomized controlled trials (two of them clustered and one prospective), two were prospective studies, one was a non-randomized 20 month follow-up study, and the remaining three were level 3 observational study designs consisting of before-after, cross-sectional with control sample, and retrospective analyses. (Christakis et al., 2001; Davis, et al., 2007; Jani et al., 2008) conducted their studies in pediatric outpatient clinics. Only Jani et al. (2008) focused specifically on nephrology care, perhaps to accentuate the risks of dosing errors in children with renal impairment. Christakis et al. (2001) focused on prescribing practices specifically for otitis media, which is a common type of infection amongst children.

Three of the studies evaluated basic electronic prescribing systems, all of which, incidentally, were prospectively planned. Gandhi et al. (2002) did a comparative analysis of two handwritten outpatient sites and two computerized outpatient sites for a total of 1,868 prescriptions generated by 24 primary care physicians. A similar cohort study was performed 3 years later by the same primary researcher who screened 1,879 prescriptions from 1,202 patients at 4 primary care clinics and then compared the e-prescribing sites with the handwritten ones (Gandhi et al., 2005). This study added another useful dimension to their analysis by also assessing the rates, types and severity of outpatient medication errors (Gandhi et al., 2005). It demonstrated that the most recurrent types of errors were related to dosing and frequency (Gandhi et al., 2005). The study by Galt et al. (2005), which evaluated basic electronic prescribing, had some differences. First, the

system studied was specifically PDA-based. Second, it was the only randomized controlled trial of the bunch. The total amount of prescriptions evaluated for this study was 19,372 at baseline and 14,378 after the intervention from 78 physicians across 31 office-based practices. The resulting large sample size gave this study great statistical power. The final study of the basic e-prescribing group had a cross-sectional with control sample design and compared the surveyed responses of physician e-prescribers with those of non e-prescribers regarding their perceptions of prescription safety and workload (Wang et al., 2009).

Interestingly, most of the studies which assessed e-prescribing systems with clinical decision support measured physician adherence to optimal or recommended prescribing practices (level 3). Only two studies of basic e-prescribing systems, both of which were conducted by Gandhi et al. (2002; 2005), introduced a measure of change in ADE rates into the mix (level 1). However, neither study detected any significant difference in the rates of ADEs and preventable ADEs in its comparison of computerized to handwritten sites. Moreover, these two similar studies had conflicting results in terms of medication error rates. One found that computerized sites were much less likely to encounter medication errors with statistical significance ( $p < .0001$ ) (Gandhi et al., 2002). The other one found little difference in the occurrence of medication errors at sites with basic e-prescribing compared to handwritten sites (4.3% vs. 11%) and these results were not statistically significant ( $p=.31$ ) (Gandhi et al., 2005). However, it should be noted that these two studies evaluated different electronic patient records, which helps to explain the contradictory results. The most typical medications associated with prescribing errors were antibiotics ( $n=31$ , 22%), NSAIDS ( $n=10$ , 7%), narcotics ( $n=9$ , 6%), corticosteroids,

(n=8, 6%) and antidepressants (n=8, 6%) (Gandhi et al., 2005). It was predicted that more advanced e-prescribing systems with dose and frequency checking could have prevented 97% of medication errors and 95% of potential ADEs, indicating that basic systems alone may be insufficient to lower the rate of errors (Gandhi et al., 2005). Galt et al. (2005) found substantial reductions in errors of legibility, omissions, and use of abbreviations and symbols on a basic e-prescribing system based on PDA devices. The larger sample size and stronger research design for this study made its findings particularly noteworthy.

The study by Jani et al. (2008) was the only one on e-prescribing with clinical decision support to measure surrogate level 2 outcomes. It showed a drastic decline in errors of omission and legibility with an error rate of 74.4% pre-intervention to 4.8% post-intervention, which was statistically significant ( $p < .001$ ). Also, error free patient visits increased by 70% after system implementation. The remaining e-prescribing studies with CDS all measured changes in some form of prescribing practice. The study by Wang et al. (2009) was the only one on e-prescribing with CDS to measure physician's perception of improved prescribing safety practices via responses to a survey. Of particular importance was the reporting from the e-prescribing users (n=139) of a greater ability to pinpoint clinically relevant drug-drug interactions than non-e-prescribers (83% vs. 67% of non-e-prescribers; n=89) which was the most statistically significant result ( $p=0.004$ ). 83% of users versus 73% of non-users ( $p=0.07$ ) reported the perception that the system enhanced prescribing safety (Wang et al., 2009). Isaac et al. (2009) retrospectively measured clinician acceptance of 233,537 medication safety alerts generated by 2,872 physicians using a common e-prescribing system. Alerts were

categorized as high, moderate, or low severity interactions. The acceptance rate for high severity alerts was 10.4%, which was only about 3% greater than the acceptance rate for moderate to low severity interaction alerts ( $p < 0.001$ ) (Isaac et al., 2009). The wide fluctuation in the acceptance of high severity alerts was a result of the classes of medications and variables such as whether the patient had tolerated the alerted medication previously (Isaac et al., 2009).

Two studies measured safety in clinician prescribing practices in ambulatory pediatrics. In a computerized point-of-care evidence-based messaging module interfaced with an e-prescribing system for the ordering of antibiotics in children suffering from otitis media, intervention providers had a significant reduction ( $p < 0.01$ ) in antibiotic therapy duration below the standard 10 day course. These intervention providers were also less likely to prescribe antibiotics ( $p=0.095$ ) as the course of treatment (Christakis et al., 2001). Similarly, another point-of-care evidence based intervention, which was part of an e-prescribing system with CDS, demonstrated considerable improvements in prescribing practices for ordinary pediatric outpatient maladies (Davis et al., 2005). Specifically, the proportion of medications prescribed in accordance with evidence based guidelines increased by 4 percentage points from baseline (38%) to post-intervention (42%) with an adjusted difference between intervention and control groups at 8% (Davis et al., 2005).

