Research in Ambulatory Patient Safety

2000–2010: A 10-year review

Disclaimer

This report comprises a review of publicly available research and other efforts to address ambulatory patient safety between 2000 and 2010. The authors have attempted to avoid statements of opinion, focusing instead on compiling and describing research findings, including apparent gaps. Any views or opinions expressed are those of the authors and should not be construed as statements of the American Medical Association, nor of the advisors to this project nor their employers or other organizations that they may represent.

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Introduction

Dear Colleagues,

In recent years a great deal of attention has been directed toward better understanding and addressing important problems of patient safety in hospitals. At the same time, researchers have noted that addressing ambulatory patient safety poses distinct challenges compared to studying safety in the inpatient setting. There has been a broad recognition that research on ambulatory safety is desperately needed. Each year, far more patients receive care as outpatients than as inpatients, and errors in ambulatory settings can be just as devastating as those in hospitals.

More than 10 years ago, in December 2000, the Agency for Healthcare Research and Quality (AHRQ) called together a group of experts to review the state of ambulatory patient safety research and to establish an agenda for the future.

Ten years later, in December 2010, the American Medical Association (AMA) Center for Patient Safety called together another group of experts in patient safety, this time to survey progress in ambulatory safety over the last decade.

In preparation for that meeting, the AMA contracted with Computer Sciences Corporation (CSC) to collate all available research in ambulatory patient safety conducted between 2000 and 2010. In early 2011 the AMA asked an additional set of experts to review each section of the report that CSC had produced. This feedback was then combined with additional background research by AMA staff to create the present report, Research in Ambulatory Patient Safety 2000–2010: A Ten-Year Review.

Our team is very pleased to provide this summary of ambulatory patient safety research and selected additional initiatives and resources. While no such endeavor can be perfect, we hope this compilation and overview will prove to be a useful resource.

We also believe it will contribute to a growing recognition that research in ambulatory safety deserves greater and more focused attention, intervention and resources.

While we conclude that ambulatory safety should be a focus of much more research on patient safety in the next decade, this report also brings attention to the critical contributions to our understanding of ambulatory safety that have been made by a large number of researchers. We provide citations to more than 100 studies on ambulatory safety carried out by investigators over the past decade.

We invite you to read this report and use it in your own work. Please let us know how the report has been helpful, and if there are ways we could make it better. In particular, because we surveyed a very large field of research with many potential areas of overlap, we are cognizant of the risk that we have missed important work. If you find gaps or missing references, please let us know and we will produce updates as needed.

Thank you for the work you do to help the medical profession live up to our ancient credo: First, do no harm.

Matthew K. Wynia, MD, MPH
Director, AMA Center for Patient Safety
Executive summary

While a great deal of research and effort has been devoted to understanding and improving patient safety in hospitals, ambulatory safety has long been recognized as equally important, and as posing distinct challenges compared to safety in the hospital setting. Far more patients are cared for in ambulatory settings than are seen as inpatients; the harm that can occur in ambulatory settings is serious, and there are a number of ways in which the ambulatory setting is even more complex and prone to error than the inpatient setting.

Recognizing these facts, in December 2000 the Agency for Healthcare Research and Quality (AHRQ) convened a group of experts to establish a research agenda on ambulatory safety (Hammons et al, 2001). Ten years later the American Medical Association (AMA) Center for Patient Safety conducted a project to summarize the last decade’s research in ambulatory safety, culminating in the publication of this report.

Ten years worth of research on ambulatory safety is detailed in the sections of this report and summarized in the Appendix, but a concise summary is this: Though some very high-quality work on ambulatory safety took place between 2000 and 2010, research and initiatives in ambulatory safety were remarkably limited, both in quantity and in the ability to generalize from the studies that were reported. In fact, many of the studies on ambulatory safety between 2000 and 2010 were conducted in a very limited number of sites. For example, two sites (Brigham and Women’s Hospital in Boston and the Michael E. DeBakey VA Medical Center in Houston) contributed six of ten original studies related to ambulatory communication errors.

Findings and observations

Beyond the general finding that research on ambulatory safety has been limited in some critical ways, a number of more specific observations are possible based on a review of research in this arena between 2000 and 2010.

Research focusing on harm to patients

Three general types of studies have been reported in the literature on ambulatory safety in the last decade: research on events that caused harm to patients, research that includes events that did not cause harm to patients, and, far less common, research on interventions that have the potential to improve ambulatory safety. Studies of events that caused harm often relied on malpractice claims information and insurance claims for their data. As a result, there have been a number of recognized weaknesses among these studies. Malpractice claims may be with or without merit, and studies could not always make this distinction. The details of errors that resulted in malpractice suits were not
always available beyond broad categories (diagnostic error, medication error, etc.). Malpractice claims data also include only those events where the patient or family chose to file a claim. Studies based on insurance claims could often examine evidence of potential harm (e.g., patients with potentially duplicate medications) and subsequent claims (e.g., hospitalizations), but often did not include enough information to assess if there was an actual error or if the error was preventable. Patient harm in ambulatory care was sometimes studied by tracking patients who were hospitalized or seen in an emergency department, but these studies by their nature exclude patients who may have been harmed but did not seek further care or sought care elsewhere.

Most research has been in primary care settings
Most reported studies of ambulatory safety during the last decade have been conducted in primary care practices. Studies that include non-primary care data have often used a very broad definition of ambulatory care, including hospital-based ambulatory care and emergency departments. Studies of office-based surgery have taken place, but are mainly based on reports to state agencies, especially in Florida, where reporting is mandated. There were no reported studies that compared results for similar errors or harms across practice sizes or types.

Taxonomy issues persist
Most researchers have developed their own definitions and taxonomy systems for classifying errors in ambulatory care, many of which go beyond errors that could cause clinical harm. The lack of a standard taxonomy for errors in the ambulatory setting, noted by the AHRQ consensus conference in 2000, persists and continues to pose challenges in comparing results across studies.

Research on medication safety
Medication safety is arguably the most well-researched area in ambulatory safety in the last decade. Yet reviewing this research calls attention to taxonomic issues and other limitations common to research on ambulatory safety. Definitions of key terms, such as adverse drug event (ADE), medication error and ameliorable ADE have been consistent within research teams (e.g., the research team at Harvard’s Brigham and Women’s Hospital) but less so across teams. In addition, patient age groupings, drug classifications, categories of comorbidities and severity ratings used to categorize ADEs and medication errors are inconsistent.

Still, as a common area of study in ambulatory safety, there has been substantial research to identify high-risk medications, and several systems have been developed and tested that report on high-risk medications and make that information available to providers. There have also been studies that included events that did not cause harm
Many studies examining errors in the ambulatory setting included both errors causing harm and those where no harm was suffered. Very few included an assessment of which errors could have been prevented.

Intervention research has been very rare
There has been a great deal more research on understanding the problems in ambulatory patient safety than on evaluating interventions, and several intervention studies in the last decade have shown no difference or negative results. For instance, studies of an intervention to improve medication reconciliation in two hospitals showed improvements in one site and no improvement at another (Schnipper, 2009), and studies of an intervention to improve follow-up of test results found that sending results to multiple providers actually decreased rather than increased follow-up (Singh, 2009a).
of interventions to prevent use of confusing abbreviations in prescriptions.

Two clear findings in this area include that: (1) Drugs in widespread use and those with a narrow therapeutic range and high toxicity are most frequently associated with identified ADEs and/or medication errors; and (2) advancing age of the patient and increasing numbers of medications and comorbidities are associated with increased risk of experiencing a medication error and/or an ADE.

One reason researchers have been able to study medication safety is that information about medications has been available electronically and codified in various databases for decades. As electronic medical records are implemented more widely, it will be important that other patient information needed for research on ambulatory safety be codified consistently. Obvious examples are patient allergies, problem lists and symptoms.

Finally, some causes of adverse drug events are only indirectly under the control of an ambulatory practice, including dispensing errors and problems with adherence to medications as prescribed. Interventions to improve communications, team-based care and patient engagement might affect these causes of errors and adverse events, but studies of these interventions and their effects on safety are scarce.

Research on diagnostic safety

Diagnostic errors, including missed, delayed and incorrect diagnoses, are some of the most common threats to patient safety in ambulatory care. For instance, research shows that one in four malpractice claims in ambulatory care is related to diagnostic error (Singh, 2007b).

While it is not possible to compare most diagnostic safety studies directly, the research offers some important insights regarding the occurrence of diagnostic errors, their implications for patients and the factors that contribute to such errors.

- Diagnostic errors were frequently associated with patient harm, and were a more frequent reason for malpractice claims in outpatient care than medication errors.

- Several conditions were more commonly associated with diagnostic error, the most common of which was cancer.

- System factors, provider factors and patient factors all have been associated with diagnostic errors.

Research on office-based surgery

An increasing number of surgeries once restricted to inpatient settings are now being performed in ambulatory settings. This has created considerable controversy. Some maintain that office-based surgical procedures are safe and offer patients numerous benefits, while others point to the lack of oversight and regulation of such procedures and express fear that such procedures place patients at risk. The research base is inconclusive as to whether ambulatory surgery for a variety of conditions is less safe, or as safe as inpatient surgery for the same conditions, but certain themes are discernable.

- Office-based surgery has been associated with patient harm in several studies.

- Using general anesthesia in office-based surgeries has sometimes resulted in adverse events, including hospital transfer and death.

- Adverse events related to office-based surgery more often involve cosmetic procedures than medically necessary procedures.

Patient factors that affect ambulatory safety

Patients are expected to play an active role in ambulatory care and may have roles in ensuring safe care in the ambulatory setting that are very different from those among hospitalized patients. Patients may be responsible for care planning, such as helping to establish plans and for sharing relevant information with providers, and for execution of care plans, including carrying out home monitoring and therapeutic regimens, and remembering to take medications and attend follow-up appointments. Research on the patient's
Role in ambulatory safety in the last decade has been very sparse and suffers from many of the same limitations found in other research on ambulatory safety: the use of disparate methods, definitions, taxonomies, data sources and populations. In addition, there have been debates on how best to classify patient choices that lead to adverse outcomes; whether all such choices should be considered “errors” is not a settled question. Still, a few themes are discernable across the studies we found.

- The most frequently discussed issues are medication administration or dosing errors, missed appointments, nonadherence or poor adherence, and failure to share information, such as comorbidities.
- Patient “errors” are sometimes matters of active choice, which might contribute to them being less frequently studied as potentially representing system-wide failures.
- Ineffective communication between patients and clinicians is an important contributor to patient nonadherence and other safety issues.
- Interventions aimed at improving communication and patient education have shown success, though specific reductions in errors or harms are not usually documented.

Research on communication safety

Studies of error and harm often have cited “miscommunication” as a cause of harm, but generally have not specified the nature of the communication breakdowns responsible.

There has been a great deal of research on communication issues in health care, in particular physician-patient communication and communication among clinicians caring for patients before and after discharge from the hospital setting. However, this research generally has not related problems identified in communications with documented patient harm.

Two exceptional research topics, where interventions have been studied, are improving communication around care transitions and the follow-up of abnormal lab results, both of which are promising areas for future work.

Conclusions

Over the last decade there have been more than a hundred of studies on ambulatory safety, carried out by many talented and dedicated researchers. These studies have examined an array of problems and potential problems for safe patient care in the ambulatory setting. Yet a comprehensive review reveals that we still know very little about patient safety in the ambulatory setting, and next to nothing about how to improve it. Studies of ambulatory patient safety have too often been small, used differing and sometimes conflicting taxonomies and categories, and derived from work in unique practice settings that might not provide generalizable results. Studies of interventions to improve the safety of ambulatory care have been extremely rare.

While a number of promising policy and practice interventions are now underway to improve patient safety in ambulatory care, the research base for ambulatory safety needs to be dramatically strengthened.
A 10-year review of ambulatory patient safety research

Rationale and methods

The 1999 publication of the landmark Institute of Medicine (IOM) report To Err is Human: Building a Safer Health System drew unprecedented public attention to the issue of medical errors. Defining errors as “the failure of a planned action to be completed as intended or the use of the wrong plan to achieve an aim,” the IOM report especially focused attention on research findings that medical errors were frequent occurrences in hospitals, which the report estimated resulted in roughly 44,000 to 98,000 deaths each year (Kohn et al, 1999; Wachter, 2010a). Hence, though the IOM study succinctly defined patient safety as “freedom from injury,” it essentially launched the modern patient safety movement by focusing attention on freedom from injury in hospitals (Kohn et al, 1999; Wachter, 2010).

In the years following the release of the IOM report, hospitals, regulators and others have undertaken a wide array of efforts to address patient safety concerns associated with inpatient care. Hospitals and skilled nursing facilities have experienced increasingly stringent patient safety accreditation standards, reporting requirements and payment incentives. A great deal of research has also taken place to better understand and improve safety in the inpatient setting (Wachter, 2010a; Dentzer, 2011).

In the ambulatory arena, by contrast, fewer and less coordinated patient safety activities have taken place. Although ambulatory patient safety research during the past decade has produced good data, the volume of research on ambulatory safety has been much less than on the inpatient setting, perhaps in part because patient safety issues occurring in the diverse ambulatory care environment are often hard to analyze, classify and discern (Dovey et al, 2002; Elder and Dovey, 2002; Elder et al, 2006.).

Given that outpatient visits far surpass the quantity of hospital admissions, the IOM has suggested that the number of medical errors in ambulatory care may exceed those occurring in inpatient care settings (Aspden et al, 2003). In 2006 roughly 11 billion outpatient visits took place in the United States, whereas only 34.9 million hospital discharges occurred during the same year (Gandhi and Lee, 2010).
Inpatient versus outpatient care: Important differences for patient safety

While much has been learned from inpatient patient safety efforts, it is unclear whether the lessons learned can be applied to ambulatory care settings (Wachter, 2006). Ambulatory care settings are different than inpatient care facilities in a number of important ways.

First, inpatient and ambulatory care serve different patient populations. Ambulatory care facilities provide care for a more diverse body of patients, ranging from healthy individuals to individuals with one or more chronic conditions to those in need of rapid triage to inpatient care (Hammons et al, 2003; Wachter, 2006). Because of the wide range of health and illness among the patient base in ambulatory care, there is a very low “signal to noise” ratio with regard to patient acuity in the ambulatory setting, even while ambulatory care visits have become increasingly intense and multifaceted with corresponding increases in the patient’s exposure to risk (Sarkar et al, 2009).

Inpatient care settings and ambulatory care settings also have very different organizational structures (Hammons et al, 2003; Gandhi and Lee, 2010). While ambulatory care is often less technologically complex than inpatient care, ambulatory care settings are often more logistically complex and suffer from greater information exchange challenges than do care teams in hospitals (Hammons et al, 2003; Chenot, 2007; Gandhi and Lee, 2010). “An episode of ambulatory care often requires communication and coordination among a number of clinicians, the patient and family among several different sites” (Hammons et al, 2003). Existing infrastructures and often the workflow of ambulatory care frequently can fail to provide the support necessary to adequately manage and coordinate patient care, placing patient safety at risk (Hammons et al, 2003; Gandhi and Lee, 2010). Sarkar et al note, for example, that “transitions among care settings and among primary care, specialty care, pharmacy, other providers, caregivers and home care all pose a risk for adverse events” (Sarkar et al, 2009).

Additionally, the dispersed nature of outpatient care poses a patient safety challenge, because it may take longer to identify and document errors than in inpatient facilities (Gandhi and Lee, 2010).

Another important difference between ambulatory care and inpatient care settings is the role of the patient (Hammons et al, 2003). In hospitals, patients receive near-constant care and surveillance from health professionals, which aides in both the provision of care and error detection efforts (Sarkar et al, 2003). In contrast, patients often assume (or are expected to assume) an extremely active role in their ambulatory care, often including responsibilities such as monitoring their condition, managing their medications, diet and other self-care activities, conducting self-triage and seeking care when needed, communicating across multiple providers, clinicians and settings of care, and, in general, navigating various aspects of an often disjointed health care system (Sarkar et al, 2003; Budnitz and Layde, 2007). Additionally, for clinicians in the outpatient setting, patients are often the primary source of essential information on the progression of their conditions (Hammons et al, 2003). For that reason, patient understanding of and agreement with care protocols, as well as provider appreciation of the patient’s health literacy, culture and preferred language, are major issues in providing safe ambulatory care (Wachter, 2010).

In recognition of these differences between inpatient and ambulatory settings, and in light of the volume and importance of ambulatory care, in 2000 the Agency for Healthcare Research and Quality (AHRQ) sponsored a consensus conference to set a national agenda for research in ambulatory patient safety. The conferees made a number of specific recommendations (see recommendations at end of this section), including the need to develop standardized nomenclature and reporting systems, and to support “experiments and demonstrations,” rather than just observational studies in ambulatory safety (Hammons et al, 2001).
To mark the 10-year anniversary of the IOM report, a number of experts produced assessments of the progress made in patient safety, mostly focusing on the inpatient setting (e.g., Wachter, 2010a; Dentzer, 2011). They noted a remarkable array of resources and programs to address safety in hospitals, with some modest progress, though often noting the “frustratingly” or “agonizingly” slow pace of change.

A 10-year review of research in ambulatory safety: Methods

In December 2010 the American Medical Association (AMA) Center for Patient Safety (the Center) convened a group of patient safety experts to discuss the current state of work on ambulatory patient safety, 10 years after the AHRQ consensus conference, and to elicit ideas for how to move the field forward. As background for that meeting, the Center contracted with Computer Sciences Corporation (CSC) to help us conduct a comprehensive review of ambulatory safety research conducted between 2000 and 2010, using the following methods.

CSC researchers first conducted a literature review using a number of search terms, including combinations of “ambulatory patient safety,” “ambulatory care errors,” “ambulatory medication safety,” “adverse drug events in ambulatory care,” “ambulatory diagnostic errors,” “ambulatory medication errors” and “patient error in ambulatory care.” Once a relevant article was found, subsequent articles were identified through the reference lists. The initial analysis focused on the general types and causes of patient safety issues in an office-based practice. Subsequent literature reviews focused on frequent safety issues identified, such as medications, diagnostic errors, communication and the complex roles that patients play in ambulatory safety.

The initial review revealed a number of limitations in the published literature. For instance, the initial review was to have focused especially on research examining preventable adverse events, i.e., errors resulting in harm. However, most studies either included harm from any cause, including harm not caused by errors, or errors of any type, including those that did not cause harm. Both types of studies are therefore included in the review.

In addition, there were a limited number of studies that included only office-based practices, so studies were often included that encompassed office-based practices and other ambulatory settings. Specific searches were done to find studies that covered both primary care and specialists practice, but most of the research has been conducted in primary care settings only. There was a priority on finding research that could be generalized, so small studies that looked at a single medication or a single condition were not usually included, unless they addressed aspects of ambulatory safety not found elsewhere.

Because of the significant differences in ambulatory care structure across countries, U.S. studies were preferentially sought. However, some meta-analyses were included that contained work from outside the United States and a few other international studies were included because they provided results not available in U.S. studies.

Because there are many studies on quality that could also be considered to address safety, a distinction was drawn between quality and safety. In particular, research on failure to receive recommended care or inability to access care (quality issues) were not included.

The scope of the review included research on any errors that could be affected by the actions in an office-based practice, but research was included only if it examined errors or harms specifically. For some topics identified as contributing to errors or harm (for example, communications errors), there is an extensive body of research literature, but the vast majority of these studies do not relate the findings of interventions to either reduction of errors or harm, and therefore they were not
included. For the topic of the patient’s role in ambulatory safety, where research was very limited, these criteria were relaxed and some literature reviews were included that relate to safety but did not include an explicit analysis of errors or harms.

Even using relaxed criteria, the peer-reviewed literature on ambulatory safety was often limited and publications of research on ambulatory safety interventions were almost nonexistent. The literature search was therefore expanded to include an examination of efforts by organizations like the Institute for Safe Medication Practices (ISMP), The Joint Commission (TJC), the research and publications sponsored by AHRQ and initiatives promoted in federal legislation.

The results of this work were summarized in a series of initial drafts of this final report, which were circulated by AMA staff to a set of external reviewers (see Acknowledgements). For each section of the report, reviewers were selected based on their contributions to the research cited in the section. When possible, individuals cited most frequently in each section were asked to review the section and provide comments on its structure, content and conclusions. The sections were then revised, often in only modest ways but sometimes extensively, by AMA staff to address these expert reviewer comments and produce this final report.

Finally, for each section of the report there is an accompanying table, summarizing research design, settings and results of the cited research. These tables and more information are included as a separate appendix to the report. Where studies were relevant to more than one section, they are cited in more than one section, but they are included in the table only once under the section for which they were deemed most relevant.

AHRQ consensus conference recommendations:

**Recommendation 1:**
AHRQ should support a feasibility study to:

1. Identify appropriate methods to conduct a large-scale study of the epidemiology of safety/error in ambulatory care.
2. Perform pilot testing of the methodologies.
3. Estimate the projected value and costs of such a study.

**Recommendation 2:**
Support research that examines and evaluates claim and incident data from liability insurers, and how the rates and patterns of incidents and injuries from these sources would be expected to differ from the “true” rates and patterns. Specific efforts could assess the value of case studies. Support evaluation of interventions by liability insurers that are designed to improve ambulatory patient safety, and identify those that are effective and should be widely disseminated.

**Recommendation 3:**
Support research that builds on experiences from risk management activities of liability insurers, provider organizations, and integrated healthcare systems, and from other industries to:

1. Understand risks and injuries in ambulatory safety.
2. Where to focus efforts to further understand risks and to reduce them.

**Recommendation 4:**
Support pilot studies to determine the potential of administrative data, alone and in combination with other data sources, for research in ambulatory patient safety. Identify appropriate methods for using these data, and barriers to their use.

**Recommendation 5:**
Research should be conducted that assesses the perspectives of patients and families about ambulatory care, and characterizes the information they can provide about safety in ambulatory settings. Assess the reliability and validity of that information, identify methods that could ensure high rates of unbiased responses, and design potential studies that could yield population-based estimates of adverse events in ambulatory care and their causes.

**Recommendation 6:**
Further research should be supported on the role of information technology to improve ambulatory patient safety, including computerized physician order entry and electronic medical records. These technologies should be evaluated within the larger contexts where they would be implemented and used:
• The processes within which the technology will be embedded (e.g., the medication process).

• The systems within which the technology will be used (e.g., the physician office practice).

**Recommendation 7:**
Support research to understand teamwork in health care and how greater teamwork contributes to patient safety. Assess approaches to teamwork in health care to understand their contribution to improving patient safety, particularly ambulatory care, and identify or synthesize approaches that are well suited to health care and its culture. This work would require expertise from a number of fields, including business and the social sciences, to understand the human and cultural aspects.

**Recommendation 8:**
Support research to assess the degree to which the prevalent culture is a limiting factor in achieving improved patient safety (and quality of care) through greater teamwork and a systems approach to management, coordination, and communication. Identify ways to enable physicians to more easily understand and see the potential of these approaches to improve safety and quality, and to understand their role in leading work to improve.

**Recommendation 9:**
Support research and demonstrations in ambulatory care that identifies, develops, and disseminate successful approaches to implementing changes that improve patient safety.

**Recommendation 10:**
Provide sustained multiyear support for projects designed to improve patient safety (and quality) through changes in both clinical processes and in clinical support and administrative support processes and systems. Consider multistage projects, with the hypotheses and experimental design for each stage based on what has been learned in previous stages. Consider projects that also attend to “organizational” aspects of care including structure, culture, and compensation. Provide support for attention to managing change, and for increasing our understanding of how to successfully implement changes that improve safety. Anticipate how “lessons learned” and best practices identified can be disseminated and implemented by others. Attend to aspects of the environment that inhibit or promote improvement in safety, including payment mechanisms and the legal and regulatory environment.

**Recommendation 11:**
Model the financial implications of improving safety and quality for various players in the current organization and financing of care, including physicians, medical group practices, hospitals, integrated care systems including staff model group practices that provide prepaid care to populations, traditional health insurers, self insured employers, patients, and the Medicare program. Explore the effects of adverse selection. Develop potential modifications in or alternatives for organization and financing that would align interests to support and reward the various professionals and organizations to improve safety and quality.

Reprinted from AHRQ. Research Agenda for Ambulatory Patient Safety: www.ahrq.gov/qual/ptsafety/
Section I. General research on ambulatory patient safety

Introduction

In the last decade a growing body of literature has confirmed that patient safety problems exist in ambulatory care. A number of studies have shed light on the frequency and nature of the errors that occur in ambulatory settings. However, published studies on the topic often have had different objectives, used different taxonomies and different definitions of errors and harm, and frequently involved small sample sizes in atypical care settings. Defining and measuring patient safety poses a significant challenge in all care settings, but the last 10 years of research suggest this is especially evident in ambulatory care, where the origin of an error may be in one location (e.g., a doctor’s office) while the adverse event plays out in another (e.g., the patient’s home), and may be discovered in yet another (e.g., the emergency department) (Wilson et al, 2005). Consequently, the existing body of research presents a fragmented view of the safety of ambulatory care.

Characteristics of the research

Definitions

Studies have used a number of differing definitions to study ambulatory safety. As Elder et al (2006) noted the various definitions of error, adverse events, reportable events, near-miss events and other terms used in research on ambulatory patient safety reflect that “there is a lack of consensus about what constitutes an error both in the medical literature and in decision-making” by clinicians. In research conducted between 1985 and 2005, the most commonly used error definition was “failure of a planned action to be completed as intended or use of a wrong plan to achieve an aim,” which was developed by James Reason and adopted by the Institute of Medicine (IOM) in the report To Err is Human: Building a Safer Healthcare System (Kohn et al, 1999; Elder et al, 2006).

Many authors have used variants of the IOM definition. For example, Plews-Ogan et al (2004) combined terms to define a “near miss/adverse event” as “any event in a patient’s medical care
which did not go as intended and either harmed or could have harmed the patient.” The Patient Safety Reporting System (PSRS) separated adverse events from near misses, or “close calls,” and defined close calls as “events or situations that could have resulted in accident, injury, or illness, but did not, either by chance or through timely intervention” (PSRS, 2011). Rubin et al (2003) defined an error as “an event that was not completed as intended and/or meant that work was disrupted in some way.” Kuzel et al (2004) defined error as “all forms of improper, delayed, or omitted care that unnecessarily injures patients by either worsening health outcomes or by causing physical or emotional distress.”

Several studies have significantly reframed the IOM definition of error in order to collect more comprehensive data. Research by Makeham et al (2002), Phillips et al (2006), Rosser et al (2005) and Makeham et al (2006) used variants of the following definition of an error as proposed by Dovey et al (2002): “…anything that happened in your own practice that should not have happened, that was not anticipated and that makes you say, ‘That should not happen in my practice, and I don’t want it to happen again.’” In other research, Fernald et al (2004) and Pace et al (2005) used the term “reportable events” rather than errors. Pace defined reportable events as “any event you don’t wish to have happen again that might represent a threat to patient safety” (Pace et al, 2005).

In his work on diagnostic error, which could presumably be applied to other types of error, Schiff developed a Venn diagram to describe the overlapping definitions of diagnostic error, diagnostic process error and adverse events. This work made points of distinguishing between different types of error and also between harmless error and error leading to harm (Schiff, 2008).

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- Relationships between diagnostic process errors, misdiagnosis and adverse events

**Group A** = Errors in diagnostic process (blood sample switched between two patients, MD doesn’t do a physical exam for patient with abdominal pain)

**Group B** = Diagnostic process error with resulting misdiagnosis (patient given wrong diagnosis because blood samples switched)

**Group C** = Adverse outcome resulting from error-related misdiagnosis (Patient is given toxic treatment and has adverse effect as result of switched samples. Fail to diagnose appendicitis because of failure to examine abdomen, and it ruptures and patient dies)

**Group D** = Harm from error in diagnostic process (colon perforation from colonoscopy done on wrong patient)

**Group E** = Misdiagnosis, delayed diagnosis or missed diagnosis, but no error in care or harm (incidental prostate cancer found on autopsy)

**Group F** = Adverse event due to misdiagnosis but no identifiable process error (death from acute MI but no chest pain or other symptoms that were missed)

**Group G** = Adverse events but not related to misdiagnosis, delay, or error in diagnostic process, e.g., death from correctly diagnosed disease complication, or nonpreventable drug reaction (PCN anaphylaxis in patient never previously exposed)

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**Research on error versus harm**

With some notable exceptions, much of the work on patient safety in ambulatory care since 2000 has focused on identifying errors, whether or not they resulted in harm, rather than on actual harm to patients. This focus has not been wholly consistent with the IOM definition of patient safety as “freedom from accidental injury” (Kohn et al, 1999). These studies on errors often include instances of “close calls,” near misses or other instances that have the potential to cause harm, and do not differentiate between actual and potential harms (Layde et al, 2002). To date, only a few studies have exclusively addressed patient harm in ambulatory care, though many have addressed some aspects of harm. For example, one study on patient harm relied on the physicians’ judgment as to whether harm occurred or could have occurred; another study aimed to discern which medical errors and harms were most important to patients (Elder et al, 2004; Kuzel et al, 2004).

Other studies restricted their focus to subsets of populations that may have experienced harm, e.g., patients who sought further care (Woods et al, 2007) or those who filed malpractice claims (Phillips et al, 2004). Phillips et al (2004) addressed harm, but included all claims involving primary care physicians; consequently their data also included hospital-based errors.

**Classification of errors**

Elder and Dovey drew on data obtained from a systematic review of the “limited number of small studies” conducted between 1965 and 2001 to inform their classification taxonomy. The authors studied preventable adverse events and process errors. They classified preventable adverse events into three subcategories (diagnosis, treatment and preventive services) and process errors into four subcategories (administrative factors, blunt-end factors, such as government regulation and insurance, communication factors and clinician factors) (Elder and Dovey, 2002).

Kuzel et al (2004) used data from 38 qualitative patient interviews to create a patient-reported error taxonomy. They classified errors by apparent cause, as being due to “access breakdown, communication breakdown, relationship breakdown, technical error and inefficiency.”

A number of authors drew upon physician error reports to develop their classification systems. Variation exists within these studies, especially regarding the number of reports used and the resulting classification systems. Dovey et al (2002) used 330 physician error reports to craft their taxonomy of medical error types occurring in primary care. They created two primary categories, process errors and knowledge and skills errors (Dovey et al, 2002). Process errors were then classified as administrative errors, investigatory errors, treatment errors, communication errors and payment errors. Knowledge and skills errors were classified as clinical task errors, misdiagnosis and errors in treatment decisions. This system was used in the development of the American Academy of Family Physicians’ Linnaeus Taxonomy (Dovey et al, 2002; Pace et al, 2005).

Makeham et al (2006) analyzed 418 physician error reports from six countries and identified 171 kinds of errors that they subsequently organized into two primary categories of knowledge/skills errors and process errors. Rubin et al (2003) also used voluntary physician reports on 101 reported errors, but arrived at a different classification system with five error types: “prescriptions,
communications, appointments, equipment, and clinical errors.”


Pace et al (2005) adapted the methodology from the Dimensions of Medical Outcomes (DMO) model, a multiaxial taxonomy, and adopted four of the five DMO dimensions to develop reporting categories for errors reported to the ASIPS: outcome, course of the event, participants and observation. A total of 357 error reports submitted to the ASIPS PSRS informed the adaptation of the DMO taxonomy, and an additional 608 ASIPS error reports were used to test the adapted version. Three constructs were used for analysis: “individual code, hierarchical construct (care process level analysis) and derived construct (clinical activity level analysis) groupings.” Eight derived constructs were associated with harm: “communication to patient, clinical data, error in diagnosis, examination process errors, referral process errors, delay in therapy (medical/surgical or drug), error in knowledge/skill/judgment, and provider of record” (Pace et al, 2005).

Classification of harm

The few ambulatory care error taxonomies developed in the last decade that incorporated whether an error is associated with adverse patient consequences or harm were limited in their scope (West et al, 2008). For example, in physician-based error reports collected for various countries, Makeham et al (2002) discussed general error categories that resulted in patient hospitalization or death.

Woolf et al (2004) studied only 75 reports of errors, less than half of which were thought by the physician to have resulted in harm, and they categorized patient harm into three categories:

1. Physical injuries (physical health complications from errors during the reporting period)
2. Errors that had no reported immediate effect but that heightened the patient’s risk for complications after the reporting period
3. Psychological or emotional injuries

Data sources

Research on ambulatory patient safety has used various data sources, but the most common data source has been voluntary physician reports of errors (Dovey et al, 2002; Elder et al, 2004; Makeham et al, 2002; Makeham et al, 2006; Pace et al, 2005; Phillips et al, 2006; Plews-Ogan et al, 2004; Rosser et al, 2005; Woolf et al, 2004).

A few studies incorporated patient and/or nonclinical staff reports of errors in addition to the data offered by doctors (Phillips et al, 2006; Fernald et al, 2004; Rubin et al, 2003; West et al, 2008). One study used qualitative data obtained through patient interviews (Kuzel et al, 2004).

Though self-reporting by physicians or practice staff was the source of most research on ambulatory errors and patient injury, it was also widely reported that physicians and staff frequently underreported errors (Elder et al, 2007). Elder et al (2007) explored barriers to reporting and found that efforts required to submit reports, as well as a “lack of clarity regarding the requested information,” were the primary obstacles to/for physicians and staff. Research by Woolf et al (2004) indicated that physician reports are not a reliable source of information for assessing patient harm, with physicians often underreporting the consequences of errors for patients.

A few of the studies that investigated ambulatory patient safety used electronic health records (EHRs) and hospital discharge records as a source of information. For example, Woods et al (2007)
reviewed hospital discharge records in efforts to study errors that occurred in an ambulatory care setting and led to hospital admission.

Malpractice claims were a source of information for studies focused on patient harm (rather than errors). One study analyzed claims involving primary care physicians, filed between 1985 and 2000, to examine the major causes of adverse events associated with primary care (Phillips et al, 2004).

Researchers have noted weaknesses in each of these data collection methods. Physician self-reporting is vulnerable to bias and underreporting, which could affect the accuracy of classification systems due to the use of incomplete data (Avery, 2003; Wilson et al, 2005). Patient-reported events suffer from recall bias and are also limited to events that are known to the reporter. Hospital discharge records may suffer from incomplete documentation that could hinder their usefulness. Malpractice claims are limited to those patients who file suit.

Types of errors most likely to result in harm

The work of West et al (2008) was one of the first large-scale studies to examine patient harm resulting from ambulatory medical errors. Analyzing 608 error reports submitted to the ASIPS Reporting System by approximately 500 clinicians and staff affiliated with the Colorado Research Network and the High Plains Research Network, the authors found that patient clinical harm was associated with 62 of the error reports (10.2 percent), and that an additional 55 reports (9 percent) involved increased patient risk, which encompass the two highest levels of harm. The authors concluded that four types of errors were associated with elevated risk of harm:

1. Prescription drug errors
2. Coordination of care errors (specifically errors involving communication)
3. Errors in clinical activities (generally timing of these activities)
4. Errors related to cognition

Other research from the ASIPS Collaborative (Pace et al, 2005) has also suggested some common causes of errors causing harm:

1. Therapeutic intent
2. Language barrier
3. Judgment
4. No system exists

Finally, the same group (Pace et al, 2005) looked at ten hierarchical constructs associated with harm:

1. Discrete event
2. Recurring event
3. Correct drug with wrong frequency/route/dose
4. Disclosure/explanation of need for test/treatment or exam
5. Mistimed procedure
6. Chart documentation
7. Drug error
8. Communication from another office
9. Patient care outside of the office
10. Distraction

Moore et al (2003) found that work-up errors, such as inadequate follow-up on a recommended patient test or procedure, contributed to rehospitalization risk. In particular, “multivariate analysis showed that patients with at least one work-up error were 6.2 times more likely to be rehospitalized within three months after the first post-discharge PCP visit compared to patients with no work-up error” (Moore et al, 2003).

Phillips et al (2004) concluded that patient harm, including low/moderate/severe injury and death, was related to “diagnostic errors (34 percent), failure to supervise or monitor case (16%), improper performance (15%), and medication errors (4 percent).” Lastly, Woolf et al (2008) indicated that patient harm often resulted from a cascade of errors, often initiated by communication problems.
Notably, most studies have not described the typical level of harm caused by a particular type of error. One study reported that errors broadly categorized as knowledge-skill-based or process-based had resulted in patient hospitalization or death, but did not provide detailed information regarding which errors caused these outcomes (Makeham et al, 2002).

Conclusions from research

As a result of the differences described above, authors have arrived at various conclusions regarding the nature and causes of errors and harm occurring in ambulatory care settings. However, certain themes are discernable. In particular, research over the last decade has shown that some of the most widely documented ambulatory errors include:

- **Medication errors** such as prescriptions for incorrect drugs or incorrect dosages (Elder and Dovey, 2002; Fernald et al, 2004; Kuzel et al, 2004; Makeham et al, 2002; Moore et al, 2003; Pace et al, 2005; Phillips et al, 2004; Phillips et al, 2006; Plews-Ogan et al, 2004; Rosser et al, 2005; Rubin et al, 2003; West et al, 2008; Woods et al, 2007)

- **Diagnostic errors** such as missed, delayed and wrong diagnoses (Dovey et al, 2002; Dovey and Elder 2002; Kuzel et al, 2004; Makeham et al, 2002; Pace et al, 2005; Phillips et al, 2004; Rubin et al, 2003; West et al, 2008; Woods et al, 2007)

- **Laboratory errors** such as missed and delayed tests as well as errors in patient follow-up on test results (Dovey et al, 2002; Fernald et al, 2004; Makeham et al, 2002; Moore et al, 2003; Phillips et al, 2006; Plews-Ogan et al, 2004; Rosser et al, 2005)

- **Clinical knowledge errors** such as knowledge, skill and general performance errors on the part of clinicians (Dovey et al, 2002; Elder and Dovey, 2002; Elder et al, 2004; Makeham et al, 2002; Pace et al, 2005; Phillips et al, 2004; Rosser et al, 2005; West et al, 2008)

- **Communication errors** such as doctor-patient communication errors, doctor-doctor communication errors or other miscommunications between parties (Dovey et al, 2002; Elder and Dovey, 2002; Elder et al, 2004; Fernald et al, 2004; Kuzel et al, 2004; Makeham et al, 2002; Pace et al, 2005; Phillips et al, 2006; Plews-Ogan et al, 2004; Rosser et al, 2005; Rubin et al, 2003; West et al, 2008; Woods et al, 2007)

Research on the consequences of error and/or patient harm in ambulatory settings has been much more limited and the results are varied. However, research has demonstrated that the following can occur as a result of errors in ambulatory care:

- Hospital admission or readmission (rehospitalization) (Makeham et al, 2002; Woods et al, 2007)
- Increased complications (Woolf et al, 2004; Elder et al, 2004)
- “Known clinical harm” (West et al, 2008)
- Minor physical harm, such as pain, discomfort or exacerbation of illness (Kuzel et al, 2004; Phillips et al, 2004; Elder et al, 2004)
- Physical injury, severity not specified (Woolf et al, 2004)
- Psychological harm, such as anger and other emotions (Kuzel et al, 2004; Woolf et al, 2004)
- Economic harm, such as lost pay (Kuzel et al, 2004)
- Moderate to severe physical injury (Phillips et al, 2004)
- Death (Makeham et al, 2002; Phillips et al, 2004)
Given the limitations in this body of research on ambulatory patient safety, it is difficult to conclude which types of errors have produced the most patient harm and what kind of harm. One study, perhaps the most robust to address patient harm, found that “prescription drug errors,” “coordination of care errors” [including communication], “errors in clinical activities” and “errors related to cognition” were most associated with “known clinical harm” or “future risk of clinical harm” (West et al, 2008).

Research has also shown that multiple mistakes may contribute to errors in ambulatory care (Woolf et al, 2004). Following a review of 75 error reports anonymously submitted by 18 U.S. physicians, Woolf et al found that 77 percent of incidents involved a chain of errors. The majority of these errors (80 percent) stemmed from miscommunication, including those that ultimately resulted in misdiagnoses (Woolf et al, 2004).