The final two studies, respectively, evaluated the MOXXI integrated e-prescribing and drug management system's impact on inappropriate prescribing in the elderly (Tamblyn et al., 2003) and assessed the perceived improvement in the quality and continuity of care by clinician users (Tamblyn et al., 2006). The first of the two was a

cluster randomized controlled trial with a sample size of 12,560 and showed an 18% lower rate of inappropriate prescriptions for the elderly (RR=0.82; 95% CI: 0.69 – 0.98) (Tamblyn et al., 2003). Differences between intervention and control groups in the discontinuation rate of potentially risky prescriptions were only significant for duplication of therapy (RR=1.66) and drug interactions (RR=2.15) (Tamblyn et al., 2003). The second study was a 20-month follow-up and measured clinicians' perceptions of the MOXXI portable system by computing an average rating with the standard deviation on a Likert Scale (1=Strongly Disagree; 5=Strongly Agree) (Tamblyn et al., 2006). The score for improved quality of care was 4.20 (SD=0.91) and the score for improved continuity of care was 4.38 (SD=0.69). However, the small sample sizes corresponding to these results may somewhat weaken their significance.

**Table 4. Studies of Basic Electronic Prescribing Systems and Those with Varied Clinical Decision Support**

Research Description	Research Design	Study Outcome Metrics	Results
Christakis et al., 2001. Tested point-of-care decision support in an integrated EP system on prescribing practices for otitis media at an outpatient pediatric care center	Level 1 (RCT)	Level 3 (Measure of improvement in prescribing practices)	Intervention providers had a 34% greater reduction in duration of antibiotic therapy below typical 10 day course ( $p < .01$ ). Intervention providers were less likely to prescribe antibiotics ( $p=.095$ )
Gandhi et al, 2002. Compared ME and ADE rates in handwritten sites vs. sites with computerized prescribing. Sites consisted of 4 of 4 outpatient clinics in the Boston area	Level 2 (Prospective study)	Levels 1 and 2 (ADE and ME rates)	Computerized sites were much less likely to have medication errors ( $p < .0001$ ). No significant difference between computerized and handwritten sites in ADE rates and preventable ADE rates (37%, 35%)
Tamblyn et al, 2003. Assessed whether CDS integrated into the MOXXI system reduced inappropriate prescribing by random assignment of 127 PCPs with at least 100 patients aged 66 or older ( $n=12,560$ ) to the intervention or control group	Level 1 (Cluster-RCT)	Level 3 (Measure of reduction in inappropriate prescribing)	Initiation rate of inappropriate scripts was significantly lower (18%) in the intervention group (RR=0.82; 95% CI: 0.69-0.98). $\Delta$ between groups in discontinuation rates of potentially risky meds were significant only for therapy duplication (RR=1.66; 95% CI: 0.99-2.79) and prescription drug interactions (RR=2.15; 95% CI: 0.98-4.70)
Galt et al, 2005. To determine the impact of EP PDA use on medication prescribing errors. 78 Physicians participated In 31 primary care office-based practices	Level 1 (Prospective RCT)	Level 2 (Medication errors)	Significant reductions in errors of legibility, omissions, use of abbreviations and symbols

<p>Gandhi et al, 2005. Assessed the rates, types and severity of outpatient med errors and understand potential impact of basic e-Rx by screening 1879 prescriptions from 1202 patients at 4 primary care clinics; 2 hospital-based 2 community-based</p>	<p>Level 2 (Prospective cohort with intervention and control groups)</p>	<p>Levels 1 and 2 (ADE and prescription error rates)</p>	<p>No significant difference for medication error and potential ADE rates at sites with basic e-prescribing compared to handwritten sites (4.3% vs 11%, p=.31; and 2.6% vs 4.0%, p=.16). Estimated that advanced e-Rx with dose and frequency checking would prevent 97% of ME's and 95% of potential ADEs</p>
<p>Tamblyn et al, 2006. Evaluation of acceptability and use of a portable e-Rx and drug management system for PCPs</p>	<p>Level 2 (20 month follow-up study)</p>	<p>Level 3 (Perceived improvement in the quality and continuity of care by physician users)</p>	<p>Mean rating with st.dev on Likert scale (1=strongly disagree; 5=strongly agree). Will improve quality of care – 4.20 (SD = 0.91); % strongly agree = 48% (n=12); correlation w/ expected use = 0.32 (p=0.13); Will improve continuity of care – 4.38 (SD = 0.69); % strongly agree = 46.2% (n=12); correlation w/ expected use = 0.71 (p &lt; 0.001)</p>
<p>Davis et al, 2007. To assess whether the e-Rx and decision support system improved pediatric prescribing behavior in choice of treatment, frequency and dosage in a primary care pediatric clinic</p>	<p>Level 1 (Cluster RCT)</p>	<p>Level 3 (Proportion of prescription dispensed in accordance with "optimal" or "recommended" prescribing practice)</p>	<p>Proportion of medications dispensed in accordance with evidence improved 4 percentage points from baseline 38% to 42% after intervention. Adjusted difference b/w intervention and control groups = 8% (95% CI 1%, 15%)</p>
<p>Jani et al, 2008. Assessed the effect of an EP system on the incidence and type of medication errors and the number of error-free visits in a nephrology outpatient clinic at an acute tertiary care pediatric hospital</p>	<p>Level 3 (before-and-after study)</p>	<p>Level 2 (Errors of omission and legibility errors)</p>	<p>74.4% (n=1219) prescription error rate before EP. Only 4.8% (n=31) post EP (p &lt; 0.001). Error free visits increased from 21% pre EP to 91% post EP</p>

<p>Isaac et al, 2009. A retrospective analysis of 233,537 med safety alerts generated by 2872 physicians using EP systems</p>	<p>Level 3 (Retrospective analysis)</p>	<p>Level 3 (Clinician acceptance of medication safety alerts)</p>	<p>Clinicians accepted 9.2% of drug interaction alerts and 23% of allergy alerts. 61.6% of alerts stemmed from high severity interactions. Of those, the acceptance rate was slightly more than for moderate to low severity interaction alerts (10.4%, 7.3% and 7.1%, respectively, <math>p &lt; 0.001</math>). Acceptance rate of high severity alerts depended on the classes of meds and thus varied from 2.2% to 43.1%. Clinicians were less likely to accept a drug interaction if the patient had previously received the alerted med (OR=0.03, 95% CI: 0.03 – 0.03)</p>
<p>Wang et al, 2009. Compared experiences e-prescribe users vs. non-users regarding Rx safety and workload via survey taken by eligible physicians</p>	<p>Level 3 (Cross-sectional study with control sample)</p>	<p>Level 3 (Physician perception of improved safety prescribing practices)</p>	<p>E-prescribers (n=139) reported better ability to identify clinically significant, potential drug-drug interactions (83% vs 67% of non e-prescribers (n=89), (<math>p=0.004</math>); identify clinical circumstances where alternative meds may be less risky (75% vs 65%, <math>p=0.10</math>); and prescribe meds more safely overall (83% vs 73%, <math>p=0.07</math>)</p>

\*ADE indicates adverse drug event; CI, confidence interval; ME, medication error; OR, odds ratio; RCT, randomized controlled trial; RR, relative risk; and EP, e-prescribing

**Table 5** lists eight studies that evaluated ambulatory computerized physician order entry (ACPOE) systems with CDSSs ranging from basic to more refined. Three were randomized controlled trials, two were non-randomized consisting of a prospectively planned and pre- to post-intervention analysis, and the remaining studies were observational research designs consisting of a retrospective series and two interrupted time series analyses.

Several of the studies (Weingart et al., 2003; Steele et al., 2005; Palen, Raebel, Lyons, & Magid, 2006; Smith et al., 2006) focused on alerts or reminders generated within the electronic order entry systems. Two studies specifically targeted the effect of drug-laboratory alerts (Steele et al., 2005; Palen et al., 2006), one study looked at drug-



allergy and drug-interaction alerts (Weingart et al., 2003), and one study examined the effect of alerts providing alternative medications when clinicians ordered high risk drugs for elderly patients (Smith et al., 2006). Each study took very different approaches. Weingart et al. (2003) analyzed past data (retrospective) on the physician override rate of alerts as well as ADE rates from 3,481 consecutive alerts on medication orders at 5 primary care clinics affiliated with Beth Israel Deaconness Medical Center. Steele et al. (2005) performed a before-after analysis of the intervention at a primary care clinic within a larger safety net institution in Colorado. Palen et al. (2006) randomly assigned 207 primary care physicians to be given or not be given drug-laboratory monitoring alerts within the CPOE system. The study by Smith et al. (2006) evaluated data from a 39-month period to detect changes in medication ordering resulting from the installment of a CPOE alert system using interrupted time series.

McPhillips et al. (2005) used children as the target base for the study. Two paper-based HMO sites were compared to one HMO site with a CPOE module that had very basic decision support and lacked dose calculations or error checking (McPhillips et al., 2005). A random selection of 120 children receiving any drug of interest gave a sample size of 1,933 (McPhillips et al., 2005). The study by DuBeshter et al. (2006) was unique in that it assessed errors related to chemotherapeutic medications and the impact of the IntelliDose order entry system, which was developed for outpatient oncology practices. Data were collected and analyzed for dosing errors from 2,558 chemotherapy drugs given to a total of 235 patients (DuBeshter et al., 2006). Murray et al. (2004) performed a randomized clinical trial on a sophisticated outpatient CPOE intervention designed to promote compliance with treatment suggestions or outcomes for patients with

uncomplicated hypertension. Data from the Regenstreif Medical Record System (RMRS) were used to compile the computerized treatment recommendations and the setting was an academic ambulatory clinic affiliated with the Indiana University School of Medicine (Murray et al., 2004). Finally, El-Kareh et al. (2009) administered a survey to 86 primary care physicians to measure their perceptions on patient safety at 1-, 3-, 6- and 12-month intervals after implementation of an EHR system with CPOE. It took place across 19 ambulatory health clinics affiliated with Atrius Health (El-Kareh et al., 2009). The small sample size may have attenuated this study.

Five of the studies in **Table 5** had some combination of levels 1, 2 and 3 outcome measures, and the clinical outcomes frequently occurred as secondary analyses. The remaining three studies consisted of two level 3 outcomes and one level 2 outcome. In the first study, physicians ignored 91.2% of drug-allergy and 89.4% of high severity drug interaction alerts (Weingart et al., 2003). Physicians (n=189) were less likely to prescribe alerted medications under two primary circumstances: if the physician was a young, entry-level clinician ([OR] = 0.26; CI: 0.08 – 0.84) or if the patient had multiple drug allergies ([OR] = 0.70; CI: 0.53 – 0.93) (Weingart et al., 2003). Such occurrences indicate both a possible correlation between younger doctors and a higher acceptance rate of the technology and the possibility that drug-allergy alerts are a particularly valuable element of decision support to providers. When physicians observed the alert, no ADEs were found, but among patients with physician alert overrides, 3 ADEs were found (Weingart et al., 2003). However, these findings were not significant (p=0.55) (Weingart et al., 2003). The findings of the two studies assessing drug-laboratory related medication errors were quite different. In the study performed by Steele et al. (2005), when an alert was

displayed regarding abnormal lab results to providers, particularly those dealing with high-risk prescriptions, the providers canceled more medication orders and more lab tests were ordered. Both findings were significant ( $p=0.03$  and  $p < 0.001$ , respectively) (Steele et al., 2005). A non-significant 6% decrease ( $p=0.23$ ) was also observed in “definite” or “probable” ADEs as defined by Naranjo scoring (Steele et al., 2005).

Palen et al. (2006) found no substantial overall difference in recommended lab monitoring between the intervention and control groups. Instances of statistical significance favored the intervention group only for certain medications such as statins ( $p=0.05$ ) and gemfibrozil ( $p=0.003$ ) (Palen et al., 2006). Murray et al. (2004) demonstrated that a refined outpatient CPOE system failed to improve adherence to either suggested modes of evidence-based treatment or the outcomes of patients with uncomplicated hypertension. Likewise, McPhillips et al. (2005) showed that an HMO site installed with a basic CPOE system had no difference in the rates of dosing medication errors compared to the non-CPOE sites. As a secondary outcome, it found that analgesics are likely associated with potential overdosing and that anti-epileptics are likely associated with potential under-dosing (McPhillips et al., 2005). The negative results of the former two studies on basic and sophisticated CPOE systems are gripping and perhaps testify to the need for improvements in design that allow the systems to integrate into clinical workflows more smoothly.

DuBeshter et al. (2006), on the other hand, reported no errors in dosing, decimal points, and medication selection at the stage of ordering using the IntelliDose system for outpatient chemotherapy patients. As a secondary endpoint, the average time saved per order set using the CPOE system was 10 minutes ( $p < 0.05$ ) (DuBeshter et al., 2006). El-

Kareh et al. (2009) illustrated from survey results that physician acknowledgement of a reduction in medication related errors increased by 9% from 1 month to 12 months past the intervention (p=0.03); they also found a 19% increase in the perception of improved follow-up test results (p < 0.001). Both results show statistical significance but may be overvalued in light of the relatively small sample sizes. Finally, Smith et al. (2006) demonstrated a 22% relative reduction (p=0.004) in non-preferred medications for the elderly just 1 month after a CPOE with CDS intervention.