### Policy and other initiatives

**Measures of ambulatory patient safety**

In addition to research on ambulatory safety, the last decade also saw important efforts to measure the safety of ambulatory care for purposes other than research. Several organizations, including the Agency for Healthcare Research and Quality, The Joint Commission, the National Committee for Quality Assurance and National Quality Forum have endorsed measures related to ambulatory patient safety. In addition, several measures span delivery settings. Ambulatory safety measures endorsed by these and several other organizations between 2000 and 2010 are included in Table 1 below.

| **Table 1. Endorsed ambulatory patient safety-relevant measures** |
| --- | --- | --- | --- |
| **Agency for Healthcare Research and Quality (AHRQ) measures** | **CMS Physicians Quality Reporting Initiative (PQRI) Measures** | **Falls: Plan of Care (PQRI 155)** | **Oncoology: Radiation Dose Limits to Normal Tissues (PQRI 156)** |
| • Potentially inappropriate prescription medications for elderly (adults 65+) | • Communication with the Physician Managing Care for Osteoporosis (PQRI 24) | • Referral for Otologic Evaluation for Patients (PQRI 188) | • Referral for Otologic Evaluation for Patients with History of Active Drainage (PQRI 189) |
| • Medication Reconciliation (PQRI 46) | • Breast Cancer Resection Pathology Reporting (PQRI 99) | • Referral for Otologic Evaluation for Patients with Hearing Loss (PQRI 190) | • Oncology: Cancer Stage Documented (PQRI 194) |
| • Advance Care Plan (PQRI 46) | • Colorectal Cancer Resection Pathology Reporting (PQRI 100) | • Functional Communication Measure – Spoken Language Comprehension (PQRI 209) | |
The Joint Commission National Patient Safety Goals (NPSG)

- Use of Two Patient Identifiers (NPSG.01.01.01)
- Eliminate Transfusion Errors Due to Misidentification (NPSG.01.03.01)
- Label Medications (NPSG.03.04.01)
- Reduce Harm from Anticoagulation Therapy (NPSG.03.05.01)
- Comply with Hand Hygiene Guidelines (NPSG.07.01.01)
- Prevent Surgical Site Infections (NPSG.07.05.01)
- Conduct a Pre-Procedure Verification Process (UP.01.01.01)
- Mark the Procedure Site (UP.01.02.01)
- Perform a Time-Out (UP.01.03.01)

NOTE: Established NPSGs for ambulatory care but not in effect at this time:

- Compare Current and Newly Ordered Medications (NPSG.08.01.01)
- Communicate Medications to Next Provider (NPSG.08.02.01)
- Provide a Reconciled Medication List to Patient (NPSG.08.03.01)

Meaningful Use Clinical Quality Measures

- Breast Cancer Screening (NQF 0031/PQRI 112)
- Colorectal Cancer Screening (NQF 0034/PQRI 113)
- Anti-Depressant Medication Management (NQF 0105/PQRI 9)
- Diabetic Retinopathy Documentation of Severity (NQF 0088/PQRI 18)
- Diabetic Retinopathy Documented Communication (NQF 0089/PQRI 19)
- Prostate Cancer: Avoidance of Overuse of Bone Scan (NQF 0389/PQRI 102)
- Cervical Cancer Screening (NQF 0032)

National Committee for Quality Assurance NCQA (Ambulatory Care Measures)

- Annual monitoring for patients taking persistent medications
- Medication reconciliation post-discharge
- Potentially harmful drug-disease interactions in the elderly
- Use of high-risk medications in the elderly
- Fall risk management
- Use of High Risk Medication in the Elderly (Received at least one)
- Use of High Risk Medication in the Elderly (Received at least two)

National Quality Forum (NQF) Measures (spans care settings)

- Documentation of Medication List in the Outpatient Record (NQF 19)
- Documentation of Allergies and Adverse Reactions in the Outpatient Record (NQF 20)
- Drugs to Be Avoided in the Elderly (NQF F 21)
- Universal Documentation/Verification of Current Medications in the Medical Record (NQF 419)
- Adoption of Medication e-Prescribing (NQF 486)
- Medication Reconciliation Post-Discharge (NQF 554)
- Monthly INR Monitoring for Beneficiaries on Warfarin (NQF 555)
- INR for Beneficiaries Taking Warfarin and Interacting Anti-Infective Medications (NQF 556)
- Fall Risk Management in Older Adults (NQF 35)
- Screening for Fall Risk (NQF 101)
- Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF 267)
- Influenza Vaccination Coverage among Healthcare Personnel (NQF 431)
- Surgical Site Infection Prevention
- Radiation Dose Limits to Normal Tissues (NQF 382)
- Exposure Time Reported for Procedures Using Fluoroscopy (NQF 510)
- Adoption of Health Information Technology (NQF 488)
- Tracking of Clinical Results Between Visits (NQF 491)

National Quality Forum (NQF) – Voluntary Consensus Standards for Ambulatory Care – Using Clinically Enriched Administrative Data

- Cancer Screening and Surveillance
- Diabetes
- Medication Management
- HIV Screening

National Quality Forum (NQF) Endorsed Safe Practices (SP) for Better Health Care (pertaining to ambulatory care)

- Leadership Structure and Systems to Address Patient Safety Issues (SP 1)
- Culture Measurement, Feedback, and Intervention (SP 2)
- Teamwork Building and Skill Building (SP 3)
- Identification and Mitigation of Risks and Hazards (SP 4)
- Improved Patient Informed Consent (SP 5)
- Life-Sustaining Treatment Preference Documentation (SP 6)
- Disclosure of Serious Unintended Outcome to Patient (SP 7)
Interventions to improve patient safety

Research on broad-based interventions to improve patient safety has been much less frequent than research on the most common causes of errors. However, there are a number of efforts to implement interventions based on the information that is available. Subsequent sections in this report discuss research and interventions specific to medication safety, communication, patient contribution and diagnostic errors. The following are some of the broad-based activities undertaken in the last 10 years to address ambulatory safety in general.

**Agency for Healthcare Research and Quality**

For general information on ambulatory safety interventions, the website of the Agency for Healthcare Research and Quality (AHRQ) contains patient safety primers and other resource materials, including information on diagnostic errors, medication reconciliation, adverse events after hospital discharge and wrong site surgery. One primer, “Patient Safety in Ambulatory Care” (AHRQ, 2010), specifically addresses the issues related to safety in ambulatory care; one section, “What’s New,” lists recent publications including research findings.

**The Patient Safety and Quality Improvement Act of 2005**

The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) authorized the creation of Patient Safety Organizations (PSOs) to improve the quality and safety of U.S. health care delivery. The aim of the Patient Safety Act is to encourage physicians, health care providers, hospitals and health care organizations to voluntarily report and share quality and patient safety information on a privileged and confidential basis without fear of legal discovery (AHRQ, 2011). Implementation of the Patient Safety Act as of 2010 has focused largely on the inpatient setting, but the aims are applicable in the ambulatory setting. Information that is assembled and developed by providers and PSOs, called “patient safety work product,” is privileged and confidential; the purpose of patient safety work product is to identify patient safety events and unsafe conditions that increase risks to patients, in any care setting, and the intent of the Patient Safety Act is to allow sharing of information and lessons across a variety of settings.

The Patient Safety Act established a framework for a voluntary reporting system through the creation of PSOs. Patient Safety Organizations can be public or private organizations that collect, aggregate and analyze information regarding the quality and safety of care delivered in any health care setting (AHRQ, 2011).

The term “Common Formats” is used to describe the technical requirements and reporting specifications that allow health care providers to collect and submit information regarding patient safety events in a standardized manner (PSO Privacy Protection Center, 2011). The structure of the Common Formats allows reporters to capture:

- **Incidents**—Patient safety events that reached the patient
- **Near misses (or close calls)**—Patient safety events that did not reach the patient
- **Unsafe conditions**—Any circumstance that increases the probability of a patient safety event

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- Well-Designed Nursing Workforce and Non-Nursing Direct Care Workforce (SP 9-10)
- Communication of Patient Care Information (SP 12)
- Order Read-back and Abbreviations (SP 13)
- Label Diagnostic Studies (SP 14)
- Safe Adoption of CPOE (SP 16)
- Medication Reconciliation (SP 17)
- Pharmacist Leadership Structures and Systems (SP 18)
- Hand Hygiene (SP 19)
- Influenza Prevention (SP 20)
- Surgical Site Infection Prevention (SP 22)
- Multidrug-Resistant Organism Prevention (SP 24)
- Wrong-Site, Wrong-Procedure, Wrong-Person Surgery Prevention (SP 26)
- Anticoagulation Therapy (SP 29)
- Contrast Media-Induced Renal Failure Prevention (SP 30)
- Falls Prevention (SP 33)
- Pediatric Imaging to Reduce Radiation Exposure (SP34)
There are three generic forms to capture basic information along the spectrum of harm. Additionally reporters may provide a narrative to capture specific information on an event. There are eight event-specific forms, structured to supplement the information on the generic forms.

While PSOs have arisen far more often around inpatient care, many of the elements expressed in the Common Formats are transferable to ambulatory settings of care. For example, the Common Formats includes a specific form for medication or other substance events that involve, biological products, nutritional products or medical gases. Visit the AHRQ Patient Safety Organization website at www.pso.ahrq.gov to learn more about the Patient Safety Act and the Common Formats.

Additionally, in its efforts to support the original intent of the Patient Safety Act, the AMA provides information on the Patient Safety Act and the reporting mechanism it creates in “The Physician’s Guide to Patient Safety Organizations” (available at: www.ama-assn.org/go/patientsafety).

**American Recovery and Reinvestment Act of 2009**

The American Recovery and Reinvestment Act of 2009 (ARRA) legislation, passed in February of 2009, provided incentive funds for “Meaningful Use” of electronic health records systems (EHRs). Many of the requirements for obtaining these incentive funds are related to information technology interventions that have been suggested to improve ambulatory patient safety. Some of the requirements for office-based practices to qualify for financial incentives are to use an EHR for:

- Maintaining active problem, medication and medication allergy lists on an EHR system
- Using computerized physician order entry with drug-drug and drug-allergy checks
- E-prescribing (including electronic submission of the prescription to the pharmacy)
- Providing the patient an encounter summary after each visit
- Testing the capability to exchange electronically clinical information among providers

Some optional activities include:

- Reconciling medications at transitions in care
- Providing a summary record for transitions in care
- Providing patients with electronic access to their information stored in the EHR
- Sending reminders for follow-up care for patients over 65 or under 5

Hospitals also have optional requirements for medication reconciliation and providing summary records at transitions in care, and a mandatory requirement to provide patients with copies of discharge instructions on request.

Some posit that health information technology, such as electronic clinical decision support tools, could improve provider performance and reduce errors (Bates and Gawande, 2003; Johnston et al, 2003; Schiff and Bates, 2010; Singh et al, 2009a). While evidence is largely lacking, a small body of research indicates that such interventions may improve safety in addition to patient outcomes.

Chaudhry et al (2006) reviewed 257 studies, including comparative and descriptive studies as well as systematic literature reviews of the effect of health information technologies (health IT). The majority of studies focused on EHR or decision support systems, and 25 percent of the studies focused on four academic institutions with implemented systems. Among other quality improvements, the authors found the interventions reduced medication errors (Chaudhry et al, 2006).

Garg et al (2005) reviewed 97 controlled trials that examined the impact of computerized clinical decision support systems, including 10 diagnostic systems, 21 reminder systems, 23 disease management systems and 19 drug or prescribing systems. The authors report that these interventions improved performance among clinicians in the majority of studies (Garg et al, 2005). The authors also found that limited evidence indicates that such interventions also improve patient outcomes; 52 of the 97 reviewed trials...
examined one or more patient outcomes, and seven trials (13 percent) “reported improvements” (Garg et al, 2005).

While health IT may confer benefits, some research has also suggested that health IT systems can create new issues or exacerbate existing problems. Wachter (2010b) noted that, “[i]n both professional and lay publications, concerns have been raised that today’s electronic health records promote the copying and pasting of clinical information, instead of its thoughtful analysis; foster a focus on completing computerized checklists and templates rather than detailed probing of the patient’s history, and support less thoughtful diagnostic reasoning and more automatic behavior on the part of caregivers.”

Research indicates that a great deal depends on the design of the health information technology system, with poorly designed systems contributing to instances of errors (Ash et al, 2004). Where user interface designs are cumbersome to use and do not fit into the clinician’s natural work context, some have noted the potential for “cognitive overload,” among other reactions, and ultimately the possibility of increasing errors in data entry and retrieval as well as errors in the process of communication and coordination (Ash et al, 2004; Singh et al, 2009a).

There are some reports of EHR-related errors contributing to patient harm (sometimes referred to as “e-iatrogenesis”) in ambulatory settings (Myers et al, 2011). For instance, a software configuration error described in one EHR resulted in a number of patients not receiving timely follow-up for abnormal test results (Singh et al, 2009a).

To address these issues, the federal Office of the National Coordinator (ONC) for Health Information Technology recently sponsored an IOM committee to “review the available evidence and the experience from the field on how the use of health information technology (HIT) affects the safety of patient care.”

Future developments

Future research

In 2007 AHRQ funded a number of planning grants to identify areas of risk in ambulatory care. Based on the results of these efforts, in 2008 AHRQ awarded $3.7 million in three-year grants to implement safe practices to mitigate the risks identified in the planning grants. One of these grants (Karsh, 2011) will develop, test and share interventions to improve primary care in the elderly. Another grant (Kennerly, 2008) will develop and disseminate training materials and implementation resources related to use of a “trigger tool” to measure the rate of adverse events in ambulatory care settings (AHRQa).

- **Human Factors Intervention to Reduce Risk in Primary Care of the Elderly** (Karsh, 2011)
  “The development and implementation of an intervention to improve health care professionals’ awareness of their administration of primary care to elderly patients” (AHRQa)

- **Improving the Safety of Primary Care by Measuring Adverse Events and Improvement** (Kennerly, 2008)
  “The development and dissemination of training materials and implementation resources for the adoption of a BHCS/IHI Outpatient Trigger Tool to measure adverse events in ambulatory care” (AHRQa)
Concluding observations

• Research in the last decade on errors in ambulatory care included many studies that did not distinguish between errors that caused harm and those that did not.

• Most studies on ambulatory safety have been conducted in primary care practices.

• Taxonomies for classifying errors and harm are not consistent and ambulatory error reporting lacks standardization. Consequently it is not possible to make many comparisons across studies.

• The use of electronic health records has the potential to improve patient safety and early research shows some promise, but these systems have also been linked to errors and harm. It is not yet clear how many providers will adopt these systems, nor the extent to which health IT will improve patient safety in ambulatory care versus generating new types of errors.
Section II. Ambulatory medication safety research

Introduction

Research in the last decade suggests that medication errors are one of the top categories of errors causing harm in ambulatory care. Additionally, of the categories of ambulatory patient safety research explored in this report, medication safety has received the most research attention and has generated the most safety and quality interventions.

At the same time, research on medication safety in ambulatory settings has been challenging. In comparison to the relative advantages of the contained hospital environment (frequently including tightly controlled medication delivery processes), the fragmented ambulatory care environment, coupled with the periodic nature of patient interaction with providers, has made research on medication safety in ambulatory care settings more difficult. Researchers also noted challenges, such as the increased responsibilities of patients to obtain and manage their medications, less contact with the prescribing physician or health care professional, and—even assuming that patients seek care consistently from one practice site—the possibility that resultant medication problems would be unknown to the patient’s physician or health care team expeditiously (Gandhi et al, 2000a).

Research on ambulatory medication safety also consistently demonstrated the difficulty in ascertaining and understanding the frequency or nature of medication errors. Even as the most researched area of ambulatory safety, the research base was fairly small, employed inconsistent definitions and attempted to identify medication errors from different starting points in terms of data sources, patient populations and settings of care.

Based on the last decade’s research, it would be difficult to determine an accurate assessment of the rates, types, and severity of medication safety incidences in ambulatory care settings. However, common themes emerged specific to the identification of increased risk when medication-related errors could occur and potentially harm patients. Research results identified classes of medications most frequently associated with errors and patient characteristics, whether singly or in combination, that heighten the risk of experiencing adverse drug events.
Characteristics of the research

Definitions

Though not identical, definitions employed in medication safety research have been mostly consistent over the last decade, particularly in associating a medication event with injuries or errors associated to the medication use process. The most common terms used by investigators to define medication events are medication errors, adverse drug events (ADEs) and adverse drug reactions (ADRs). The definitions below include descriptions that delineate “preventable” and “non-preventable” ADEs as these have been widely used when describing medication events and errors, though the research presented in this section did not always distinguish between “preventable” and “non-preventable.”

- Following the Institute of Medicine report “To Err is Human: Building a Safer Health System,” medication errors have been most often defined as “the failure of a planned (medication use) action to be completed as intended or the use of a wrong plan to achieve the aim,” which includes the delineation of errors of omission (such as failing to take a medication) and commission (such as taking the wrong medication or dose).

- An adverse drug event was consistently defined as any adverse outcome or patient injury caused in the medication use process (prescribing, dispensing and taking medications) or as “injuries resulting from use of drugs.” ADEs are considered to be either preventable or non-preventable.

- That medication errors are preventable has usually been considered implicit to the definition of an error. Therefore ADEs that involve an element of error (of either omission or commission) are often referred to as preventable ADEs. Medication errors that reached the patient but, by good fortune, did not cause any harm have often been called potential ADEs.

- An adverse drug reaction, as defined by the World Health Organization (WHO), is “a response to a drug which is noxious and unintended and which occurs at doses normally used in humans for prophylaxis, diagnosis, or therapy” or simply as “harm caused directly by a drug at normal doses during normal use.” Of note is that medication safety research in the United States early in the last decade did not classify this type of harm as ADRs, but “ADR” is now a widely accepted term used to define non-preventable adverse medication outcomes.

Thomsen et al (2007) offered a slight variation on the above definition of ADE in their research by identifying an ADE as “an injury resulting from drug therapy.” Budnitz et al (2006) explicitly defined and classified ADEs in subcategories, including allergic reactions (immunologically mediated effects), adverse effects (undesirable pharmacologic or idiosyncratic effects at recommended doses), unintentional overdoses (toxic effects linked to excess dose or impaired excretion) or secondary effects (e.g., falls, choking); they excluded from their definition of ADE intentional self-harm (e.g., suicide attempts), drug therapeutic failures, drug withdrawal and drug abuse.

Investigators at Brigham and Women’s Hospital (BWH) introduced the term “ameliorable ADE” to classify an event that is not always preventable but could have been less severe with an appropriate response by the health care system (Gandhi et al, 2003). This terminology seemed to be exclusive to research conducted at BWH.

The BWH Department of Medicine adopted the following definitions, including when working with research teams from other institutions (Pippins et al, 2008; Field et al, 2004; Forster et al, 2005; Gandhi et al, 2003, 2005 and 2010; Gurwitz et al, 2003; Honigman et al, 2001):

- Medication error—Any error that occurred in the medication use process (including ordering/ prescribing, dispensing, adherence and monitoring)

- Adverse drug event—An injury resulting from use of a medication
Research focused on specific subcategories of medication errors has defined errors according to their area of concentration. Each of the following studies included a definition of the type of medication error specific to their research.


1. **Potential overdose:** 110 percent or more of the maximum recommended daily dose (MaxRDD) or total mg/kg/d dispensed at more than the maximum recommended adult dose
2. **Potential underdose:** total mg/kg/d dispensed below 90 percent of the minimum recommended daily dose (MinRDD) and below the adult minimum recommended daily dose in total mg/d

In a study to monitor organ function and drug levels, Hurley et al (2005) stated that a “monitoring error” occurred when one or more tests (e.g., lab tests or other scans) ordered for the purpose of monitoring the effects of the drug intervention was not done during the recommended timeframe.

A study by Solberg et al (2004) defined the term “drug-drug interactions” (DDIs) as two or more drugs interacting in such a manner that alters the effectiveness or toxicity of one or more drugs. Using combined administrative and pharmacy claims data from two large health plans to identify prescribing practices of medical groups within the plans, the investigators calculated the potential exposure rates for patients taking selected chronic medications to a second drug known to increase harmful drug-drug interactions (Solberg et al, 2004). They required that each DDI combination be identified as a problem in at least two of the three following references, with a clinical significance rating of 1, 2 or 3:

1. Hansten and Horn’s *Drug Interactions, Analysis and Management*
2. The DRUG-REAX system of Micromedex
3. *Evaluations of Drug Interactions (EDI)*

**Taxonomies**

Several studies have classified ADEs by the severity of harm to the patient, though these classifications lack consistency. For example, some studies have categorized symptoms experienced by the patient to determine relative severity (Zhang et al, 2006; Gurwitz et al, 2003; Gandhi et al, 2000). A study of potential drug-drug interactions (Solberg et al, 2004) selected combinations of drugs rated as problematic by key reference sources and assigned a clinical significance rating to determine whether the level of severity was severe, moderate or mild.

Three studies (Gandhi et al, 2010; Gurwitz et al, 2003; Forster et al, 2005) categorized ADE severity by the following four patient outcomes:

1. Fatal
2. Life-threatening (the potential to lead to a fatality, e.g., respiratory failure, anaphylaxis)
3. Serious (caused a temporary or permanent disability or was associated with a high risk of long-term consequences to the patient, e.g., gastrointestinal bleed, altered mental status)
4. Significant (caused minimal symptoms or was associated with a low risk of long-term consequences to the patient, e.g., rash, diarrhea)

A number of studies have classified ADEs by preventability (Gurwitz et al, 2003; Thomsen et al, 2007; Gandhi et al, 2005) or by both preventability and ameliorability (Forster et al, 2005; Gandhi et al, 2010; Gandhi et al, 2003; Honigman et al, 2001).

Forster et al (2005) rated ADE outcomes as to whether there were laboratory abnormalities only, symptoms only, nonpermanent disability or permanent disability. This study additionally categorized health service use by the following outcomes: none; additional visit to physician; additional visit for laboratory testing in addition...
to a physician visit; visit to an emergency room; or readmission to a hospital.

Other studies limited their focus to patients experiencing severe enough ADEs to seek care in the emergency room (Budnitz et al, 2006) or to patients admitted to the hospital (Zhang et al, 2006).

Data sources
Research in ambulatory medication safety can be constrained by data availability. Health information technology systems (health IT) present the possibility of providing consistent and comprehensive medical record information, including on medications delivered and their effects. Electronic data sources also avoid the significant inefficiencies of manual chart abstraction and permit examining much larger patient populations. For example, research on primary care visits using computerized data has examined the sensitivity and specificity of computer searches for adverse drug events in outpatients, using a retrospective analysis of one year of data from an electronic health record (EHR), including records for 23,064 patients with a primary care physician (Honigman et al, 2001). The investigators found that free-text searches were especially productive when using computerized search programs to detect ADEs.

Claims data are readily available (especially electronic claims data), coded, relatively inexpensive and easy to use for research, but this data source also has limitations. For example, claims data usually provide no demographic information beyond age and sex, and only include information on services rendered and billed to a patient account, often after a significant time lag. Consequently, using claims data often limits the scope of research inquiry.

An Australian study conducted by Zhang et al (2006) used the Western Australian Hospital Morbidity Data System to extract information about first-time and repeat ADRs for patients 60 years and older, focusing on ADEs that resulted in hospital admissions or extended hospital stays. The study followed 37,296 patients with first-time ADRs for up to 24 years. The retrospective cohort design used population-based quality data, routinely collected and audited, which overcame issues related to selection and recall bias as well as issues of poor response rates and loss to follow-up. The authors stated that an advantage of this study over their earlier work included the analysis of data at the individual patient level, which permitted them to follow up with hospital separation records individually and identify repeat ADRs in the same patient regardless of changes in the treating hospital. At the same time, they noted that an important limitation of their study was the lack of detailed specification available from ICD codes for the particular drugs responsible for specific ADR-related hospital admissions. Only very broad groupings of drugs were available (e.g., antineoplastics and immunosuppressives were grouped together under one code). Furthermore, their study focused only on ADRs resulting in hospitalization, i.e., ADRs that either caused hospital admission or extended the hospital stay. The authors also concluded that because the presence of an ADR is subject to clinical judgment, reliability to ascertain an ADR could vary (Zhang et al, 2006).

Solberg et al (2004) and Hurley et al (2005) based their studies on insurance claims data (Solberg et al examined drug-drug interactions by looking at pharmacy benefit claims, and Hurley et al examined whether patients receiving medications which require laboratory monitoring had appropriate follow-up laboratory tests performed). Direct abstractions from medical records were the source of data for all of the other identified studies.

Researchers often used chart reviews in combination with patient surveys or telephone calls to obtain data on ambulatory medication safety (Gandhi et al, 2000; Forster et al, 2005). These studies acknowledged challenges in soliciting patient input about their symptoms, including lack of patient recall and patients who chose to opt out, were too ill or did not speak English well enough. Additionally, these studies required considerable analysis by clinical pharmacists and/or other clinicians to evaluate the extent to which patient-reported symptoms were likely to be related to medication use. In addition, one study found that...
chart review alone only detected 3 percent of patients who received a prescription and had a subsequent drug complication, whereas 18 percent of patients contacted by survey or telephone reported a problem (Gandhi et al, 2000).

The BWH research group has attempted to gain an understanding of the frequency and types of ADEs in the following two seminal studies:

- In a study that included all persons aged 65 years or older in an ambulatory group practice, the investigators combined physician self-reported incidents, hospital discharge summaries, emergency department (ED) notes, computer-generated signals (rules applied to EHR data) and automated free-text review of EHR encounter notes to detect drug-related incidents (Gurwitz et al, 2003). The study identified 1,523 adverse drug events, of which 27.6 percent (421) were considered preventable.

- In a study conducted at two large health systems, Partners HealthCare and Regenstrief Institute Inc., Gandhi et al searched EHR data for four months (68,000 patients) using an ADE monitor that included a large number of logical rules based on diagnoses, medications and laboratory values. These EHR systems included the capability to search text for predefined combinations of medication use and symptoms (Gandhi et al, 2010). This study estimated the incidence of medication errors in outpatients over a four-week period at 27 per 100 patients, which is a higher incidence than has been generally found in hospitalized patients. Additionally, the investigators determined that most of these errors were not preventable. Using several different algorithms, the investigators identified one ADE for every seven patient-years; the highest yield screening algorithms were triggers that identified patients with abnormal lab values in combination with high-risk medications (Gandhi et al, 2010).

**Patient populations and settings of care**

With few exceptions, adults seen in primary care practices have been the focus of ambulatory medication studies in the last decade. McPhillips et al (2005) focused on two components of pediatric medication safety, i.e., types of drugs prescribed to children and weight-based dosing in children 1 to 4 years old. Another study examined patients receiving orders for outpatient infusion chemotherapy or another infusion medication in two adult and one pediatric chemotherapy infusion units (Gandhi et al, 2005). The study found an ambulatory medication error rate of 3 percent, i.e., 306 of 10,112 orders, of which the potential to cause harm was evident in 82 percent of errors in the adult population and 62 percent of errors in the pediatric population. Approximately one-third of these errors were potentially serious, though pharmacists and nurses intercepted 45 percent of potential ADEs before they reached the patient (Gandhi et al, 2005).

Several medication safety studies in the last decade focused on older adult populations. Zhang et al (2006) focused on patients aged 60 years or older; Gurwitz et al (2003) worked with Medicare patients 65 years and older; Field et al (2004) studied patients 80 years and older. Many other studies of adult primary care clinics included elderly patients. Gandhi et al (2000) included patients 20 to 75 years old at the time of data collection; Budnitz et al (2006) included patients in the National Electronic Injury Surveillance System who were seen in the emergency department (ED) and called specific attention to the study’s findings for patients aged 65 years and older. They found that adverse drug events among outpatients that lead to emergency department visits are an important cause of morbidity in the United States, particularly among individuals aged 65 years or older. Gurwitz et al (2003) assessed the incidence and preventability of adverse events among persons aged 65 or older receiving health care services in an ambulatory group practice setting and demonstrated the potential utility of longitudinal information to examine the monitoring stages of the medication use process, concluding that prevention strategies should target the prescribing and monitoring stages of pharmaceutical care.
Medications studied

A number of studies examined medication errors according to specific medication types. Some studies limited the research hypothesis to subcategories of medications; for example, in their study of pediatric medications, McPhillips et al (2005) focused on either those medications commonly prescribed or those most commonly associated with errors. Other studies analyzed medications taken for chronic conditions that required laboratory monitoring (Hurley et al, 2005) or specific medication pairs that had the potential to cause drug-drug interactions (Solberg et al, 2004). Long et al (2010) focused solely on characteristics of ADEs associated with anticoagulant therapy in ambulatory settings of care.

Other studies of medication safety in ambulatory care settings were broader in their scope and included all medications in their research of errors and/or ADEs (Budnitz et al, 2006; Field et al, 2004; Forster et al, 2005; Gandhi et al, 2000, 2003, 2005, 2010; Gurwitz et al, 2003; Honigman et al, 2001; Thomsen et al, 2007; Zhang et al, 2006).

The results of studies between 2000 and 2010 that examined high-risk medications are summarized in Table 2.1. In these studies, investigators generally categorized ADEs or potential ADEs by the medication class involved in the event. Notwithstanding the variation in research hypotheses and methodologies reviewed, the results of this type of research presented a fairly consistent picture. High-risk medication classes include drugs in widespread use (e.g., cardiovascular agents and analgesics) and those with a narrow therapeutic range and/or high toxicity (e.g., hypoglycemic agents, chemotherapeutics). For example, Thomsen et al (2007) found cardiovascular drugs were most frequently associated with ADEs, potential ADEs and potential ADEs that required hospital admission (46.6 percent), followed by CNS-active drugs (14.9 percent), and respiratory drugs (12.2 percent). Cardiovascular agents were among the top three medication classes in more than half of the studies in Table 2.1. Other medication classes commonly rated as presenting the highest risk included analgesics, anticoagulants, hormone agents, diuretic and psychoactive agents.

More specifically, Gurwitz et al (2003) studied preventable ADEs among older persons in the ambulatory setting and cited the following types of medications as most often involved in ADEs: cardiovascular (26 percent), antibiotics/anti-infectives (14.7 percent), diuretics (13.3 percent), nonopioid analgesics (11.8 percent) and anticoagulants (7.9 percent). Zhang et al (2006) found that in older patients the drugs most often involved in repeat ADEs were similar to the high adverse event medications identified by Gurwitz et al (2003), i.e., cardiovascular agents (15.6 percent), antineoplastics (11 percent), corticosteroids (10.1 percent), anticoagulants (8.6 percent), antirheumatics/NSAIDs (5.1 percent) and opioids (4.9 percent).

McPhillips et al (2005) reported the prevalence of potential dosing errors for 22 common medications dispensed to children. In this study, errors were defined as potential overdoses or potential underdoses. Medications most overdosed were analgesics, asthma/allergy preparations and psychotropics; medications most often underdosed were antiepileptics, antibiotics and isotretinoin (McPhillips et al, 2005).
### Table 2.1: Medication classes associated with adverse drug events and/or medication errors

<table>
<thead>
<tr>
<th>Study metric</th>
<th>Medication class</th>
<th>Results</th>
<th>Additional information</th>
<th>Study and year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distribution of ADEs by medication class</td>
<td>1. Antihypertensive</td>
<td>27.3%</td>
<td>• Percentage based on study sample of 121 ADEs</td>
<td>Honigman et al, 2000</td>
</tr>
<tr>
<td></td>
<td>2. ACE inhibitor</td>
<td>20.7%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Antibiotic</td>
<td>8.3%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Diuretic</td>
<td>7.4%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5. Anticoagulant</td>
<td>6.6%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percentage of adverse events by medication category</td>
<td>1. Selective serotonum – reuptake inhibitors</td>
<td>10.0%</td>
<td>• Based on sample of 181 adverse events from adult population</td>
<td>Gandhi TK et al, 2003</td>
</tr>
<tr>
<td></td>
<td>2. Beta blockers</td>
<td>9.0%</td>
<td>• Chart review and patient survey</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Angiotensin-converting-enzyme inhibitors</td>
<td>8.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Non-steroidal anti-inflammatory medications (NSAIDs)</td>
<td>8.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5. Calcium channel blockers</td>
<td>7.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency of ADEs by drug class</td>
<td>1. Cardiovascular</td>
<td>26.0%</td>
<td>• Percentage based on total ADEs in study</td>
<td>Gurwitz et al, 2003</td>
</tr>
<tr>
<td></td>
<td>2. Antibiotics/anti-infectives</td>
<td>14.7%</td>
<td>• N=1523</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Diuretics</td>
<td>13.3%</td>
<td>• Patients are 65 years and older</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Non-opioid analgesics</td>
<td>11.8%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5. Anticoagulants</td>
<td>7.9%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADE rate per 1,000 prescriptions</td>
<td>1. Corticosteroid</td>
<td>7.1%</td>
<td>• Prescription review plus follow-up phone calls from adult population</td>
<td>Forster et al, 2004</td>
</tr>
<tr>
<td></td>
<td>2. Anticoagulants</td>
<td>7.1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Anti-infectives</td>
<td>5.1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Analgesics (including narcotics)</td>
<td>3.1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rates of members with &gt;1 potential DDI by drug class</td>
<td>1. Cardiovascular</td>
<td>13.3%</td>
<td>• Percentage based on total members with &gt;1 DDI within each one-year study period</td>
<td>Solberg et al, 2004</td>
</tr>
<tr>
<td></td>
<td>2. Hematologics</td>
<td>9.02%</td>
<td>• Data based on pharmacy benefit claims</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Antilipemics</td>
<td>4.12%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Psychoactives</td>
<td>3.07%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Independent risk factors for having an ADR for patients on current medications</td>
<td>1. Anticoagulant</td>
<td>1.8%</td>
<td>• Result is a study-defined and calculated odds ratio</td>
<td>Field et al, 2004</td>
</tr>
<tr>
<td></td>
<td>2. Antidepressant</td>
<td>1.5%</td>
<td>• 1,299 patients with ADEs compared to 1,299 controls</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Antibiotic</td>
<td>1.6%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Hormone agents</td>
<td>1.5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5. Corticosteroid</td>
<td>1.5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>6. Cardiovascular agents</td>
<td>1.4%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>7. Diuretic</td>
<td>1.3%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dosing errors for children by type of error and drug class</td>
<td>Overdosed</td>
<td>15.0%</td>
<td>• Based on the total number of dosing errors by type and then drug</td>
<td>McPhillips et al, 2005</td>
</tr>
<tr>
<td></td>
<td>1. Analgesic</td>
<td>12.0%</td>
<td>• Sample size was 1,933 children</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Asthma/allergy</td>
<td>7.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Psychotropic</td>
<td>20.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Underdosed</td>
<td>9.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. Antiepileptic</td>
<td>9.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Antibiotic</td>
<td>9.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Isotretinoin</td>
<td>9.0%</td>
<td></td>
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</tbody>
</table>
### Table of contents

<table>
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<th>Results</th>
<th>Additional information</th>
<th>Study and year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual estimated percentage of ADEs by drug category</td>
<td>1. Central nervous system agents &lt;br&gt; 2. Systemic antimicrobial agents &lt;br&gt; 3. Hormone-modifying agents &lt;br&gt; 4. Hematologic and oncologic agents &lt;br&gt; 5. Cardiovascular</td>
<td>21.4% &lt;br&gt; 18.0% &lt;br&gt; 12.0% &lt;br&gt; 10.3 % &lt;br&gt; 7.6 %</td>
<td>• Based on emergency department surveillance data collected in the United States, 2004–2005</td>
<td>Budnitz et al, 2006</td>
</tr>
</tbody>
</table>

| Drug categories for first-time/repeat ADRs resulting in hospitalization | 1. Cardiovascular agents <br> 2. Analgesic/NSAID <br> 3. Hormone agents <br> 4. Primary systemic agents (e.g., immunosuppressives, antieoplastics) <br> 5. Hematologic agents | 17.9%/15.6% <br> 17.4%/14.7% <br> 7.3%/13.3% <br> 7.4%/11.3% <br> 9.3%/9.6% | • Patients were > 60 years <br> • Study done in Western Australia <br> • Timeframe: 1980–2003 | Zhang et al, 2006 |

### Patient risk factors

Several studies examined patient characteristics that might increase the risk of ADEs, such as age, disease burden and numbers and types of current medications (Budnitz et al, 2006; Gandhi et al, 2000; Forster et al, 2005; Gandhi et al, 2003; Gurwitz et al, 2003; McPhillips, 2005; Zhang et al, 2006).

These studies are summarized in Table 2.2. Many are in agreement that advancing age, the number and types of current medications and an increasing number of comorbidities each increase a patient’s risk of experiencing an ADE.

#### Table 2.2: Patient risk factors for ADEs and drug complications

<table>
<thead>
<tr>
<th>Study objective/Metric</th>
<th>Patient characteristics/Risk factors</th>
<th>Study and year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug complications in outpatients</td>
<td>Age, number of medical problems, number of medications, renal disease</td>
<td>Gandhi TK et al, 2000</td>
</tr>
<tr>
<td>Adverse events in ambulatory care (chart review plus patient survey)</td>
<td>Age, English as primary language, educational level, number of medications</td>
<td>Gandhi TK et al, 2003</td>
</tr>
<tr>
<td>Incidence and preventability of ADEs among older patients</td>
<td>Age (65 years and older), outpatient visits, number of prescriptions, number of medications, medication class</td>
<td>Gurwitz et al, 2003</td>
</tr>
<tr>
<td>Risk factors for ADEs among older adults</td>
<td>Age (65 years or older), disease rating/Charlson comorbidity index, number of medications, medication class</td>
<td>Field et al, 2004</td>
</tr>
<tr>
<td>ADEs occurring after discharge</td>
<td>Age, Charlson comorbidity index, number of admissions six months prior to current admission, length of stay, side effects explained, number of medications</td>
<td>Forster et al, 2004</td>
</tr>
<tr>
<td>Potential medication dosing errors in outpatient pediatrics</td>
<td>Age, number of medications, clinic visit within two days</td>
<td>McPhillips et al, 2005</td>
</tr>
<tr>
<td>Repeat ADRs causing hospitalization in older Australians</td>
<td>Age (60 years and older), number of comorbidities, repeat ADR vs. first time ADR, medication class</td>
<td>Zhang et al, 2006</td>
</tr>
<tr>
<td>Frequency and characteristics of ADEs that lead to ED visits</td>
<td>Age (65 years and older) and sex</td>
<td>Budnitz et al, 2006</td>
</tr>
</tbody>
</table>
Studies of interventions to improve medication safety

Identification of high-risk medications and instances of harm

As seen in Table 2.1, research over the last decade has identified a number of medication types that are most likely to be involved in ADEs and cause harm. Correspondingly, there have been several efforts to introduce interventions to prevent or mitigate harm, errors, ADEs, and ADRs from high-risk drugs. Not all of these have been the subject of research, however. The following includes both research studies and non-research projects that aim to improve ambulatory medication safety.

The U.S. Food and Drug Administration (FDA) offers three programs to assist efforts in identifying medication events (www.fda.gov/Safety/MedWatch). The FDA encourages health care professionals, consumers, and patients to report adverse reactions and quality problems, primarily with drugs and medical devices, but also for other FDA-regulated products (e.g., dietary supplements, cosmetics, medical foods, and infant formulas), by means of the FDA’s voluntary Safety Information and Adverse Event Reporting Program (MedWatch). The FDA’s Vaccine Adverse Event Reporting System (VAERS) collects data on vaccine-related adverse events. The FDA also has an email alerting system that provides notifications of newly identified safety issues.

The Institute for Safe Medication Practices (ISMP) (www.ismp.org) maintains a national voluntary reporting system, the Medication Error Reporting Program (MERP), for medication errors or preventable adverse drug reactions. ISMP uses this information to create a list of “high-alert medications,” i.e., those medications known to have heightened risks of harm associated with their use and that, when involved in an error, produce more devastating consequences for patients and therefore require greater safeguards. In their efforts to enhance medication safety, ISMP reviews reports and other submitted information to identify safety issues likely to cause confusion or errors. Based on their findings, ISMP creates reference lists and sends out alerts on abbreviations, symbols and dose designations that have caused errors. ISMP also publishes case studies of adverse events and errors, and maintains a list of look-alike/sound-alike drugs, an archive of research results and a registry of safety experts.

The Joint Commission has identified specific medication abbreviations (a subset of the ISMP list) that must appear on an organization’s “do-not-use list” to meet the national patient safety goals (NPSG). The NPSG requires accredited organizations to maintain and annually review a list of at least 10 look-alike/sound-alike name pairs, and to take action to prevent the interchange of these products (ISMP, May 21, 2009).