**Table 5. Studies of Ambulatory Computerized Physician Order Entry (ACPOE) systems with Varying Levels of Clinical Decision Support**

Research Description	Research Design	Study Outcome Metrics	Results
Weingart et al, 2003. Measured the override rate of drug-allergy and drug interaction alerts among 3481 consecutive alerts integrated into a common CPOE system for med orders at 5 primary care facilities associated with Beth Israel Deaconess Medical Center. ADE rates also observed	Level 3 (Retrospective series)	Levels 1 and 3 (Observed ADEs from overridden alerts vs those not ignored and changes in prescribing behavior from the alerts)	Physicians ignored 91.2% of drug-allergy and 89.4% of high-severity drug interaction alerts. Physicians (n=189) were less likely to prescribe an alerted med if he/she was a house officer/entry level physician [OR]=0.26; CI: 0.08 - 0.84 and if patient had numerous drug allergies [OR]=0.70; CI: 0.53 - 0.93. No ADEs found in cases where physicians observed the alert and 3 ADEs among patients with alert overrides (p=0.55)
Murray et al, 2004. Measuring compliance with treatment suggestions for patients with uncomplicated hypertension at an IUSM affiliated ambulatory clinic	Level 1 (RCT)	Levels 1 and 3 (Care suggestions for antihypertensive drug regimens and avoiding complications of hypertension)	Intervention group: 35% of suggestions implemented where both physicians and pharmacists received suggestions; 29% physicians only; 25% pharmacists only (p=0.13)

McPhillips et al, 2005. Compared 2 paper-based HMO sites with 1 HMO site that has a CPOE module on dosing error rates in children given a new prescription for each drug of interest (n=1933)	Level 1 (RCT)	Level 2 (Medication dosing errors)	15% (280) of the children across the sites had potential dosing errors. Of those, 8% were potentially overdosed and 7% potentially under-dosed. The CPOE site had similar rates of meds ordered within the recommended dosage range compared with other 2 sites (87% vs 84%). No observed difference in error rate at site with CPOE compared with non-CPOE sites
Steele et al, 2005. Impact of automated alerts on drug-lab related medication errors at a primary care clinic in an integrated safety net institution in Colorado	Level 2 (Non-RCT; Pre/post comparison of intervention)	Levels 1 and 3 (Potential ADE rates from chart reviews pre/post intervention and changes in ordering practice)	Providers canceled more medication orders when alerted about abnormal lab results particularly with high risk meds (5.6% vs 10.9%, p=0.03). Observed increase in ordering of lab tests when alert was displayed (39% at baseline vs 51% post intervention, p < 0.001). Non significant decrease in "definite" or "probable" ADEs as defined by Naranjo scoring (10.3% at baseline vs 4.3% post intervention, p=0.23)
Dubeshter et al, 2006. ACPOE system: IntelliDose assessed for impact on error relating to 26 chemo-therapy regimens over 12 month period in 235 ambulatory patients	Level 2 (Non RCT prospective planning)	Levels 2 and 3 (Errors of drug selection, dose calculations and decimal point; time saving measures)	Of 2,558 drug regimens to 235 ambulatory patients there were no errors reported in dosing, decimal points or drug selection at the ordering stage; average time saved per order set using CPOE was 10 minutes (p < .05)
Palen et al, 2006. Evaluated how reminders presented during CPOE for medications effects physicians' compliance with guidelines for lab monitoring at therapy initiation	Level 1 (RCT)	Level 3 (Measure of improvement in prescribing practices)	Overall, no significant difference in recommended lab monitoring for prescriptions given in intervention vs. control group (56.6% vs. 57.1%). Cases of statistical significance favored the intervention group for certain medications: 71.2% vs 62.3% [P = .003] for gemfibrozil, 75.7% vs 73.9% [P=.05] for statins and 52.8% vs 46.0% [P=.05] for colchicine

El-Kareh et al, 2009. Measured changes in PCP (n=86) attitudes on multiple levels via survey in 1, 3, 6 and 12 month intervals after EHR implementation at Atrius Health consisting of 19 ambulatory health clinics	Level 3 (change in survey response after intervention)	Levels 2 and 3 (Perceived impact on patient safety in terms of ME reduction and improvement in the follow-up of test results)	Physician agreement that system reduced medication related errors from 1 month to 12 months post intervention (72% to 81%, p=0.03, n=79 and 69 respectively). Significant physician perception of improved follow-up of test results (62% to 81%, p < 0.001, n=79 and 69, respectively)
Smith et al, 2006. Examined the effects of CPOE with CDS in decreasing the use of high risk meds for the elderly. The setting was a large HMO	Level 3 (Interrupted time series)	Level 3 (Measure of reduction in non-preferred meds prescribed for the elderly)	22% relative reduction in non-preferred meds to 5.1 scripts per 10,000 (p=0.004) 1 month post intervention

\*ADE indicates adverse drug event; CI, confidence interval; ME, medication error; OR, odds ratio; RCT, randomized controlled trial; and RR, relative risk

**Table 6** shows three studies that evaluated ambulatory handheld computer-based CDSSs. Two were randomized controlled trials and the last one was an observational study nested within a larger randomized controlled trial (levels 1 and 3). Rothschild et al. (2002) evaluated clinician use of a drug knowledge base (e-pocrates Rx) on a palmtop computer. 3,000 system users were randomly selected to take a week-long online survey. Berner et al. (2006) evaluated the efficacy of a PDA-based CDSS, used specifically for the risk assessment and prescribing safety of non-steroidal anti-inflammatory drugs (NSAIDs), by randomly assigning 68 internal medicine residents in an urban outpatient educational center to an intervention and control group. Rubin et al. (2006) assessed the adequacy and use of another PDA-based CDSS for diagnosis and treatment suggestions, specifically for acute respiratory tract infections (RTIs), at six rural outpatient clinics. A total of 14,393 provider-logged cases from the devices were analyzed electronically.

All of the studies on ambulatory handheld CDSSs used level 3 outcome measures. Only one of the studies included physician perceptions of reductions in preventable

ADEs as a secondary endpoint. It found that 86.3% of primary care physician respondents (n=754) noted improved efficiency processes in their outpatient practices (Rothschild et al., 2002). The secondary analysis found that 63.1% of respondents (n=597) perceived a reduction in potential ADEs (Rothschild et al., 2002). This figure should be used with caution, however, because it includes provider responses from both inpatient and outpatient settings. Nonetheless, the perceived positive direction in the lowering of potential ADEs from both ends of healthcare is of value.

In the study by Berner et al. (2006), there was a large safety-prescribing differential for NSAIDs between experimental and control groups from baseline (0.27 vs. 0.29,  $p > 0.05$ ) to post-intervention (0.23 vs. 0.45 [ $F=4.24$ ,  $p < 0.05$ ]). The intervention group prescribed more safely than controls after use of the CDSS and had a greater ability to document more comprehensive assessments of gastrointestinal dangers for patients taking NSAIDs (Berner et al., 2006). In contrast, Rubin et al. (2006) focused on changes in antimicrobial prescribing practices, particularly for patients with respiratory tract infections, and demonstrated an overall adherence with CDSS recommendations including drug, dose, and therapy duration at 82% (n=10,771). When antibiotics were ordered as the choice of treatment (53%, n=7,624), provider adherence to suggested antibiotic use for the five most common RTIs was 76% (Rubin et al., 2006). Furthermore, a logistic regression showed, at a statistically significant level ( $p=0.001$ ), that the odds of adherence to CDSS suggestions considerably increased with the completion of each of the ten cases (Rubin et al., 2006). In summary, all of these studies demonstrated positive changes in provider prescribing practices with the use of handheld-based CDSSs in outpatient settings; the evidence showed that erring on the side of safety constituted the

changes in provider prescribing practices. Two of the studies in **Table 6** seem to reinforce some of the findings by Gandhi et al. (2005) that antibiotics and NSAIDs are amongst the top medications associated with errors and patient safety issues in the ambulatory setting.

**Table 6. Studies of Outpatient Clinical Decision Support Systems on Handheld Devices**

Research Description	Research Design	Study Outcome Metrics	Results
Rothschild et al, 2002. Rx drug reference for clinician use on palm top technology	Level 1 (RCT)	Levels 1 and 3 (Clinician perception of reduction in preventable ADEs and improvement in practice efficiency)	86.3% of physician respondents (n=754) noted improvement in outpatient efficiency; 63.1% of 63.1 % of respondents (n=597) noted perceived reduction in potential ADEs (Note: this figure includes responses from both inpatient and outpatient practitioners)
Berner et al, 2006. Evaluated the efficacy of a PDA-based CDSS in a primary care residency educational center on the prescribing safety of NSAIDs. CDS included rule for gastrointestinal risk assessment and treatment suggestions	Level 1 (RCT)	Level 3 (Measure of differential changes in unsafe prescribing of NSAIDs in the intervention vs control Group)	The baseline average proportion of cases per physician for the experimental and control groups were similar (0.27 vs 0.29, $p > 0.05$ ). Intervention group prescribed more safely than controls after using the CDSS (0.23 vs 0.45 [F=4.24, $p < 0.05$ ])
Rubin et al, 2006. Assessed the acceptability and use of a standalone PDA-based CDSS for diagnosis and treatment suggestions (including drug, dose or therapy duration) for acute respiratory tract infections (RTIs) at six outpatient rural clinics	Levels 1 and 3 (2 study designs)	Level 3 (Measure of changes in antimicrobial prescribing practices)	Adherence with CDSS-recommended antibiotic use for the five most common RTIs was 76% of the 53% of all cases (n=7624). Overall adherence with CDSS recommendations was 82% (n=10771).

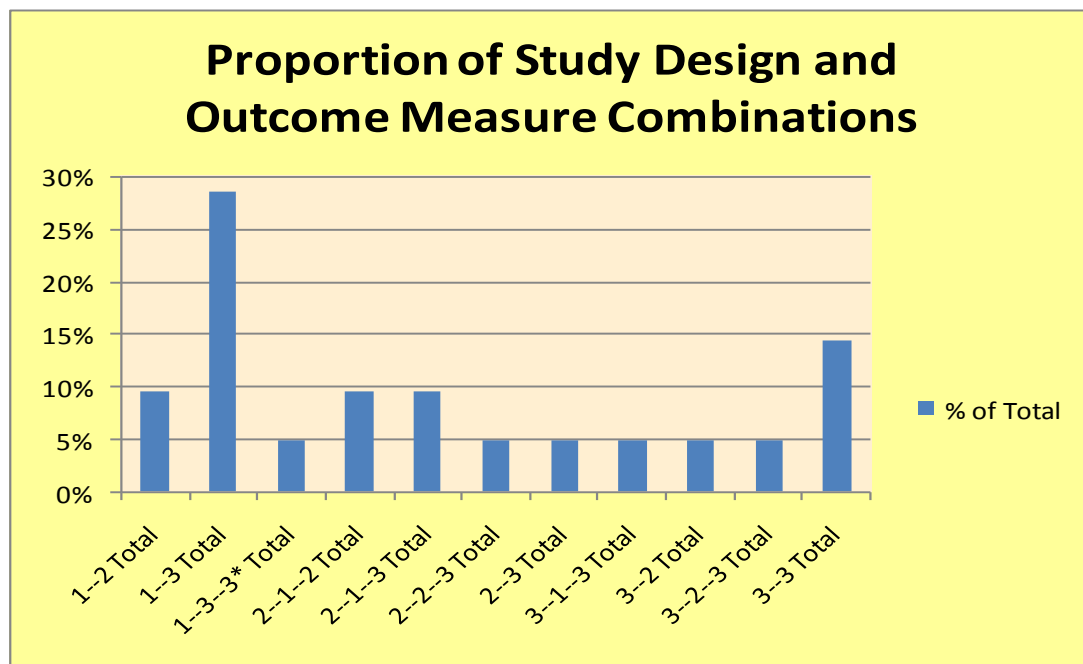
\*ADE indicates adverse drug event; CDSS, clinical decision support system; CI, confidence interval; ME, medication error; OR, odds ratio; PDA, personal digital assistant; RCT, randomized controlled trial; and RR, relative risk



## Overall Patterns of Study Design, Outcome Measures and System Types

**Chart 1** illustrates the overall proportion of study design and outcome measure combinations. The most frequent combination appears to be randomized controlled trials with a level 3 outcome measure. There were no clinical outcomes as a single measure. They were all presented in combination with surrogate or other measures with a circuitous connection to medication safety. Furthermore, 4/5 of the clinical outcome measures were yielded from non-randomized level 2 study designs. Clinical and surrogate measures, either independently or in combination, could be found in roughly 43% of the studies. Level 2 and especially level 3 outcome measures predominated because of the particularly high cost, and thus lower frequency, of more robust studies that assess the effect of an intervention on ADE rates (Kaushal et al., 2003). Moreover, the less abundant research of computerized safety interventions on the ambulatory side makes such studies even more difficult to locate.