Use of e-prescribing and CPOE in ambulatory practice

The Centers for Medicare & Medicaid Services (CMS) and a number of health plans have provided financial and regulatory incentives to adopt e-prescribing (a prescriber’s ability to electronically send an accurate, error-free and understandable prescription directly to a pharmacy from the point of care) and to purchase computerized physician order entry (CPOE) systems. Both technologies replace handwritten paper prescriptions and have the potential to provide automated checks for allergies, drug-drug interactions, appropriate dosage, etc., which are believed to improve medication safety. However, research studies in the last decade have mainly quantified their level of adoption in the health care community rather than any impact on patient safety. For example, in 2009, 12 percent of ambulatory prescriptions were routed electronically; 156,000 prescribers submitted 191 million prescriptions electronically and 81 million prescription histories were delivered to prescribers. In 2008 comparable numbers for their use were 4 percent of prescriptions; 74,000 prescribers submitted 68 million prescriptions and created 16 million prescription histories (Surescripts, 2009/2010).
The use of CPOE in ambulatory EHR systems (the vehicle for some e-prescriptions) has been strongly encouraged, but uptake has been slow. The most comprehensive study, which was conducted in late 2007 and early 2008, surveyed 2,758 physicians and received responses from 62 percent. The study found that only 4 percent of ambulatory practices with EHRs had a “fully functional system” with capabilities to maintain electronic lists of medications, enter orders for medications, transmit those orders electronically and provide warnings of drug interactions and contraindications. Of those with fully functional systems, 80 percent reported that the system had prevented a drug allergy, and 71 percent were warned of a potentially dangerous medication (DesRoches et al, 2008).

Two recent studies show the impact of CPOE and e-prescribing and the potential they have to avoid ambulatory prescribing errors:

- In a study analyzing more than 3,500 paper-based prescriptions filled prior to e-prescribing adoption and more than 3,500 paper-based and electronic prescriptions filled one year after the adoption of e-prescribing, error rates decreased from 42.5 per 100 prescriptions to 6.6 per 100 prescriptions one year after electronic adoption. Illegibility errors were high pre-adoption and were completely eliminated by e-prescribing after one year of adoption (Kaushal et al, 2010).

Another study evaluated the effect of a basic ambulatory CPOE system on medication errors and associated ADEs. The study compared more than 5,000 prescriptions written before implementation of CPOE and more than 5,000 prescriptions after CPOE implementation. The frequency of errors declined from 18.2 percent to 8.2 percent, with the highest reductions seen in illegibility errors and missing information. The study concluded that “a basic CPOE system in a community setting was associated with a significant reduction in medication errors of most types and severity levels” (Devine et al, 2010).

Research on the effectiveness of medication safety alerts

Electronic medical record (EMR) systems have been programmed to issue alerts to physicians who attempt to order medications that might pose a safety risk due to drug interactions or toxicity problems. Research on the effectiveness of these alerts has taken place mainly in the inpatient setting, but could be applicable to ambulatory care. In particular, a number of these studies suggest that clinicians often override alerts, for several reasons.

- A study by Abookire et al (2000) analyzed trend data over a five-year period and discovered decreasing compliance to CPOE allergy alert functions, finding that allergy alerts were routinely overridden. The study separated the drug allergy alerts based on whether they were “definite” or “possible,” and found that both groups showed decreasing compliance over time from 51 percent to 27 percent for definite alerts and from 46 percent to 20 percent for possible alerts. They also found that 65 percent of all allergy alerts were repeat alerts on the same patient for a drug the patient was already taking. The percent of such “re-order” overrides rose from 48 percent to 83 percent during the study period.

- A study analyzing the characteristics of alerts during a four-week period at a hospital found that in the 42,641 orders where an alert could potentially be generated, 11 percent generated at least one alert and many generated more than one alert. The rates at which the ordering practitioner overrode “critical drug interaction” and “allergy-drug interaction” alerts were 88 percent and 69 percent respectively. This was in part due to the frequent presence of alerts for potential interactions between systemic and topical medications and for alerts generated during medication renewals (Payne et al, 2002).

- A study that calculated the override rate among 3,481 consecutive alerts generated in five adult primary practices using CPOE systems and showed that physicians overrode 91.2 percent of drug allergy alerts and 89.4 percent of high-severity drug interaction alerts. Physicians were more likely to override alerts for drug renewals (Weingart et al, 2003).
In a study to improve clinician acceptance of drug alerts, Shah et al. (2006) designed a selective set of drug alerts for the ambulatory care setting and minimized workflow disruptions by designating only critical to high-severity alerts to be interruptive to clinician workflow. There were 18,115 drug alerts generated during the six-month study period. Of these, 12,933 (71 percent) were noninterruptive and 5,182 (29 percent) interruptive, of which 67 percent of the interruptive alerts were accepted. The study found various reasons for overrides and that the reasons varied for each drug alert category. The investigators concluded that their study provided potentially useful information for future alert improvement and that data suggested that it is possible to design computerized prescribing decision support with high rates of alert recommendation acceptance by clinicians (Shah et al., 2006).

Medication reconciliation

**AMA activities**

In 2006 the American Medical Association (AMA) convened an expert panel to heighten physician awareness of the integral role of medication reconciliation in the safe use of medications (see below). Recognizing that medication reconciliation had been primarily focused on inpatient settings of care, the panel developed a framework and principles for medication reconciliation across all care settings. The panel aimed to develop principles and tools that could minimize patient harm, lessen the burden of illness, maximize patient efforts to understand and safely self-manage their medications, and enhance the flow of medication information between patients and their health care team (AMA Medication Reconciliation Panel, 2006).

The AMA panel on medication reconciliation developed the following statements to define medication reconciliation, its aims, and scope.

**Definition**

Medication reconciliation is a formal process for creating the most complete and accurate list possible of a patient’s current medications and resolving conflicts between different sources of information (e.g., the patient or patient’s caregivers, the patient’s physicians and other prescribing professionals, and the patient records or medication orders). It is an ongoing, dynamic, episodic and team-based process that is essential to minimize harm and optimize the safe and effective use of medications. It is one element in the process of therapeutic use of medications and medication management.

**Aims**

The process of medication reconciliation aims to promote patient safety by providing a structured process for physicians and other health care professionals to acquire and transfer accurate, detailed information about current prescribed medications, nonprescription and over-the-counter drugs or nutraceuticals patients may be taking.

**Scope**

The medication reconciliation process is an integral component of care coordination and should take place at every transition in the patient’s care, regardless of the setting of care or type of care transition, but at a higher level of vigilance when transitions involve medication encounters. Medication encounters include but are not limited to: prescription changes; additions or subtractions of medications, whether temporary or permanent; or changes that reflect the patient’s inability to continue a medication or the patient’s confusion about a medication or medication regimen; or changes based on the patient’s values, personal requests, economic hardship or other preferences.
Activities of The Joint Commission
According to The Joint Commission, medication reconciliation is "the process of comparing a patient’s medication orders to all of the medications that the patient has been taking" (JCAHO, 2006). In 2005 The Joint Commission (JCAHO) included medication reconciliation as a national safety goal (#8). Medication reconciliation is traditionally performed at admission to and discharge from the hospital; however, it is also recommended at every ambulatory visit and at movement from one unit to the other within the hospital. In 2006 JCAHO began to audit hospitals to determine if medication reconciliation was occurring at admission, discharge and transitions of care within the hospital as part of the JCAHO accreditation. However, in March 2010 JCAHO, renamed The Joint Commission (TJC), announced that medication reconciliation would still continue to be part of TJC on-site surveys, but would not be included in accreditation decisions. They announced that they would create a new statement for medication reconciliation to be implemented in January 2011 (TJC, 2010).

Activities of the Agency for Healthcare Research and Quality
The AHRQ maintains a Patient Safety Primer on medication reconciliation, which notes:

While the importance of medication reconciliation is universally recognized, the optimal method for reconciling medications has yet to be determined. A variety of methods have been studied, including having pharmacists perform the entire process, linking medication reconciliation to existing computerized provider order entry systems, and integrating medication reconciliation within the electronic medical record system. Patients are also increasingly being involved in the medication reconciliation process, especially in the ambulatory setting.

The evidence supporting patient benefits from reconciling medications is relatively scanty. Interventions led by pharmacists may be the most promising, as at least one study, utilizing a pharmacist-led medication reconciliation process at discharge did improve clinical outcomes, and other studies have shown reductions in actual and potential medication errors. While information technology solutions are being widely studied, and do appear to significantly reduce medication discrepancies, their effect on clinical outcomes remains unclear (AHRQ Patient Safety Primer September 2010).

Activities of the Institute for Safe Medication Practices
ISMP receives many medication error reports that include instances of failed communications during care transitions and at other vulnerable points in the continuum of care. In 2005, based on information from those reports, ISMP developed five steps for a medication reconciliation process. ISMP disseminated the process in its quarterly newsletter, ISMP Medication Safety Alert®.

1. Obtain a medication history. Obtain an accurate list of the patient’s current medications before administering the first dose of medications (except in emergency or urgent situations). Use a specific form to document the dose, route, frequency, indication and time of last dose for each medication, as well as patient compliance and the information source. Sources of information may include the patient and family, visual inspection of the medications, medical records, the pharmacy and the physician’s office.

2. Prescribe medications. As soon as the list is reasonably complete, have the prescriber review and act upon each medication on the list while prescribing the patient’s admission medications.

3. Reconcile and resolve discrepancies. Require another person to compare the prescribed admission medications to those on the medication history list and resolve any discrepancies.

4. Reconcile again upon transfer and discharge. When the patient is discharged or transferred, the reconciled list of admission medications must be compared against the physician’s discharge orders, along with the most recent medication administration record. Any discrepancies must be fully reconciled before discharge.
5. **Share the list.** Communicate a complete list of the patient’s medications to the next provider of service. This may include sending a list of medications prescribed upon hospital discharge to the patient’s primary care physician or encouraging the patient to share the list with their pharmacy.

### Activities related to performance measurement and improvement

Organizations including the National Quality Forum (NQF), the AMA-convened Physician Consortium for Performance Improvement® (PCPI™), the Institute for Safe Medication Practices (ISMP) and The Joint Commission (TJC) have each provided guidelines and performance measures for medication reconciliation. Although the majority of measures are hospital-based, providers may find that using these guidelines and measures as “checklists” or “roadmaps” can assist the process of medication reconciliation in ambulatory care settings.

For example, the NQF identified the following patient survey measures to monitor the medication reconciliation practices in hospitals, though they seem potentially applicable to the receipt of a new prescription in any setting:

1. During this hospital stay, were you given any medicine that you had not taken before?
2. Before giving you any new medicine, how often did hospital staff tell you what the medicine was for?
3. Before giving you any new medicine, how often did hospital staff describe possible side effects in a way you could understand?

In addition, the NQF suggested collecting the following indicators to measure performance improvement of medication reconciliation:

### Outcome measure

Adverse drug events causing harm to patients, including death, disability or preventable harm requiring further treatment

### Process measures

- Number of unreconciled medications per 100 patient admissions
- Unreconciled medications per patient site
- Number of patients with unreconciled medications in the area of focus (admission, transfer, or discharge)

### Structure measures

- Verification of implementation of medication reconciliation
- Formal accountability for performance improvement

### Patient-centered measures

- Patient participation in maintaining their medication lists
- NQF-endorsed HCAHPS patient satisfaction survey

In 2008 the Physician Consortium for Performance Improvement® (PCPI™), convened the “Ad Hoc Committee on Priorities” to develop recommendations about the future activities of the PCPI in light of the NQF National Priorities Partnership initiative. Following the ad hoc committee’s identification of care coordination as a priority area, the PCPI Care Transitions Work Group identified several indicators of success associated with improving outcomes for patients undergoing transitions in care (PCPI Ad Hoc Committee, 2008).

The proposed measures address several processes of care that are linked to the identified indicators of success; one indicator identified by the PCPI Care Transitions Work Group is that the patient at discharge receives a reconciled medication list.

The PCPI clinical performance measures are designed for practitioner- and/or system-level quality improvement to achieve better outcomes for patients undergoing transitions in care. Unless otherwise indicated, the measures are also appropriate for accountability if the appropriate methodological, statistical and implementation rules are achieved (PCPI Ad Hoc Committee, 2008).

Of note is that Measures 1, 2 and 3 in the PCPI Care Transitions performance measurement set below are “bundled” (i.e., always used together) since the three measures address closely related aspects of...
the transition in care for patients discharged from an inpatient facility.

- **Measure 1:** Reconciled medication list received by discharged patients—Percentage of patients, regardless of age, discharged from an inpatient facility to home or any other site of care, or their caregiver(s), who received a reconciled medication list at the time of discharge including, at a minimum, medications in specified categories

- **Measure 2:** Transition record with specified elements received by discharged patients—Percentage of patients, regardless of age, discharged from an inpatient facility to home or any other site of care, or their caregiver(s), who received a transition record (and with whom a review of all included information was documented) at the time of discharge including, at a minimum, all of the specified elements

- **Measure 3:** Timely transmission of transition record—Percentage of patients, regardless of age, discharged from an inpatient facility to home or any other site of care for whom a transition record was transmitted to the facility or primary physician or other health care professional designated for follow-up care within 24 hours of discharge

Research consistently demonstrates that complex medication regimens increase the likelihood of ADEs and ADRs. Given the aging population's exposure to both complex medication regimens and frequent transitions in care, the American Geriatrics Society, the PCPI and the National Committee for Quality Assurance collaborated in the development of the Geriatrics Physician Performance Measurement Set (2009). Measure 1 of this set is specific to medication reconciliation in the ambulatory care setting. The measure in its entirety follows.

**Measure 1: Medication reconciliation, appropriate for the ambulatory care setting only; this measure may be used as an accountability measure**—Percentage of patients aged 65 years and older discharged from any inpatient facility (e.g., hospital, skilled nursing facility or rehabilitation facility) and seen within 60 days of discharge in the office by the physician providing ongoing care who had reconciliation of the discharge medications with the current medication list in the outpatient medical record documented

Clinical performance measure

**Numerator:** Patients who had a reconciliation of the discharge medications with the current medication list in the outpatient medical record* documented

*The medical record must indicate that the physician is aware of the hospital discharge medications and will either keep the hospital discharge medications or change the hospital discharge medications or the dosage of a hospital discharge medication.

**Denominator:** All patients aged 65 years and older discharged from any inpatient facility (e.g., hospital, skilled nursing facility or rehabilitation facility) and seen within 60 days following discharge in the office by the physician providing ongoing care.

**Denominator exclusions:** None

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**Identifying and reporting events and conditions that increase patient risk**

**The U.S. Food and Drug Administration (FDA) Amendments Act of 2007**

The FDA Amendments Act of 2007 required the FDA to develop a system for using automated health care data to identify risks of marketed drugs and other medical products. To accomplish this, a public-private consortium of 17 different organizations (including the FDA, NIH, academic institutions, data owners such as Mayo Clinic and Cleveland Clinic, and the pharmaceutical industry) have been working as the Observational Medical Outcomes Partnership (OMOP) to study the governance, data access, technology and methods necessary to use existing observational databases for active drug safety and benefit monitoring. The research program is attempting to clarify the
understanding of methods and data needed for active drug safety surveillance, including validation of data transformation, method feasibility in each computing environment and performance. The work is also exploring the relative value of EHR information compared with information from administrative claims databases.

In this regard, Lasser et al (2006) conducted an important study addressing the FDA’s “black box” warnings system. The investigators conducted an observational study of 51 outpatient practices using electronic health records and measured the frequency with which those patients received prescriptions in violation of black box warnings for drug-drug, drug-laboratory and/or drug-disease interactions. Their study revealed that about seven in 1,000 outpatients received a medication that ran counter to black box warnings, but that very few instances of patient harm were associated with these prescriptions. The investigators observed that older patients with multiple medical problems and taking more medications appeared to be at greater risk for receiving prescriptions in violation of black box warnings. The authors suggest that improvements in decision support systems in EHRs may minimize black box warning violations.

**Forthcoming research**

Through its Ambulatory Safety and Quality program, AHRQ supported research efforts to improve quality measurement using health IT. The following grants related to medication safety are scheduled to be completed during 2010 (AHRQb):

- “Surveillance for Adverse Drug Events in Ambulatory Pediatrics”—Use of a computer system to detect and report on adverse drug events in pediatric patients in the outpatient setting, emergency departments and during hospital admissions and admission and discharge
- “Electronic Support for Public Health, Vaccine Adverse Event Reporting System”—Improve the quality of physician’s detection and reporting of adverse events to the national vaccine adverse event reporting system

In 2007 AHRQ funded grants to identify areas of risk in ambulatory care. Based on the results of these efforts, in 2008 AHRQ funded $3.7 million in three-year grants to implement safe practices to mitigate the risks identified in the planning grants. Two of these grants focus on aspects of medication safety: “Risk-informed Intervention to Improve Ambulatory Drug Monitoring and Safety” focuses on medication monitoring and intends to reduce medication errors associated with high-risk medications by improving laboratory monitoring; “Improving Medication Management in Ambulatory Care” aims to implement an evidence-based quality/safety improvement process to enhance medication monitoring in ambulatory practices (AHRQa).

**Summary observations**

1. Though medication safety was the best-studied area in ambulatory patient safety over the last 10 years, there remains a need for large-scale studies of the incidence and types of ambulatory medication errors, related or non-related ADEs and potential ADEs, and the harms they cause. In the last decade many studies have addressed medication errors or harm, but very few (only four) addressed both aspects of patient safety (Forster et al, 2005; Gandhi et al, 2010; Gurwitz et al, 2003; Honigman et al, 2001). Due to the difficulty and cost of obtaining the necessary data for these types of large-scale studies, it will be challenging to overcome the limitations described in the research to date. Wider adoption of electronic medical records may help, especially in systems where ambulatory records can be linked to pharmacy, emergency department and hospitalization records.

2. Several studies have identified high-risk medications and various organizations maintain
information about these medications. As in the
inpatient setting, ambulatory interventions have
been tested to help avoid the use of confusing
abbreviations in prescriptions.

3. Codified data from pharmacy and pharmacy
benefit management claims systems has been
available electronically for decades, providing
researchers with valuable data, albeit with some
notable limitations. EHRs that provide consistent,
codified information on patient allergies, patient
problem list, patient symptoms and other key
information are likely to enhance ambulatory
medication safety research.

4. Definitions of key terms such as ADE, medication
error and ameliorable ADE have been consistent
within research teams but less so across
research teams. Other inconsistencies that
hamper the ability to compare research findings
include varying patient age groupings, drug
classifications, categories of comorbidities, and
severity ratings used to categorize ADEs and
medication errors. A common set of terms for
this research might help yield greater insight
into the true incidence and nature of ADEs.

5. Research over the last decade summarized in
this report has shown that certain categories of
drugs, and certain patient factors, are associated
with greater risk of ADEs and harms.
   - Drugs in widespread use and/or with a
     narrow therapeutic range and high toxicity
     are most frequently associated with identified
     ADEs and/or medication errors.
   - Advanced patient age, multiple medications
     or complex medication regimens and
     comorbidities are associated with increased
     risk of experiencing a medication error and/or
     an ADE.

6. Some causes of adverse drug events are only
indirectly under the control of an ambulatory
practice, including dispensing errors and
problems with adherence to medications
as prescribed. Interventions to improve
communications, team-based care and patient
engagement might affect these causes of
medication errors and adverse events, but
studies of these interventions and their effects
on medication safety are sparse.
Section III. Ambulatory diagnostic errors research

Introduction

Diagnostic errors comprise delayed, missed and incorrect diagnoses, and research in the last decade has shown these to be some of the most common errors in ambulatory settings (Graber et al, 2002; Singh and Weingart, 2009; Schiff and Bates, 2010) as well as the leading cause of primary care malpractice litigation (Singh and Graber, 2010). Among practicing clinicians, missed or delayed diagnosis of conditions from anemia or depression to pulmonary embolism or myocardial infarction are both feared and understood to be all too common.

A number of investigators have also reported that studies on diagnostic errors lag behind other areas of patient safety research in both inpatient and outpatient settings (Sanders et al, 2003; Graber, 2005; Woods et al, 2007; Singh and Weingart, 2009; Singh and Graber, 2010; Wachter, 2010). One reason is that the dispersed nature of care delivered in ambulatory settings complicates efforts to study these errors. They are often hard to identify and measure, poorly defined and distributed over time and place, and they typically are the result of multiple breakdowns at both individual and system levels. All these factors conspire to make diagnostic errors complex and obscure, frequently detectable only at autopsy (Graber, 2005; Schiff et al, 2005, 2008a; Gandhi et al, 2006; Woods et al, 2007; Kostopoulou, 2008; Singh and Weingart, 2009). According to Schiff et al (2009) there is frequent disagreement on whether an error or delay has even occurred in a given case, and “few studies have examined diagnostic errors in detail, in part because of the challenges of reliably identifying and analyzing them.”

Most studies of diagnostic error in the last decade have been retrospective rather than prospective, and another barrier to this research has been that retrospective screening for diagnostic errors requires time-consuming and costly manual chart reviews. When chart reviews are undertaken, an important type of diagnostic error, missed diagnosis, is often characterized by omissions in the record; hence insufficient documentation often hampers efforts to understand diagnostic errors through root-cause analysis or other typical methods of safety investigation (Gandhi et al, 2006; Woods et al, 2007; Kostopoulou, 2008; Singh and Weingart, 2009). Research also has suggested that a significant portion of diagnostic errors stem from clinicians’ cognitive processes, which can be difficult to follow, quantify or analyze (Graber et al, 2002; Graber et al, 2005; Wachter...
Finalized, standardized diagnostic error reporting requirements have not been developed for any care setting. Newman-Toker and Pronovost noted that “[n]one of the 20 evidence-based Patient Safety Indicators established by the Agency for Healthcare Research and Quality (AHRQ) or the 30 safe practices recommended by the National Quality Forum (NQF) specifically measures failure to diagnose” (Newman-Toker and Pronovost, 2009).

Characteristics of the research

Definitions

Over the last decade, a general understanding existed that diagnostic error includes missed, delayed and incorrect diagnoses, but a more specific standard definition has not taken hold (Singh and Weingart, 2009). For example, Gandhi et al (2006) used the Institute of Medicine’s general definition of error, i.e., “the failure of a planned action to be completed as intended or use of a wrong plan to achieve an aim.” Other studies have adopted definitions more specific to diagnostic error and detection methods such as diagnostic errors being defined as instances of diagnoses that were “unintentionally delayed, wrong or missed, as judged from the eventual appreciation of more definitive information” (Graber et al, 2005; Singh et al, 2007b). Other researchers have accentuated the contributing role of the process within the definition of diagnostic error (Kachalia et al, 2007; Schiff et al, 2009). For example, in one study Schiff et al (2009) defined error as “any mistake or failure in the diagnostic process leading to a misdiagnosis, a missed diagnosis or a delayed diagnosis.” Two studies did not provide a specific definition (Holohan et al, 2005, Kostopoulou et al, 2008b).

Fisseni et al (2008) referred to “serious diagnostic error” in their research, which they defined as “an error with serious or potentially serious consequences for the patient.” Schiff (2010) also distinguished diagnostic errors that were more serious, stating that some diagnostic errors are more important than others, particularly when they affect treatment (e.g., giving an anticoagulant to a patient with a presumed acute myocardial infarction but who actually is having an aortic dissection, where anticoagulation may lead to life-threatening bleeding) or where timely diagnosis is critical to life and limb (such as a missed spinal epidural abscess leading to spinal cord compression and paralysis).

Schiff and Gruber (2008) provided a comprehensive narrative definition of diagnostic error:

A diagnostic error is any mistake or failure in the diagnostic process leading to a misdiagnosis, a missed diagnosis or a delayed diagnosis. This is an operational definition that includes any failures in the process of care, including timely access in eliciting or interpreting symptoms, signs, or laboratory results; formulating and weighing of differential diagnosis; or lack of timely follow-up and specialty referral and evaluation. A diagnostic error is a construct that is usually based on reference to a subsequent test, clinical outcome, consultant’s diagnosis or autopsy—gold standards that are themselves often imperfect or unavailable. Errors in diagnosis-related processes are ubiquitous, ranging from trivial failures to ask an insignificant historical question or overlooking minor lab abnormalities, to switching of specimens between two patients, to more serious errors in interpretation of data which may or may not have clinical adverse consequences in terms of labeling a patient with an erroneous diagnosis or impacting clinical actions or outcomes. Detecting diagnostic errors is critical to correction of the ongoing care for a current patient, as well as for learning how to avoid similar errors in the future.
Taxonomy

Over the past decade, studies have not reached a consensus on the classification of diagnostic errors beyond the categories of missed, delayed and incorrect diagnoses noted above (Singh and Weingart, 2009). Graber et al classified diagnostic error as including “no-fault errors,” system errors and cognitive errors on the part of the clinician (Graber et al, 2002; Graber et al, 2005). One review of the literature indicated that the AHRQ Diagnostic Error Evaluation and Research (DEER) Project Taxonomy developed by Schiff et al (2005) had been used in a few studies (Schiff et al, 2005; Singh et al, 2007; Schiff et al, 2009). This taxonomy outlines the diagnostic process into seven stages, with the potential for error at each stage (Schiff et al, 2005):

1. Access and presentation
2. History taking/collection
3. Physical exam
4. Testing
5. Assessment
6. Referral
7. Follow-up

The intent of the DEER taxonomy was to classify “what went wrong” by localizing it in the diagnostic process. This tool went on to itemize subcategories of what can go wrong in each of these seven stages of the diagnostic process.

A variety of other taxonomies to classify diagnostic errors and their clinical impact have been developed, including:

- National Association of Insurance Commissioner’s Severity Scale created by Sowka (1980) (used by Gandhi et al, 2006)
- National Practitioner Data Bank Negligence Classification System (used by Holohan et al, 2005)
- Physician Insurance Association of America Categories for Underlying Cause (used by Phillips et al, 2004)
- Veteran’s Health Administration impact scale (Bagian et al, 2002 and VA National Center for Patient Safety, 2005) (used by Graber et al, 2005)

In addition, studies have used various taxonomies to classify factors that contribute to the occurrence of diagnostic error, including:

- Working Taxonomy of System-Related and Cognitive Components to Diagnostic Error created by Graber et al, 2005 (used by Graber et al, 2005)
- Taxonomy of Communication Breakdowns established by Weinger and Blike (2003) (used by Singh et al, 2007b)
- International Taxonomy of Medical Errors in Primary Care developed by the Linnaeus-PC Collaboration (2005 Version) (used by Hickner et al, 2008)
- Adaptation of cognitive factor categories proposed by Chimowitz et al (1990); Kassirer and Kopelman (1989) and Bordage (1999) to create a new taxonomy (used by Graber et al, 2005)

Data sources

Historically autopsy studies were considered the “gold standard” for studying diagnostic mistakes, but they have limited relevance in the outpatient setting where they are rarely performed and require a fatal outcome.

Historically autopsy studies were considered the “gold standard” for studying diagnostic mistakes, but they have limited relevance in the outpatient setting where they are rarely performed and require a fatal outcome (Schiff, 2005). Instead, in the last decade malpractice claims have been widely used as a data source for studies of diagnostic error (Kachalia et al, 2007; Phillips et al, 2004; Holohan et al, 2005; Gandhi et al, 2006; Schiff et al, 2009). Several studies have used voluntary reports submitted by clinicians or by clinicians and staff (Wahls et al, 2007; Fisseni et al, 2008; Kostopoulou et al, 2008; Schiff et al, 2009). A few studies combined voluntary reports from clinicians with reports from nonclinical staff (Poon et al,
2004; Hickner et al., 2008). One study used autopsy reports; another study used a combination of autopsy data, quality improvement information and voluntary clinician reports (Shojania et al., 2003; Graber et al., 2005). Additionally, several diagnostic error studies extracted patient record and/or data from electronic health records (EHRs) (Singh et al., 2007a; Singh et al., 2007b; Woods et al., 2007; Singh et al., 2009).

### Patient populations and settings of care studied

Most research on diagnostic error to date has not specified the type or size of clinical practices under study. A few studies specified that their study setting was large practices (Graber et al., 2005; Singh et al., 2007a; Singh et al., 2007b; Singh et al., 2009). A study by Wahls et al. (2007) specified that their focus included both small clinics and large academic medical centers.

### Research topics and findings

#### Risk factors for diagnostic error

Investigative studies on diagnostic errors and events in the last 10 years have most often aimed to develop frameworks for investigating missed and delayed diagnoses, advance understanding of causes and identify opportunities for prevention (Gandhi et al., 2006). They frequently relied on small sample sizes. Several used data obtained through malpractice claims and therefore only included patients who pursued litigation. Despite limitations, however, research to date provides insight into the frequency of diagnostic errors, their implications for patients and the process breakdowns that contribute to such errors.

The reviewed research identified common system-related factors that contributed to diagnostic errors, such as problems with policies and procedures, inefficient processes, teamwork and communication. The most common cognitive problem identified was faulty synthesis, specifically “premature closure,” i.e., the failure to continue considering reasonable alternatives after reaching an initial diagnosis. Other problematic cognitive issues identified included faulty context generation, misjudging the salience of findings, faulty perception and errors arising from the inappropriate use of heuristics or stereotypes. Interestingly, faulty or inadequate knowledge has not been listed as a common cause of diagnostic errors.

Graber et al. (2002) concluded that diagnostic error is commonly multifactorial in origin, typically involving both system-related and cognitive factors.

Gandhi et al. (2006) conducted a retrospective review of 307 closed malpractice claims in which patients alleged a missed or delayed diagnosis in the ambulatory setting. They identified the following process breakdowns as contributing to diagnostic errors:

- Initial delay by the patient in seeking care
- Failure to obtain adequate medical history or physical examination
- Failure to order appropriate diagnostic or laboratory tests
- Adequate diagnostic or laboratory tests ordered but not performed
- Diagnostic or laboratory tests performed incorrectly
- Incorrect interpretation of diagnostic or laboratory tests
- Responsible provider did not receive diagnostic or laboratory test results
- Diagnostic or laboratory test results were not transmitted to patient
- Inappropriate or inadequate follow-up plan
- Failure to refer
• Failure of a requested referral to occur
• Failure of the referred-to clinician to convey relevant results to the referring clinician
• Patient nonadherence to the follow-up plan

Schiff et al (2005) developed “a model that identifies four key challenges in assessing potential diagnosis error cases”:

1. Uncertainties about diagnosis and findings
2. Sorting out the relationship between diagnosis failure and adverse outcomes
3. Challenges in reconstructing clinician assessment of patient and clinician actions
4. Assessment of whether and ways improvements could impact the diagnosis and patient outcomes

Kostopoulou et al (2008) identified five factors related to diagnostic difficulties, including “atypical presentations, non-specific presentations, very low prevalence, comorbidity and perceptual features that could be missed,” and added that “multiple factors contributed to misdiagnosed illnesses.”

In sum, research has found that numerous factors contribute to diagnostic error (Gandhi et al, 2006; Graber et al, 2005; Fisseni et al, 2008; Kostopoulou, 2008; Schiff et al, 2009). While authors use different terminology, they appear to be describing similar factors.1 Frequently identified diagnostic process breakdowns identified in the literature include:

• Failure or delay in ordering tests (Gandhi et al, 2006; Hickner et al, 2008; Schiff et al, 2009)
• Failure in patient follow-up (Gandhi et al, 2006; Singh et al, 2007b; Hickner et al, 2008; Singh et al, 2009)
• Failure to obtain adequate patient history (Gandhi et al, 2006; Singh et al, 2007b)
• Missed test results (Hickner et al, 2008; Wahls et al, 2007)
• Delays in receiving test results (Poon et al, 2004; Singh et al, 2007b; Schiff et al, 2009; Singh et al, 2009)

The most frequently identified factors contributing to diagnostic error in the literature have included:

• Cognitive factors, such as failed use of heuristics and faulty knowledge, data gathering and synthesis; failure to consider or premature closure around an erroneous diagnosis (Graber et al, 2005; Singh et al, 2007b; Schiff et al, 2009)
• Patient factors, such as nonadherence, atypical presentation and complicated medical histories (Graber et al, 2005; Kachalia et al, 2007; Zwaan et al, 2010)
• Communication, such as between doctor and patient and among providers (Gandhi et al, 2006; Hickner et al, 2008; Kostopoulou et al, 2008; Kripalani et al, 2007; Singh et al, 2007b)
• System flaws, including organizational and training issues, time stresses and information availability (Graber et al, 2005; Schiff and Bates 2010)
• Combinations of factors (Graber et al, 2005; Gandhi et al, 2006; Hickner et al, 2008; Kostopoulou, 2008; Weingart et al, 2009)

Most recently, Singh and Weingart (2009) identified five diagnostic error risk domains that largely reflect the body of literature on this topic.

• Provider-patient encounter: Most diagnoses occur during primary care office visits, in which providers are increasingly pressed for time. Providers may not obtain sufficient information to make an accurate diagnosis.

• Performance and interpretation of diagnostic test: Limited patient information may have a bearing on the performance and interpretation of diagnostic tests. In the absence of complete patient information, providers may order inappropriate, incorrect or unnecessary tests and/or misinterpret diagnostic tests. If the patient’s insurance does not cover a certain test, the doctor may request an inferior alternative. Misinterpretation may also arise from inadequate information sharing among treating clinicians

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1 Due to the different terminology used by the various studies, some overlap may occur in the respective categories. Please note that this discussion is only meant to highlight emergent themes. For a more exhaustive list of studies, please refer to the Appendix.
on the patient’s background. Patient factors can contribute to testing errors if the individual does not adhere to test preparation instructions, such as fasting, or misses the test appointment.

• **Follow-up of patients and diagnostic test results:** Lost or delayed test results present a risk for diagnostic error. Inadequate test result management systems may fail to alert clinicians to abnormal test results or present delayed results. Clinicians in turn may fail to notify their patients of their test results. Furthermore, if multiple providers are involved in a patient’s care, it may be unclear who is responsible for patient follow-up or implementation of the treatment plan. Patient factors may also play a role if the patient receives feedback on a test result but does not understand the instructions for follow-up on their part. Logistical barriers may also impede prompt follow-up on the part of patients if they are not able to receive timely appointments or obtain the requisite insurance coverage for recommended tests.

• **Subspecialty consultation:** Providers may not appropriately refer a patient to a specialist or encourage them to seek a specialty consultation. Specialists may not always address the issue that the referring physician had in mind and/or properly follow up with the referring physician and “conflicting diagnoses from different consulting physicians may be difficult for the primary care provider to adjudicate.”

• **Patient behaviors:** Not seeking care and not adhering to care plans can affect diagnostic errors; inability to accurately articulate symptoms, limited health literacy, language barriers, cultural preferences and misunderstandings also affect patient perception, behavior and, subsequently, outcomes (see section V).

**Patient harms associated with diagnostic error**

Diagnostic errors have been associated with patient harm in a number of studies over the last 10 years (Sanders and Esmail, 2003; Graber et al, 2005; Holohan et al, 2005; Gandhi et al, 2006; Woods et al, 2007; Fisseni et al, 2008; Schiff et al, 2009). The types of harm associated with diagnostic errors have been described using the following terms:

- Minor injury/impact (Holohan et al, 2005; Schiff et al, 2009)
- Moderate impact (Schiff et al, 2009)
- Major patient harm/clinical impact (Sanders and Esmail, 2003; Schiff et al, 2009)
- Serious harm (Gandhi et al, 2006; Fisseni et al, 2008)
- Serious injury (Holohan et al, 2005)
- Death (Graber et al, 2005; Holohan et al, 2005; Gandhi et al, 2006)

Based on the information available, it is not clear which types of diagnostic errors most commonly produced which types of harm, nor which produced the greatest patient harm over the last decade.

**Other research findings**

While the research base on ambulatory diagnostic errors is small, variable and limited, certain additional themes have emerged over the last decade:

- Diagnostic errors are the most common category of error in the ambulatory setting (Sanders and Esmail, 2003).
- Based on the volume of care delivery, diagnostic errors are more common in outpatient physician offices or clinics than in hospitals (Gandhi et al, 2006; Holohan et al, 2005).
- Diagnostic errors (and ambulatory preventable adverse events) were frequently attributed to primary care physicians, internists or general practitioners; however, studies also found that diagnostic errors occur across a range of medical specialties and care settings, for example, in emergency departments (Gandhi et al, 2006; Fisseni et al, 2008; Schiff, 2008a; Woods et al, 2007; CRICO/RMF).
- Diagnostic errors and adverse events were commonly associated with a diagnosis of cancer (Phillips et al, 2004; Gandhi et al, 2006; Kostopoulou et al, 2008; Schiff et al, 2009; CRICO/RMF).
There has been limited consensus in the literature on which other conditions might be frequently affected by diagnostic error; commonly cited conditions include (in alphabetical order):

- Anemia (Kostopoulou et al, 2008; Schiff et al, 2009)
- Appendicitis (Phillips et al, 2004; Gandhi et al, 2006; Schiff et al, 2009)
- Depression (Kostopoulou et al, 2008; Gandhi et al, 2006; Schiff et al, 2009)
- Fractures (Gandhi et al, 2006; Schiff et al, 2009)
- Infections (other than meningocoea) (Schiff, 2008b)
- Meningococcal disease/Meningitis (Phillips et al, 2004; Kostopoulou et al, 2008)
- Pulmonary embolism (Phillips et al, 2004; Schiff et al, 2009)
- Skin lesions and other conditions with pathology specimens (Schiff, 2008)
- Spinal cord compression (Kostopoulou et al, 2008; Schiff et al, 2009)
- Surgical emergencies (Schiff, 2008b)

### Interventions to avoid diagnostic errors

Various strategies have emerged from this research base to address diagnostic errors, both broadly across all care settings and specifically in office-based settings. Proposed solutions have centered largely in two categories: improving providers’ cognitive processes and systems improvements. Several studies proposed enhancing health information technology systems (health IT) to include provider decision-support tools and other features (Gandhi et al, 2006; Wachter, 2010; Schiff and Bates, 2010), though investigators have noted that, to date, there is little evidence to support their effectiveness (Wachter, 2010; Rosenthal and Sutcliffe, 2002, as cited in Singh and Weingart, 2009).

There is also disagreement on whether diagnostic error should address faulty cognitive processes as a first priority. While some have argued that this is a promising starting point for improvement efforts (Graber et al, 2002; Graber et al, 2005), others disagree (Schiff, 2010). The science of cognitive psychology, which considers the manner in which individuals reason, consider information and make decisions, has studied reasoning, perception, judgment and memory processes extensively (AHRQd, 2010; Redelmeier, 2005).

Research has found that practitioners often employ heuristics, or reasoning shortcuts, in diagnosing patients (AHRQ, 2010; Redelmeier, 2005). While heuristics can be helpful to practitioners facing complex situations and time constraints, they can also be restrictive and serve to bias the practitioners’ perception of information (AHRQ, 2010). To prevent diagnostic errors resulting from a practitioner’s thought processes, some have proposed encouraging providers to think “better” and be cognizant of “common cognitive traps” inherent in heuristics (Croskerry, 2003a; Redelmeier, 2005; Wachter, 2010). Some have advocated educating practitioners and medical students in strategies to “de-bias” their diagnostic decision-making (Croskerry, 2003a). Others have proposed establishing mechanisms to ensure provider feedback on diagnostic decisions, to help increase awareness of diagnostic shortcomings and promote improvement (Schiff, 2008b; Wachter, 2010).

Yet the use of heuristics and cognitive processes might be challenging, or impossible, to change in any substantive way (Schiff, 2010. Recently, a blended approach has been proposed, which would combine systems interventions to help
address cognitive error (Wachter, 2010; Schiff, 2010). For example, Health IT has been proposed as a means to improve diagnostic accuracy in ways other than through computerized decision-support systems, including better ways to filter and organize clinical information, functions that promote provider-to-provider communication, more dynamic problem lists and the incorporation of diagnostic checklists into the electronic medical record (Schiff and Bates, 2010; Wachter, 2010).

There has been no published research on whether a systems-focused, cognition-focused or combined strategy reduces diagnostic errors (Wachter, 2010). Robust systems for cognitive feedback do not yet exist and even many of the health IT features that have been developed to assist diagnostic accuracy are not widely available through existing health IT systems (AHRQ, 2010; Wachter, 2010). However, anecdotal evidence suggests that health IT improvements are not a comprehensive solution, but rather they can act as triggers to enhance or aid human performance, like paper checklists or mnemonics (Singh and Graber, 2010). Some have pointed to the Veteran’s Administration (VA) health care system to support this view. The VA has implemented an advanced EHR system with numerous supports, though diagnostic and process errors persist (Holohan et al, 2005; Singh et al, 2007b; Singh and Graber, 2010).

Schiff has also recently suggested that improvement efforts to reduce diagnostic errors should include patients (Schiff, 2010).