**Chart 1**



\*Indicates a study which had two designs

**Table 7** represents an excel pivot table that illustrates where each system type is spread out along the study design and outcome measure spectrum. Totals appear in the last row and in the column furthest to the right. The system type column indicates both the kind of technology used for the safety intervention and whether the technology is homegrown or commercially available. Some gripping patterns are revealed. All but one of the randomized controlled trials with level 3 outcome measures were generated from homegrown systems consisting of one CPOE with CDS, three electronic prescribing systems with CDS, and one PDA-based CDSS. Nearly one half (10/21) of the included studies, more than originally expected, evaluated commercially available systems. Interestingly, nearly all of the studies with clinical or surrogate outcome measures, either separately or in combination with another measure, evaluated commercial technologies consisting of three common electronic prescribing systems, three ACPOE systems, and one handheld-based CDSS. Only two studies evaluated homegrown systems with measurements of higher relevance to the target safety outcome. One homegrown electronic prescribing system was analyzed along with another commercial system to measure reductions in both ADE and prescribing error rates (Gandhi et al., 2005). The other study looked at a sophisticated homegrown ACPOE system but measured the clinical outcome of avoidance in complications from hypertension as a secondary analysis (Murray et al., 2004). Neither study presented significant results. In summary, the studies evaluating homegrown systems tended to have stronger designs but produced measures with a roundabout connection to medication safety, whereas studies evaluating commercial systems tended to have weaker designs but more clinically relevant outcome measures.

**Table 7 Study Design and Outcome Measure Spectrum by System Type**

System Type	Design_outcome													Grand Total
	1--1--3	1--2	1--3	1--3--3*	2--1--2	2--1--3	2--2--3	2--3	3--1--3	3--2	3--2--3	3--3		
Basic e-prescribing - Commercial													1	1
Basic e-prescribing - Commercial and homegrown					1									1
Basic e-prescribing - Unknown					1									1
Common EP system on desktop - Commercial													1	1
CPOE with alert CDS integrated with an E-H-R system- Commercial													1	1
CPOE with alert CDS integrated with an E-H-R system- Unknown													1	1
CPOE with basic CDS integrated with an E-H-R - Commercial			1											1
CPOE with basic CDS integrated with an E-H-R system - Homegrown										1				1
CPOE with CDS integrated with an E-H-R system - Commercial						1	1							2
CPOE with CDS integrated with an EMR - Commercial				1										1
CPOE with cds integrated with E-H-R system - Homegrown			1											1
EP PDA device - Commercial			1											1
EP system with basic CDS - Homegrown				1										1
EP system with basic CDS integrated with electronic patient flow manager - Homegrown				1										1
EP system with evidence-based CDS - Homegrown				1										1
Integrated EP system with basic CDS - Commercial												1		1
PDA CDSS - Homegrown				1	1									2
Portable EP with CDS on PDA - Homegrown										1				1
Rx drug reference handheld - Commercial							1							1
Grand Total		1	2	5	1	2	2	1	1	1	1	1	3	21

\* Indicates a study which had two designs

## CHAPTER FIVE: DISCUSSION

### Overall Findings and Implications

The studies included in this review provide ample testimony to the notion that outpatient order entry systems are an effective means of reducing medication errors and promoting both safer prescribing practices and evidence-based medicine (EBM) among physicians. The PDA-based CDSSs had a pattern of demonstrating effectiveness in provider adherence to treatment recommendations or guidelines. There was little or no effect on reductions in ADE rates in those studies that included such clinical measures. However, these studies were not powered to detect such differences. A solid correlation exists between prescribing errors and ADEs, which thus greatly increases the likelihood that such outpatient safety interventions will decrease ADE rates (Kaushal et al., 2003). It

seems as though emphasis was placed on reducing the potential for harm instead of reducing actual harm. However, it is a logical to do what is medically necessary to avoid arriving at that situation in the first place. While a good handful of the studies addressed only level 3 outcome measures, it can be deduced that the demonstrated improvement in prescribing practices can certainly, albeit indirectly, lead to a reduction in errors.

The patient demographics in many of these studies either focused on samples of the pediatric or geriatric populations. Such demographic components are not surprising because these groups are at greatest risk for medical errors. Children are specifically prone to dosing errors from antibiotics and other drugs for common pediatric conditions because each child's dose must be individually calculated based on his or her age and weight (Kaushal, Barker & Bates, 2001). The elderly are at greater risk because many of them take numerous drugs to treat multiple conditions; physiological changes due to aging can also modify the chemical make-up of certain drugs when ingested (Monane et al., 1998).

The presence of these patient demographics in the ambulatory setting can be especially difficult because, whereas inpatient providers have more comprehensive patient information at their fingertips, providers in an ambulatory setting must rely on fragmented and incomplete bits of information emanating from disparate electronic and paper-based sources. Such a discrepancy in available information between the two settings shows a need not only for improvements in the design of future outpatient order entry systems but also for the creation of streamlined processes which enable better communication between inpatient and outpatient systems. It has been found that the pervasiveness of medical errors stemming from a discontinuity of care between the

inpatient and outpatient settings is excessive and may be linked to a greater chance of re-hospitalizations (Moore et al., 2003). Since the population will continue to age and most prescriptions and medical care in general will continue to be rendered in the ambulatory setting, there is much room for continued research and improvement through technological interventions.

As a final point, the inclusion of studies assessing different types of outpatient systems revealed that each system may be better suited for a specific task. For example, it was demonstrated that electronic prescribing and ACPOE systems are effective for reducing medication errors. ACPOE systems tended to have more refined CDS features but with mixed results, and PDA-based CDSSs were portrayed as quick, convenient, and less labor-intensive tools effective for drug referencing and compliance with treatment recommendations.