The International Diagnostic Error in Medicine (DEM) Conference, first held in 2008 and with ongoing annual meetings (information at: www.smdm.org) has served as a locus for work in efforts to reduce diagnostic errors. Given the importance of establishing uniformity and a common language to help identify, analyze and develop improvement methodologies specific to diagnostic errors, a new society, the Society for Improving Diagnosis in Medicine (SIDM), is in its formative stages (www.smdm.org/diagnostic_errors.shtml). Members hope the society will accelerate progress in funding research and advancing solutions.

Future developments

In 2007 AHRQ issued a Special Emphasis Notice calling for research on diagnostic errors occurring in ambulatory care (AHRQc, 2007). The announcement specified that “in FY 2008, AHRQ intend[ed] to support research designed to gain a better understanding of the incidence, cost, determinants, and strategies for preventing or mitigating diagnostic errors (i.e., misdiagnosis, missed diagnosis, delayed diagnosis) in ambulatory care settings” (AHRQc, 2007). AHRQ included emergency departments and ambulatory surgical centers in this notice. Subsequently, through its Ambulatory Safety and Quality program, AHRQ funded grants to improve quality measurement using health IT, which are scheduled for completion during 2010. The following grants may be relevant to diagnostic and process errors (AHRQb, 2010):

- Closing the Feedback Loop to Improve Diagnostic Quality (Berner and Graber 2008)—Use of clinical decision support to address gaps in the feedback loop and improve diagnostic decision-making (AHRQ, 2010)
- A Toolkit for Primary Care Practices to Improve the Safety of Testing Processes (Elder et al, 2008)—The development and implementation of a toolkit to improve testing processes in health centers and primary care offices (AHRQa).
Summary observations

Diagnostic errors, including missed, delayed and incorrect diagnoses pose a significant threat to patients in ambulatory care. In spite of their prevalence, diagnostic errors have received less attention than other areas of patient safety.

A small but growing body of research exists on diagnostic error in ambulatory care. The research suffers from the limitations that affect the majority of work on patient safety in ambulatory care. Studies employ different definitions, various taxonomies and often small or skewed samples.

While it is not possible to compare studies, research in the last decade has offered some important insight on the occurrence of diagnostic error, their implications for patients and the factors that contribute to such errors.

• Diagnostic errors have been the most common category of error leading to malpractice claims.
• Several conditions were commonly associated with diagnostic error, the most common of which (in malpractice cases at least) was cancer.
• Diagnostic errors and delays were frequently associated with a variety of patient harms, including very serious harms such as permanent disability or death.
• Several factors were found to contribute to diagnostic error, including system factors, provider factors and patient factors.

Based on the existing research base, some areas in which future research might be productive are:

1. Failure of timely diagnosis of life-threatening medical, surgical and trauma emergencies
2. Delays and misdiagnosis of cancer
3. Errors in interpreting radiological images, pathology specimens or skin lesions
4. Cognitive failures in making the correct diagnosis
5. Failure to follow up on the results of diagnostic tests

Some potential strategies that have been proposed to help minimize the frequency and impact of diagnostic errors include:

• Redesigning health care systems to decrease dependence on human memory
• Providing a supportive infrastructure to facilitate processes that minimize or ameliorate the harmful impacts of diagnosis errors and delays
• Establishing a blame-free environment to enhance reporting on and learning from diagnostic errors
• Implementing career-long education and training to enhance cognitive skills and recognize cognitive “traps”
Section IV. Ambulatory safety in office-based surgery and anesthesia research

Introduction

The term “ambulatory surgery” could mean any surgery performed on an outpatient, including surgeries that take place in outpatient sections of hospitals or in freestanding ambulatory surgery centers. But institutional surgical providers face a regulatory environment more similar to hospitals than to most other ambulatory practices. Therefore in this section we focus our review of research over the last decade on office-based surgery and anesthesia.

Improvements in equipment, technology and techniques over the past two decades led to both increasing numbers of surgeries performed in office-based practices (Lepetina and Armstrong, 2002) and an increase in the complexity of cases handled in these settings (Vila et al, 2003). In 2007 the New York Committee on Quality Assurance in Office-Based Surgery reported that roughly 10 million office-based surgical procedures, including dental and podiatric surgeries, were performed annually across the nation (Rosof, 2007). In 2010 The Wall Street Journal reported that the number of office-based surgeries had grown to roughly 15 million procedures (Landro, 2010).

In the last decade some reports on office-based surgery have suggested a number of potential benefits (Clayman and Seagle, 2006). Frequently mentioned benefits of office-based surgery have included the following (Lepetina and Armstrong, 2002; Balkrishnan et al, 2003a; Bitar et al, 2003):

- Office-based surgery can be less expensive than inpatient surgery.
- Office-based surgery can be easier to schedule than comparable procedures performed in hospitals.
- Office-based surgery can offer patients greater convenience, privacy and personalized care.

Others have expressed concern about the current oversight of office-based surgeries and argued that increased regulation of these procedures might...
improve safety (Vila et al, 2003). According to The Wall Street Journal, some experts are concerned about the ability of office-based practices to address patient needs and emergency situations because they might not be properly equipped to deal with unexpected complications (Landro, 2010).

Characteristics of the research

General limitations

Overall the published research on office-based surgical safety has been characterized by small studies using varied methods, as well as other significant limitations. Most of the research on office-based surgery in the last decade has come from the dermatology and plastic/cosmetic surgery literature. As in other areas of ambulatory safety research, a standard set of definitions or taxonomies has not arisen for research on patient safety in office-based surgery and anesthesia. Additionally, in this area, many studies also have not described any explicit definitions or classification systems used in the research. The terms “office-based surgery” and “ambulatory surgery” have been used interchangeably in some studies, but were compared separately in other studies. Sample sizes in many studies were very small. Two studies used data obtained through malpractice claims, which cannot account for patients who may have been adversely affected by office-based surgery but did not pursue malpractice litigation. The American Society of Anesthesiologists developed a standard tool to measure severity of illness and suitability of patients to undergo surgery, but this was not uniformly used in published research studies. Lastly, a lack of accurate data on the total number of surgeries occurring in office-based settings largely prevented consideration of relative risk in most of the studies.

While this section presents data from the published research literature, it should be noted that a great deal of data on ambulatory surgical safety might exist that was not collected for purposes of research and that has not been published. The Oral and Maxillofacial Surgery Insurance Company, which insures 99 percent of American Association of Oral and Maxillofacial Surgeons members, has reported that the incidence of adverse surgical and anesthetic events in its database since 2000 is 109 of 29 million procedures performed. However, specifics of these data are confidential and have not been published.

Definitions

The majority of studies published in the last decade referred to “adverse events” stemming from office-based procedures and/or surgeries, but most did not provide a guiding definition of this term. Coldiron and his colleagues provided the only detailed definition that could be found in the authors’ research. His body of work has been based on definitions established by the State of Florida, which defined adverse events as “the death or transfer of a patient; brain or spinal damage; procedures involving the wrong patient, surgery or surgical site; other damages not included in the informed consent; and removal of foreign objects” (Coldiron et al, 2002; Coldiron et al, 2003; Coldiron et al, 2004; Coldiron et al, 2008).

Taxonomies

No explicit taxonomies for the types of errors or harms that might occur in office-based surgery have been presented or discussed in the literature on office-based surgery and/or office-based anesthesia.

Data sources

Many of the research reports on office-based surgical safety that were published in the last decade drew upon reported adverse event data that were publicly released by the State of Florida.  

1 Information reported by the OMSINC to the authors on July 14, 2011.
(Coldiron et al, 2002; Coldiron et al, 2003; Coldiron et al, 2004; Coldiron et al, 2008; Clayman and Seagle, 2006; Venkat, 2004; Vila et al, 2003). Other studies used data from closed malpractice claims (Domino, 2001; Robbertze et al, 2006). In addition, one study drew upon data collected from several states (Balkrishnan et al, 2003a), one study used Medicare claims data (Fleisher et al, 2004), one study used patient record information (Bitar et al, 2003) and one study used information reported by physicians and office staff as well as patient survey data (Perrott et al, 2003).

**Patient population/setting**

The majority of the literature reviewed focused on adverse events in office-based practices, as reported to the State of Florida (Coldiron et al, 2002; Coldiron et al, 2003; Coldiron et al, 2004; Coldiron et al, 2008; Clayman et al, 2006; Venkat, 2004; Vila et al, 2003).

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**Results**

Authors have arrived at different conclusions regarding the overall safety of office-based surgery. Some investigators have concluded that office-based surgery is generally safe (Balkrishnan et al, 2003a; Venkat et al, 2004; Hancox et al, 2004a). Others have concluded that office-based surgery is safe only for certain procedures or if certain conditions are met (Hoefflin et al, 2001; Clayman et al, 2006; Coldiron et al, 2008). Others have concluded that office-based surgery or anesthesia may expose patients to additional risk (Cote et al, 2000; Vila et al, 2003; Fleisher et al, 2004). Still others have concluded that more information would be needed to establish the safety of office-based surgery (Balkrishnan et al, 2003b; Cao et al, 2010).

**Risk factors for adverse events associated with office-based surgery**

Despite limitations that largely prevent strong conclusions, published research on office-based surgery over the last decade has generally supported several common themes regarding the types of patients and types of procedures more often associated with adverse events:

- Most adverse events related to office-based surgery have involved elective cosmetic procedures; adverse events involving medically necessary procedures were less frequent and more “isolated” (Clayman et al, 2006; Coldiron et al, 2008).

For instance, Coldiron et al (2008) examined seven years of data from Florida and found that of 31 reported deaths between 2000 and 2007, 18 were associated with cosmetic procedures and 13 were associated with medically necessary surgical procedures. Medically necessary procedures leading to adverse events included the following: “Three deaths occurred with cardiac catheterization, two took place in conjunction with pregnancy termination, two deaths with dialysis catheter placement and two delayed deaths with gastrointestinal perforations (one colonoscopy and one after an upper endoscopy)” (Coldiron et al, 2008). In addition, of 143 procedures that resulted in hospital transfer during the same period in Florida, 87 were associated with cosmetic procedures and 56 were due to medically necessary procedures. Medically necessary procedures resulting in hospital transfer included “19 after a colonoscopy or polypectomy; five after ovarian aspiration or oocyte retrievals; four after a pregnancy termination; four after skin cancer excisions; three after cardiac catheterization; two after endovascular vein closure, cystoscopy, ureteroscopy, liver biopsy and angioplasty” and other singular cases involving other procedures (Coldiron et al, 2008).

- Among the adverse events that have been reported, many were associated with liposuction, especially when this procedure has been
performed under general anesthesia (Balkrishnan et al, 2003a; Vila et al, 2003; Venkat et al, 2004; Clayman et al, 2006; Coldiron et al, 2008).

- General anesthesia used in office-based surgeries has resulted in adverse events, including hospital transfer and/or death (Balkrishnan et al, 2003a; Perrott et al, 2003; Venkat et al, 2004; Clayman et al, 2006; Coldiron et al, 2008).

Fleisher et al (2004) studied elderly patients undergoing ambulatory surgical procedures and found an increased risk of emergency department visit, hospital admission or death during the week following surgery for those with advanced age (older than 85 years), significant comorbidity, a history of recent hospital admissions and more invasive procedures. In addition, the authors found increased risk for elderly patients undergoing some specific procedures in physicians’ offices as compared to ambulatory surgical centers, including inguinal hernia repair, arteriovenous graft placement, knee arthroscopy, transurethral resection of the prostate and umbilical hernia repair (Fleisher et al, 2004).

Office/physician characteristics addressed in the reviewed research

- Most of the physicians reporting adverse events have been board certified (Clayman et al, 2006; Coldiron et al, 2008; Bitar et al, 2003; Perrott et al, 2003; Balkrishnan et al, 2003a).

- Most of these physicians also have had hospital privileges (Clayman et al, 2006; Coldiron et al, 2008; Bitar et al, 2003).

- Plastic surgeons performing cosmetic procedures were most frequently associated with incidents involving death and hospital transfers (Coldiron et al, 2008; Balkrishnan et al, 2003a; Bitar et al, 2003).

- In Florida, 38.5 percent of the offices reporting adverse events had been accredited by an independent agency as of 2007 (Coldiron et al, 2008; Perrott et al 2003).

Patient harm associated with office-based surgery errors

Several studies in the last decade have provided information on patient harm related to office-based surgery (Balkrishnan et al, 2003a; Bitar et al, 2003; Clayman et al, 2006; Coldiron, 2002; Coldiron et al, 2008; Coldiron et al, 2005; Fleisher et al, 2004; Venkat et al, 2004; Vila et al, 2003; Fleisher et al, 2004).

Office-based surgical safety events have been associated with the following:

- Patient complication (Bitar et al, 2003; Coldiron, 2002; Coldiron et al, 2008; Coldiron et al, 2005; Coldiron et al, 2004)

- Patient injury (Balkrishnan et al, 2003a; Vila et al, 2003)

- Hospital transfer and/or admission (Bitar et al, 2003; Coldiron et al, 2008; Coldiron et al, 2005; Coldiron et al, 2004; Fleisher et al, 2004)

- Patient death (Clayman et al, 2006; Coldiron, 2002; Coldiron et al, 2008; Coldiron et al, 2005; Fleisher et al, 2004; Venkat et al, 2004; Vila et al, 2003)

A disproportionate number of adverse events leading to significant patient harm (harm established by reported patient hospitalization and/or death) involved the use of general anesthesia (Bitar et al, 2003; Balkrishnan et al, 2003a; Venkat et al, 2004; Clayman et al, 2006; Coldiron et al, 2008; Perrott et al, 2008). In particular, patient harm has been associated with office-based liposuction procedures and especially liposuction under general anesthesia (Balkrishnan et al, 2003a; Clayman et al, 2006; Coldiron, 2002; Coldiron et al, 2005; Coldiron et al, 2008).
Interventions

Three studies have concluded by calling for the increased use of local anesthesia to improve the safety of office-based procedures, but each also pointed to the limited evidence in support of this recommendation (Perrott et al, 2008; Shapiro, 2008; Coldiron et al, 2008). In a 2008 review of the literature on anesthesia performed in office-based settings, Perrott concluded that selecting only appropriate patients for ambulatory procedures was critical and that "expanded use of local anesthesia, regional blocks and variation on sedation techniques offer alternatives that may reduce risks but still maintain a high quality of care" (Perrott et al, 2008). In a separate 2008 review of the cosmetic surgery literature, Shapiro recommended several interventions to improve patient safety. In particular, he asserted that tactics for "improved safety and efficacy in aesthetic facial surgery include oral sedation and local anesthesia, the addition of dexmedetomidine to intravenous anesthesia and defining the ‘safest’ dose of lidocaine with epinephrine" (Shapiro, 2008). Lastly, Coldiron et al (2008) concluded that "liposuction under general anesthesia deserves continued scrutiny because deaths due to this procedure continue to occur and this procedure can be performed with dilute local anesthesia, with which no deaths were reported."

State and professional interventions to improve office-based safety

Concern for the safety of office-based surgery has prompted states and professional societies to implement oversight initiatives. According to the Federation of State Medical Boards (FSMB), by 2009 25 states had issued guidance on office-based surgery or procedures involving anesthesia in office settings through rules, regulations, or legislation (FSMB, 2009; Page, 2010). Among other provisions, 14 states (Alabama, Arizona, Colorado, Florida, Indiana, Kentucky, Louisiana, Massachusetts, New Jersey, Oklahoma, Oregon, South Carolina, Vermont and Washington) and the District of Columbia had hospital transfer plan requirements for emergency situations; 11 states (California, Connecticut, Indiana, Kentucky, Massachusetts, New York, North Carolina, Ohio, Oregon, Pennsylvania and Washington) required or encouraged facility accreditation; and 9 states (Alabama, California, Florida, Kentucky, Louisiana, New Jersey, New York, North Carolina and South Carolina) required reporting of certain events (FSMB, 2009).

In addition, a number of professional societies have also issued guidelines and recommendations for improving the safety of ambulatory or office-based surgery and/or anesthesia.

- The Federation of State Medical Boards convened a Special Committee on Outpatient (Office-Based) Surgery in 2001 to develop recommendations for the oversight of office-based surgery. The Committee subsequently issued model guidelines in the same year outlining recommended policies and procedures for physicians performing office-based surgery (FSMB, 2002).

- The American Society of Plastic Surgeons (ASPS) convened a Task Force on Patient Safety in Office-Based Surgery Facilities in 2000 to develop guidelines for office-based surgery, which were approved in 2002 (Iverson, 2002).

- In 2002 the American Society for Anesthetic Plastic Surgery (ASAPS) established a policy stating that members should only perform office-based surgeries involving anesthesia in state-licensed, accredited or Medicare-certified facilities (Carraway, 2002).

- In 2003 the American College of Surgeons (ACS) and the American Medical Association (AMA) jointly convened a consensus meeting on the topic of office-based surgery and approved a core set of guiding principles for the

- The American Society of Anesthesiologists (ASA) issued guidelines for office-based anesthesia in 2003, which were reaffirmed in 2008 (ASA, 2010).

- In 2010 the Society for Ambulatory Anesthesia (SAMBA) issued a consensus statement for the care of diabetic patients undergoing surgery in ambulatory settings (SAMBA, 2010).

- The American Association of Oral and Maxillofacial Surgeons (AAOMS) has developed educational videos, materials and standardized informed consent processes. They offer risk mitigation courses regarding office-based surgery and anesthesia in an effort to not only educate the surgeons on best practices, but also to provide an opportunity to reduce their malpractice costs by 5 percent.2

Some similarity can be discerned across these guidelines, including the following common recommendations:

- Patient informed consent should be obtained (FSMB, 2002; ACS et al, 2003).

- Patient evaluation, including patient history and physical examination, should be performed prior to surgery (ASPS, 2000; FSMB, 2002).

- Physicians should use the ASA patient selection classification system in considering patients for surgery (ASPS, 2000; ACS et al, 2003; ASA, 2008).

- Physicians should have proper qualifications, such as board certifications and/or hospital admitting privileges (ASPS, 2000; FSMB, 2002; ASAPS, 2002; ACS, 2003; ASA, 2008; ASA, 2009).

- Facilities should be accredited (ASAPS, 2002; ACS, 2003).

- Necessary equipment should be in place (ASPS, 2000; FSMB, 2002; ASAPS, 2002; ASA, 2008; ASA et al, 2009).

- Emergency transfer protocols should be in place (ASPS, 2000; FSMB, 2002; ASAPS, 2002; ASA, 2008; ASA et al, 2009).

- A physician should remain at the facility until the patient has recovered (ASPS, 2000; ASAPS, 2002; FSMB, 2002; ACS, 2003; ASA, 2008; ASA, 2009).

- Patient discharge should be decided by a physician (ASPS, 2000; FSMB, 2002; ASA, 2008; ASA, 2009).

2 Information reported by the OMSINC to the authors on July 14, 2011.

Summary observations

Over the last decade a growing number of surgical procedures were performed outside of traditional operating rooms and in office-based or other ambulatory settings. A small and growing body of research exists on this development, especially in Florida, but research using national data has not been published and might not exist. As a result, the research base on these changes is sparse, and in the absence of solid data, considerable debate has arisen around the safety of office-based surgeries and anesthesia. Some suggest that office-based surgery is generally safe and offers benefits such as convenience and lower cost, while others suggest that more oversight and regulation of these procedures is needed to ensure patient safety.
Section V. Patient roles in ambulatory safety research

Introduction

A number of patient factors can affect ambulatory safety, including patient roles in both preventing and causing errors, adverse events and harm.

A hallmark of ambulatory care is that patients and caregivers, such as the parents of young children, often must be very active participants in care planning and execution. While hospitalized patients are seen and cared for by health care professionals multiple times each day, in the ambulatory arena this is rarely the case. More commonly patients and their loved ones and caregivers are primarily responsible for seeking care, selecting their providers, administering self-care, managing their medications and treatment regimens, and carrying out myriad other tasks – all in the context of a complex and often confusing health care system (Vincent and Coulter, 2002; Hammons et al, 2003). Patients are also expected to explain their symptoms to clinicians accurately and completely and to provide other essential information for diagnosing and tracking the progression of their conditions (Hammons et al, 2003). Given the central roles of patients and caregivers in ambulatory care—especially their responsibilities associated with managing their care and communicating crucial information—the possibility that patients’ acts of omission or commission might cause harm directly or raise the risk of error is an important safety issue (Kohn et al, 1999; Buetow and Elwyn, 2007).

Although the concept of medical error emphasizes mistakes made by practitioners in medical settings (Buetow and Elwyn, 2007), the seminal 1999 Institute of Medicine (IOM) report To Err Is Human: Building a Safer Health System acknowledged that patients “make errors too.” The report also warned that the number of opportunities for patients to make errors was likely to increase given “greater emphasis on community-based long-term care, increased ambulatory surgery, shorter hospital length of stay and greater reliance on complex drug therapy” (Kohn et al, 1999). At the same time, safety experts have observed that while patients can play roles in the occurrence of errors and adverse outcomes in ambulatory care, they also can play important roles in efforts to prevent errors and promote safety (Schwappach, 2010; Wachter, 2006; Schiff, 2010).

One challenge to studying patients’ roles in ambulatory safety has been the inherent difficulty in classifying whether a patient made an “error” versus a bad choice. Errors in health care have sometimes been classified as active (acts of
commission) or latent (acts of omission), with latent errors posing the more common threat to patient safety (Kohn et al, 1999). Patient actions that lead to adverse outcomes are often viewed as active, and moreover as being related to explicit or implicit patient choices, and they are less likely to be seen as the result of system-wide failures (Buetow and Elwyn, 2006; Buetow and Elwyn, 2007). In addition, patient errors and other types of errors can occur in tandem; patient errors can arise from system or provider errors, or they can make such errors more likely (Buetow and Elwyn, 2007). For instance, patient actions, such as missed or delayed appointments, can make delayed follow-up of abnormal test results by clinicians more common, or can contribute to delayed diagnosis or other errors that are often subsequently attributed primarily to systems and/or health professionals.

In addition, there has been growing controversy around the extent to which patients are, or can be, responsible for some of their personal characteristics that might make error and harm more likely. Not every patient characteristic reflects a patient choice. For example, there are a series of important patient factors that can affect patient-clinician communication – including limited English proficiency (LEP), cultural factors, and low health literacy – over which patients often have little or no direct control. Yet these and other patient characteristics have been related to errors and adverse events (Reenen and Wymia, 2006; Wooff et at, 2004; Flores et al, 2003). Perhaps because of these challenges, in the last decade there has been relatively little research that explicitly addressed the patient’s role in ambulatory safety, despite a great deal of research in related areas. For example, research has shown that patient nonadherence to clinician-advised care and/or medication regimens occurs very frequently in the ambulatory arena. One literature review estimated that roughly one-third to one-half of patients do not use their medications as directed (Barber, 2002). But most research on non-adherence has not been framed as research on “patient error” and there is disagreement among researchers as to whether nonadherence ever constitutes an error on the part of a patient. In some cases, a decision not to follow medical advice or a medication schedule can be both conscious and subjectively rational (Barber, 2003). In other cases, nonadherence may result from unintentional factors, such as forgetfulness on the part of the patient, or may be due to barriers to adherence over which the patient has little or no control (Barber, 2002). Some researchers have identified unintentional nonadherence as a patient error, while others maintain that it is inappropriate to consider any form of nonadherence as an error (Buetow and Elwyn, 2007; Buetow et al, 2009; Barber, 2002).

A number of researchers have considered the roles of multiple “patient factors” that might contribute to patients misunderstanding their health care needs, including nonadherence, failure to follow up, complex comorbidities, atypical presentations and communication barriers such as LEP, though many of these patient factors are not under the patient’s control (Kachalia et al, 2007; Wahls and Peleg, 2009; Zwaan et al, 2010).

Because the research literature specifically on patient roles in ambulatory safety was so sparse over the last decade, this section includes studies that examined patient factors leading to adverse events that were detected in the inpatient setting or the emergency department, if the adverse events reflected patient actions (or inaction) in the ambulatory arena. Finally, the latter part of this section includes a brief summary of research on patient characteristics that can raise the likelihood of errors due to miscommunication, such as patients with LEP, low health literacy or those facing cross-cultural communication barriers. These latter topics reflect patient characteristics, but they have most often been framed as issues of shared responsibility for effective communication across patients, practitioners, organizations and systems (Ethical Force program, 2006; The Joint Commission, 2010). They have rarely been presented specifically as patient safety research. Because much of this research was beyond the scope of our research review, we summarize the findings in brief, but do not provide a comprehensive listing of studies in these areas over the last decade.
Limitations of the research

The contributions of patients and caregivers to medical errors were not directly addressed in most ambulatory patient safety research over the last decade (Buetow and Elwyn, 2007). The research that did so often suffered from various limitations, including disparate methods, definitions, data sources and populations, in addition to sometimes small sample sizes (DiMatteo, 2004). As noted in prior sections of this report, a number of taxonomies of errors were developed in the last ten years, but few specifically addressed patient errors, and some studies that addressed patients' roles have not employed any systematic classification system. Studies often combined “patient factors” over which patients might exercise some control (such as providing a complete history, or returning for follow-up care) and factors over which patients typically have little or no control (such as low health literacy, uninsurance or comorbidities). Also, most research that has considered the patient's role in ambulatory safety was focused on medication errors and (to a lesser degree) on diagnostic errors; patients' roles in other aspects of safety or types of errors have rarely been explored. Still, while the literature of the last decade is limited, it offers some insight into an important, unique and perhaps emerging domain of patient safety research.

Definitions

There is no standard definition of patient error. One study (Buetow et al, 2009) specifically defined patient error as “patient actions that:

1. Are not completed as the patient intended, or
2. Do not achieve the outcome that the patient intended because the plan was not based on informed and strong patient beliefs.”

Point 1 of this definition draws from the IOM definition of error (Kohn et al, 1999), while Point 2 blends the IOM definition with work on patient preferences and values and the role of patient engagement in the practice of evidence-based medicine (Sackett, 1996).

Some researchers have sought to distinguish patient error from patient nonadherence, and some have drawn a distinction between intentional and unintentional nonadherence. For example, according to Buetow et al (2009), if a patient refuses a recommended screening test, this is nonadherence, but it is not an error if the planning and execution of the refusal are “subjectively rational.” A decision to forgo screening would be subjectively rational if (a) the outcome intended is freedom from screening, (b) the patient is operating with all necessary information (e.g., with knowledge of the risks and benefits of the screening test) and (c) the decision is freely made.

Other studies have addressed patients' roles in the context of broader error definitions, or using common descriptions for terms like medication error, adverse drug event (ADE) and potential or ameliorable ADE, or they have not provided a specific definition of patient error and instead examined a range of patient "factors" that can contribute to adverse events (Field et al, 2007; Kaushal et al, 2007; Lokker et al, 2009; Metlay et al, 2008; Yin et al, 2010).

Taxonomies

Medical error taxonomies of the last decade largely did not address the roles of patients in ambulatory safety. Buetow et al (2009) are the only authors to have directly classified a variety of potential types of patient errors. They proposed two main levels of patient error: action errors and mental errors. Action errors included errors of attendance, assertion and adherence, as reflected in missing appointments, not communicating with providers and unintentionally diverging from prescribed treatments, among other behaviors. Mental errors included errors resulting from memory lapses, lack of mindfulness and misjudgments. Examples included forgetfulness in taking medications, lack of attentiveness to information and failed assessments, such as inappropriately discontinuing medications early, despite instructions, because symptoms improve. The same authors also
reported qualitative research suggesting that groups of patients and health professionals perceive patients’ action errors and mental errors as equally important (Buetow et al, 2010).

Field et al (2007) also developed a classification system for patient errors, but focused only on medications and specifically patient medication handling activities that could lead to errors. In particular, the authors identified the following steps in medication management that could result in patient error:

- Filling and refilling
- Administering
- Modifying the medication regimen
- Following clinical advice
- Reporting information to health care providers
- Adhering to follow-up

To classify types of patient errors, these researchers drew upon previous error taxonomies, took an inductive approach to the analysis of qualitative data (Buetow et al, 2009; Buetow et al, 2010) or drew upon computer-generated signals of possible drug-related incidents (Field et al, 2007).

**Data sources**

Studies that specifically addressed patients’ roles in safety drew data from several sources. Most extracted data from a combination of sources (Kaushal et al, 2007; Metlay et al, 2008; Lemer et al, 2009; Yin et al, 2010). Four studies used data collected through patient interviews or telephone surveys (Kaushal et al, 2007; Metlay et al, 2008; Lemer et al, 2009; Lokker et al, 2009). Three studies used patient medical record data (Field et al, 2007; Kaushal et al, 2007; Lemer et al, 2009). Two studies used malpractice claims (Kachalia et al, 2007; Zwaan et al, 2009). Two studies used direct observation of study participants (Lokker et al, 2009; Yin et al, 2010) and two studies extracted qualitative data from patient focus groups (Buetow et al, 2009; Buetow et al, 2010).

Studies on patient characteristics that can make errors more common, such as low health literacy and cultural factors, have drawn their data from a wide array of sources.

**Patient populations/setting**

Most research reports on patients’ roles in ambulatory safety have not specified the setting or the size of practices in their work and some have combined data across setting (inpatient, emergency department and ambulatory). One study specified that their study setting was a large practice (Field et al, 2007).

**Types of patient errors studied**

The most frequently discussed possible or actual direct contributions by patients to errors are instances of patients taking medications incorrectly, missing appointments, nonadherence or poor adherence, and failing to share relevant information with providers. It is important to reemphasize that without knowledge of patients’ intentions, it is not settled how to classify these events, since a rational decision not to follow medical advice is not generally considered a medical error (Buetow et al, 2009). For example, studies on reasons for non-adherence suggest that both intentional and unintentional non-adherence are common and that both can stem from a wide array of cognitive, cultural and pragmatic issues (Heath et al, 2002; Lowry et al, 2005; Kim et al, 2007). Whether to label intentional or unintentional non-adherence arising from these types of issues as a “patient error” has not been resolved and most of this broader literature on nonadherence is therefore not part of this review.

**Research on medication adherence and adverse events**

In the last decade a large number of studies were conducted on medication adherence, showing that poor or nonadherence to prescribed medications or care regimens occurs frequently and is related to worse outcomes, such as hospital readmissions. But research on non-adherence has not often categorized it as a patient error, nor have outcomes associated with non-adherence been framed in
terms of adverse events. Hence most of this work fell outside the scope of this review. In general, our review also did not consider research in emergency departments, but given the paucity of research on patient roles, one important study we examined was Kachalia et al (2007), who reviewed closed malpractice claims to consider the causes of missed or delayed diagnoses in the emergency department. The authors noted that patient-related factors contributed to diagnostic error in 34 percent of the cases, of which 10 percent was due to patient nonadherence.

Several studies of the causes of adverse events found that patients or caregivers frequently used medications incorrectly, including incorrect medication administration and dosing. Field et al (2007) studied 30,000 patient records of Medicare patients from a large multispecialty group practice and found that 31.8 percent of adverse events arising from patients using medications incorrectly were due to incorrect administration of the correct medication. Kaushal et al (2007) studied 1,788 pediatric patients (age 21 or younger) in six office practices in the Greater Boston area and found that the majority (70 percent) of preventable adverse drug events were due to parents not administering drugs correctly. Metlay et al (2008) followed 2,268 low-income elderly members of the Pennsylvania Pharmacy Assistance Contract for the Elderly programs who used Warfarin for two years; incorrect dosing of Warfarin by patients resulted in 126 hospitalizations. Lemer et al (2008) collected information on 1,685 pediatric patients in six office practices in the Greater Boston area and found that most adverse drug events in the study population were due to parents administering medications incorrectly. Lokker et al (2009) surveyed 182 caregivers of infant children and found that caregivers were frequently confused by over-the-counter medication instructions and approximately one-third had given infants over-the-counter products that were not intended for children under the age of 2 years. Yin et al (2010) conducted interviews and observed 300 caregivers to assess their drug administration practices and found that caregivers commonly made dosing errors. Patients and caregivers have also described the contribution of lay forgetfulness to medication timing errors for conditions such as Parkinson’s disease (Buetow, 2009).

**Research on patients providing an inadequate history**

As with medication adherence, it is not clear whether a patient providing an incomplete historical account of an illness is always committing an error. If such instances were to be classified as errors, it is not clear whether the error should always be attributed to the patient. After all, an incomplete history can result from incomplete or unclear questioning, as well as from patients intentionally withholding information.

Though a large number of studies examined patient-clinician communication, only a few focused on measuring the errors that can result from poor patient-clinician communication. Some focused on poor clinician communication, where patients did not receive (or remember) care instructions (Britten et al, 2000; Metlay et al, 2005; Tarn et al, 2006; Lemer et al, 2009). A few directly addressed patients failing to inform clinicians of symptoms or medical history (Britten et al, 2000; Gandhi et al, 2003; Kachalia et al, 2007).

**Frequency of patient contributions to errors**

Several studies in the last decade reported that patient factors often contribute to error, with reports that patients contribute in one way or another to between 30 and 70 percent of all errors. All of these studies relied on clinician reviews to determine whether patient characteristics, actions or inactions contributed to errors or adverse outcomes, and many combined “patient factors” over which patients might have some control (such as nonadherence or providing an incomplete history) and factors over which they commonly have no control (such as the presence of comorbid conditions like psychiatric illness).

Wahls and Peleg (2009) examined barriers to timely colorectal cancer diagnosis among 150 patients with a delayed diagnosis of colon cancer and found that in 38 percent of cases patient factors played
a role, including patients who frequently missed or canceled appointments or declined further evaluation. Zwaan et al (2010) reviewed 7,926 patient records at 21 hospitals in the Netherlands and found that problems with patient treatment adherence or other patient factors contributed to 30 percent of diagnostic adverse events.

Two studies found that patients often did not share relevant information with their providers (Gandhi et al, 2003; Kachalia et al, 2007). Gandhi et al (2003) conducted interviews with and reviewed the charts of 661 patients at four Boston-based primary care practices to identify and explain adverse drug events (ADE). The authors concluded that 19 of 51 ameliorable ADE (37 percent) were due to the patient’s failure to inform the physician of their symptoms and that patients “often had symptoms for months without any changes in their medications.” In their study of the causes of diagnostic error described above, Kachalia et al (2007) found that patient-related factors contributed to diagnostic error in 34 percent of the cases, of which 5 percent were due to the patient’s failure to provide an adequate history.

Field et al (2007) followed 30,000 Medicare enrollees over a 12-month period and classified 129 of 188 adverse drug events (67 percent) as being due, at least in part, to patient error. Most patient errors were related to improperly administering medication (31.8 percent), modifying the regimen (41.9 percent) or not following clinical advice about medication use (21.7 percent). Kaushal et al (2007) found that 70 percent of preventable adverse drug events among a cohort of pediatric outpatients were related to parent drug administration errors, noting that “none of the preventable ADE were life-threatening, although eight (14 percent) were serious.” Metlay et al (2008) identified 126 hospitalizations (among 2,268 patients) which likely resulted from incorrect administration or dosing of Warfarin by patients; three of these events resulted in patient death.

Level of harm attributable to patient contributions to adverse events

The adverse effects of nonadherence on patient outcomes have been studied extensively among patients with AIDS, congestive heart failure and many other conditions, but the level of harm attributable to “patient errors” has not been widely discussed. While Buetow and Elwyn (2007) refer to patient errors having grave implications, studies have largely not provided information on the level of harm that resulted from such errors. Only two studies of patient errors discussed resultant harm explicitly. Kaushal et al (2007) attributed 40 preventable adverse drug events (ADE) out of 57 ADEs identified in pediatric patients to parent drug administration errors, noting that “none of the preventable ADE were life-threatening, although eight (14 percent) were serious.” Metlay et al (2008) identified 126 hospitalizations (among 2,268 patients) which likely resulted from incorrect administration or dosing of Warfarin by patients; three of these events resulted in patient death.

Risk factors for patients making medication management errors

Two studies examined ambulatory patients’ medication management tactics and offered insight on risk factors for when patients are more likely to take medications incorrectly, including:

- No established organization system (Metlay et al, 2005)
- No established medication administration routine (Sorensen et al, 2005)
- Therapeutic duplication (Sorensen et al, 2005)
- Hoarding medications (Sorensen et al, 2005)
- Confusion between generic and trade names (Sorensen et al, 2005)
- Multiple prescribers (Sorensen et al, 2005)
- Retained medication refills for discontinued medications (Sorensen et al, 2005)
- Medications stored in multiple locations (Sorensen et al, 2005)
Patient factors related to communication errors

Section VI of this report summarizes research on the prevalence and consequences of miscommunication among care teams in ambulatory care. But studies in the last decade also specifically found that patient-clinician miscommunication contributed to inappropriate patient actions in the management of their own care. This literature raises further questions about the extent to which subsequent adverse events can be characterized properly as resulting from “patient errors” (i.e., because the patients’ inappropriate actions were often a result of inadequate communication on the part of a clinician or a third party such as an interpreter).

In any event, the last decade saw the emergence of a growing body of research on several patient-clinician communication barriers that can lead to adverse events in the ambulatory setting, including:

- Cultural factors that affect patient-clinician communication or patients’ health decisions (Smedley et al, 2003; DiMatteo et al, 2007; Barksdale, 2009; Koenig, 2004)
- Language barriers, especially leading to medical interpretation errors (Flores et al, 2003; Karliner et al, 2004; Wilson et al, 2005; Karliner et al, 2007)
- Low patient health literacy (Davis et al, 2006a; Davis et al, 2006b; Persell et al, 2007; Yin et al, 2009; Yin et al, 2010), especially relating to misunderstood drug labels (Davis et al, 2006a; Davis et al 2006b; Lokker et al, 2009; Metlay et al, 2008; Yin et al, 2009) and medication adherence (Dewalt et al, 2004)

Patient cultural factors

Researchers have hypothesized that patient-clinician communication errors and harm can stem from a variety of patient (and clinician) “cultural” factors including mistrust, varying perceptions of illness, fatalism, religious beliefs and so on (Smedley et al, 2003; DiMatteo et al, 2007; Barksdale, 2009; Koenig, 2004). Such factors have been widely discussed in the literature on patient-clinician communication, and especially the literature on health disparities and cultural competence, where the intersection of patient and clinician cultures has been of particular interest (Smedley et al, 2003). However, these issues are not fully explored in this report because there has been relatively little research to demonstrate directly how these cultural issues relate to error, adverse events or harm.

Health disparities can be seen as a harm, of course, but the seminal IOM report on health disparities, Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care, reviewed over 600 studies demonstrating the pervasiveness of disparities in U.S. health care, and discussed several mechanisms by which patient and clinician cultural factors could create miscommunication and lead to errors, but research on errors per se was lacking (Smedley et al, 2003). For example, studies have shown a dramatic difference in rates of diagnosis of schizophrenia by race, presumably due to some level of diagnostic error resulting from patient-clinician cultural miscues, stereotyping, “aversive racism” or other issues (Smedley et al, 2003); but the reasons for these disparate rates of diagnosis have not been settled (Bresnahan et al, 2007). Similarly, studies on patient trust (or mistrust) in clinicians, organizations or health care in general showed relations to satisfaction, disenrollment, changing physicians and poorer adherence, but these studies have not tracked errors or adverse events (Pearson and Raeke, 2000; Keating et al, 2002; Keating et al, 2004). Another example is research on health and religion or spirituality, which burgeoned in the last decade, but which focused mainly on the health benefits of spiritual or religious beliefs and activities, though sometimes mentioning the potential for religious beliefs to conflict with medical recommendations (Koenig, 2004).

Communication errors in non-English language encounters

A great deal of research in the last decade has shown that patients with limited English proficiency (LEP) are at increased risk for a variety of poor health outcomes (Schenker et al, 2010; Wilson et al, 2005; Weech-Maldonado, 2001; Green et al, 2005). But interpretation errors were
not discussed in the IOM report *To Err is Human: Building a Safer Health System*, and in the last decade relatively few studies specifically examined miscommunication due to language discordance as an error (Ku and Flores, 2005). Even fewer studies examined miscommunication errors among LEP patients in the outpatient setting specifically, though the findings from these few studies suggest remarkably high rates of communication errors may be common. Flores et al (2003) examined pediatric outpatient visits in California where a Spanish language interpreter was used and found an average of 31 interpretation errors per visit. Errors included missing information about patient allergies and communication of incorrect information about medication dosing (examples included instructing a mother to put amoxicillin in both ears for otitis media, and to put hydrocortisone cream all over a baby, rather than just on a facial rash); communication errors were more common when untrained interpreters were used. Elderkin-Thompson et al (2001) examined transcriptions of medical encounters of 21 Spanish speaking patients in an outpatient clinic where untrained bilingual nurses were used to interpret and found that approximately one-half of the encounters included “serious miscommunication problems.”

A community health center in Minneapolis studied drug therapy “problems” among 91 patients, 38 of whom had LEP (Westberg and Sorenson, 2003). They found a total of 186 drug therapy problems, with adherence problems being significantly more common among LEP patients (31 percent versus 12 percent). Wilson et al (2005) examined LEP patients cared for by bilingual versus English speaking physicians and found the rate of patient-reported drug reactions was four times greater in language discordant relationships. Two systematic reviews concluded that interpretation errors are less frequent when trained interpreters are used (Flores, 2005; Karliner et al, 2007), and a third examined interpreters in psychiatric settings and found that both trained and untrained interpreters make errors, but untrained interpreters’ errors “may have greater clinical impact” (Bauer and Alegria, 2010). Notably, none of these three reviews focused on ambulatory care exclusively.

### Patients with low health literacy

The demands of patient self-management—monitoring and measuring progress, recognizing change or deterioration, responding to these changes and communicating information to caregivers and health professionals—are hallmarks of ambulatory care. Yet understanding and accomplishing self-management tasks demands of patients the ability to obtain, use and transmit health information. In 2004 the IOM published a landmark report, *Health Literacy: A Prescription to End Confusion*, finding that approximately one-half of all American adults—90 million people—had difficulty understanding and acting upon basic health information and noting the potential for this to adversely affect patient safety and other aspects of quality (Nielsen-Bohlman et al, 2004).

The link between health literacy and health had been recognized by health educators by the 1980s, but two compelling reports at the close of the 1990s heightened national awareness of the need to understand the effects of low literacy on health outcomes. In 1998 the U.S. Department of Health and Human Services included a section on health communication and health literacy in Healthy People 2010, making addressing health literacy a national priority. And in 1999 a report from the American Medical Association (AMA) focused on health literacy and explained its role in health (American Medical Association Ad Hoc Committee, 1999; Rudd et al, 1999). With this report the AMA became the first medical professional association to create a policy recognizing limited literacy as a barrier to safe and effective medical diagnosis and treatment, prompting the AMA Foundation to support a set of key health literacy initiatives over the last decade (www.ama-assn.org/go/healthliteracy).

Every 10 years the U.S. Department of Education conducts a National Assessment of Adult Literacy (NAAL). In 2003 the NAAL included a specific health literacy assessment, examining participants’ ability to perform 28 tasks in three health-related domains: clinical, prevention and navigation of the health care system (Weiss, 2007; White, 2008). While not explicitly oriented toward ambulatory care, many of the 28 tasks were related to self-management in the ambulatory setting and the findings included, for example, that almost 50 percent of adult
Americans could not correctly “determine what time a person can take a prescription medication based on the information on the prescription drug label that relates the timing of medication to eating” (Weiss, 2007; White, 2008).

The IOM’s Health Literacy: A Prescription to End Confusion in 2004 noted that health literacy is not merely a patient-level characteristic but rather “arises from a convergence of education, health services and social and cultural factors” (Nielsen-Bohlman et al, 2004). This characterization of health literacy made it the shared responsibility of patients, health care practitioners, provider organizations and systems.

In 2007 the AMA specifically considered the effects of health literacy on patient safety and found that the two were innately intertwined (Abrams et al, 2007). Also in 2007, Paasche-Orlow and Wolf described a set of causal pathways by which low health literacy could result in adverse health outcomes, including an increase in the number of errors (Paasche-Orlow and Wolf, 2007). The Joint Commission issued a report on health literacy and patient safety in 2007 that noted “the safety of patients cannot be assured without mitigating the negative effects of low health literacy and ineffective communication on patient care” (The Joint Commission, 2007).

These reports included citations to a body of research in the last decade linking low health literacy to a variety of adverse outcomes (Shillinger et al, 2002; Baker et al, 2002; Howard et al, 2005; Schillinger et al, 2004; Kalichman and Rompa, 2000; Sarkar et al, 2006). An unpublished study also suggested that the effects of low health literacy on patient care were commonly experienced by physicians. A 2004 survey of 706 physicians in Iowa found that 45 percent reported having “experienced, witnessed or heard about errors in patient care that were a result of patient difficulties with reading and writing skills or understanding/communicating with medical personnel” (Iowa physician needs assessment, cited in Abrams et al, 2007). Of the physicians reporting such errors, 31 percent reported some physical pain, harm or damage, and 18 percent reported some emotional pain, harm or damage, resulting from them.

Definitions of health literacy

The IOM adopted a definition of health literacy as “the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions” (Nielsen-Bohlman et al, 2004; Ratzan and Parker, 2000; ). The American Medical Association (AMA) initially defined health literacy as “a constellation of skills, including the ability to perform basic reading and numerical tasks required to function in the health care environment. Patients with adequate health literacy can read, understand and act on health care information” (American Medical Association Ad Hoc Committee, 1999). The AMA also stressed that health literacy is fluid and depends on various factors, including the patient’s emotional response to the information, the complexity of the information and how it is presented.

Recently the AMA and Healthy People 2020 expanded their definitions to reflect the increasing demands of patient self-management and the new skills of using health information technology (HIT), such as establishing and maintaining a patient portal, engaging in the exchange of health information in email correspondence with health professionals, and receiving health information by way of interactive patient education programs (see below).

According to Healthy People 2020, individuals who have proficient health literacy have the ability to:

- Read and identify credible health information.
- Understand numbers in the context of their health care (numeracy).
- Make appointments.
- Fill out forms.
- Gather health records and ask appropriate questions of physicians.
- Advocate for appropriate care.
- Navigate complex insurance programs, Medicare/Medicaid and other financial assistance programs.
- Use technology to access information and services.

According to the American Medical Association, health literacy is the ability to read and comprehend prescription bottles, appointment slips and other essential health related materials required to successfully function as a patient (Weiss, 2007; Healthy People 2020).
Intervention research on literacy, patient engagement and adherence

Well-informed and engaged patients have been found to be more likely to adhere to their care plans. Pointing to research published before 2000, Vincent and Coulter (2002) asserted that “patients who are well informed about the prognosis and treatment options—including benefits, harms and side effects—are more likely to adhere to treatment, leading to better health outcomes.” A study by Metlay et al (2008) also supported the premise that better communication can improve safety and patient outcomes. Examining warfarin use among a cohort of older adults, they found patients who indicated receiving medication instructions were 60 percent less likely to experience a serious bleeding event over the subsequent two years. Schillinger et al (2002) demonstrated that clinicians can employ the “teach-back” technique (asking the patient to repeat instructions back to verify comprehension) to improve diabetes control among patients with low health literacy. Kaushal et al (2007) also estimated that the majority (72 percent) of preventable adverse drug events in their study could have been prevented through improved communication.

Picture-based instructions have been shown to help patients better understand how to take their medications and to decrease patient medication errors (Machtinger et al, 2007; UCSF, 2007; Yin et al, 2008). Machtinger et al (2007) developed a visual medication schedule to improve patient-clinician communication and found that it increased both medication regimen concordance and anticoagulation control among study participants. Yin et al (2008) similarly found that a pictogram helped reduce parental administration errors in young children.

Finally, Buetow et al (2010) recently recommended a set of research-based actions for individualized community care that might help manage patient error, using the acronym GERM: “Grow relationships, Enable patients and professionals to recognize and manage patient error, be Responsive to their shared capacity for change, and Motivate them to act together for patient safety.”

Future developments

Buetow et al (2009) have advocated for not seeing patient, clinician, and system errors as separate categories. They called for crosscutting research on people, settings and systems to better describe and explain “how the complex interactions of patients, clinicians and systems can create and reduce errors.”

Increased use of patient-centered medical care has been proposed as a way to address patient factors that lead to adverse outcomes, such as poor medication adherence. For instance, the use of care teams comprising clinician and nonclinician caregivers as well as community pharmacists has been employed with some success (van Dulmen, 2007; Hubbard and Daimyo, 2010). A literature review found that nine of 13 studies of cross-functional care teams in primary care “showed significant differences in adherence between intervention and usual care groups, with an average increased adherence of 25 percent” (van Dulmen, 2007). Still, the evidence base behind the use of care teams is relatively small (Hubbard and Daimyo, 2010). The New England Healthcare Institute (NEHI) recently called for demonstration projects to fully explore the potential of care teams to improve patient adherence (NEHI, 2010). “Potential funding vehicles for these projects could come both from private investments, as well as from complementary programs created by the Patient Protection and Affordable Care Act, such as programs to promote medical homes, chronic care coordination and the meaningful use of healthcare information technology” (NEHI, 2010).

Efforts to address low health literacy among patients will likely have implications for patient...
errors. Greater provider recognition of the prevalence of low health literacy and its fluidity, and how to ensure effective communication while concurrently focusing efforts on methods that enhance patient health literacy, are expected to improve patient-provider communication and the patient’s ability to make informed health care decisions (U.S. Department of Health and Human Services, 2010). Numerous groups have published recommendations on improving communication and enhancing patient health literacy, including the AMA, IOM, Institute for Safe Medication Practices, The Joint Commission (TJC) and the American College of Physicians Foundation (Ethical Force program, 2006; Abrams et al, 2007; Institute for Safe Medication Practices, 2001; Adams et al, 2003; Bohlman et al, 2004; TJC, 2007; Wolf and Bailey, 2010; Weiss, 2009). Throughout the last decade the American Medical Association and its Foundation developed a robust program to promote physician awareness of, and capacity to address, low health literacy (www.ama-assn.org/go/healthliteracy).

Finally, in the last decade health literacy and health communication were included as objectives of the U.S. Department of Health and Human Services prevention framework, Healthy People 2010 (U.S. Department of Health and Human Services, 2010). More recently, the U.S. Department of Health and Human Services released its National Action Plan (2010) to Improve Health Literacy, which seeks to engage a variety of stakeholders in a “multi-sector effort to improve health literacy.”

Summary observations

In general, patients receiving care in ambulatory settings play much more active roles in their care compared to those receiving care in hospitals. Moreover, a number of systemic and other factors over the last decade have increased the roles and responsibilities of patients regarding self-management. Hence, while patients can play important roles in ensuring safe and effective care, patient characteristics and decisions (over which they may have more or less control) can also contribute to mishaps, errors and harm.

Controversy surrounds the terminology associated with patient characteristics, actions and inactions that can contribute to adverse outcomes. Depending on the patient’s intent and other possible factors affecting their decisions, investigators have been challenged to develop intuitive classification systems for “patient errors.” At minimum, patients can make both intentional, or planned errors (“errors of planning”) such as actively avoiding care or choosing not to share relevant symptom information with providers, and unintentional, unplanned errors (“errors of execution”), such as forgetting appointments or forgetting relevant information (Buetow and Elwyn, 2007). But whether either of these should generally be characterized as an “error” is a matter of dispute. In any event, the existing body of research that explicitly addresses patient contributions to error is relatively small and suffers from various limitations that are commonly found in research on ambulatory patient safety, including the use of disparate methods, definitions, taxonomies, data sources and populations (DiMatteo, 2004). It is not possible to draw firm conclusions, though some themes are discernable:

- The most frequently discussed patient contributions to error include medication administration or dosing errors, missed appointments, nonadherence or poor adherence, and failure to share information.
- Patient errors are more frequently active errors and less frequently considered the result of system-wide (latent) failures.
- Poor communication between patients and clinicians is probably an important contributor to patient error and is often considered the result of a combination of patient and clinician factors.
• Patients with limited English proficiency are at risk for miscommunication adverse events, especially when untrained interpreters are used.

• Low health literacy affects patients’ ability to safely self-manage their care, but interventions aimed at improving communication and patient education, such as using pictograms and the “teach-back” technique, have shown some success.
Section VI. Ambulatory communication safety research

Introduction

Section V concluded with a brief overview of research in the last decade on patient characteristics (such as language, literacy level, and cultural background) that can affect safety, often because these factors have been correlated with adverse outcomes due to miscommunication. Over the last decade a large number of studies have also shown that effective communication between clinicians and patients is linked to higher quality of care. For example, Table 6.3, adapted from a table produced by the Agency for Healthcare Research and Quality (AHRQ), shows a set of exemplary studies over the last 10 years that linked communication and quality care, though most did not address safety, harm, or the ambulatory setting specifically.

In fact, the research base on communication in health care has become vast in the last 10 years, with a number of journals devoted entirely to the topic. This review is therefore primarily focused on just those communication studies in the last 10 years that directly addressed errors, patient safety or patient harm in the ambulatory setting. Also, unlike section V, this section will examine communication errors primarily from the point of view of clinicians, focusing on research that has examined communication within and between health care teams.

In a few instances, studies that included data from inpatient settings are reviewed here, when the implications of a particular line of work seemed to bear directly on ambulatory patient safety (e.g., work on communication during care transitions between the inpatient and ambulatory settings).

Typical studies of miscommunication events that can lead to patient harm in ambulatory care have included research on failure to communicate patient discharge information to ambulatory clinicians and others who need to know, failure to follow up on abnormal test results, communication failures or lapses between primary care physicians and specialists, and communication failures or lapses between patients (and their caregivers) and providers. While section V addressed several issues in patient-clinician communication, section II reviewed research on medication safety, and section III covered diagnostic errors, so this section will call specific attention to studies not covered elsewhere.
Research characteristics

Definitions and taxonomies

Despite a great deal of research on communication in health care over the last decade, a widely-adopted definition of “communication error” has not become apparent, nor is there an accepted taxonomy of types of communication errors or their consequences. In fact, the vast majority of research on health care communication in the last decade did not use an explicit patient safety framing. Only a few studies specifically examined miscommunication in patient care as an error, *per se*.

Singh et al (2010) distinguished communication errors according to the part of an interactive encounter in which they might arise:

- Patient-provider encounter (such as inaccuracies in the history or physical exam)
- Diagnostic tests (such as tests ordered but not performed or performed but misreported)
- Follow-up and tracking (such as inadequate follow-up of abnormal test results or scheduling follow-up visits)

Singh et al (2007a, 2010) also suggested that outpatient communication breakdowns could involve one or more of the following three steps:

- Message transmission (sending accurate, complete and unambiguous information)
- Message reception (perceiving the information accurately and taking appropriate next steps)
- Message acknowledgement (providing feedback that the message has been received and/or acted upon)

Kripalani et al (2007) characterized errors in discharge instructions under four “common themes” of availability, timeliness, content and format.

Areas of research on communication errors

The volume of research on communication in health care is enormous, and some important communication issues, such as miscommunication leading to diagnostic errors, are addressed more directly in other sections of this report. Also, as noted above, most research on communication in ambulatory care has not focused on errors or harms. Below we provide summaries of several studies over the last decade that bear more or less directly on communication errors and attendant harm in ambulatory care.

Hospital discharge communication

As an illustration of the vast body of research on communication, consider the study by Kripalani et al (2007), who performed a literature review on discharge communication and found 73 peer-reviewed English-language studies on communications between hospital-based and primary care physicians (PCPs) for patients discharged from the hospital. Of these, 55 were observational studies related to hospital discharge communication and 18 were controlled studies of interventions to improve communications. The review included literature published between 1970 and 2005, and many studies came from outside the United States. While most of these studies were not intended to examine communication errors specifically, the findings were of interest and included the following.
The average time between discharge and receipt of the patient’s discharge summary by the PCP was:

- 14.5 percent within one week
- 29 percent within two weeks
- 52 percent within four weeks
- 25 percent of the time discharge summaries were never received by the PCP

The average time between discharge and receipt of discharge letters by the PCP was:

- 53 percent within one week
- 62 percent within two weeks
- 79.5 percent within four weeks
- 11 percent of the time discharge letters were never received

More than 15 percent of the time the following clinical information was missing from the discharge summary:

- Main diagnosis
- Other diagnoses
- Presenting symptoms
- Diagnostic test results
- Consultant recommendations
- Discharge medications
- Test results pending at discharge (most commonly microbiology and imaging studies)
- Patient and family counseling

Bell et al (2008) followed patients (N=1,078) of PCPs (N=908) after discharge from six U.S. academic medical centers to determine whether PCPs had knowledge of their patient’s hospital admission, receipt of a discharge summary and direct communication with the inpatient medical team. This study found that at four weeks post-discharge, 23 percent of PCPs were unaware that their patients had been hospitalized. While 77 percent were aware of the hospitalization, many fewer (23 percent) had direct communication with the general medicine service and less than half (42 percent) reported receiving a discharge summary within two weeks. Remarkably, however, the investigators examined potential harm using composite patient outcomes (emergency department (ED) visit, readmission or death) four weeks after discharge and found no significant relationship between the composite outcome and PCP communication with the hospital, availability of a discharge summary or even knowledge of the hospitalization.

Research on follow-up of tests pending at discharge

At two large academic hospitals, Roy et al (2005) examined the prevalence, characteristics and physician awareness of potentially actionable laboratory and radiologic test results that returned after the patient had been discharged from the hospital and was in the ambulatory setting. These investigators found that 1,095 of 2,644 patients (41 percent) had a total of 2,033 test results pending on the day of discharge and, according to chart reviews by board-certified internists (both hospitalists and PCPs), 877 of these results (43 percent) eventually returned abnormal. The reviewers found 191 (9.4 percent) results from 177 patients were potentially actionable, based on the result and a review of the discharge orders and summary. The researchers then surveyed both the patients’ ambulatory PCPs and their inpatient physicians (both groups received the same survey) 14 days after test results were first available. The survey revealed that physicians were unaware of almost two-thirds of these potentially actionable results; more than one-third would change the patient’s diagnostic or therapeutic plan based on the results; and 12.6 percent thought the result required urgent action. The researchers stated, “Despite these small numbers, the implications for patient safety remain impressive: Almost half of all patients had pending test results when they left the hospital, 6 percent of these patients had results considered potentially actionable by a physician-reviewer, and physician awareness of these results was low.”
PCP-specialist communications

Gandhi et al (2000b) investigated satisfaction and issues with the current referral process by studying ambulatory referrals between PCPs and specialists in gastroenterology, cardiology and orthopedics at an academic tertiary care teaching and referral center. Though the study did not directly examine errors or harm, it is instructive in considering the potential for them. In this study, physicians received two surveys: one asked about the major problems with the system and what they felt was important content to convey in referral letters; the other questioned providers about specific individual referrals. Both the responding PCPs and specialists reported they were dissatisfied with their referral systems, with PCPs expressing greater dissatisfaction than specialists.

PCPs identified the three biggest problems as:
- Lack of timely information from specialists
- Redundancy of the referral process
- Time required to create adequate referral notes

PCPs additionally expressed dissatisfaction with the difficulty finding a specialist, lack of knowledge about the role of medical management (in a managed care plan) and time required for medical management approvals.

Specialists, meanwhile, reported dissatisfaction with the time required for insurance approvals, time required for medical management approvals, clarity of content from the PCP, time required to create the note to the PCP and redundant aspects of the current process.

In response to survey questions, specialists wanted the following from PCPs: problems to be addressed, clinical questions to be answered, details the patient was unable or unlikely to provide, medical problems and medications. Among responding PCPs, 74 percent reported that they do not include medications and 68 percent stated that they often do not include medical problems in referral information.

PCPs responded that they believed that the following from specialists was most important:
- answers to specific questions, the specialist’s assessment of the patient, results of tests and procedures, and therapy proposed or initiated. Among responding specialists, a substantial percentage reported that they often omit this information.

Discontinuity of care at care transitions

In a large academic medical center, Moore et al (2003) compared the discharge plans of 86 patients with care plans being used in the ambulatory setting by their PCPs within two months post-discharge "to determine the prevalence of medical errors related to the discontinuity of care from an inpatient to an outpatient setting, and to determine if there is an association between these medical errors and adverse outcomes." Researchers determined whether discharge medications were being used or had been discontinued by the PCP, if pending test results had been received, and if patients received follow-up ambulatory tests and procedures recommended at discharge.

The investigators found that 42 percent of recently-discharged patients had an unexplained medication continuity error; 12 percent had failed to receive recommended diagnostic tests and procedures; and 8 percent had not received pending test results. Although there was “no difference in readmission rates for patients with medication continuity errors, 49 percent of patients experienced at least one medical error; patients with a work-up error were 6.2 times more likely to be rehospitalized within three months after the first outpatient visit.”

Foy et al (2010) conducted a meta-analysis on studies of interactive communication and care outcomes. The researchers defined interactive communications as timely, two-way exchanges of pertinent clinical information directly between primary care and specialist physicians, including face-to-face, video conferencing, telephone and email exchanges. The study focused on outcomes for patients with diabetes, psychiatric diagnoses or cancer. Their literature search identified 5,566 citations, including 23 experimental studies, 11 randomized controlled trials and seven
nonrandomized studies of interventions. Outcomes measures used in the analysis were HbA1c results for patients with diabetes and a depression scale or symptom checklist for patients with psychiatric diagnoses. The meta-analysis showed that interactive communications significantly improved outcomes for patients with diabetes or a psychiatric diagnosis. In particular, studies that included efforts to improve the quality of information exchange demonstrated statistically and clinically significant benefits, but studies involving shared care planning failed to show a difference. There were no differences in results for participants in an integrated delivery system.

Singh et al (2010) studied electronic health record-based referral communications between generalists and specialists in an integrated health system. The majority of referrals were completed, but among those left unresolved or discontinued, between 16 percent and 77 percent were not clinically justifiable, and these conferred a greater risk of harm according to the chart reviews.

**Missing information at primary care visits**

Smith et al (2005) investigated missing information at the time of primary care visits. For this study, information was “missing” if it was known to exist but not located before the visit ended. In 32 primary practices in Colorado, 253 clinicians coded information that was missing during the patient encounter; researchers reviewed 1,563 patient visits. Important information was missing at 13.6 percent of the visits. Missing information included laboratory test results (6.1 percent), letters/dictation (5.4 percent), radiology results (3.8 percent), history or physical exam (3.7 percent) and medications (3.2 percent). Although analysis revealed few strong predictors of missing clinical information, researchers noted that clinicians were most likely to report missing information during visits in which the patient had recently moved to the United States, the patient was new to a practice or the patient had multiple medical problems. Seventeen of the 253 clinicians reported they had a “full EHR,” and these clinicians were significantly less likely to report missing information, but there was no significant difference in information availability for clinicians reporting that they had a “partial EHR.”

The missing information was thought to be within the “clinical system” 41.8 percent of the time and “within the United States” 93 percent of the time. In 44 percent of the visits with missing information, clinicians believed that the patient would be at least “somewhat negatively” affected.

**Communication of test results**

Poon et al (2004b) studied communication factors in the follow-up of abnormal mammograms. Sites in the yearlong study included 10 academically affiliated ambulatory medical practices, two of which were neighborhood health centers. Using guidelines from the American College of Obstetrics and Gynecology stating that abnormal mammograms should be followed up with a repeat mammogram within six months or be referred for surgical evaluation, the researchers identified 181 patients (out of 8,892 mammogram reports) with new abnormal mammograms requiring short-term follow-up. The researchers conducted a telephone survey with 126 patients; patients were called within six to eight weeks of their mammogram to collect information on their experience and how their results were communicated to them. Researchers made a second call at seven to eight months to determine whether patients received appropriate follow-up. This study deemed an appropriate follow-up to include a repeat mammogram, a surgical consult and/or a breast biopsy within seven months.

The study identified the following trends:

- Of the 126 patients who were interviewed, 81 (64 percent) had adequate follow-up and 45 (36 percent) did not.
- Socioeconomic factors (with the exception of age), education, family history, the patient’s perception of their health and their reported worry prior to getting the mammogram were found not to significantly affect the adequacy of follow-up.
- Patients covered by managed care plans were more likely to receive adequate follow-up.
Patients over 50 were more likely to have adequate follow-up.

Research identified certain communication factors that correlated with inadequate follow-up, as noted in Table 6.1.

**Table 6.1: Communication factors associated with inadequate follow up of abnormal mammograms**

<table>
<thead>
<tr>
<th>Factor</th>
<th>Adequate follow-up</th>
<th>Inadequate follow-up</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MD documented discussion of results with patient</td>
<td>76.3%</td>
<td>62.2%</td>
<td>0.096</td>
</tr>
<tr>
<td>MD explained further tests in a way the patient understood</td>
<td>45.7%</td>
<td>28.9%</td>
<td>0.065</td>
</tr>
<tr>
<td>MD documented follow-up plan in the record</td>
<td>79.1%</td>
<td>62.2%</td>
<td>0.042</td>
</tr>
<tr>
<td>Patient reported being advised she needed follow-up</td>
<td>80.2%</td>
<td>55.6%</td>
<td>0.003</td>
</tr>
</tbody>
</table>

Notably, the following communication factors were not correlated with inadequate follow-up:

- Patients being new to the physician (<1 year)*
- Patients given results to take home
- Patients received results within one week of the mammogram
- PCP contacted by phone by the radiologist*
- Patient saw the PCP after the mammogram*

* denotes small sample size

In another study, Poon et al. (2004a) recognized that failure to review and follow up on outpatient test results in a timely manner is important to a patient’s safety, but also a malpractice concern, and focused on identifying problems in current test result management systems and possible improvements to these systems. They surveyed 262 physicians working in 15 internal medicine practices affiliated with two large urban teaching hospitals to determine the processes they used to manage test results. All the practices used an electronic medical record (EMR) system, and the hospital IT system automatically sent test results to the physician EHRs. At the time of the study, many practices also used human or paper systems to manage test results.

Physicians reported spending 74 minutes per day managing test results, and only 41 percent were satisfied with the process. Overall, 59 percent of physicians reported having a staff member review all incoming test results, and 52 percent kept a record of the tests ordered. However, only 32 percent of the practices had systems in place to detect if patients missed tests. Eighty-three percent of physicians reported at least once in the prior two months that they had reviewed a test result where they "wished they had known about that earlier."

The survey identified the following top features that the physicians would like to see in an electronic results management system, beyond what they already had (Poon et al. 2004a):

- Prioritization of results with abnormal results listed first
- Letter writing capabilities (to notify patients of results) with predefined text
- Warning systems to detect when a patient had missed a test

Casalino et al. (2009) conducted a retrospective medical record review of 5,434 randomly selected patients aged 50 years to 69 years in 19 community-based and four academic medical center primary care practices to determine how often primary care physicians fail to notify patients or fail to document notification for “significantly abnormal test results.” A panel of physicians defined “significantly abnormal results” for 11 blood tests and three screening tests. The study defined “failures to document” as instances where the physician stated that the patient had been informed but this was not documented. They defined “failures to inform” as instances where patient notification was not documented and the physician either stated that the patient had not been informed or failed to reply. Researchers considered the patient informed if there was a note stating that the patient had been informed, if the abnormal test was repeated, or if a relevant consultation or
procedure (e.g., referral to a urologist and/or results of a prostate biopsy) was performed.

The researchers found that 7.1 percent of “clinically significant results” involved apparent failures to document or follow up. Practices that used a partial EHR had lower rates of documented follow-up than those using a full EHR (odds ratio 2.37 \( p = 0.007 \)) or no EHR (odds ratio 1.92 \( p = 0.03 \)). Higher process scores were associated with lower rates of failure to follow up. The rate of lack of timely follow-up in this study was close to those found in two studies by Singh et al (2009, 2010): 7.7 percent and 6.8 percent, respectively.

**Communication and nonadherence**

Zolnierek and DiMatteo (2009) conducted a meta-analysis of the impact of physician communication on patient adherence that included 106 empirical studies that examined the correlation between a physician’s communication skills and patient adherence to the physician’s recommendations. The extent of the literature search to identify patient-physician communication research included all English language publications in peer-reviewed journals from 1949 to August 2008, and all but two of the 106 studies demonstrated a positive relationship between the physician’s communication skills and the patient’s adherence to the physician’s recommendations. The conclusion of the meta-analysis was that the relationship between communication skills and patient adherence is “strongly positive and significant.”

**Research on interventions to improve between-team communication**

**Hospital-primary care communications**

Kripalani et al’s 2007 review of research on hospital-primary care communications identified three controlled trials of interventions, all conducted outside of the United States (England, Canada and Australia) and all published prior to 2000. One study showed that hand delivery of a discharge letter by the patient to the general practitioner (GP) resulted in earlier receipt of information by the GP (the statistical significance of this result was not reported.) Another showed that a database-generated discharge summary arrived significantly faster than a dictated report. The third study involved enhanced discharge planning and found that it could enhance the GPs understanding of hospital care, hospital communications and the GPs role in post-hospital care.

Kripalani et al (2007) also found 15 non-controlled studies of interventions. The following interventions had a statistically significant impact (\( p = 0.05 \) or better) on a variety of outcomes:

- Hand delivery of the discharge letter to the GP resulted in a mean time of delivery of 2.5 days versus 7.5 days for mailed delivery.
- GPs judging paired discharge summaries (one that was computer generated and one that was dictated) judged the computer-generated summary to be clearer (67 percent vs. 28 percent) and preferred (69 percent vs. 28 percent).
- Discharge summaries generated by a computer had a mean time to receipt of 3.8 days vs. 20.9 days for typed summaries.
- Ninety-four percent of patients received a discharge letter when it also included discharge medications versus 68 percent receipt when the discharge letter and discharge medications were separate documents.
- Family practitioners judging discharge summaries in standard format versus narrative format rated the standard format 4.28 vs. 3.84 for a narrative format (on a scale of 1 to 7).
• Medical residents who received training on dictating discharge summaries in a standard format had summaries with higher ratings.
• Discharge summaries that were dictated using a template had higher quality scores and were shorter than those dictated without a template.

Based on their review of the literature, Kripalani et al (2007) recommended the following safety practices for information transfer to outpatient physicians at discharge.
• Discharge summaries should contain:
  — Primary and secondary diagnosis
  — Medical history and physical findings
  — Dates of hospitalization, treatment and brief description of the hospital course
  — Procedure results and abnormal test results
  — Consult reports
  — Information given to patients and family
  — Patient’s condition at discharge
  — Reconciled medications with reasons for changes since admission
  — Details of follow-up arrangements made
  — Follow-up needs (appointments, procedures, pending test results)
  — Name and contact information of responsible hospital physician

• Discharge summaries should be structured with subheads to organize the information and to highlight the most important information for follow-up care.
• Information technology should be used to extract information to ensure accuracy and timely availability.
• Patients should be given a copy of the discharge summary and told to bring it to their follow-up visit.

Research on interventions to improve care transitions

A large body of research exists on care transitions interventions, though most research has focused on improving quality of care and outcomes rather than measuring error or harm prevention. Still, if rehospitalization is considered at least sometimes to be a preventable adverse outcome or a harm, then research on preventing rehospitalizations can be seen as a type of work in ambulatory patient safety. This section summarizes a few of these interventions, but an exhaustive review of the research on care transitions interventions is beyond the scope of this report.

Project BOOST (www.hospitalmedicine.org)
Project BOOST (Better Outcomes for Older Adults through Safe Transitions) is a national initiative led by the Society of Hospital Medicine to improve the care of patients as they transition from hospital to home. BOOST objectives are to (1) identify high-risk patients on admission and target risk-specific interventions; (2) reduce 30-day readmission rates for general medicine patients; (3) reduce length of stay; (4) improve facility patient satisfaction and HCAHPS scores; and (5) improve information flow between inpatient and outpatient providers.

Preliminary data from sites that implemented Project BOOST for at least six months revealed a reduction in 30-day readmission rates from 14.2 percent to 11.2 percent after implementation, for a 21 percent reduction in 30-day all-cause readmission rates (Forth et al, 2010). Pilot sites indicated that BOOST tools improved communication and collaboration across hospital functions and outpatient physicians. Patients also reportedly perceived an increased level of service and medical attention.

Project RED (www.bu.edu/fammed/projectred)
Project RED (Re-Engineered Discharge), from a research group at Boston University Medical Center, is a set of tools and strategies to improve the
hospital discharge process, promote patient safety and reduce rehospitalization among ambulatory patients following discharge. The RED intervention is based on 11 discrete, mutually reinforcing components, and has been proven to reduce rehospitalizations and improve patient satisfaction.

In one study of Project RED, the 370 patients who participated in Project RED were one-third less likely to be readmitted to the hospital or visit the emergency department compared to 368 patients not in the project. Jack et al (2007) stated nearly all of the patients in the intervention group left the hospital with a follow-up appointment with their primary care physician, compared with 35 percent of other patients. Further, 91 percent of participants had their discharge information sent to their ambulatory PCP within one day of leaving the hospital. More than half (52 percent) of intervention subjects who completed a medication review by a pharmacist had at least one prescription drug problem that needed corrective action.

Jack et al (2007) also found the Project RED intervention subjects had lower emergency department costs ($21,389 versus $11,285) and readmission costs ($412,544 versus $268,942) over the 30 days following hospital discharge. The study estimated Project RED participants had an average overall lower cost of $412 per person.

Care Transitions Intervention® (www.caretransitions.org)

The Care Transitions Intervention (CTI) is based on the work of Eric Coleman, MD, from the University of Colorado. CTI is a four-week process that encourages patients being discharged from hospitals to take an active role in their care. Patients receive specific tools and skills that are reinforced by a “transition coach” (a nurse, social worker or trained volunteer) who follows patients across settings for the first four weeks after leaving the hospital and focuses on the following components: medication self-management; use of a patient-centered health record that helps guide patients through the care process; PCP and specialist follow-up; and patient understanding of red flag indicators of worsening condition and appropriate next steps.

One study of CTI reported that use of the program resulted in lower hospital readmission rates. Coleman et al (2006) indicated intervention patients had lower rehospitalization rates at 30 days (8.3 percent versus 11.9 percent) and at 90 days (16.7 percent versus 22.5 percent) than non-participants. Also, the average hospital costs were lower for intervention patients ($2,058) versus nonparticipants ($2,546) at 180 days.

Research on interventions to improve communication of test results

Veterans Health Care (Department of Veterans Affairs [VA]) has long used an EHR system. In one VA facility, the EHR system was programmed to proactively alert clinicians of certain abnormal test results among ambulatory patients. Singh et al (2007a) studied the effectiveness of the system by identifying alerts that had not been acknowledged, to determine whether appropriate follow-up action had been taken. “Acknowledgement” was defined as the ordering clinician clicking and opening the alert. During the study period, the computer system generated 1,017 alerts for abnormal imaging results. Seven days after the alert was not acknowledged in the computer system by the receiving clinician, the researchers performed a chart review to see if there was documentation of a response to the alert, or if the patient had been hospitalized. Phone calls were then made to the clinicians who had not acknowledged the alert if there was no evidence in the medical record that they had responded to the alert. Thirty-four percent of the alerts were not acknowledged in the computer system and were followed up by chart review. After chart review, physicians were contacted regarding the 14 percent of the alerts that had not been acknowledged nor documented...
action found in the chart. Four percent of the abnormal imaging results were determined to be “completely lost to follow-up.”

A later study at the same facility followed up on 1,196 alerts for abnormal imaging studies, 18 percent of which were not acknowledged within 14 days. In Singh et al (2009) the researchers reviewed medical records in both unacknowledged and acknowledged groups to determine if there was evidence of follow-up action; 7.7 percent of the 1,196 alerts were found to not have proper follow-up after four weeks. There was no statistical difference between the unacknowledged and acknowledged groups, suggesting that clinicians sometimes do not follow up on abnormal test results despite reading them. Dual alerting (sending the alert to both the PCP and the ordering clinician, if different) was associated with lower rates of follow-up, which the authors attributed to possible diffusion of responsibility. Verbal communication from the radiologist to the ordering clinician increased the probability of follow-up, but this was only required for results needing urgent action.

The VA has also used their computer system to automatically generate alerts for “high priority” abnormal laboratory test results (Singh et al, 2010). For this study, researchers followed “high priority alerts for four abnormal test results: hemoglobin A1c ≥ 15%, positive hepatitis C antibody, thyroid stimulating hormone ≥ 15 mIU/L, and prostate specific antigen ≥ 15 ng/ml.” After two weeks, researchers examined abnormal test results that had not been acknowledged (opened) by the receiving clinicians. At four weeks, medical records were reviewed to determine if follow-up actions had been taken for alerts that had been opened and those that had not. If follow-up actions were not taken, clinicians were contacted to determine if there was a reason for lack of follow-up. About 10 percent of the alerts were not opened. Overall, timely follow-up was not performed for 6.8 percent of all the abnormal test results that generated alerts. Again, similar to the imaging study above, there was no difference in appropriate follow-up between alerts that were acknowledged and those that were not. The authors also found that 17.4 percent of alerts were related to redundant tests.

A multifaceted approach to improving EHR-based communication has been suggested. This includes attention to EHR technology, clinician-EHR interaction and clinical workflow, as well as to organizational issues such as policies and procedures to ensure fail-safe communication of test results (Singh and Vij 2010; Singh et al, 2010).

Research on alert fatigue

Some studies have suggested that “alert fatigue” can be an unintended consequence of clinical decision support systems, EHRs and computerized physician order entry (CPOE) systems that notify clinicians of abnormal test results. Most studies on alert fatigue are not focused on the ambulatory setting, though some lessons might be applicable across settings. In particular, the way alerts are presented to the user might affect clinicians’ ability or willingness to notice the alerts and act upon them (Ash, et al 2007; Judge, et al 2006). The most common reasons given for overriding or disregarding alerts is that clinicians receive a large number of inappropriate or unhelpful alerts (Weingart et al, 2003; Grizzle, et al, 2007).

In a study by Shah et al (2006) that was summarized in Section III, “Research on ambulatory medication safety,” improving the design of electronic alerts was suggested as a way to avoid alert fatigue and enhance clinician acceptance of alerts (Shah et al, 2006). In particular, these investigators suggested maintaining accurate clinical documentation and improving the linkage of patient information from all electronic clinical repositories, using these other data sources to ensure that clinicians only receive alerts for issues of high clinical importance.
Future developments

Health IT and EHRs

Several researchers have cited the potential for EHRs to improve communication between patients and clinicians and between PCPs and specialists. Researchers have also cited the potential of EHRs in tracking acknowledgement and follow-up of abnormal test results. At the same time, others have found no impact or even an adverse impact, especially when studying partial EHRs and some alerting systems as noted above. In any event, EHRs are nascent tools. Issues of patient communications, referral management and follow-up of abnormal test results were not included in the most detailed assessment of EHR use in ambulatory care in the last decade (DesRoches, 2008).

Funding for interventions

The American Recovery and Reinvestment Act of 2009 (ARRA) provided money to fund incentives for the “meaningful use” of EHR systems. The government published the final rule for qualifying for incentives in July 2010. Under ARRA, physicians could qualify for up to $44,000 from Medicare or $63,700 from Medicaid for meaningful use of EHR systems beginning in April 2010. The first stage of meaningful use requirements includes several items that might serve to improve communication and are listed in Table 6.2.

Table 6.2 Eligible professional “meaningful use” core objectives

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1.</td>
<td>Use computerized physician order entry (CPOE) of medications.</td>
</tr>
<tr>
<td>2.</td>
<td>Generate and transmit permissible prescriptions electronically (eRx).</td>
</tr>
<tr>
<td>3.</td>
<td>Report a total of six ambulatory clinical quality measures to CMS (Medicare EHR Incentive Program) or States (Medicaid EHR Incentive Program).</td>
</tr>
<tr>
<td>4.</td>
<td>Implement one clinical decision support rule.</td>
</tr>
<tr>
<td>5.</td>
<td>Provide patients with an electronic copy of their health information upon request.</td>
</tr>
<tr>
<td>6.</td>
<td>Provide clinical summaries for patient for each office visit.</td>
</tr>
<tr>
<td>8.</td>
<td>Enable a user to electronically record, modify and retrieve patient demographic data including preferred language, gender, race, ethnicity and date of birth.</td>
</tr>
<tr>
<td>9.</td>
<td>Maintain an up-to-date problem list of current and active diagnoses based on ICD–9–CM or SNOMED CT’.</td>
</tr>
<tr>
<td>10.</td>
<td>Maintain the patient’s active medication list.</td>
</tr>
<tr>
<td>11.</td>
<td>Maintain the patient’s active medication allergy list.</td>
</tr>
<tr>
<td>12.</td>
<td>Record and chart changes in vital signs (height, weight, blood pressure); calculate and display BMI; plot and display growth charts for children, including BMI.</td>
</tr>
<tr>
<td>13.</td>
<td>Record smoking status for patients 13 years or older.</td>
</tr>
<tr>
<td>14.</td>
<td>Enable the capability to exchange key clinical information among providers of care and patient-authorized entities electronically.</td>
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<td>15.</td>
<td>Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities.</td>
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In addition to the “core” meaningful use requirements in Table 6.2, all of which must be met to obtain the financial incentive, there are some “optional requirements” that are relevant to communication, which are in a “menu” from which clinicians must select 5. These include providing a “summary record” for 50 percent of transitions in care between PCPs and specialists, and providing at least 10 percent of patients with access to information in the EHR. Systems that are certified for meaningful
use are required to provide capabilities to meet both the mandatory and all optional requirements, meaning that all certified EHR systems should soon have the potential to provide these capabilities (Federal Register, July 28, 2010).