### **Study Contributions**

This research review is, to my knowledge, one of only two that have been done on studies specifically evaluating CPOE systems in the ambulatory setting. To date, little is known regarding the value of these systems in such an environment. Because it is the most recent review on the aforementioned topic, this review provides a fresh perspective on the effect that such systems have on medication safety and quality of care in the outpatient setting. Furthermore, it is the first review to show sufficient evidence of a positive effect of such systems on medication safety in ambulatory care; this is likely a result of both the relatively broad time frame used and the increasing number of relevant primary studies that have been published to date. This review contributes to the growing body of literature in this area by representing and summarizing the state of knowledge

and by helping to pinpoint where future research is needed. Finally, this review is unique in its incorporation of studies assessing different forms of CPOE systems, including electronic prescribing on either desktop computers or handheld devices. Studies evaluating PDA-based CDSSs were also included. Although these were a secondary endpoint of the analysis, they either had a strong study design or moderate to large sample sizes, and all three of the studies in this group had significant, valuable results.

### **Strengths of the Study**

The primary strength of this study lies in its review of current research on an under studied topic, which helps to illuminate, on multiple levels, the effect of ACPOE technologies on medication safety in the ambulatory setting. A snapshot overview of the existing primary research highlights the general direction in which these technologies are going towards influencing the improvement of safety and quality of care in outpatient settings. To substantiate this point, Cook, Mulrow and Haynes (1997) note that “[h]igh quality systematic reviews can define the boundaries of what is known and what is not known and can help to avoid knowing less than has been proven” (p. 378). A broad and thorough search of relevant literature was performed by using major bibliographic databases, initiating casual communications with primary researchers, and reviewing the references of preceding research (Cooper, 1989). Following these protocols increases the likelihood that another reviewer using multiple information sources would arrive at a parallel conclusion (Cooper, 1989). Furthermore, the methods for study selection were clearly explained (Cooper, 1989). To ensure that the selection criteria would be reproducible, I developed reliable search algorithms derived from a variety of MeSH terms that were tested, either independently or in various combinations, for precision and

recall of documents. All documents from the initial selection were thoroughly abstracted for evidence of methodological quality using established and reliable guidelines for studies evaluating patient safety interventions. Such testing and procedures safeguarded me from the potential disadvantage of being the only reviewer. Finally, many of the studies included in this review had large sample sizes, statistical power, and significant results.

### **Comparison to Preceding Work**

As stated previously, there have not been many integrative, systematic reviews dedicated specifically to studies of the effects of ambulatory order entry systems on medication safety. Eslami et al. (2007) performed a similar review but did not generate any conclusive evidence because it only reviewed four studies specifically assessing the effect of outpatient CPOE systems on safety. Of those studies, only one showed significant decreases in medication errors and none of them had any significant effect on the rate of ADEs (Eslami et al., 2007). Such conclusions can, perhaps, be attributed to the review's relatively broad and unfocused nature: it covered too many aspects of these systems, including safety, cost, efficiency, usage, usability, guidelines, alerts, time, and satisfaction (Eslami et al., 2007). Another explanation for their conclusions may rest in the even greater dearth of available studies published on the issue when they performed their search than there is now; though it is still low, the level of relevant studies published has risen during the several years since they performed their search. In addition, they did not include studies assessing electronic prescribing systems, which seem to be a prevalent form of CPOE in outpatient settings. The only one of their findings consistent with that in this review is ACPOE systems provide evidence for raising adherence to guidelines. A

study by Royal et al. (2006) also broached this topic and found no evidence of effectiveness, but, again, that review is several years old; more importantly, its focus, on primary care pharmacist-led safety interventions, is quite different from that of this review.

### **Limitations**

A potential limitation in all research reviews is publication bias, which is the tendency for only significant results to be published (Cooper, 1989). To try to avoid this limitation, efforts were made to reach unpublished data. These efforts were unfortunately futile. However, I contend that publication bias is less of an issue in the biomedical sciences because the publication of both significant and non-significant results is essential for the future development and improvement of information technologies in healthcare. The review was not overly optimistic because some of the included studies did have non-significant results, but this limitation was not enough to undermine the overall evidence of a positive effect on patient safety. Because ambulatory care constituted the setting for this review, it is difficult to compare these results to those of studies where the setting was inpatient care. This limitation in the ability to compare results stems from three factors: the different requirements demanded of such systems, the perceived differences in the granularity of information available, and differences in the type of drugs given and errors that arise in each setting, respectively. It would be more practical to compare the overall direction that inpatient and outpatient CPOE systems appear to be going in terms of improving patient safety and quality of care. Any shortcomings of ACPOE systems with respect to their level of safety, as inferred from the



review by Thomsen et al. (2007), could be attributed to the incomplete nature of information found in an ambulatory setting relative to an inpatient setting.

Another limitation is that clinical and surrogate outcomes (levels 1 and 2), measures of utmost importance for this review, had a tendency to be assessed in non-randomized studies. Such an occurrence is a potential threat to validity because it introduces selection bias into the results of those outcome measures. Still, while the gold standard for assessing medical interventions are randomized clinical trials, non-randomized and controlled observational studies tend to be more practical, less costly, and nonetheless productive of meaningful results (Thomas et al., 2004). Moreover, systematic reviews often need updating and eventually become outdated (Shojania et al., 2007). Finally, it has been shown that shorter survival of a systematic review is correlated with heterogeneity in the initial review (Shojania et al., 2007).

### **Value of the Findings to Practitioners**

The findings of this review can help practitioners understand the overall effect of both ACPOE systems and PDA-based CDSSs on patient safety and the quality of care rendered. It can help inspire them to make more informed decisions. It can also help them appreciate that such systems are not designed to replace them or rid them of their professional autonomy, but rather are meant to complement their medical expertise and make their respective practices more efficient and cost-effective. The informational needs of providers are especially great in the outpatient setting, and thus refined ACPOE systems with CDS are a critical necessity. Perhaps these findings can also help providers to realize that the long-term advantages and return on investment outweigh the short-term disadvantages such as high upfront and maintenance costs as well as disruption of clinical

workflow. In summary, such findings will help keep practitioners up to date on the state of these types of medical safety interventions. This promising and practical summary of evidence from the biomedical literature should prove to be a vital part of clinical decision making (Cook et al., 1997).

## CHAPTER SIX: CONCLUSION

The review provided evidence of a positive effect of ACPOE systems on patient safety and quality of care. Errors of omission, legibility, dosage, and frequency appeared to be the most common types of errors reduced. It was also demonstrated that PDA-based CDSSs tended to both facilitate provider adherence to safer prescribing practices and to provide convenient tools for access to drug reference and knowledge bases. Thus, future research is needed in the following areas: a comparison of different outpatient technologies to assess what they are best suited for in helping to promote patient safety, the direction and place for handheld devices in medicine based on their strengths, weaknesses, and growing popularity amongst providers, and an evaluation and comparison of commercial to homegrown systems. There is evidence from this review that the market for outpatient commercial CPOE and electronic prescribing systems may be growing and that their functional capabilities could be catching up with those of homegrown systems. More research is needed on the effects of natural language processing within such systems to promote better overall provider acceptance and patient safety. It would also be productive to not only investigate the question of whether error prevention outnumbers error causation in ACPOE systems, but also to identify and examine elements of success in the implementation of these systems (Ash et al., 2009).