A summary of ARRA's health-related provisions can be found on the American Medical Association web site at: www.ama-assn.org/ama/pub/advocacy/current-topics-advocacy/additional-advocacy-topics/american-recovery-and-investment-act.page

The Patient Protection and Affordable Care Act of 2010 (PPACA) provided several funding opportunities to improve care transitions and ambulatory care coordination, both for Medicare and Medicaid beneficiaries. One program will provide $500 million of funding over five years as part of the Community-Based Care Transitions Program, starting in 2011. This program is intended for hospitals with high Medicare readmission rates who partner with community-based organizations to provide improved ambulatory services, focusing their efforts on at least one of five interventions for improving post-discharge services, providing self-management or caregiver support, and conducting medication management review (PPACA § 3026).

Under the Independence at Home Demonstration, PPACA will provide funding of $5 million per year for five years for house calls to help Medicare beneficiaries remain healthy at home, starting in 2012 (PPACA § 3024).

The Avoidable Readmission Penalty (PPACA § 3025) provides incentives to improve care transitions and reduce avoidable readmissions by reducing Medicare payments by 1 percent and rising to 3 percent for certain "avoidable" readmissions exceeding a threshold, beginning in 2012 and expanding by 2015.

Section 3502 of PPACA (Community Health Teams) directs the Secretary of the U.S. Department of Health and Human Services to establish a program to provide funding for community-based, interdisciplinary health teams to support primary care practices.

The Medicaid Health Homes for Chronic Conditions (PPACA § 2703), also known as Medical Homes, provides funding to state Medicaid offices matching funds totaling up to $25 million. To receive funding, states must track avoidable readmissions, estimate savings from care coordination and report lessons learned.

Summary observations

Effective communication is strongly related to quality care and good outcomes, while miscommunication can certainly be a source of error and harm. This has been well established in hospitals where, according to The Joint Commission, miscommunication is the single most frequent cause of sentinel events, or serious medical errors (The Joint Commission, 2010). In the outpatient setting, by contrast, there has been a tremendous amount of research on communication issues over the last decade, but most of this work did not use a patient safety lens to examine these issues. A number of studies have focused on ambulatory patient-physician communication, communication between various health professionals caring for patients, and communication around care transitions, such as discharges from hospitals into the ambulatory setting. But even where miscommunication has been studied specifically, it has not usually been framed as an “error.” As such, only a few studies have explicitly examined ambulatory communication errors and their attendant harm.

Still, some notable studies have found that communication breakdowns in the following areas can and do lead to errors and harm in ambulatory settings:
• Miscommunication around abnormal test results, leading to diagnostic errors
• Miscommunication between patient and physician, leading to non-adherence
• Miscommunication of information during referrals, leading to inadequate follow-up
• Miscommunication at hospital discharge, leading to ED visits and readmissions

More important, recent work in both research and policy has turned toward the implementation and assessment of promising strategies to improve communication within and between health care teams. In light of the rapidly evolving nature of American health care, this research is of pressing importance. Early work on health information technology as a means of improving communication, for example, shows both promise and risk; and highlights the need for careful studies of ambulatory safety interventions in the next decade.

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TABLE 6.3
Background material provided by the Agency for Healthcare Research and Quality for the Institute of Medicine’s Evidence Communication Innovations Collaborative Meeting on October 28, 2011.

RESEARCH TAKEAWAYS of Studies related to “Questions Are the Answer” Web site
9-14-11

The following studies found that effective communication between patients and providers produces a host of good results. Each provides a nice summary (often in the introduction) of the existing literature on the topic. All of the following blurbs were pulled from each of the studies verbatim.


To participate meaningfully in decisions regarding invasive procedure use, patients should understand the benefits and risks. Patient understanding of the benefits of coronary revascularization procedures were assessed. Results found that little is known about the patient understanding of the factors that influence important medical care decisions. Efforts to increase patient involvement in medical decision making would be helped by better understanding of how well patients understand the important components of decisions they are making.


Communication between doctor and patient plays an important role in developing a trusting doctor–patient relationship, and the patient’s trust in the physician is one of the leading correlates of important outcomes of care. Communication that achieves information exchange and negotiation of mutual expectations, reassures patients, and demonstrates positive affect from the practitioner increases patient adherence. Communication during history taking or discussion of the management plan has a significant association with patient outcomes.


Previous research has demonstrated a strong relationship between patient-centered patterns of communication and higher levels of satisfaction and trust. Clinicians with open communication styles that invite patient participation have been found to have fewer malpractice claims and are more likely to provide preventive services. Better communication also correlates with higher rates of compliance, particularly among pediatric patients. Among diabetics,
better communication results in lower levels of glycosylated hemoglobin, a surrogate marker for diabetes management.


Because more active patient participation contributes to improved health outcomes and quality of care, it is important to understand factors affecting the way patients communicate with healthcare providers. Regardless of their desire for involvement in medical decisionmaking, patients who actively participate in the consultation by expressing their concerns, asking questions, detailing their symptoms, and stating their expectations for care are providing the doctor with valuable information for diagnosis and treatment. Moreover, patients who take a more active role often are more satisfied with care, receive more information and support from physicians, are more committed to treatment plans, have a better understanding of treatment options, and experience greater improvement in health than do more passive patients.


The more questions that patients ask, and the more concerns, worries, and emotions that they express, the more medical information that physicians provide (for review, see Anderson, DeVellis, & DeVellis, 1987; Street, 1991). Furthermore, both patient question asking and physician information giving are positively associated with patients’ satisfaction and, perhaps more importantly, physical health (Anderson, DeVellis, & DeVellis, 1987; Greenfield, Kaplan, & Ware, 1985).


This era is ending, being replaced with consumerism and the movement toward shared decisionmaking. Patients are advising each other to ‘educate yourself and ask questions.’ Patients’ satisfaction with their care rests heavily on how successfully this transition is accomplished. Ready access to quality information and thoughtful patient–doctor discussions are at the fulcrum of this revolution.


Patient satisfaction was the most commonly measured outcome, but few significant improvements were found. However, there were significant improvements in other outcomes, including perceptions of control over health, preferences for an active role in health care, recall of information, adherence to recommendations, attendance, and clinical outcomes. Few studies examined the links between patient characteristics and the success of the interventions. The importance of doctor–patient communication in the process of health care has been established, with studies demonstrating clear links between the quality of communication and patient satisfaction, adherence and clinical outcomes. Recognition of the importance of doctor–patient communication has led to the formal teaching of communication skills being considered as an essential aspect of medical education, and this is now an integral component of most medical curricula. While concerted efforts at behavioral change have been directed at health care professionals, considering only the doctor’s input into the consultation has the consequence of neglecting half of the relationship. The patient’s contribution to the consultation has also been found to be related to outcomes. Patients who are more active during consultations (in terms of asking questions, proffering information, and expressing opinions) are more likely to understand, and these active patients may experience improved medical outcomes.


A communicative provider–patient relationship is especially important in the management of chronic diseases, such as diabetes, hypertension, coronary artery disease, and congestive heart failure. When patients are informed and involved in decisionmaking, they are more adherent to medical recommendations and carry out more health-related behavior change (e.g., exercise, smoking cessation, and dietary modification). Such joint decisionmaking requires patients to be fully informed about alternatives and potential risks of treatment and to have trust in their physician. There is no doubt that the physician–
patient interaction makes up a central and critical element of ambulatory care medicine. A favorable medical interview is essential to creating a good interpersonal relationship, information exchange, and optimal medical decision making. The character of the interactions influences a variety of patient outcomes, including short-term outcomes such as satisfaction and recall, intermediate outcomes such as adherence, and long-term outcomes such as symptom resolution and quality of life.

Haskard Zolnierek KB, DiMatteo MR. Physician communication and patient adherence to treatment: a meta-analysis. Medical Care 2009 August;47(8):826-34.

Physician communication is significantly positively correlated with patient adherence; there is a 19 percent higher risk of non-adherence among patients whose physician communicates poorly than among patients whose physician communicates well. Training physicians in communication skills results in substantial and significant improvements in patient adherence such that with physician communication training, the odds of patient adherence are 1.62 times higher than when a physician receives no training.
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Phillips R, Dovey L, Graham D, Elder N, Hickner J. Learning from Difference Lenses: reports of Medical Errors in Primary Care by Clinicians, Staff, and Patients. Patient Safety. 2006;2:140-146


Poon EG, Gandhi TK, Sequist TD, Murff HJ, Karson AS, Bates DW. “I wish I had seen this test result earlier!” Dissatisfaction with Test Result Management Systems in Primary Care. *Arch Intern Med*. 2004a;164:2223-2228


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Solberg LI, Hurley JS, Roberts MH, Nelson WW, Frost FJ, Crain AL, Gunter MJ, Young LR.


Spath P, Nash D. Partnering with Patients to Reduce Medical Errors. Chicago, IL: Health Forum; 2004


White S., Assessing the nation's health literacy. 2008 American Medical Association Foundation.


Kelly B. Haskard Zolnierek and M. Robin DiMatteo

Appendix: Annotated bibliography of published research

The following annotated bibliography includes a separate table for each section of the report. Each table summarizes the research reports referenced in the section, including design, settings, and results. Some studies apply to multiple categories; these are referenced in each relevant chapter but only included in the table for the chapter where they were most relevant. Only research studies are included in the tables. Non-research references cited in the report are provided for context, but are not included in the annotated bibliography.
### I. General Research on Ambulatory Patient Safety

<table>
<thead>
<tr>
<th>Study</th>
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<tr>
<td>Dovey SM, Meyers DS, Phillips RL, et al.</td>
<td>To classify medical errors reported by family physicians.</td>
<td>Medical Error: “… anything that happened in your own practice that should not have happened, that was not anticipated and that makes you say ‘that should not happen in my practice, and I don’t want it to happen again.’”</td>
<td>Study participants included 42 family physicians and members of the AAFP National Network for Family Practice and Primary Care. Participants were evenly located across the United States: <em>9 in the Midwest, 10 in the Northeast, 11 in the West and 12 in the South.</em> Breakdown between small and large practices was not specified.</td>
<td>Analysis of voluntary physician reports of error submitted between 5/9/2000 – 9/26/2000. Taxonomy used: Created two categories and eight subcategories of medical errors. (See Results) Measurement of error: Distribution of reported errors into established categories and subcategories.</td>
<td>Participants submitted 344 error reports, of which 14 were excluded. The authors organized the 330 included error reports into two categories: <em>Process errors (n=284/86.1%) and Knowledge and skills errors (n=46/13.9%).</em> Process errors incorporated: <em>Administrative errors (n=102/30.9%); Investigatory errors (n=82/24.8%); Treatment errors (n=76/23%); Communication errors (n=19/5.8%); and Payment errors (n=4/1.2%).</em> Knowledge and Skill errors included: <em>Clinical task errors (n=19/5.8%); Misdiagnosis (n=13/3.9%); and Errors in treatment decisions (n=14/4.2%).</em></td>
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<tr>
<td>Elder N, Meulen M, Cassedy A.</td>
<td>To consider errors prospectively identified by physicians as well as how physicians perceive the patient harm attributable to such events. N/A (Listed components of various errors but not systematically defined) Study population included nine outpatient physician practices in greater Cincinnati region, including large, small, rural and suburban locations. Study sample consisted of 15 physician members of 7 family practices within the greater Cincinnati region.</td>
<td>Survey of and qualitative interviews with family physicians. The authors developed a survey instrument that, based on the literature and prior work, identified potential sources of process error and preventable adverse events in outpatient care. Following requisite training, participating physicians completed the survey on these</td>
<td>Participating physicians completed a total of 351 surveys. A total of 117 errors or adverse events were identified in 83 patient visits – 1 error was noted in 61 visits and roughly 2 errors were found in 22 visits. Identification of errors was highly variable among physicians, the frequency of error detection ranged from 3.2% to 60% of visits. Commonly identified errors and preventable ADEs included:</td>
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| Fernald D, Pace W, Harris D, West D, Main D, Westfall, J. Event Reporting to a Primary Care Patient Safety Reporting System: A Report from the ASIPS | To depict reporting errors and consider the differences between confidential and anonymous reports. | Reportable event: “Any event you don’t wish to have happen again, that might represent a threat to patient safety.” | Breakdown between small and large practices not specified. Study participants included 475 clinicians and staff from 33 practices in the Colorado Research Network and High Plains Research | Data included voluntary physician reports of errors reported to the Applied Strategies for Improving Patient Safety (ASIPS) project collected from October 2001 through August 2003. The majority of reports (66%) were made confidentially, which enabled follow-up. | Participating practices submitted upwards of 708 error reports, of which 608 were codable. The most frequently reported errors included:  
- “Communication problems (70.8%);”  
- Diagnostic tests (47%);  
- Medication problems (35.4%); and  
- Both diagnostic tests and |
| | | | Physicians at the two largest area practices were also invited but did not participate. | errors immediately following patient encounters for between 20-40 encounters. Physicians were interviewed at the end of each day and asked to describe identified errors and offer opinions on any resulting patient harm. Data included physician-identified process and preventable adverse events. Taxonomy used: Elder and Dovey, 2002 (adapted). Measurement of error: Quantitative and qualitative distribution of reported errors and interview data into established categories of patient communication errors, physician-related errors, preventable adverse events, and office administration errors. | • Office administration errors (n=57/16.5%);  
• Physician-related errors (n=28/8%);  
• Patient communication errors (n=16/4.5%); and  
• Preventable adverse events (n=15/4.3%). Qualitative interviews were held with physicians to examine 76 of the 83 patient visits identified as having errors. Physicians identified 18 patients (23.7%) who experienced harm and 53 patients (69.7%) had the potential to be harmed. |
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<tr>
<td>Collaborative. <em>Ann Fam Med.</em> 2004; 2:327-332.</td>
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<td>Network in Colorado.</td>
<td>Follow-up calls were made to parties who submitted confidential data to obtain additional information.</td>
<td>With regard to harm, the authors found that most errors did not result in known harm to the patient (n=134) but that roughly 10% of patients (n=21) experienced clinical harm and an additional 10% of patients (n=21) were placed at greater risk of harm.</td>
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<td>The authors then considered how the anonymous reports differed from the confidential reports in terms of the detail provided and how well harm information was captured. Taxonomy used: Dimensions of Medical Outcome (DOM), a multiaxial taxonomy of medical errors which included ten axes and four domains (Victoroff, 2001).</td>
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|                                            |           |                    |                         | Harm was classified into five categories:  
|                                            |           |                    |                         |  - "Clinical harm;"  
|                                            |           |                    |                         |  - Future risk of clinical harm;  
|                                            |           |                    |                         |  - Nonclinical harm;  
|                                            |           |                    |                         |  - Unstable; and  
|                                            |           |                    |                         |  - No known harm."  
|                                            |           |                    |                         | Measurement of error: Quantitative (statistical) distribution of reported errors into established categories/axes.                                                                                           |                                                                                                                                                              |
|                                            |           |                    |                         |                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                              |
| Kuzel A, Woolf S, Gilchrist V et al. Patient Reports of Preventable Problems and | To establish a "patient-focused" medical error classification system and consider which | Error: "All forms of improper, delayed, or omitted care that unnecessarily injures patients. Study population composed of 41 | Breakdown between small and large practice patients not specified. | Qualitative study to consider the patients perspective on the nature of problems occurring in primary care. Participants were asked to classify the incidents into five categories:  
|                                            |           |                    |                         | The 38 interviews documented 221 problematic events.  
|                                            |           |                    |                         | The authors classified the incidents into five categories:  
|                                            |           |                    |                         |  - Relationship breakdowns (n=82);  
|                                            |           |                    |                         |                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                             |
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<tr>
<td>Harms in Primary Care. <em>Annals of Family Medicine</em>. 2004; 2.4:333.</td>
<td>errors and harm patients attach the most importance to.</td>
<td>by either worsening health outcomes or causing physical or emotional distress.</td>
<td>patients of general internists or family physicians or parents of children who received care from pediatricians or family physicians in Virginia and Ohio. Rural, urban, and suburban areas were each included. Sample includes 38 randomly-selected patients for whom interviews were completed and entirely recorded.</td>
<td>provide a description of any preventable incidents that had caused harm. Participants were then asked to group errors based on &quot;most and least disturbing.&quot; Results were compiled and analyzed by researchers. Data included 38 anonymous qualitative phone interviews, including patient-reported &quot;problematic incidents.&quot; Measurement of error: Qualitative distribution of patient-reported incidents into established categories.</td>
<td>• Access breakdowns (n=63); • Technical error (n=54); • Communication breakdowns (n=17); and • Inefficiency of care (n=5). Of these incidents, 170 resulted in harm, including psychological (n=119/70%) and physical harm (n=39/23%). &quot;Patients were more likely to report being harmed psychologically and emotionally, suggesting that the current preoccupation of the patient safety movement with adverse drug events and surgical mishaps could overlook other patient priorities.&quot;</td>
</tr>
<tr>
<td>Makeham M, Dovey S, County Mm, and Kidd M. An International Taxonomy for errors in General Practice. <em>MJA</em> 2002; 177:68-72.</td>
<td>To create an international taxonomy of errors occurring in general practices.</td>
<td>Errors: &quot;Events in your practice that make you conclude: , that was a threat to patient well-being and should not happen. I don't want it to happen again.&quot; Study population included general practitioners (GPs) in Australia, Canada, The Netherlands, New Zealand, the United Kingdom, and the United States. Sample comprised 23 GPs in Australia, and roughly 8-20 GPs in other countries. Study participants submitted anonymous error reports between June and December 2001 (depending on location). Taxonomy used: The authors began with Dovey et al 2002 and then refined it to include all internationally reported errors. Measurement of error: The distribution of reported errors.</td>
<td>A total of 17 Australian doctors submitted 134 error reports and 63 doctors from the other countries submitted 301 reports. The authors classified the errors in a manner similar to Dovey et al (2002). Errors were categorized as process errors or knowledge and skills errors and then organized into relevant subcategories. The nature of reported errors across</td>
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| LINNAEUS Collaboration Taxonomy. | | | Breakdown between small and large practices not specified. | errors into established categories. | countries was similar, which implies that doctors are facing similar patient safety challenges. Overall comparisons between Australia and the rest of the countries was as follows:  
- Process errors (79% vs. 79%) and  
- Knowledge and skills errors (21% vs. 21%). Comparisons of Australian reports versus other international reports for process error subcategories were as follows:  
  - Office administration error: (20% vs. 19);  
  - Investigation error: (13% vs. 19%);  
  - Treatment errors: (29% vs. 24%);  
  - Communication errors: (15% vs. 14%);  
  - Payment errors: (1% vs. 1%); and  
  - Workforce management errors (2% vs. 3%). Australian and international comparisons for knowledge and skills errors subcategories were as follows:  
  - Errors in execution of clinical task (5% vs. 2%);  
  - Errors in diagnosis (14% vs. 12%); and  
  - Wrong treatment decision with right diagnosis (2% vs. 6%). Patient harm was also indicated in a portion of error reports (32% in Australian reports and 31% of error reports from other countries). Of these reports, 9% were “very serious” or... |
# I. General Research on Ambulatory Patient Safety

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<tr>
<td>Makeham M, Kidd M, Saltman DC et al.</td>
<td>Consider the nature of errors reported anonymously by general practitioners.</td>
<td>Error: &quot;Errors are events in your practice that make you conclude: that was a threat to patient well-being and should not happen. I don’t want it to happen again,&quot;</td>
<td>Breakdown between small and large practices not specified. Study population included 320 General Practitioners (GPs) with offices in New South Wales, Australia (including rural, remote and metropolitan areas). Sample consisted of 84 GPs who were randomly selected and agreed to participate in the study.</td>
<td>Researchers reviewed anonymously submitted error reports as well as the &quot;the number of items billed that related to a patient encounter and the number of individual patients that were seen during the study&quot; to calculate the number and incidence of medical errors. Data included the incidents of reported errors submitted from October 2003 until September 2004. Taxonomy used: N/A Measurement of error: &quot;Total number of error reports and incidence of reported errors per Medicare patient encounter item and per patient seen per year.&quot; Reports within each grouping were matched with &quot;the group's average number of Medicare items and average number of patients seen, and assigned a sampling weight to adjust for the larger representation ... in the sample design.&quot;</td>
<td>Participating practitioners “submitted 418 error reports, claimed 490,864 patient encounter items, and saw 166,569 individual patients over 12 months.” The incidence of reported errors per patient encounter item per year was 0.078%. The incidence of reported errors per patient seen per year was 0.240%. The authors concluded that under an anonymous reporting system, providers reported about one error for every 1,000 patient encounters billed and roughly two errors for each 1,000 patients seen.</td>
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### Study 1: Learning from Errors in Ambulatory Pediatrics

**Objective:** To identify types and range of errors and identify errors that can be generalized across practices.

**Guiding Definition:** The failure of a planned action to be completed as intended or the use of a wrong plan to achieve the aim (IOM definition). Classification into medical domains developed for the study.

**Setting/Sample:** 14 pediatric practices; 5 practices piloted in March 2003; 14 sites reported from June-Sept 2003

**Study Design:** Self-reporting of errors by physicians within the practice. (Most errors were discovered by physicians (52%), nurses (13%), and parents (15%), but reporting was done by a physician.)

Review by 3 experts to code reports, reconciliation of differences in coding.

Results from the pilot and final data period were combined. However, after the pilot, physicians were instructed not to report "minor, non-substantive errors;" "trivial errors" were eliminated during the analysis.

The Critical Incident technique was used in the analysis.

**Results:** 136 reports with 147 errors (some reports had multiple errors).

Error categories and frequency:
- 38% treatment: medications, procedures, appointment follow-up and consultation, and "other treatment;"
- 22% administrative: chart, billing, or "other clinical administration" related;
- 15% preventive (immunizations and screenings);
- 13% diagnostic; appropriate ordering and interpretation of tests;
- 8% communication to patient;
- 3% patient identification;
- 1% falls; and
- 1% equipment.

Within treatment errors 84% were related to medications, and ordering or failure to order were the source of most (85%) of the medication errors. Transcription errors accounted for 1% of medication errors. Problems with communication contributed to 67% of all errors.

### Study 2: Developing a Taxonomy for Coding Ambulatory Medical Errors: A Report from the ASIPS Collaborative

**Objective:** To assess the utility of the Dimensions of Medical Outcomes taxonomy created for the ASIPS collaborative and Reportable Event: “any event you don’t wish to have happen again, that might represent a threat to patient safety.”

**Guiding Definition:**

**Setting/Sample:** 34 primary care practices participating in the ASIPS Patient Safety Reporting System collectively submitted a total of 965 error reports.

**Study Design:** The authors used 357 error reports to inform the adaption of the Dimensions of Medical Outcomes taxonomy. The authors then used 608 error reports to test the adapted version.

**Results:** The authors used 4 of the 5 DMO domains, including: Outcome, Course of the Event, Participants, and The Observation.

Three constructs were used for analysis, including "individual code, hierarchical construct (care process level analysis) and derived construct..."
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<tr>
<td>Advances in Patient Safety: From Research to Implementation Vol. 2. Concepts and Methodology. AHRQ Publication No. 05-0021-1. Rockville, MD: AHRQ, 2005.</td>
<td>its ability to show how such errors relate to patient harm.</td>
<td>Statistical analyses were used to assess the taxonomy’s ability to capture error events and “their relationship to harm.”</td>
<td>49,000 primary care malpractice claims involving primary care practitioners from 1985-2000</td>
<td>(clinical activity level analysis) groupings.”</td>
<td>Four codes were found to be related to harm, including:</td>
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<td>Taxonomy used: Dimensions of a Medical Outcome (DMO) (adapted)</td>
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<td></td>
<td>• &quot;Therapeutic intent;</td>
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<td>Measurement of error: Distribution of reported errors into categories.</td>
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<td></td>
<td>• Language barrier;</td>
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<td></td>
<td>• Judgment;</td>
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<td></td>
<td></td>
<td></td>
<td>• No system exists.</td>
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<tr>
<td>Phillips, RL, Bartholomew LA, Dovey SM. Learning from</td>
<td>To understand the major cause of adverse events</td>
<td>Ten hierarchical constructs were associated with harm, including:</td>
<td>26,126 claims were peer reviewed and classified according to condition, setting, and cause.</td>
<td></td>
<td>Eight derived constructs were also associated with harm, including:</td>
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<td>&quot;discrete event, recurring event, correct drug with wrong frequency/route/dose, disclosure/explanation of need for test/treatment or exam, mistimed procedure, chart documentation, drug error, communication from another office, patient care outside of office and distraction.”</td>
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<td>• &quot;Communication to patient;</td>
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<td>Eight derived constructs were also associated with harm, including:</td>
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<td>• Clinical data;</td>
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<td>• Error in diagnosis;</td>
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<td>• Examination process errors;</td>
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<td>• Referral process errors;</td>
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<td>• Delay in therapy (medical/surgical or drug);</td>
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<td>• Error in knowledge/skill/judgment;</td>
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<td>• Error in knowledge/skill/judgment; and</td>
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<td>• Provider of record.</td>
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<td>• Provider of record.”</td>
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68 percent of negligent claims involved ambulatory settings. 23% of peer-reviewed claims (5,921) judged to involve
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<tr>
<td>Malpractice Claims about Negligent, Adverse Events in Primary Care in the United States. Quality and Safety in Healthcare. 2004; 13:121-126.</td>
<td>associated with primary care: where they occurred, conditions they affected, and causes</td>
<td>were judged to be negligent 2000. Note: claims involved inpatient and ambulatory settings.</td>
<td>Rates of negligent events by condition were compared to outpatient visits for the condition. Note: claims involved inpatient and ambulatory settings.</td>
<td>Taxonomy used: 19 categories for underlying cause of malpractice claims (Physician Insurance Association of America/PIAA). Measurement of error: Distribution of negligent claims by condition, diagnosis, severity, cause</td>
<td>68% of claims from outpatient settings. Outcome severity included 2,148 deaths; 1,124 severe injuries; 1,542 moderate injuries; 1,107 injuries with low severity. Ambulatory claims involving negligence, were less likely to be severe (17.6% ambulatory vs. 22.7% inpatient) or cause death, 30.6% outpatient, 48.6% inpatient). Most common causes for negligent claims: 2003 diagnostic errors; 972 failure to supervise or monitor; 898 improper performance; and 489 medication errors.</td>
</tr>
<tr>
<td>Phillips R, Dovey L, Graham D, Elder N, Hickner J. Learning from Difference Lenses: Reports of Medical Errors in Primary Care by Clinicians, Staff, and Patients. Patient Safety. 2006; 2:140-146.</td>
<td>To test whether family doctors, staff and patients will report medical errors and investigate differences in reports.</td>
<td>Reporting Errors: things that happen in your practice “that should not have happened and that you don’t want to happen again.” Ten Family Medicine Clinics; 5 private practices, 5 family medicine residency clinics. Mix of urban, suburban, and rural settings.</td>
<td>Self-reporting of errors by patients, physicians, residents and other clinicians, and office staff. Reporting via web-based AAFP error reporting system, mailed paper forms or (for patients) telephone.</td>
<td>“Routine” reports focused on “errors with the potential to cause harm or that did cause harm” were submitted for 10 negligence; 2,751 involved general internists; 2,600 FP/GP, and 571 pediatricians). A total of 717 error reports about 935 errors were received; an average of 1.9 reports were submitted by each potential reporter (excluding patients). One-third of the routine reports and 52% of the intensive reports came from one site (which had only 6.5% of the potential reporters). Patients submitted only 18 reports of errors. The top categories of errors related to: Chart completeness/availability: 19%; Medications: 14%;</td>
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<tr>
<td>Plews-Ogan M, Nadkarni M, Forhren S, et al. Patient Safety in the Ambulatory Setting: A</td>
<td>To investigate the impact of the implementation of a voluntary reporting system (indirectly), consider the near miss/adverse event: “Any event in a patient's medical care which did not go as intended and</td>
<td>The study focused on a single large (12 faculty physicians and 88 residents) academic ambulatory care practice for internal medicine which</td>
<td>A patient safety committee was established to continually review reported errors. Submitted reports were reviewed to: categorize the error, identify the root cause</td>
<td>In a one-year period, 100 voluntary error reports were submitted, including 83 near misses and 17 adverse events. Documented process errors included:</td>
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<td>• Appointments: 12%; • Filing system: 9%; • Laboratory: 9%; and • Communication with patients: 7%;</td>
<td>Clinicians were more likely to report medication and laboratory errors; clinic staff were more likely to report appointment and patient communication errors. For 706 reports consequences were reported – 701 reports reported the seriousness of the error – 6% were rated as extremely serious, 13% very serious, 28% serious, 26% somewhat serious, and 20% not very serious.</td>
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Weeks. On five selected days “intensive” reporting of “all errors” was requested. Patients were asked to report only on the “intensive reporting” days. Demographic and practice data and assessment of the seriousness of the errors were recorded using structured responses. Description of the error, potential consequences, result, contributing factors, and what could have prevented the error were reported in free text.

Data included error reports by patients, physicians, residents and other clinicians, and office staff.

Taxonomy used: AAFP/Linnaeus Taxonomy, March 2005 Version (modified).

Measurement of error: Distribution of practice errors by type, consequence, and severity.
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<tr>
<td>Clinician-based Approach. <em>J Gen Intern Med.</em> 2004; 19:719-725.</td>
<td>nature of errors in ambulatory care.</td>
<td>either harmed or could have harmed the patient.&quot;</td>
<td>received 25,000 annual patient visits.</td>
<td>and contributing factors, and develop interventions to address the problem.</td>
<td>processes (47%); X-rays or laboratory work (22%); Office administration (21%); and Communication (10%). 72 interventions were designed to address reported errors, of which 75% were implemented.</td>
</tr>
<tr>
<td>Rosser W, Dovey S, Bordman R, White D, Crighton E, and Drummond N. <em>Medical Errors in Primary Care: Results of an International Study of Family Practice. Canadian Family Physician.</em> 2005; 51:387-392.</td>
<td>To assess the errors identified and reported anonymously by Canadian family physicians in comparison with errors reported by physicians in 5 other countries.</td>
<td>Error: “Events in your practice that made you conclude, ‘That was a threat to patient well-being and should not have happened. I don’t want it to happen again. …’”</td>
<td>Breakdown between small and large practices not specified.</td>
<td>Descriptive study of preventable errors. Researchers analyzed and classified anonymously-submitted error reports. A total of 508 errors were reported during the study period, including 95 from physicians in Canada. The types of errors reported by the Canadian physicians mirror the types of errors reported from international providers. Comparisons of Canadian reports versus other international reports are as follows: Office processes error (29% vs. 39%); Treatment error (e.g., medication error) (26% vs. 24%); External investigations (e.g., lab tests) (18% vs. 16%); Clinical knowledge (13% vs. 22%); Work force management</td>
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<td>Absence of denominator information prevented true error rate calculation, which ultimately prohibited statistical comparisons among countries.</td>
<td>(3% vs. 2%); and Financial accounting (2% vs. 1%). Contributing factors were similar for both groups and included (in order of importance) process, provider, environment, and patient factor.</td>
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| West D, Pace W, Dickinson M, Harris D, Main D, Westfall J, Fernald D, Staton E. | Relationship Between Patient Harm and Reported Medical Errors in Primary Care: A Report from the ASIPs Collaborative. | Not specified      | Error reports submitted to the ASIPS Reporting System by 500+ clinicians and staff from the Colorado Research Network and the High Plains Research Network. | Error reports were classified based on the type of errors as well as the level of harm. Frequency distributions were calculated. Error and harm associations were tested using statistical methods. | The authors analyzed 608 reported errors and found that 39 reports involved patient discomfort/inconvenience, 55 reports involved "increased risk to the patient or others," and 62 reports involved clinical patient harm. The errors most associated with harm include:  
  - "Prescription drug errors;"  
  - "Coordination of care errors;"  
  - "Errors in clinical activities;" and  
  - "Errors related to cognition." |

Error reports were classified using Dimensions of Medical Errors (DMO) Taxonomy (2003).

Harm was categorized according to five categories:
- "Unknown or no known harm;"
- Unstable or too early to tell if harm has occurred;
- Patient discomfort or inconvenience;
- Increased risk to patient or others; and
- Known clinical harm to the patient.

namely "prescriptions, communication, appointments, equipment, and clinical errors."

Measurement of error: Distribution of reported errors into established categories: statistical calculation of frequency of errors and error rates per 1000 appointments.
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<td>Woods D, Thomas E, Holl J et al. Ambulatory Care Adverse Events and Preventable Adverse Events Leading to a Hospital Admission. <em>Qual Saf HealthCare</em>. 2007; 16:127-131.</td>
<td>To identify and quantify the extent of ambulatory care adverse events (AAEs) and ambulatory care preventable adverse events (APAEs) and ultimately the number of hospitalizations that are due to such events occurring in ambulatory care settings.</td>
<td>Adverse Event: “An injury caused by medical management (rather than the disease process) that led to a hospitalization.” Preventable Adverse Event: “An injury caused by medical management (rather than the disease process) that led to hospitalization, where there was enough information currently available to have avoided the event using currently accepted practices.”</td>
<td>The authors drew upon a representative sample of 14,700 hospital discharge records from Utah and Colorado which were collected in 1992 and used in the Thomas EJ, Studdert DM, Burstin HR et al (2000) study.</td>
<td>Physician reviewers supported by nurse reviewers assessed the data to determine which records contained adverse events and if the event was preventable.</td>
<td>The authors identified 587 adverse events, including 70 ambulatory care adverse events (AAEs) and 31 ambulatory care preventable adverse events (APAEs). Weighted to the general population in Utah and Colorado in 1992, the authors estimate that 2,608 AAEs and 1,296 APAEs occurred in the state and resulted in 75,000 hospitalizations. Most AAEs and APAEs occurred in the physician office (n=972/37.3% and n=559/43.1% respectively). “The majority of AAEs were medication events (31.7%), surgical events (28.3%), or diagnostic adverse events (17.9%).” Incidents of APAEs stemmed from “diagnostics (36%), surgery (24.1%), non-surgical procedures (14%), medication (13.1%) and therapeutic events (12.3%).” Diagnostic adverse events caused the greatest harm in AAEs and surgery and diagnostics caused the greatest harm in APAEs. The Primary Care Services were most frequently involved in APAEs (31.4%) followed by Medical Specialty (21.8%),</td>
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| Woolf SH, Kuzel AJ, Dovey SM et al. | To consider the value of cascade analysis in classifying ambulatory medical errors and the sensitivity of physician reports on the patient consequences of errors. | The authors “defined the overall story of what went wrong as an incident, and the individual mistakes within the incident as errors. An incident involving multiple errors was designated as a cascade if one error led causally to another.” | Study population included 73 physicians in six countries who participated in the LINNEAUS Primary Care International Study of Medical Errors (PCISME) Study and submitted 431 anonymous error reports from 6/2001-12/2001. Sample consisted of 75 anonymous error reports submitted by 18 U.S. physicians | Authors analyzed error reports to identify proximal errors and consider whether a chain of events took place. Data included voluntary error reports submitted by physicians. **Taxonomy used:** The authors classified errors into 5 domains, including diagnosis, informational communication, personal communication, treatment, and other. **Measurement of error:** Distribution of errors into established categories. | 77% of reported incidents included a chain of errors. The majority of error chains (80%) began with communication breakdowns or miscommunication. The authors classified harms as:  
- “Physical injuries (physical health complications from errors during the reporting period);  
- Errors that had no reported immediate effect but that heightened the patient’s risk for complications after the reporting period…; and  
- Psychological or emotional injuries.” | Surgical Specialty (22.6%), Emergency Medicine (18.5%), Radiology (13%) and Paediatrics (1%) |
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<tr>
<td>Abookire SA, Teich JM, Sandige H, et al. Improving Allergy Alerting in a Computerized Physician Order Entry System. Proc AMIA Symp; 2000: 2-6</td>
<td>To test the feasibility of locally developed, institutionally based software oversight processes.</td>
<td>“Drag” is the impact of all of the alerts of one given medication on the overall compliance figure. Drag is calculated by taking the weighted number of alerts (# of alerts for this drug in the year, divided by # of all alerts for the year), and multiplied that by the average compliance rate of that drug minus 50%.</td>
<td>The study focused on The Brigham and Women’s Hospital’s (BWH) physician order entry system called The Brigham Integrated Computing System (BICS). All orders that were changed due to an active suggestion by the computer were analyzed.</td>
<td>Approximately 400 of 14,000 orders that were changed as a result of active suggestions by the computer were analyzed over a five-year period to determine trends of allergy alerting and user response to allergy alerts.</td>
<td>The study showed a continual increase in the number of allergy alerts over time along with a steady decline in compliance to these alerts. Compliance for definite alerts decreased from 51% to 27% and from 46% to 20% for possible alerts. Alerts that triggered the narcotics/phenanthrene (the morphine - codeine group) allergy table accounted for 33% of all alerts. The proportion of total alerts represented by this group grew over time. The volume of ordered Lasix (and therefore Lasix alerts) rose over time. The override behavior climbed steadily and compliance to this alert dropped from 20% to 10%. 65% of all allergy alerts were on the same patient for the same drug/allergy alert (&quot;re-orders&quot;). Of these, the percent</td>
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<tr>
<td>Budnitz DS, Pollock DA, Weidenbach KN, Mendelsohn AB, Schroeder TJ, Annest JL. National Surveillance of Emergency Department Visits for Outpatient Adverse Drug Events. JAMA. 2006; 296:1858-1866.</td>
<td>To describe the frequency and characteristics of adverse drug events that lead to Emergency Department visits in the US.</td>
<td>Adverse events include allergic reactions (immunologically mediated), adverse effects (undesirable pharmacologic or idiosyncratic effects at recommended doses), unintentional overdoses, or secondary effect (e.g., falling, choking). For this study adverse drug event was defined as an incident ED visit for a condition that the treating physician explicitly attributed to the use of a drug or a drug-specific effect.</td>
<td>Surveillance from January 2004 to December 2005 through the National Electronic Injury Surveillance System-Cooperative Adverse Drug Event Surveillance Project. Sixty-three (63) participating hospital EDs.</td>
<td>Coders reviewed physician diagnoses recorded in the clinical chart to determine if it was an ADE case. From there the coders transcribed physician diagnoses, reason for visit, diagnostic tests, therapies administered, and the name, dose, route, frequency, and duration for up to two drugs associated with the ADE.</td>
<td>Adverse drug events accounted for 2.5% of all unintentional injuries and 6.7% of those leading to hospitalization and accounted for 0.6% of estimated ED visits for all causes. Individuals &gt;/= 65 were more likely to sustain ADEs (4.9 vs. 2.0 per 1000) and more likely to require hospitalization (1.6 vs. 0.23 per 1000). Drugs for which regular outpatient monitoring is used to prevent acute toxicity accounted for 41.5% of estimated hospitalizations overall, and 54.4% of estimated hospitalizations for patient &gt;= 65 years.</td>
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<td>Devine E, Hansen R, Wilson-Norton J, et al. The Impact of Computerized Provider Order Entry on Medication Errors in a Multispecialty Group Practice. <em>J Am Med Inform Assoc.</em> 2010; 17: 78-84</td>
<td>To evaluate the effect of a basic, ambulatory CPOE system on medication errors and associated ADEs.</td>
<td>A list of error types created: inappropriate abbreviations; missing information; illegibility; wrong-directions, strength, drug, dose, dosage form, patient, physician, or route; allergy; drug–drug interaction; drug–disease interaction; therapeutic duplication; contraindication in patients ≥65 years of age; and lack of appropriate laboratory monitoring.</td>
<td>Quasi-experimental, pretest–post-test study was conducted in a community-based, multispecialty health system not affiliated with an academic medical center. The intervention was a basic CPOE system with limited clinical decision support capabilities.</td>
<td>The CPOE system was implemented at Clinic/pharmacy site A in July 2003. At this site, preimplementation prescriptions were written between March 1 and July 15, 2002; postimplementation prescriptions were e-prescribed between January 14 and July 13, 2004. At clinic sites B, C, and all others, the CPOE system was implemented in July 2004. These sites are served by pharmacies B and C. At these sites, preimplementation prescriptions were written between January 2 and March 4, 2004; postimplementation prescriptions were e-prescribed between July 1, 2005 and April 26, 2006.</td>
<td>The frequency of errors declined from 18.2% to 8.2% with use of the CPOE system, an unadjusted reduction of 55%. The greatest reduction in odds occurred with illegibility (97%), followed by inappropriate abbreviations (94%) and information missing (85%) errors. E-prescribing was associated with a significant, 57% reduction in the odds of an error occurring that did not cause harm, potential ADEs. Errors, which by definition did not reach the patient, decreased from 445 to 84 (8.9% to 1.6%). Prescriptions for patients ≥65 (vs &lt;65) years were more likely to be associated with an error, whereas those written for antibiotics were less likely to be associated with an error than other classes</td>
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<tr>
<td>Field TS, Gurwitz JH, Harrold LR, et al. Risk Factors for Adverse Drug Events among Older Adults in the Ambulatory Setting. <em>J Am Geriatr Soc</em> 52: 1349-1354, 2004.</td>
<td>Assess patient-level risk factors for ADEs.</td>
<td>ADEs = injuries resulting from the use of drugs.</td>
<td>All Medicare enrollees cared for by a multispecialty group practice 1999-2000 with possible drug-related incidents detected. 1,299 older adults had identified ADEs.</td>
<td>Nested case control study. Patient-level factors: age, sex, co-morbidities, medication use at the time of the event extracted from medical records.</td>
<td>Subjects with an ADE significantly more likely to be older, have higher Charleston Comorbidity Index, take more medications, and be taking identified classes of medications.</td>
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<tr>
<td>Forster AJ, Murphy HJ, Peterson JF, et al. Adverse Drug Events Occurring Following Hospital Discharge. <em>J Gen</em></td>
<td>Assess incidence, type, and severity of ADEs post-discharge.</td>
<td>ADE = any adverse outcome or patient injury caused by medication use. Preventable ADE =</td>
<td>Urban academic medical center. 581 consecutive patients discharged to home from general</td>
<td>Prospective cohort study, secondary analysis of a previously published study. Chart summary at discharge.</td>
<td>1 ADE/100 prescriptions 11 percent of patients developed an ADE • 27 percent preventable. • Less likely if patient recalled having side effects explained.</td>
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<td><em>Intern Med</em> 20:317-323, 2005.</td>
<td>Understand the causes of medication errors</td>
<td>Error defined as: Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer (per the National Coordinating Council on Patient Safety). Errors classified as prescription, delivery, availability, patient, or reporting error.</td>
<td>Patients who had received at level, kidney, or pancreas transplant at Yale medical Center, and who had an ambulatory encounter at Yale post-op from April 1, 2004, to March 31, 2005.</td>
<td>Outreach telephone call 24 days post-discharge (new or worsening symptoms).</td>
<td>Risk highest corticosteroids, anticoagulants, antibiotics, analgesics, and cardiovascular medications.</td>
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<tr>
<td>Friedman A, Geoghegan S, Sowers N, et al. Medication Errors in the Outpatient Setting. <em>Archives of Surgery</em>. 142, (278-283).</td>
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<td>Despite the fact that patients received specific education about the medications and had to demonstrate competence in taking them before discharge. Patient errors were the most common (56%); 26% were prescription errors, 13% delivery errors. The root cause was found to be the patient in 68%, care providers 27%, financial issues 5%, pharmacy 10%. Thirty-two percent of errors led to an adverse event.</td>
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</table>
- “Almost all” offices confirmed drug allergy status before prescribing.  
- 18% provide written information about prescribed drugs.  
- 90% have access to drug information resources in a location outside of the exam room.  
- 88% have a system in place for reporting errors.  
- 45% distribute information to prescribers and nurses about error prone situations in the office. |
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<tr>
<td>Gandhi TK, Burstin HR, Cook EJ, et al. Drug Complications in Outpatients. <em>J Gen Intern Med.</em> 2000; 15:149-154.</td>
<td>Assess incidence and characteristics of outpatient drug complications through chart reviews and patient surveys.</td>
<td>ADE = injuries due to drugs.</td>
<td>Eleven Boston-area ambulatory clinics. Random sample of patients 20-75 years of age with one visit during prior year. Patient outreach letter with opt-out postcard. 500 chart reviews per site. Telephone survey.</td>
<td>Analyze data from chart review and telephone survey. Electronic health records scanned for combinations of variables suggesting an ADE: medication, laboratory result, diagnosis, and symptoms (from notes). Conduct univariate and multivariate analysis of clinical and non-clinical correlates.</td>
<td>Most problems not reported in medical record. 18 percent of patients reporting Rx use reported a complication; chart review detected 3 percent. In univariate analysis, correlates of patient-reported complications were number of medical problems, number of Rx, renal disease, failure to describe side effects, lower Rx compliance, and non-English primary language. Correlates in multivariate analysis: number of problems, renal disease, failure to explain side effects.</td>
</tr>
<tr>
<td>Gandhi T, Seger A, Overhage M, et al. Outpatient Adverse Drug Events Identified by Screening Electronic Health Records. <em>Journal of Patient Safety.</em> 2010; 6:91-96.</td>
<td>Identify ADE rates using an outpatient ADE monitor; describe severity, preventability and types of events; identify high-yield rules for identification and prevention.</td>
<td>ADE = injury due to a medication. Incidents = identified by ADE monitor. Preventable = due to a medication error.</td>
<td>Two health systems with EHRs (Partners and Regenstrief).</td>
<td>Four months of data run against ADE monitor to ID incidents in patients with at least one visit during period. 50 incidents per rule reviewed by clinician to derive predictive value.</td>
<td>1 ADE/7 person years. 15 preventable ADEs/1000 person-years. About one-quarter of ADEs were serious or life threatening. Rules with highest yields were lab (8 percent) and text/symptoms (86 percent).</td>
</tr>
<tr>
<td>Gandhi T, Weingart S, Seger A, et al. Outpatient Prescribing Errors and the Impact of Computerized Prescribing. <em>J Gen Intern Med.</em> 2005;</td>
<td>Assess rates, types, and severity of outpatient prescribing errors and potential impact of computerized prescribing.</td>
<td>Medication error = occurs in medication use process. Called ADE if results in injury.</td>
<td>Four adult primary care practices in Boston – two with computerized prescriptions. All patients receiving Rx during one month,</td>
<td>Prospective cohort study, including prescription review, chart review, and patient survey. Pharmacist review of prescriptions.</td>
<td>7.6 percent of prescriptions contained prescribing error: Dose (54 percent), Frequency (18 percent), Route (13 percent). Routes of prescribing errors and potential ADEs were not significantly different.</td>
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<td>20:837-841.</td>
<td>prescribing.</td>
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<td>capable of study (MD), and did not opt-out (1202).</td>
<td>Compared error and potential ADE rates of computerized vs. non-computerized sites.</td>
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<tr>
<td>Gandhi T, Weingart S, Borus J, et al. Adverse Drug Events in Ambulatory Care. <em>N Engl J Med</em>. 2003; 1556-64.</td>
<td>Determine the rates, types, severity, and preventability of ADEs.</td>
<td>ADEs = injuries due to drugs.</td>
<td>Four adult primary care practices in Boston – two with computerized prescriptions.</td>
<td>Prospective cohort study, including chart review and survey of patients (symptoms of ADEs).</td>
<td>27 ADEs per 100 patients. 13 percent serious. 28 percent ameliorable: • MD failure to respond to symptoms (63 percent). • Patient failure to communicate symptoms (37 percent). 11 percent preventable (20 ADEs). • Inappropriate drug (9). • Wrong dose (2). • Wrong frequency (2). Article lists medication classes most commonly involved.</td>
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<tr>
<td>Gandhi T, Bartel SB, Shulman LN, et al. Medication Safety in the Ambulatory Chemotherapy Setting. <em>Cancer</em>. 2005; 104:2477-2483.</td>
<td>To identify medication error and potential adverse drug event (ADE) rates in the outpatient chemotherapy setting.</td>
<td></td>
<td>Two adult (CPOE) and one pediatric (written orders) outpatient chemotherapy infusion units at one cancer institute. Data were collected between March and December 2000.</td>
<td>Prospective cohort study including chart review and review of orders for patients receiving medication and/or chemotherapy.</td>
<td>10,112 medication orders (8008 adult unit orders and 2104 pediatric unit orders) from 1606 patients (1380 adults and 226 pediatric patients) reviewed: The medication error rate was 3% (306 of 10,112 orders). Of these errors, 82% occurring in adults (203 of 249 orders) had the potential for harm and were potential ADEs, compared with 60% of orders occurring in pediatric patients (34 of 57 orders). Among these, approximately one-third were potentially serious. Pharmacists and nurses intercepted 45% of potential ADEs before they reached the patient.</td>
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| Gurwitz J, Field T, Harrold L, et al.  
Classify identified ADEs.  
Severity classified as significant, serious, life-threatening, fatal.  
Stages of pharmaceutical care = prescribing, dispensing, patient adherence, monitoring.  
Preventable if due to an error and preventable by any means available. | ADE rate of 50.1 per 1000 person-years.  
38 percent of ADEs were serious, life-threatening, or fatal; 42 percent rated as preventable.  
Errors related to preventable ADEs most common in prescribing and monitoring stages.  
Most common med categories for preventable ADEs: cardiovascular Rx, diuretics, non-opioid analgesics, hypoglycemics, and anticoagulants. |
Using Computerized Data to Identify Adverse Drug Events in Outpatients. *J Am Med Inform Assoc*. 2001; 8:254-266.          | Use a computer program fed by an EHR and different search methodologies for detecting ADEs. | ADE defined as “an injury resulting from an intervention related to a drug. ADE is “preventable if an error in the medication process could be identified” | From July 1995 to June 1996, all patient visits to 170 primary care physicians at BWH – 88,514 visits | Identify incidents by use of allergy rules, med-lab rules, and text searches.  
Analyze random sample of each set of incidents.  
Evaluate sensitivity and specificity of each search methodology | ADE rate of 5.5 per 100 patients coming for care.  
3.4 resulting admissions per 1,000 patients.  
56 percent of ADEs involved hypertensives, ACE-inhibitors, antibiotics, or diuretics.  
Detailed list of ADEs distributed by medication class and specific medication. |
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<tr>
<td>Hurley JS, Roberts M, Solberg LI, et al.</td>
<td>To evaluate laboratory safety monitoring in patients taking selected chronic prescription drugs.</td>
<td>Absence of a recommended test was defined as a “potential laboratory monitoring error.”</td>
<td>Health Partners Minneapolis, MN, and Lovelace Clinic, Albuquerque, NM. Study population comprised of ongoing users of a chronic condition medication during the period of 1999-2001. The sample size annually was 29,823; 32,423; and 36,811 respectively for the two sites.</td>
<td>Retrospective study using outpatient and pharmacy claims from the two HMOs.</td>
<td>Between 44% and 47.1% of medication users had at least one potential laboratory monitoring error per year. Drugs with the highest percentages of lab monitoring errors include carbamazepine, valproate sodium, lithium, metformin, and digoxin. Study did not document the adverse outcomes related to inadequate monitoring.</td>
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<td>Kaushal R, Kern L, Barron Y, et al.</td>
<td>To assess the impact of a stand-alone e-prescribing system on the rates and types of ambulatory prescribing errors.</td>
<td>Near misses were defined as “potentially harmful errors that were intercepted or reached the patient but did not result in harm.” Adverse drug events (ADEs) were defined as “injuries from a medication, a subset of which were associated with errors and defined as preventable.”</td>
<td>12 adult primary care practices in the predominantly rural and suburban Hudson Valley region of New York from September 2005 to June 2007. 3684 paper-based prescriptions at baseline and 3848 paper-based and electronic prescriptions at one year of follow-up reviewed for prescribing errors through a standardized prescription and chart review.</td>
<td>Prospective study of 30 ambulatory care providers using pre-post design with concurrent controls. Paper prescriptions at baseline and e-prescriptions at one year for 15 e-prescribing adopters and paper prescriptions at baseline and one year for 15 non-adopters were reviewed.</td>
<td>Error rates decreased nearly sevenfold, from 42.5 per 100 prescriptions at baseline to 6.6 per 100 prescriptions one year after adoption. For non-adopters, error rates remained high at 37.3 per 100 prescriptions at baseline and 38.4 per 100 prescriptions at one year. At one year, the error rate for e-prescribing adopters was significantly lower than for non-adopters. Illegibility errors were 87.6 per 100 prescriptions at baseline for e-prescribing adopters and 0 at one year.</td>
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To determine how frequently clinicians prescribe drugs in violation of black box warnings for these issues and to determine how frequently such prescribing results in harm.

Baseline pregnancy testing occur within 1 month before taking a drug.

Testing for baseline hepatic or renal dysfunction occur within 3 months before taking a drug.

For all other laboratory tests, defined baseline laboratory testing as receipt of a given laboratory test within 12 months before the patient started taking a drug.

51 outpatient practices using an electronic health records, including 40 hospital-based clinics, 4 community health centers, and 7 community-based practices.

Observational study of 51 outpatient practices using an electronic health record, to measured the frequency with which patients received prescriptions in violation of black box warnings for drug-drug, drug-laboratory, and/or drug-disease interactions including medical record reviews in a sample of patients to detect adverse drug events.

33,778 (10.4%) received a medication that contained a black box warning pertaining to drug-drug, drug-laboratory, and/or drug-disease interaction.

2,354 (7.0%, or 0.7% of all outpatients) received a prescription in violation of the black box warning. 90.6% of patients who received a prescription with a black box warning were at risk for a drug-disease interaction, followed by a drug-laboratory interaction (26.6%) and a drug-drug interaction (3.3%).

Patients who received drugs with drug-drug and drug-laboratory interaction warnings frequently received the drug in violation of the black box warning (36.2% and 19.4%, respectively).

0.7% of patients who received drugs with drug-disease warnings rarely had contraindicated diseases.


To evaluate ambulatory anticoagulation ADEs and the patient

ADEs were defined as any event where bleeding was noted; pADEs were defined as all other events

167 patients and 169 events were identified from December 1, 2006, to June 30, 2008.

Retrospective chart review. An automated trigger surveillance system identified eligible events in ambulatory patient

A total of 88 events (52.1%) had documented evidence of bleeding or patient harm and were considered ADEs; 81 events (47.9%) did not document patient harm and were
## II. Research on Ambulatory Medication Safety

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<tr>
<td>Adverse Drug Events: A Descriptive Study.</td>
<td>population in which they occur within the Duke University Health System.</td>
<td>where a supratherapeutic INR was corrected but no bleeding was documented.</td>
<td>admissions with an INR &gt;3 and administration of vitamin K. Event and patient characteristics were evaluated, and quality/process improvement strategies for ambulatory anticoagulation management are described.</td>
<td>considered pADEs.</td>
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  - Potential overdoses (110% or more of the MaxRDD or total mg/kg/d dispensed at more than the maximum recommended adult dose  
  - Potential underdose – total mg/kg/d dispensed below 90% of the MinRDD and below the adult minimum recommended dose in total mg/d. | Three HMOs and up to 120 children selected for each drug of interest. The medication was determined to be NEW for that child within the study period. A total of 1,933 children were included in the study. | Drugs selected were the ones most commonly prescribed and those most commonly involved in pediatric error reports to the FDA's Medwatch system. An external panel of advisors added and subtracted from the list. To maximize prescriptions where weight-based dosing would be expected, selected children aged 1 day to 12 years. For drugs not commonly prescribed for younger children, the sample included ages 16 and under. For each index dispensing event, automated pharmacy data was used to calculate the total unit and daily dose. For PRN meds, the study calculated the daily dose as the highest possible amount at the most frequent intervals. | 15% of children were dispensed a medication with a potential dosing error – 8% were potential overdoses and 7% underdoses. Children weighing <35 kg, 67% of doses were dispensed within recommended ranges and more than 1% at twice the recommended max dose. Analgesics (e.g., oxycodone) were the most likely to be potentially overdosed (15%) whereas antiepileptics were most likely underdosed (20%). Medication commonly prescribed PRN were more than 3 times as likely to be potentially overdosed. 20% of dispensing events to children <4 years were associated with potential med errors, compared to 13% for children 4 through 12. Asthma and allergy medications were the most likely to be associated with potential med errors in the youngest age group. |
| Munir P, James S, Meakin S, et al. Adverse Drug | To determine the rate and cost of ADR as defined by Edwards and Anderson (aka the Six months of admissions for patients >16 years to | Physician review of records of admitted patients. | The most common symptom was GI bleeding; the most common drugs were: | | |
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<td>Reactions as Cause of Admission to Hospital: Prospective Analysis of 18,820 Patients.</td>
<td>admissions due to ADRs.</td>
<td>WHO definition); avoidability characterized as:</td>
<td>two large general hospitals in England.</td>
<td></td>
<td>• Low dose aspirin;</td>
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<td></td>
<td></td>
<td>• Definitely avoidable;</td>
<td></td>
<td></td>
<td>• Diuretics;</td>
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<td></td>
<td></td>
<td>• Possibly avoidable;</td>
<td></td>
<td></td>
<td>• Warfarin;</td>
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<td></td>
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<td>• Unavoidable (per Hallas).</td>
<td></td>
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<td>• NSAIDs other than aspirin.</td>
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<td>Payne TH., Nichol WP, Hoey P, et al.</td>
<td>To describe the order checks that were generated by orders entered into CPRS, and to determine how useful these order checks were regarded to be by ordering clinicians.</td>
<td>CPRS orders are defined as requests for services entered into CPRS for transmission to the filling service (such as the pharmacy or laboratory), using quick orders, order sets, or ordering dialog boxes.</td>
<td>50,000 consecutively entered orders analyzed from VA Puget Sound, which consists of 2 medical centers with 512,500 outpatient visits and 10,196 discharges annually. T</td>
<td>Studied characteristics of order checks generated in a sample of consecutively entered orders during a 4 week period in an electronic medical record at VA Puget Sound.</td>
<td>Of the 108 order checks for critical drug interaction, 95 (88%) had override text entered indicating that the ordering practitioner continued with the order despite the order check.</td>
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<td>Sensitivity or specificity of order checks were not studied.</td>
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<td>Of the 105 order checks for allergy-drug interaction, 72 (68.6%) contain text in the Override Reason field.</td>
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To improve clinician acceptance of drug alerts by designing a selective set of clinically significant drug alerts for the ambulatory care setting and minimizing workflow disruptions by designating only critical to high-severity alerts to be interruptive to clinician workflow.

Defined alerts as “interruptive” if they required a user action before the prescription could be completed.

Defined alerts as “noninterruptive” if they did not require a user action before prescription completion.

Clinicians at 31 adult primary care practices affiliated with Brigham and Women's Hospital (BWH) and Massachusetts General Hospital (MGH), two Boston teaching hospitals in the Partners HealthCare System. The sites included nine academic hospital-based clinics, 17 off-site clinics, and five community health centers. The prescribing medical staff included 701 clinicians, composed of 224 attending physicians, 249 resident physicians, 35 nurse practitioners, and 193 ancillary staff including nurses and medical assistants.

Data were electronically collected each time a clinician entered a prescription that triggered an alert during the six-month period between August 5, 2004, and January 5, 2005.

A file was created for each drug alert that included the patient's name, medical record number, clinician user's name and practice location, name of medication that generated the alert, date, alert type, severity level, and clinician action including override reasons when applicable.

Duplicate Drug Class: Override reasons included the patient was “transitioning from one drug to the other” (42%), the patient was “on long-term therapy with combination” (21%), the patient was being placed on combination for a short-term or as-needed basis only (7%), the drug was ordered as per “advice from a consultant” (5%), or as per “MD orders” (2%), and “new evidence” exists for use (2%).

Drug-Drug Interactions: Of the 1,078 interruptive drug-drug interaction alerts, 13 required the clinician to either cancel the order or discontinue the previous medication. Override reasons included the clinician would monitor the patient (49%), the patient had previously tolerated the medication (21%), the clinician would “adjust dose as recommended” (14%), and “no reasonable alternatives” (4%).

Drug Lab: Of the overridden alerts, there were 37 (67%) in which the clinician stated he or she would “monitor/manage as recommended” and the appropriate laboratory test was performed in 28 (76%). Another 10 alerts (18%) were overridden with the clinician stating there was a “more recent lab result available” (likely performed at outside facilities and not available in the LMR), and six alerts (11%) generated based on renal function were overridden with the clinician stating the patient was on dialysis.

Drug-Disease: Reasons for alert overrides were the patient had “tolerated the medication in the past” (56%), and there was “new evidence” for use of the medication (22%), “advice from a consultant” (11%), and “no reasonable alternatives” (11%).

Drug Pregnancy: Override reasons included “patient is not pregnant” (93%), “advice from a consultant” (1%), “no reasonable alternative” (1%), patient has “tolerated” in past (1%), and
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<tr>
<td>Solberg LI, Hurley JS, Roberts MH, et al. Measuring Patient Safety in Ambulatory Care: Potential for Identifying Medical Group Drug-Drug Interaction Rates Using Claims Data. <em>Am J Manag Care.</em> 2004; 10:753-759.</td>
<td>To evaluate the feasibility of using health plan administrative data to measure potential drug-drug interaction (DDI) rates in the ambulatory setting and to assess the potential use of DDI rates in performance measurement, quality improvement, and research in patient safety.</td>
<td>DDI is “2 or more drugs interacting in such a manner that the effectiveness or toxicity of 1 or more drugs is altered. The study used three key references to identify DDIs:  - Hansten and Horn’s Drug Interactions, Analysis and Management;  - The DRUG-REAX system of Micromedex; and  - Evaluations of Drug Interactions (EDI). Required that each DDI combination be identified as a problem in at least 2 of the 3 references and have a clinical significance rating of 1, 2, or 3.</td>
<td>The HMOs participating in this four-year study were HealthPartners and LoveLace Health Plan; selected HMO members who were 19 years or older, had continuous membership with pharmacy benefits during the study, and had affiliation with an eligible medical group. 44 combinations of drugs were selected (a base drug and a conflicting drug or drugs) known to have potential adverse interactions and in which the base drug is taken chronically by large numbers of people.</td>
<td>The study used claims data to identify patients with the drug combinations (prescribed simultaneously) and then divided the 44 medication combinations into those with moderate/severe significance and mild significance. Calculated yearly rates of potential DDIs for all members, overall base-medication users, and individual medical groups responsible for their care.</td>
<td>During the four-year study, one or more unique potential DDIs occurred in 6.2% to 6.7% of base-drug users, and 2.0% to 2.3% of all health plan members per year. The drug classes with the highest rates of potential DDIs were cardiovascular (13.3%) and hemalogic (9.2%). Using claims data indicates that the drugs were purchased but may not have been taken so this data source had no information on the impact of the DDIs.</td>
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<td>Thomsen, Linda Aargaard, et al. Systematic Review of the Incidence and Characteristics of Preventable Adverse Drug Events in Ambulatory Care. <em>The Annals of Pharmacotherapy</em>, 2007.</td>
<td>To estimate the incidence of pADEs in ambulatory care and describe their characteristics, defined by type of clinical outcome, type of medication error causing pADEs, and drug categories most frequently associated with these pADEs.</td>
<td>An adverse event is an injury resulting from a medical intervention, with an adverse drug event being the result of drug therapy. A pADE is an ADE attributable to a medication error. An error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve the aim. Medication errors include errors of omission (failing to take action) and commission (taking the wrong action).</td>
<td>This was a literature search of pADE studies in the ambulatory setting using PubMed (1966-March 2007), International Pharmaceutical Abstracts (1970-December 2006), the Cochrane database of systematic reviews (1993-March 2007), EMBASE (1980-Feb 2007), and Web of Science (1945-March 2007). Twenty-nine studies were included in this research.</td>
<td>A data extraction form was used to record the following information – country and year, study design, methods used to ID ADEs and pADEs, sample size, follow-up time, proportion of persons with ADEs and pADEs, proportion of ADEs and pADEs requiring hospitalization, frequency distribution of type of adverse outcome, and drug groups associated with the type of medication error that caused the event.</td>
<td>Overall, drugs associated with ADEs have not changed much over time and include drugs with large prescribing prevalence (e.g., cardiovascular agents and analgesics) and those with a narrow therapeutic range (e.g., hypoglycemic agents, digoxin). Cardiovascular drugs were the most frequently associated with ADEs, pADEs, and pADEs that required hospital admission (46.6%), followed by CNS-active drugs (14.9%), and respiratory drugs (12.2%). Drugs most frequently associated with ADEs were cardiovascular agents (33.3%), oral contraceptives, (22.5%), and central nervous system-active drugs (10.1%). Largest proportion of errors originated in the prescribing stage (64.7% of all pADEs and 56% of pADEs requiring hospitalization). Drug therapy problems most frequently associated with pADEs were use of inappropriate drugs, ignoring clinical or lab results, and inadequate monitoring. Therapy problems for ADEs requiring hospitalization were inadequate monitoring, patient non-adherence, and dosing/frequency errors.</td>
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Zhan C, Arispe I, Kelly E, et al. Ambulatory Care Visits for treating Adverse Drug Estimate rate of ADEs by analysis of visit data. | A visit coded as resulting from an ADE on the National Ambulatory Medical Care Surveys | 21,000-37,000 annual physician office visits; 21,000-37,000 hospital ambulatory care visits; 21,000- | Data extracted from the results of the national surveys. | Of the visits for ADEs reported, 75% were to office practices, 20% to EDs, and 6% to hospital ambulatory departments. |
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<td>Events in the United States, 1995-2001. <em>Journal on Quality and Patient Safety</em>. 2005, 31(7):372-378.</td>
<td>(ambulatory and hospital based ambulatory care). Coded using specific e-codes indicating the cause of the visit was an ADE.</td>
<td>34,000 ED visits from years 1995-2001.</td>
<td>Total number of visits for ADEs increased from 2.9 million in 1995 to 4.3 million in 2001.</td>
<td>The class of drug identified as responsible was categorized – antibiotics and hormones topped that list.</td>
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To examine trends in the rate of repeat adverse drug reactions causing hospitalization of older Australians and to identify the most common ADRs and drugs most often implicated in repeat and first-time ADRs.

An ADR was defined as any hospital discharge with an ICD code of E930-E949 ICD 9 code or Y40-Y59 ICD 10 code which were additional codes used to indicate an “external cause” relevant to drug use, grouped into 20 broad categories. The codes included any adverse effect caused by correct drug use, medications or biological substances properly administered in therapeutic or prophylactic dosages, excluding therapeutic failures, intentional and accidental poisoning, and abuse.

All WA residents >= 60 years with a hospital episode due to an ADR in 1980-2003 were included in the study. A total of 800,000 hospital discharges were selected and audited to ensure each patient fit the selection criteria. A total of 47,508 ADR episodes and 37,296 patients were included in the study.

An extract of the WA Hospital Morbidity Data System was used for the study. Statistical analysis was done using SPSS. ADR records were classified by sex, 10-year age groups, and drug category. The frequency and distribution of the most common ADRs and drugs responsible for repeat and first-time ADRs were also examined. If multiple drugs were thought to be responsible, only the primary drug was included.

18.4% patients had repeat ADRs. Repeat ADRs consistently increased from 1980 and reached 30.3% of all ADRs by 2003. The mean time interval declined with each successive repeat ADR.

The most common repeat ADR events in the study were nausea/vomiting (8%), hemorrhage due to anticoagulants (5.5%), drug-induced osteoporosis (4.8%), and poisoning by cardiovascular agents (3.9%).

The drugs most often involved in repeat ADRs were cardiovascular agents (15.6%), antineoplastic drugs (11%), corticoids (10.1%), anticoagulants (8.6%), antirheumatics/NSAIDs (5.1%), and opioids (4.9%).
### III. Research on Ambulatory Diagnostic Errors

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<td>Gandhi T, Kachalia A, Thomas E, et al. Missed and Delayed Diagnoses in the Ambulatory Setting: A Study of Closed Malpractice Claims. <em>Ann Intern Med.</em> 2006; 145: 488-496.</td>
<td>To develop a framework for investigating missed and delayed diagnoses, advance understanding of their causes, and identify opportunities for prevention.</td>
<td>Claims involving missed or delayed diagnoses: “those alleging an error in diagnosis or testing that caused a delay in appropriate treatment or a failure to act or follow-up on results of diagnostic tests.”</td>
<td>“Four malpractice insurance companies based in three regions (Northeastern, Southwestern, and Western United States) participated in the study.” The companies collectively covered 21,000 physicians, 390 outpatient facilities, and 46 acute care hospitals. The authors randomly-selected 307 diagnosis-related ambulatory claims closed between 1984 and 2004. Only 181 claims were determined to have involved diagnostic incidents that resulted in adverse outcomes.</td>
<td>&quot;Retrospective review of 307 [randomly-selected] closed malpractice claims in which patients alleged a missed or delayed diagnosis in the ambulatory setting.” Physicians reviewed the claims, scored them on consequence severity, and identified contributing factors. Taxonomy used: Six-point Adverse Event Confidence Scale adapted from Thomas et al (2000) and Brennan et al (1991). National Association of Insurance Commissioners Severity Scale by Sowka (1980). Measurement of error: Statistical analyses were used to examine characteristics of the claims, patients, and injuries in our sample and the frequency of the various contributing factors&quot; and to compare the</td>
<td>Diagnoses of cancer were most frequently missed, specifically breast cancer (n=44) and colorectal cancer (n=13), followed by infections (n=9), fractures (n=8), and myocardial infarctions (n=7). The majority of errors took place in the physician’s office and involved primary care providers. The authors found that 59% (n=106) of the claims assessed were associated with serious harm and 30% (n=55) resulted in death.</td>
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<td>Graber M, Franklin N, and Gordon R.</td>
<td>To “determine the relative contribution of system-related and cognitive components to diagnostic error and to develop a comprehensive working taxonomy.”</td>
<td><strong>Diagnostic Error:</strong> a diagnosis that was unintentionally delayed (sufficient information was available earlier), wrong (initial diagnosis incorrect one), or missed (no diagnosis was ever made), as judged from the eventual appreciation of more definitive information.</td>
<td>The study took place over five years at five large academic tertiary care medical centers. The authors reviewed and classified diagnostic error cases which were obtained from three sources: “autopsy discrepancies, quality assurance activities, and voluntary reports.” Data included voluntary reports and provider interviews when possible. Taxonomy used: The authors adapted categories proposed by Chimowitz et al (1990); Kassirer and Kopelman (1989); and Bordage (1999) to create their own working taxonomy of factors that contribute to diagnostic error, including cognitive, no fault, and system factors.</td>
<td>The authors identified 100 cases of diagnostic error. 90 cases involved injury, including 33 deaths. The authors developed a diagnostic error classification system that delineated three categories, namely “no-fault, system-related, and cognitive factors.”</td>
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<td>Holohan T, Colestro J, Grippi J, Converse J, and Hughes M.</td>
<td>To &quot;complement resource-intensive chart reviews and guide patient safety initiatives.&quot;</td>
<td>No definition provided.</td>
<td>Setting/Sample</td>
<td>Medical Review Pans evaluated claims information. A total of 1,949 claims were reviewed. Taxonomy used: National Practitioner Data Bank Negligence Classification System. Authors coded injury severity as &quot;none, minimal, severe or death.&quot; Measurement of error: Distribution of relevant information into established categories.</td>
<td>Review panels found that substandard care was a factor in 723 paid claims (37% of reviewed cases). &quot;Diagnostic negligent adverse events were the most frequent type present in nearly half of all paid VA malpractice claims associated with substandard care.&quot; The majority of diagnostic errors (80%) took place in outpatient settings, mainly in clinics (49%) as opposed to the ED (31%). 55% of cases (n=1,086) involved serious injury, 37% (n=397) involved patient death, and 8% (n=58) involved minor injury. &quot;Diagnostic negligent adverse events were a factor in 49% of all deaths in paid VA malpractice claims associated with substandard care.&quot; &quot;The annual incidence rate of paid malpractice claims associated with diagnosis-related substandard care was 1.95 per 100,000 veterans served.&quot; The four most common preventable adverse events involved errors in diagnosis (45%), treatment (28%), surgery (26%), and medication (16%).</td>
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<td>Phillips, RL, Bartholomew, LA, Dovey SM. Learning from Malpractice Claims about Negligent, Adverse Events in Primary Care in the United States. <em>Quality and Safety in Healthcare</em>. 2004; 13:121-126.</td>
<td>To understand the major cause of adverse events associated with primary care: where they occurred, conditions they affected, and causes</td>
<td>Malpractice claims involving primary care providers that were judged to be negligent</td>
<td>49,000 primary care malpractice claims involving primary care practitioners from 1985-2000</td>
<td>26,126 claims were peer reviewed and classified according to condition, setting, and cause. Rates of negligent events by condition were compared to outpatient visits for the condition. Taxonomy used: Nineteen categories for underlying cause of malpractices claims (Physician Insurance Association of America / PIAA). Measurement of error: Distribution of negligent claims by condition, diagnosis, severity, cause. Rates of negligent claims per office visit by diagnosis.</td>
<td>Among other findings, the study found that 68 percent of negligent claims involved ambulatory settings. Diagnostic errors were one of the most common causes for negligent claims, making up roughly a third of claims. The most common medical diagnoses associated with adverse events were: Acute myocardial infarction 269 (5); Lung cancer 166 (3); Breast cancer 147 (3); Colon cancer 145 (3); Brain damaged infant 115 (2); Appendicitis 95 (2); Meningitis 80 (1); Pulmonary embolism 79 (1); Diabetes 72 (1); and Symptoms involving abdomen and pelvis.</td>
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<td>Diagnostic Error: “...Any mistake or failure in the diagnostic process leading to a misdiagnosis, a missed diagnosis, or a delayed diagnosis.”</td>
<td>Convenience sample of largely hospital-affiliated clinicians. However, the authors assert that the reported errors occurred in various settings, include outpatient care, which they differentiated from emergency department care. The authors surveyed emergency department physicians and internists by mail at two academic medical centers and separately distributed surveys at 20 hospital-based diagnostic error-related grand round presentations. The survey asked participants to report up to three incidents that they observed or were involved in. In addition, participants were asked to provide the correct diagnosis, the erroneous diagnosis, the error that occurred, contributing factors and the frequency of the error. Participants were also asked to rank the patient impact. 310 survey respondents reported 669 cases and 583 errors (36% by mail and 64% at grand round presentations). 14 cases were excluded because they pertained to medication errors or because incomplete information was provided. Taxonomy used: AHRQ Diagnostic Error Evaluation and Research (DEER) Project Taxonomy (Schiff et al, 2005). Measurement of error: Surveys were coded, grouped, and analyzed using SAS.</td>
<td>The majority of survey respondents identified themselves as primary care physicians (47%) or specialists (22%). Most respondents (68%) indicated observing the error(s) reported, although 30% were self-reported errors. Reported errors occurred in various settings, including outpatient care. &quot;Pulmonary embolism and drug reactions (including overdose and poisoning) were the two most commonly missed diagnoses (4.5 each), followed closely by lung cancer.... All types of cancer together constituted the largest disease category.&quot; With regard to patient consequences, participants reported that 29% of errors produced “major” clinical impact, 41% of errors resulted in “moderate” impact; and 22% of errors resulted in “minor” impact.</td>
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<td>Singh H, Thomas E, Khan M, and Petersen L. Identifying Diagnostic Errors in Primary Care Using an Electronic Screening Algorithm. <em>Arch Intern Med.</em> 2007; 167: 302-308.</td>
<td>“To assess the feasibility of computerized screening to identify diagnostic errors in primary care and to categorize diagnostic breakdowns using a recently published taxonomy.”</td>
<td>Diagnostic Error: “Occurrences for which diagnosis was unintentionally delayed (sufficient information was available earlier), wrong (another diagnosis was made before the correct diagnosis), or missed (no diagnosis was ever made), as judged from the eventual appreciation of more definitive information.”</td>
<td>Setting for the study was Michael E. DeBakey Veterans Affairs Medical Center primary care clinic in Houston, TX. The clinic was very large and “consists of a rotating group of 130 internal medicine residents… and 10 rotating staff physicians who supervise them. Of approximately 6,000 patients, 1,200 are assigned to staff for direct care and the remaining are assigned to residents.” The VA uses an electronic medical record system for all of its healthcare delivery, and all appointments are electronically tracked.” Data was collected between 8/1/2004 – 9/30/2005</td>
<td>The authors used an algorithm to screen patient medical records. “A Structured Query Language-based program detected the presence of 1 of 2 mutually-exclusive electronic screening criteria: screen 1, a primary care visit (index visit) followed by a hospitalization in the next 10 days; or screen 2, an index visit followed by 1 or more primary care, urgent care, or emergency department visits within 10 days.” Patient records were pulled that met the criteria outlined above in addition to a control sample of 199 randomly-selected patient visits. Clinician reviewers evaluated the patient electronic health records for the presence of potential diagnostic errors. Taxonomy used: AHRQ Diagnostic Error Evaluation and Research (DEER) Project Taxonomy (Schiff et al, 2005). Measurement of error: Data were analyzed using Excel and SAS.</td>
<td>139 Screen 1 records met the criteria for Screen 1 and 175 met the criteria for Screen 2 and were determined by reviewers to warrant further review. 139 Screen 1 records reviewed and 34 diagnostic errors were confirmed. After excluding planned hospitalizations, “Screen 1 also revealed 12 other clinical management errors, including errors in care such as inappropriate antibiotic use, failure to increase or decrease medication dosages, failure to prescribe a medication, and failure to monitor laboratory values.” 175 Screen 2 records reviewed and 17 diagnostic errors were confirmed, as well as 13 clinical management errors. A review of the control group records found 8 diagnostic errors and 5 clinical management errors. Detailed list of types of diagnostic errors encountered is not provided.</td>
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<td>Woods D, Thomas E, Holl J, et al. Ambulatory Care Adverse Events and Preventable Adverse Events Leading to a Hospital Admission. <em>Qual Saf HealthCare</em>. 2007; 16:127-131.</td>
<td>To identify and quantify the extent of ambulatory care adverse events (AAEs) and ambulatory care preventable adverse events (APAEs) and ultimately the number of hospitalizations that are due to such events occurring in ambulatory care settings.</td>
<td>Adverse Event: “An injury caused by medical management (rather than the disease process) that led to a hospitalization.” Preventable Adverse Event: “An injury caused by medical management (rather than the disease process) that led to hospitalization, where there was enough information currently available to have avoided the event using currently accepted practices.”</td>
<td>The authors drew upon a representative sample of 14,700 hospital discharge records from Utah and Colorado which were collected in 1992 and used in the Thomas EJ, Studdert DM, Burstin HR et al (2000) study.</td>
<td>Physician reviewers supported by nurse reviewers assessed the data to determine which records contained adverse events and if the event was preventable. Identified adverse events were then categorized “into mutually exclusive types depicting the context of medicine, the types of physicians involved, and the location in which the event occurred.” Data included adverse event information extracted from hospital discharge records.</td>
<td>The authors identified 587 adverse events, including 70 ambulatory care adverse events (AAEs) and 31 ambulatory care preventable adverse events (APAEs). Among other findings, the authors identified diagnostic errors as the most common APAE (36%) and the third most common AAE (17.9%). Most AAEs and APAEs occurred in physician offices (n=972/37.3% and n=559/43.1% respectively). Diagnostic adverse events caused the greatest harm in AAEs and surgery and diagnostics caused the greatest harm in APAEs.</td>
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### III. Research on Ambulatory Diagnostic Errors