Finally, the body of literature will continue to grow in the area of patient safety interventions in ambulatory care. Therefore, once there are a substantial number of homogenous studies, a meta-analysis should be performed to confirm the evidence presented in this review.

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Wolf, Z. R. (2007). Pursuing safe medication use and the promise of technology.

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**General Background:** Solid educational foundation in public health, health administration and health care informatics. Four years experience in advanced analytics and original health system research. History of leadership, innovation and problem solving with a strong sense of teamwork. Current interests include the impact of health information technology on physician behavior, quality and safety; using experimental approaches to analyzing and evaluating clinical information systems.

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## **EDUCATION**

Indiana University, Indianapolis, IN, August 2007 – December 2009 (GPA: 3.73/4.0)

School of Informatics/Regenstrief Institute, Inc.

Master of Science in Health Informatics

Thesis: *Ambulatory Computerized Provider Order Entry and PDA-based Clinical Decision Support Systems: An Investigation of their Patient Safety Effectiveness via an Integrative and Systematic Review* (Recommended for publication in a scientific journal by committee members)

Committee: Josette F. Jones, RN, Ph.D. (Chair), David W. Bates, MD, MSc and Atif Zafar, MD

### **Relevant Coursework**

Clinical Information Systems

Laboratory Information Management Systems

Informatics Project Management

Social Impact of Information Technology

Biostatistics

Health Informatics Standards and Terminology

Informatics Research Design

Seminar for Health Informatics Applications

Entrepreneurship

Indiana University, Bloomington, IN, July 1999 – May 2003

School of Public and Environmental Affairs

Bachelor of Science in Public Health/Health Administration

### **Relevant Coursework**

Legal Aspects of Health Care Administration

Health Economics

Health Care Benefits

Human Diseases and Epidemiology

Religion, Ethics and Public Life

Health Systems Administration

Hospital Administration

Children's Health

The Nature of Cancer

Health Statistics

Techniques of Public Health Education

### **Major Academic Projects**

Direct to Consumer Advertising of Prescription Drugs: Its Implications and Effects on the U.S. Health Care System

Strategies for Improving Prenatal Care for Indigent Adolescents

Increasing Organ Donations: The AMA Proposal

Issues Involved in Using Quality of Life Criteria for Decision-making

University of Tennessee Medical Center, Knoxville, TN, July 2002 – August 2002

#### **College Internship**

- Worked closely with healthcare professionals, employees and administrators and participated in medical staff meetings.
- Provided support to Hospital Infection Control Group
- Collected, collated and statistically analyzed comparative data for a project examining the hospital's nosocomial urinary tract infection rates.
- Built the business case for purchasing new technology - silver coated urinary catheters
- Authored and presented a medical staff slide presentation demonstrating the ROI for moving to the new catheter technology. (Tape available on request)

### **WORK EXPERIENCE**

BlueCross BlueShield of Tennessee, Inc., Chattanooga, TN ([www.bcbst.com](http://www.bcbst.com))

September 2003 – August 2007

Bio-statistical Research Associate

- Created a provider survey and database, produced reports and presented findings on physician reactions to the health plan's profiling activities.
- Analyzed the impact of Cardiac Cath/Angioplasty and Carotid Endarterectomy patients' Length of Stay (LOS) at facilities.
- Produced and administered the company's quarterly Corporate Dashboard Report, which I further enhanced with new trending charts.
- Performed impact analyses on the cost of proposed medical policy.
- Created and produced a company model to test the impact of new reimbursement methodologies on the health plan and network providers.
- Created and constructed new weekly and monthly reports for the early identification of potential high utilizing ER abusers.
- Headed a project to research techniques for identifying Adverse Drug Events (ADEs) and apply these methods to analyzing health plan data.
- Assisted in designing measures to track outcomes and quality measures in various pilot studies, including Orthotripsy and Diabetes therapies.
- Provided a claims history report on the Nashville Sickle Cell Center of Excellence (COE) for upper management decision support.
- Helped SharedHealth ([www.sharedhealth.com](http://www.sharedhealth.com)), an HIT subsidiary, develop metrics to measure provider adoption of its electronic clinical record system.
- Created a continuous process for reconciling clinical edits between two Centers for Medicare/Medicaid Services (CMS) physician fee schedules to aid quarterly transmittal and data entry processes.
- Assisted with enhancements to managed care reporting and measures for a newly developed Medicare Advantage product.
- Helped develop and produce a quarterly report comparatively tracking hospital utilization performance – authorizations, denials, DRG length of stay, readmission rates – for company directors and network providers.
- Conducted a population assessment for the health plan's diabetic and obese patients.



## **AWARDS**

Michael G. Lundy, MD Memorial Award for Excellence in Research, Development or Analysis (BlueCross BlueShield of TN, 2<sup>nd</sup> Quarter 2005)

## **SKILLS**

Analysis and statistical methods

All Microsoft Office Applications

Advanced MS Excel data analysis expertise: linear regression, ANOVA, exponential smoothing, complex formulas, filters, VLOOKUPS, pivot tables, VBA macro creation and editing, data collapsing and data mining

Predictive Modeling proficiency using artificial intelligence tools (MedAI)

Expert programming languages - SAS, SQL and Excel VBA

Advanced data extraction software: ViPS MCSource, Cognos Impromptu, Cognos Powerplay, Aqua Data Studio, Oracle, PHP/MySQL

Public speaking and communications with PowerPoint presentations

Creating ERD, UML diagrams and flow charts

Laboratory Information System – Labware LIMS

Open source free software terminal emulator – Tera Term

Problem solving

Proficiency in literature review search strategies using OvidSP, Web of Science, PubMed and Google Scholar

Computer art and illustration

## **PROFESSIONAL MEMBERSHIPS AND AFFILIATIONS**

American Medical Informatics Association (AMIA)

## **LEISURELY INTERESTS AND ACTIVITIES**

Photography, art and computer graphics

Healthful cooking techniques

## **REFERENCES**

Available upon request