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<td>Gandhi T, Kachalia A, Thomas E et al. Missed and Delayed Diagnoses in the Ambulatory Setting: A Study of Closed Malpractice Claims. <em>Ann Intern Med.</em> 2006; 145: 488-496.</td>
<td>“To develop a framework for investigating missed and delayed diagnoses, advance understanding of their causes, and identify opportunities for prevention.”</td>
<td>Claims involving missed or delayed diagnoses: “those alleging an error in diagnosis or testing that caused a delay in appropriate treatment or a failure to act or follow-up on results of diagnostic tests.” Error: “The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.”</td>
<td>Four malpractice insurance companies based in three regions (Northeastern, Southwestern and Western United States) participated in the study. The companies collectively covered 21,000 physicians, 390 outpatient facilities and 46 acute care hospitals. The authors randomly-selected 307 diagnosis-related ambulatory claims closed between 1984 and 2004, of which the majority of claims (n=245) were closed in or after 1997. However, only 181 claims were determined to have involved diagnostic incidents that resulted in adverse outcomes.</td>
<td>“Retrospective review of 307 [randomly-selected] closed malpractice claims in which patients alleged a missed or delayed diagnosis in the ambulatory setting.” Physicians reviewed the claims, scored them on consequence severity, and identified contributing factors. Taxonomy used: 6 point Adverse Event Confidence Scale adapted from Thomas et al (2000) and Brennan et al (1991). National Association of Insurance Commissioners Severity Scale by Sowka (1980).</td>
<td>Among other findings, the authors noted that the most common diagnostic process breakdowns were “failure to order an appropriate diagnostic test (n=100), failure to create a proper follow-up plan (n=81), failure to obtain an adequate history or perform an adequate physical examination (n=76), and incorrect interpretation of diagnostic tests (n=67).” “The leading factors that contributed to the errors were failures in judgment (n=143), vigilance or memory (n=106), patient-related factors (n=84), and handoffs (n=36). “Patient-related factors included non-adherence (n=40), atypical clinical presentation (n=28), and complicated medical history (n=18). “The median number of process breakdowns and contributing factors per error was 3.” The authors found that 59% (n=106) of the claims assessed were associated with serious harm and 30% (n=55) resulted in death.</td>
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<td>Kostopoulou O, Oudhoff J, Nath R, et al. Predictors of Diagnostic Accuracy and Safe Management in Difficult Diagnostic Problems in Family Medicine. Med Decis Making. 2008; 28:668-680.</td>
<td>“To investigate the role of information gathering and clinical experience on the diagnosis and management of difficult diagnostic problems in family medicine.”</td>
<td>N/A</td>
<td>84 participating physicians, including 42 family physicians (with 10 or more years experience), 21 family physicians (with 1-3 years of experience), and 21 family medicine residents in Birmingham and Solihull, UK.</td>
<td>Participating physicians were tested on seven diagnostic cases/scenarios. Participants were given patient information and given the option to request additional information</td>
<td>Accuracy rates ran from 25% to 57% based on the scenario and the level of difficulty. Experience was not shown to affect diagnostic accuracy or management. More cues were requested by residents than by family physicians. “Number of critical cues requested (cues diagnostic of any relevant differential diagnoses in a scenario) was a significant predictor of accuracy in 6 scenarios: 1 additional critical cue increased the odds of obtaining the correct diagnosis by between 1.3 and 7.5, depending on the scenario.”</td>
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<td>The survey asked participants to report up to three incidents that they observed or were involved in. In addition, participants were asked to provide the correct diagnosis, the erroneous diagnosis, the error that occurred, contributing factors, and the frequency of the error.</td>
<td>The majority of survey respondents identified themselves as primary care physicians (47%) or specialists (22%). Most respondents (68%) indicated observing the error(s) reported, although 30% were self-reported errors. Reported errors occurred in various settings, include outpatient care. Among other findings, the authors noted that “[i]n terms of identifying a specific process failure that occurred, failure or delay in considering the diagnosis accounted for the largest number of diagnostic failures, followed by failure or delay in ordering needed tests, and erroneous laboratory or radiology reading of tests in almost equal frequency.” Several errors were found to cluster together.</td>
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<td>Schiff, Kim S, Abrams R, et al. Diagnosing Diagnostic Errors: Lessons from A Multi-Institutional Collaborative Project. Advances in Patient Safety: From Research to Implementation Vol. 2. Concepts and Methodology. AHRQ Publication No. 05-0021-1. Rockville, MD: AHRQ, 2005.</td>
<td>To review literature on diagnostic errors and develop a taxonomy that outlines diagnostic process stages, which will enable better understanding of where errors occur.</td>
<td>N/A</td>
<td>N/A</td>
<td>The authors reviewed evidence surrounding diagnostic error occurring in both outpatient and inpatient settings. The authors formed their taxonomy based on review of more than 300 diagnostic error cases.</td>
<td>The authors concluded that the diagnostic process can be construed as a seven-step process: 1. &quot;Access/presentation, 2. History taking/collection; 3. The physical exam; 4. Testing; 5. Assessment; 6. Referral; and 7. Follow-up.&quot; To understand the relationship between diagnostic process errors, the authors &quot;present a model that identifies four key challenges in assessing potential diagnosis error cases: 1. Uncertainties about diagnosis and findings; 2. The relationship between diagnosis failure and adverse outcomes; 3. Challenges in reconstructing clinician assessment of patient and clinician actions; and 4. Global assessment of improvement.&quot; However, the authors did not provide examples to verify their taxonomy.</td>
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<td>The setting for the study was Michael E. DeBakey Veterans Affairs Medical Center primary care clinic in Houston, TX. The clinic was very large and &quot;consists of a rotating group of 130 internal medicine residents… and 10 rotating staff physicians who supervise them. Of approximately 6,000 patients, 1,200 are assigned to staff for direct care and the remaining are assigned to residents.&quot; &quot;The VA uses an electronic medical record system for all of its healthcare delivery, and all appointments are electronically tracked.&quot; Data was collected between 8/1/2004 – 9/30/2005.</td>
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<td>Among other findings, the authors noted that &quot;[t]he most common primary errors in the diagnostic process were failure or delay in eliciting information and misinterpretation or suboptimal weighing of critical pieces of data from the history or physical examination.&quot; &quot;The most common secondary errors were suboptimal weighing or prioritizing of diagnostic probabilities and failure to recognize urgency of illness or its complications.&quot; &quot;Other common primary and secondary errors included failure to order or delay in ordering needed tests or to follow up on test results.&quot;</td>
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### Diagnostic Testing Process Errors

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<td>Hickner J, Graham D, Elder N, et al. Testing Process Errors and Their Harms and Consequences Reported from Family Medicine Practices: A Study of the American Academy of Family Physicians National Research Network. <em>Qual Saf Health Care.</em> 2008; 17: 194-200</td>
<td>&quot;To describe the types, predictors, and outcomes of testing errors reported by family physicians and office staff.&quot;</td>
<td>N/A</td>
<td>The study was based on 8 family practice offices, encompassing 243 physicians and office staff.</td>
<td>The authors reviewed 590 anonymously reported event reports, which documented 966 process errors. Taxonomy used: International Taxonomy of Medical Errors in Primary Care (2005 Version). Measurement of error: Statistical analyses of reported errors.</td>
<td>&quot;Errors occurred in ordering tests (12.9%), implementing tests (17.9%), reporting results to clinicians (24.6%), clinicians responding to results (6.6%), notifying patient of results (6.8%), general administration (17.6%), communication (5.7%), and other categories (7.8%).&quot; Significant associations were noted between error types. &quot;Adverse consequences included time lost and financial consequences (22%), delays in care (24%), pain/suffering (11%), and adverse clinical consequence (2%). Patients were unharmed in 54% of events; 18% resulted in some harm, and harm status was unknown for 28%.&quot; &quot;Using multi-level logistic regression analyses, adverse consequences or harm were more common in events that were clinician reported, involved patients aged 45–64 years of age, and involved test implementation errors. Minority patients were more likely than white, non-Hispanic patients to suffer adverse consequences.&quot;</td>
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Wahls T and Cram P. The Frequency of Missed Test Results and Associated Treatment Delays in a Highly Computerized Health System. BMC Family Practice. 2007; 8:32.

"...[T]o assess the frequency of missed results and resulting treatment delays encountered by primary care providers in Veterans Health Administration clinics."

Participants included 198 primary care providers (126 physicians and 72 mid-level clinicians, such as nurse practitioners and physician assistants) in the VA Midwest Health Care Network, which includes Iowa, Nebraska, North Dakota and South Dakota.

Study involved various settings, including "three large academic medical centers, five smaller community and rural hospitals, and numerous smaller community-based outpatient clinics."

All settings were linked by "a common electronic medical record" system.

The providers surveyed participants through an online instrument which requested feedback regarding the quantity and duration of clinical sessions, the quantity of patients who had "missed abnormal test results," and the quantity and nature of treatment delays that had been encountered within the past two-week period.

106 out of 198 providers completed the survey.

Measurement of error: Statistical analysis of survey data.

Missed test results occurred frequently

"Almost a third of the VA primary care clinicians, practicing in diverse clinical settings, encountered one or more patients with clinically important treatment delays as a result of missed results during the two weeks prior to administration of [the] survey."

64 patients had missed results and 52 patients had treatment delays within the two-week period prior to the study.

"The most common missed results included imaging studies (29%), clinical laboratory (22%), anatomic pathology (9%), and other (40%)."

"The most common diagnostic delays were cancer (34%), endocrine problems (26%), cardiac problems (16%), and other (24%)."

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| "Claims involving missed or delayed diagnosis were defined as those alleging an error in diagnosis or testing that resulted in a delay in appropriate treatment."

The authors used closed malpractice claims obtained from four malpractice insurance companies in the United States (Northeast, Southwest, and West).

The authors extracted data from random samples of closed claims.

Patient medical records were retrieved for selected claims.

The authors reviewed 429 claims. |
| The study focused on diagnostic errors occurring in hospitals EDs. However, the authors did identify errors that involved patient-related factors which contributed to diagnostic risk in 34% of the cases. |
### III. Research on Ambulatory Diagnostic Errors

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<td>Med. 2007; 49: 196-105</td>
<td>./treatment or a failure to act or follow up on diagnostic test results.&quot;</td>
<td>Collectively, the insurers covered approximately 21,000 physicians, 46 acute care hospitals (20 academic and 26 nonacademic) and 390 outpatient facilities.&quot;</td>
<td>Claims involving delayed or missed diagnoses. This study focuses on a subset of 122 claims which pertain to diagnostic error allegations involving the ED.</td>
<td>which may be relevant for our purposes.</td>
<td>Patient-related factors included: Patient non-adherence (10%), atypical presentation (8%), complicated medical history (8%), substance abuse (8%), poor [patient history] historian (5%) and language barrier (1%) among other factors.</td>
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IV. Research on Communication Safety in Ambulatory Settings

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<td>Bell C, Schnipper J, Auerbach A, et al. Association of Communication</td>
<td>To determine whether communication between hospital physicians and PCPs influences patient outcomes.</td>
<td>N/A</td>
<td>General medicine service in 6 U.S. academic medical centers.</td>
<td>Post-discharge survey of PCPs (2 weeks post-discharge) and patients (4 weeks post-discharge.</td>
<td>77% of providers know patients had been hospitalized; of those 23% had direct communication with the hospital physician and 42% had received a discharge summary within two weeks of discharge. There was no relationship between the above activities and patient outcomes at four weeks (outcomes = ED visit, readmission, or death).</td>
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<td>Between Hospital-based Physicians and Primary Care Providers</td>
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<td>with Patient Outcomes, Society for General Internal Medicine,</td>
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<td>published online December 20, 2008</td>
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<td>Casalino L, Dunham D, Chin M, et al. Frequency of Failure to Inform</td>
<td>To determine the extent to which primary care physicians fail to notify patients or fail to document notification for “significantly abnormal test results” – as defined by an expert panel as being “well outside of the reference range.”</td>
<td>Apparent failure to inform was defined as lack of documentation in the record that the patient had been informed and lack of any documented follow-up action (repeat test, follow-up procedure, visit, or referral)</td>
<td>19 community-based and 4 academic medical center primary care practices</td>
<td>Survey/interviews of the process of results management to identify use of 5 results management processes. Record review to identify documentation of follow-up in the patient’s record within 90 days of the test (21 days for two exceptionally critical results). Notification to physicians about results presumed to be lost to follow-up with request for additional information.</td>
<td>7.1% of “clinically significant results” apparent failures to document follow-up (failure to document only). The mean process score was 3.8 (of 5). Higher process scores were associated with better results. The consequence of failure to inform or document was not studied.</td>
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<td>Patients of Clinically Significant Outpatient Test Results. Arch Intern</td>
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### IV. Research on Communication Safety in Ambulatory Settings

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<td>Elderkin-Thompson V, Silver RC, Waitzkin H. When nurses double as interpreters: a study of Spanish-speaking patients in a US primary care setting. <em>Soc Sci Med.</em> 2001 May;52(9):1343-58.</td>
<td>To examine the accuracy of medical interpretations provided by nurses untrained in medical interpreting.</td>
<td>A multi-ethnic, university-affiliated primary care clinic in southern California. Medical encounters of 21 Spanish-speaking patients who required a nurse-interpreter to communicate with their physicians were videorecorded.</td>
<td>A qualitative, cross-sectional study. Encounters were transcribed by blinded research assistants. Transcriptions were translated and analyzed for types of interpretive errors and processes that promoted the occurrence of errors.</td>
<td>The 21 encounters divided evenly between complicated and uncomplicated cases. Ten contained minor interpretive errors - usually editing changes - that did not become clinically significant. Ten of the encounters had serious miscommunication problems that affected either the physician's understanding of the symptoms or the credibility of the patient's concerns.</td>
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| Foy R, Hempel S, Rubenstein L, et al. Meta-Analysis: Effect of Interactive Communication Between Collaborating Primary Care Physicians and Specialists. *Annals of Internal Medicine.* 2010; 152(4):247-258. | To assess the effects of interactive communications between primary care physicians and specialists on the outcomes of care. | Interactive communications was defined as "timely exchange incorporating pertinent clinical information shared by PCP and specialist via face-to-face, video conferencing, telephone or email exchange." | Meta-analysis of 23 studies of interactive communications that included an experimental design and reporting of patient outcomes. | Search of the literature related to communication involving PCPs and psychiatrists, endocrinologists, or oncologists. 23 studies met the study criteria (of 5,566 citations initially found in a literature review):  
- Eleven randomized controlled trials;  
- Seven non-randomized studies of interventions involving PCPs and psychiatrists;  
- Five non-randomized trials involving PCPs and endocrinologists.  
For diabetes the outcome measure was HbA1c; for psychiatry it was depression scale or symptom checklist. No studies with Oncologists met the inclusion criteria. | Interactive communications significantly improved the outcomes for diabetes and psychiatric patients. Studies that included efforts to improve the quality of information exchange had statistically and clinically significant benefits. Studies involving joint care planning failed to show a difference. There was no difference in results for participants in an integrated delivery system. |
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<th>Authors</th>
<th>Research Question</th>
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<th>Methodology</th>
<th>Findings</th>
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<tr>
<td>Gandhi T, Sittig D, Franklin M, et al.</td>
<td>Communication Breakdowns in the Outpatient Referral Process. J Gen Intern Med 2000. 15:626-631.</td>
<td>N/A</td>
<td>Two surveys – one re: satisfaction, the other sent to specialists the day after the referral visit and to PCPs two weeks after the visit to ask questions about a specific referral. Follow-up was conducted if surveys were not returned.</td>
<td>63% of PCPs and 35% of specialists were dissatisfied with the referral process. 68% of specialists did not receive prior information from the PCP. Four weeks after the visit, 25% of PCPs had not received information back from the specialist.</td>
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<td>Kripalani S, LeFevre F, Phillips C, et al.</td>
<td>Deficits</td>
<td>N/A</td>
<td>Meta-analysis</td>
<td>The authors reviewed the Cochrane Database and Communication and information transfer deficits</td>
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<td>in Communication and Information Transfer Between Hospital-Based and Primary Care Physicians: Implications for Patient Safety and Continuity of Care. JAMA. 2007; 297: 831-841.</td>
<td>in communication and information transfer at hospital discharge and to identify interventions to improve this process.</td>
<td>Medline (through November 2006) for relevant articles.</td>
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<td>In addition, the authors also searched bibliographies of relevant articles.</td>
<td>The authors arrived at a total of 73 studies, of which 55 were observational and 18 were controlled intervention trials.</td>
<td>Included literature dated primarily from 1970 – 2005.</td>
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<td>Matheny ME, Gandhi TK, Orav EJ, et al. Impact of an automated test results management system on patients' satisfaction about test result communication. Arch Intern Med. Nov 12 2007;167(20):2233-2239.</td>
<td>To assess the impact of physicians' use of a test results management tool embedded in an electronic health record on patient satisfaction with test result communication.</td>
<td>N/A</td>
<td>570 patient encounters in 26 outpatient primary care practices reviewed at Partners HealthCare System, Inc, is a large integrated delivery system in eastern Massachusetts that consists of a number of academic and community hospitals, including Brigham and Women's Hospital, Massachusetts.</td>
<td>Prospective, cluster-randomized, controlled trial where physicians were given access to a physician test results management tool with imbedded patient notification functions. Patient satisfaction surveys were conducted by telephone after the patient underwent the test and were administered before and after the intervention in both arms.</td>
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<td>Moore C, Wisnivesky J, Williams S, McGinn T. Medical Errors Related to Discontinuity of Care from an Inpatient to an Outpatient Setting. J Gen Intern Med. 2003; 18:646-651.</td>
<td>“To determine prevalence of medical errors related to the discontinuity of care from an inpatient to an outpatient setting.”</td>
<td>Failure to implement the discharge plan of care (or indicate that the plan of care had been changed).</td>
<td>Eighty-six patients who had been hospitalized at a large NYC academic medical center and seen by their PCP in an affiliated outpatient practice within two months of discharge. A total of 366 randomly selected discharged patients were identified of which 86 had a follow-up appointment with their PCP within two months.</td>
<td>Review of inpatient and ambulatory care records to see if medications, pending test result follow-up and work-up follow-up (outpatient tests or procedures) included in the hospital discharge plan had been implemented or an indication of a change in plans documented. Measurement of error: Errors per patient.</td>
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<tr>
<td>Poon E, Haas J, Pupola A. Communication Factors in the Follow-up of Abnormal Mammograms. <em>J Gen Intern Med</em> 2004; 19:316-323</td>
<td>To find communication factors that are associated with short-term follow-up of abnormal mammograms.</td>
<td>N/A</td>
<td>Two academically-affiliated medical practices.</td>
<td>Patients whose mammograms needed follow-up were interviewed to determine how their results were communicated and again at 7 to 8 months to determine what follow-up occurred.</td>
<td>64% had adequate follow-up. Adequate follow-up was associated with the MD documenting the plan of care in the record (p=0.042) and the patient reporting they were told they needed follow-up. (p=0.003) The research did not examine the consequences of lack of follow-up.</td>
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<td>Poon E, Gandhi T, Sequist T, et al. “I Wish I Had Seen This Test Result Earlier!” Dissatisfaction With</td>
<td>“…[T]o identify problems in current test result management systems and</td>
<td>N/A</td>
<td>173 physicians and 89 staff members at 15 urban teaching hospital and/or integrated delivery</td>
<td>From 10/2002-12/2002, the authors surveyed study participants regarding their established test result system, time spent managing</td>
<td>The authors found that delays occurred frequently. The majority of participants (83%) reported one or more</td>
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<td>Test Result Management Systems in Primary Care. <em>Arch Intern Med.</em> 2004: 164:2223-2228.</td>
<td>possible ways to improve these systems.&quot;</td>
<td>network-affiliated internal medicine practices in Boston, MA, were sent a survey.</td>
<td>Sites included 8 hospital-based offices, 5 off-campus offices, and 2 community health clinics. All practices had established EHR systems which enabled access to laboratory test results.</td>
<td>test results, and overall satisfaction with their system. In addition, the authors requested that participants report any delays in test results. Measurement of error: Descriptive statistics and logistic regression models were constructed from survey responses.</td>
<td>delays in test results in the past two months. “Despite reporting that they spent on average 74 minutes per clinical day managing test results, only 41% of physicians reported being satisfied with how they managed test results.”</td>
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Singh H, Arora H, Vij M, et al. Communication Outcomes of Critical Imaging Results in a Computerized Notification System. *J Am Med Inform Assoc.* 2007; 14:459-466. | "To access the effectiveness of a computerized test result notification system designed to minimize lapses in communication in the outpatient setting, to identify breakdowns in communication that could result from the use of this system, and to determine the potential impact of communication breakdowns on patients’ health outcomes." | Alerts were judged "acknowledged" if they had been opened by the receiving provider. | The setting for the study was Michael E. DeBakey Veterans Affairs Medical Center primary care clinic in Houston, TX.* | From 3/7/2006-5/28/2006, the authors "prospectively analyzed outcomes of computerized notification of abnormal imaging results (alerts) that providers did not explicitly acknowledge receiving in the electronic medical record of an ambulatory multi-specialty clinic.” The authors performed charter reviews for any unacknowledged results to see if any documented response was noted. If no response was noted, certain providers were contacted to delays in test results in the past two months. “Despite reporting that they spent on average 74 minutes per clinical day managing test results, only 41% of physicians reported being satisfied with how they managed test results.” | Even with the presence of an EHR test result notification system, imaging results were lost to follow-up. A total of 190,799 outpatient visits and 20,680 imaging studies took place during the study period and 1,017 electronic alerts were tracked. Of these, providers did not acknowledge receiving more than a third (368 of 1,017) alerts. “In 45 of these cases (4% of abnormal results), the imaging study was
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<tr>
<td>Singh H, Thomas E, Mani S, et al. Timely Follow-Up of Abnormal Diagnostic Imaging Test Results in an Outpatient Setting: Are Electronic Medical Records Achieving Their Potential? Arch Intern Med. 2009; 169: 1578-1586.</td>
<td>To consider the impact of electronic medical records in follow-up with patients regarding abnormal test results.</td>
<td>Alerts were judged “acknowledged” if they had been opened by the receiving provider.</td>
<td>The study surrounded the Michael E. DeBakey VA Medical Center and its five outpatient clinics, which were outfitted with an EHR system.</td>
<td>The authors analyzed “critically abnormal X-rays, computerized tomography (CT) scans, magnetic resonance imaging (MRI), mammography, and ultrasound alerts transmitted electronically to the multi-specialty ambulatory clinic of the VA Medical Center and its five satellite clinics”</td>
<td>A total of 123,638 laboratory tests were ordered, including CT scans, MRIs, X-rays, mammograms, and ultrasounds) which the author refers to as “studies.” 1196 image reports were flagged as abnormal and a report was sent to the requesting provider, of which...</td>
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alert them to the situation and to ascertain as to whether any undocumented follow-up had occurred. Taxonomy used: The authors used a taxonomy of communication breakdowns as established by Weinger and Blike (2007?) Measurement of error: Data was analyzed using SAS. Interestingly, the authors found that the provider had responded to the alert in 293 instances but had not acknowledged it electronically. The three main types of reported abnormal imaging were general radiology (44.5%), computerized tomography scans (34.5%), and MRIs (8.4%). The main ordering specialties were Generalists/Primary Care (60.3%). “The authors found that 45 (0.2%) of 20,680 imaging reports were lost to follow-up in the study period; when translated to 190,799 outpatient visits, the rate was 0.02% per outpatient visit.”
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<tr>
<td>Singh H, Sittig D, Willson L, et al. Notification of Abnormal Test Results in an Electronic Medical Record. <em>The American</em></td>
<td>To investigate whether alerts for abnormal test results improved follow up.</td>
<td>Alerts were judged “acknowledged” if they had been opened by the receiving provider.</td>
<td>The ambulatory care practice of a Veterans Medical Center</td>
<td>A computer system automatically generated alerts for “high priority” abnormal test results. After two weeks, the researchers determined what results had</td>
<td>17.4% of alerts were related to redundant tests; 10.2% of the alerts were not opened. Overall timely follow-up was not made for 6.8% of all the abnormal test results that</td>
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<td><em>Journal of Medicine.</em> 2010; 123(3):238-244.</td>
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<td>generated alerts.</td>
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<td>There was no difference in appropriate follow-up between alerts that were acknowledged and those that were not.</td>
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<td>Singh H, Esquivel A, Sittig DF, Murphy D, Kadiyala H, Schiesser R, Espadas D, Petersen LA. Follow-up Actions on Electronic Referral Communication in a Multispecialty Outpatient Setting. J.Gen.Intern.Med. 2010a Sep 17.</td>
<td>To examine follow-up actions on electronic referral communication in a large multispecialty VA facility.</td>
<td>N/A</td>
<td>Outpatient referrals to five subspecialties between October 2006 and December 2007, and queried the EHR to determine their status in a large multispecialty VA facility.</td>
<td>Selected 412 discontinued referrals randomly for review using an EHR to examine follow-up actions on electronic referral communication.</td>
<td>Of the 412 discontinued referrals, 52% lacked follow-up actions within 30 days. Appropriate justifications for inaction were documented in 69.8% (150/215) of those without action and included lack of prerequisite testing by the PCP and subspecialist opinion that no intervention was required despite referral. Estimated that at 30 days, 6.3% of all referrals were associated with an unexplained lack of follow-up actions by subspecialists. Conversely, 7.4% of discontinued referrals returned to PCPs were associated with an unexplained lack of follow-up.</td>
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<td>Smith P, Araya-Guerra R, Bublitz C, et al. Missing Clinical Information During Primary Care Visits. JAMA. 2005; 293(5):565-571</td>
<td>To describe primary care providers reports of missing clinical information.</td>
<td>Missing information was known to exist.</td>
<td>1,563 patient visits to 253 clinicians at 24 urban or suburban and 8 rural practices in Colorado.</td>
<td>Physicians were asked to complete a survey reporting missing information at each visit during a half-day session and estimate the consequences of that missing information.</td>
<td>Important information was reported missing at 13.6% of visits. Missing information was reported as at least “somewhat likely” to adversely affect care for 44% of visits and potentially result in delayed care or additional services in 59.5% of cases.</td>
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<td>Wilson E, Chen AH, Grumbach K, et al. Effects of limited English proficiency and physician language on health care comprehension. J Gen Intern Med. 2005 Sep;20(9): 800–806.</td>
<td>To assess the association of limited English proficiency (LEP) and physician language concordance with patient reports of clinical interactions.</td>
<td>N/A</td>
<td>Survey of 8,638 Kaiser Permanente Northern California patients with diabetes.</td>
<td>Cross-sectional survey. Patient responses were used to define English proficiency and physician language concordance. Quality of clinical interactions was based on 5 questions drawn from validated scales on communication, 2 on trust, and 3 on discrimination.</td>
<td>8,116 English-proficient and 522 LEP patients. Among LEP patients, 210 were language concordant and 153 were language discordant. In fully-adjusted models, LEP patients were more likely than English-proficient patients to report suboptimal interactions on 3 out of 10 outcomes, including 1 communication and 2 discrimination items. In separate analyses, LEP-discordant patients were more likely than English-proficient patients to report suboptimal clinician-patient interactions on 7 out of 10 outcomes, including 2 communication, 2 trust, and 3 discrimination items. In contrast, LEP-concordant patients reported similar interactions to English-proficient patients.</td>
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<td>Westberg SM, Sorensen TD. Pharmacy-related health disparities experienced by non-English-speaking patients: impact of pharmaceutical care. J Am Pharm Assoc (2003). 2005 Jan-Feb;45(1):48-54.</td>
<td>Identify services available in other languages at area pharmacies and communicate this information to patients. Identify and understand the differences, if any, in drug therapy problems identified in English vs. non-English speaking patients.</td>
<td>A federally qualified health center located in the Phillips Neighborhood of Minneapolis, MN, that provides medical, dental and mental health services. Approximately 40 pharmacies called, including neighborhood pharmacies and other pharmacies across the metropolitan area and asked what kind of services they provide for non-English patients and what languages were available. Patient encounters were documented in a pharmaceutical care management database. Of the six primary languages spoken by clinic patients, written or verbal information was available for five languages in one or more area pharmacies. The clinic pharmacist completed comprehensive assessments for 91 patients via 230 patient encounters, identifying 186 drug therapy problems (DTPs). Problems related to adherence were more prevalent in non-English speaking patients compared to English speaking patients (31% vs. 12%; p=0.0016). In all 91 patients, the percentage achieving desired drug therapy outcomes improved 24% after a pharmacist joined the team of clinic providers.</td>
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<td>Zolnierk K, DiMatteo M. Physician Communication and Patient Adherence to Treatment: A Meta Analysis. Med Care. 2009; 47 (8): 826-834</td>
<td>To analyze the relationship between physician’s communication and patient adherence.</td>
<td>N/A</td>
<td>Meta-analysis</td>
<td>Analysis of the published literature from 1949-2008.</td>
<td>The odds of patients adhering to physician recommendations were 2.16 times better if their physicians were good communicators. Training in communication skills had a positive impact on patient adherence.</td>
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<td>Baker DW, Gazmararian JA, Williams MV, et al. Functional health literacy and the risk of hospital admission among Medicare managed care enrollees. Am J Public Health. 2002;92:1278-1283.</td>
<td>This study analyzed whether inadequate functional health literacy is an independent risk factor for hospital admission.</td>
<td>N/A</td>
<td>We studied a prospective cohort of 3260 Medicare managed care enrollees.</td>
<td>Of the participants, 29.5% were hospitalized. The crude relative risk (RR) of hospitalization was higher for individuals with inadequate literacy (n = 800; RR = 1.43; 95% confidence interval [CI] = 1.24, 1.65) and marginal literacy (n = 366; RR = 1.33; 95% CI = 1.09, 1.61) than for those with adequate literacy (n = 2094). In multivariate analysis, the adjusted relative risk of hospital admission was 1.29 (95% CI = 1.07, 1.55) for individuals with inadequate literacy and 1.21 (95% CI = 0.97, 1.50) for those with marginal literacy.</td>
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<td>Bresnahan M, Begg MD, Brown A, Schaefer C, Sohler N, Insel B, Vella L, Susser E.</td>
<td>Race and risk of schizophrenia in a US birth cohort: another example of health disparity? Int J Epidemiol. 2007 Aug;36(4):751-8. Epub 2007 Apr 17.</td>
<td>N/A</td>
<td>Study subjects were offspring of women enrolled during pregnancy at Alameda County Kaiser Permanente Medical Care Plan clinics (1959–66) in the Child Health and Development Study.</td>
<td>For schizophrenia spectrum disorders, 12 094 of the 19 044 live births were followed over 1981–97. The analysis is restricted to cohort members whose mothers identified as African American or white at intake. Stratified proportional hazards regression was the method of analysis; the robustness of findings to missing data bias was assessed using multiple imputation.</td>
<td>African Americans were about 3-fold more likely than whites to be diagnosed with schizophrenia [Rate Ratio (RR) = 3.27; 95% confidence interval (CI): 1.71–6.27]. After adjusting for indicators of family SES at birth, the RR was about 2-fold (RR = 1.92; 95% CI: 0.86–4.28). Using multiple imputation in the model including family SES indicators, the RR for race and schizophrenia was strengthened in comparison with the estimate obtained without imputation.</td>
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<td>Buetow S, Kiata L, Liew T, et al.</td>
<td>&quot;...[T]o identify the types of errors that patients can contribute and help manage, especially in primary care.&quot;</td>
<td>Patient Error: &quot;...[P]atient actions that (1) are not completed as the patient intended or (2) do not achieve the outcome that the patient intended because the plan was not based on informed and strong patient beliefs.&quot;</td>
<td>Eleven homogenous nominal groups from Auckland, New Zealand. Eight of the groups were made up of patients. Three groups were made up of primary care professionals. Participants were recruited through community-based organizations and professional networks. A total of 83 participants took part in the study, of which 64 were patients. The majority of participants were female and roughly three-fifths of participants were aged 20-54.</td>
<td>Nominal group techniques were used to carry out highly structured small group discussions regarding &quot;the types of errors that patients can make.&quot; Discussions were held in late 2007. Taxonomy used: General inductive approach (Thomas, 2006). Measurement of error: Distribution of data into emergent categories.</td>
<td>Based on the analysis of the errors that participants discussed, the authors created the following taxonomy, which identifies two main categories of errors: action errors and mental errors. Action errors broadly include under-attendance, assertion errors, adherence errors. Mental errors broadly include memory errors, mindfulness errors, misjudgments.</td>
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<td>Chariatte V, Michaud P, Berchtold A, et al.</td>
<td>Missed Appointments in appointments to adolescents in an outpatient clinic for adolescents, to assess the effectiveness of a policy aimed at reducing missed appointments by introducing payment for those missed appointments not cancelled in advance, and to compare the rates between staff and resident physicians.</td>
<td>To characterize missed and cancelled appointments in a multidisciplinary outpatient clinic for adolescents, to assess the effectiveness of a policy aimed at reducing missed appointments by introducing payment for those missed appointments not cancelled in advance, and to compare the rates between staff and resident physicians.</td>
<td>32,816 consultations of patients aged 12-20 years occurring between 1999 and 2006 at an adolescent outpatient clinic of the University Hospital in Lausanne, Switzerland.</td>
<td>Appointments were considered &quot;missed&quot; if they were not cancelled 24 hours in advance.</td>
<td>The missed appointment rate was 11.8%, whilst another 10.9% were cancellations. April to October (vacation months) were associated with more missed appointments; mornings also had slightly higher rates than other times.</td>
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<td>Field T, Mazor K, Briesacher B, et al. Adverse Drug Events Resulting From Patient Errors in Older Adults. <em>J Am Geriatr Soc.</em> 2007; 55:271-276.</td>
<td>“To characterize the types of patient-related errors that lead to adverse drug events (ADEs) and identify patients at high risk of such errors.”</td>
<td>Adverse Drug Event (ADE): “an injury due to a medication.” Potential Adverse Drug Event (pADE): “a medication error with the potential to cause an injury but that does not actually cause any injury.”</td>
<td>Prospective study of 30,000 patient records of Medicare patients of a large multi-specialty group practice, using data from Gurwitz et al (2003).</td>
<td>Reviewers revisited the data used by Gurwitz et al (2003). “Signals that a possible drug-related incident had occurred were detected via electronic tracking of administrative data, as well as reports from clinicians and summaries of hospital discharges and emergency department visits.” After extensive training, clinical pharmacists reviewed the medical records related to these signals and abstracted information on possible drug-related incidents for presentation to pairs of physicians reviewers for clarification.” Taxonomy used: The authors developed their own classification system to reflect patient medication handling activities which might lead to patient errors: Filling and refilling, Administering, Modifying the medication regime, Following clinical advice, Reporting information to healthcare providers, and Adhering to follow-up.</td>
<td>The authors arrived at 188 relevant events, of which 59 did not have any patient errors. “The remaining 129 events included 99 ADEs and 30 pADEs.” The majority of patient errors leading to adverse events (n=129) occurred in administering the medication (31.8%), modifying the medication regimen (41.9%), or not following clinical advice about medication use (21.7%).” Patient-related errors most often involved hypoglycemic medications (28.7%), cardiovascular medications (21.7%), anticoagulants (18.6%), or diuretics (10.1%).” Patients with medication errors did not differ from a comparison group in age or sex but were taking more regularly scheduled medications.” The large proportion of errors leading to ADEs and pADEs that occurred when patients were advised to modify their medication regimens suggests the need for enhanced surveillance and follow-up when changes in medications are made.” “The underlying reasons for the errors identified suggest that there is a need to carefully weigh the risks and benefits of prescribing medications requiring complex handling for confused or demented patients, as well as those with psychiatric problems, depression, or inadequate support systems.”</td>
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<td>Gandhi T, Weingart S, Borus J, et al. Adverse Drug Events in Ambulatory Care. <em>N Engl J Med.</em> 2003; 1556-64.</td>
<td>Determine the rates, types, severity, and preventability of ADEs.</td>
<td>ADEs = injuries due to drugs.</td>
<td>Four adult primary care practices in Boston – two with computerized prescriptions. All patients receiving Rx during one month, capable of study (MD), and did not opt-out (1202).</td>
<td>Prospective cohort study, including chart review and survey of patients (symptoms of ADEs). Taxonomy used: Events were also classified as: “nonpreventable,” “preventable,” “ameliorable.”</td>
<td>Among other findings not specifically related to patient errors, the authors found that patients failed to inform the physician of their symptoms. 19 (37 percent) of 51 ameliorable events were due to the patient’s failure to inform the physician of their symptoms. The authors conclude that improvements are needed in doctor-patient communication.</td>
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<td>Green AR, Ngo-Metzger Q, Legedza AT, Massagli MP, Phillips RS, Iezzoni LI. Interpreter services, language concordance and health care quality. Experiences of Asian Americans with limited English proficiency. <em>J Gen Intern Med.</em> 2005 Nov;20(11):1050-6.</td>
<td>To compare self-reported communication and visit ratings for LEP Asian immigrants whose visits involve either a clinic interpreter or a clinician speaking their native language.</td>
<td>N/A</td>
<td>Two thousand seven hundred and fifteen LEP Chinese and Vietnamese immigrant adults who received care at 11 community-based health centers across the U.S.</td>
<td>Cross-sectional survey-response rate 74%.</td>
<td>Patients who used interpreters were more likely than language-concordant patients to report having questions about their care (30.1% vs 20.9%, P&lt;.001) or about mental health (25.3% vs 18.2%, P=.005) they wanted to ask but did not. They did not differ significantly in their response to 3 other communication measures or their likelihood of rating the health care received as &quot;excellent&quot; or &quot;very good&quot; (51.7% vs 50.9%, P=.8). Patients who rated their interpreters highly (&quot;excellent&quot; or &quot;very good&quot;) were more likely to rate the health care they received highly (adjusted odds ratio 4.8, 95% confidence interval, 2.3 to 10.1).</td>
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<td>Heath KV, Singer J,</td>
<td>To estimate the frequency and possible predictors of patient-mediated intentional</td>
<td>Population-based dynamic cohort of antiretroviral recipients in a province-wide</td>
<td>Cross-sectional survey. Program participants voluntarily complete program</td>
<td>Of 638 study subjects, 70 (11%) reported intentional nonadherence with</td>
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<td>O'Shaughnessy MV, Montaner J,</td>
<td>adherence due to adverse symptoms associated with antiretroviral therapy.</td>
<td>antiretroviral medication regimens in direct response to symptoms associated</td>
<td>surveys on an annual basis. Study subjects were those who responded to the</td>
<td>between 4% and 7.4% reporting this activity over the preceding year</td>
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<td>Hogg, RS.</td>
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<td>with antiretroviral therapy.</td>
<td>with antiretroviral therapy use.</td>
<td>depending on the symptom group. Multivariate analysis revealed that a</td>
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<td>plasma viral load of &lt;400 copies/mL (adjusted odds ratio [AOR], 0.35;</td>
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<td>95% CI, 0.21-0.61) and completion of high school (AOR, 0.43; 95% CI,</td>
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<td>0.24-0.78) were both inversely associated with intentional nonadherence.</td>
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<td>Those subjects reporting at least one severe symptom were more than twice</td>
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<td>as likely to report intentional nonadherence (AOR, 2.24; 95% CI, 1.16-4.33).</td>
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<td>Similarly, each additional symptom considered to be objective and to</td>
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<td>require clinical action was associated with a 25% increase in the risk of</td>
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<td>intentional nonadherence (AOR, 1.25; 95% CI, 1.10-1.43).</td>
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<td>Howard DH, Gazmararian J,</td>
<td>To examine the impact of low health literacy on medical care use and costs.</td>
<td>The study sample consisted of 3260 noninstitutionalized elderly persons enrolling</td>
<td>Health literacy was measured using the Short Test of Functional Health</td>
<td>When compared to those with adequate health literacy, emergency room costs</td>
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<td>Parker RM.</td>
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<td>in a Medicare managed care plan in 1997 in Cleveland, Ohio; Houston, Texas;</td>
<td>Literacy in Adults. We used a 2-part regression model to examine the</td>
<td>were significantly higher ($108; 95% CI: $62 to $154; P &lt;0.0001) among</td>
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<td>South Florida; and Tampa, Florida.</td>
<td>association between health literacy and medical costs, adjusting for age,</td>
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<td>sex, race/ethnicity, education, income, alcohol and tobacco consumption,</td>
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<td>and comorbid conditions.</td>
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<td>Total costs were higher in the marginal health literacy group, but the</td>
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<td>difference was not significant ($596; 95% CI: - $1437 to $2630; P = 0.57).</td>
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<td>Hussain-Gambles M, Neal R,</td>
<td>“To understand the perceptions of primary care staff as to why patients miss</td>
<td>All (482) General Practices in Yorkshire, U.K. were invited to attend and sent</td>
<td>The authors surveyed general practices and used the findings to prompt</td>
<td>Participants indicated that “patient factors rather than practice factors</td>
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<td>Dempsey O, Lawlor D, and</td>
<td>appointments.”</td>
<td>surveys; 361 offices responded but 25 indicated that they</td>
<td>discussion among focus groups of primary care staff.</td>
<td>were perceived as most important in causing missed appointments.”</td>
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<td>Hodgson J.</td>
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<td>Identified patient factors included:</td>
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|                               |           |                                                                                     |                                                                              | • “Patient forgot the


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<td>Focus Group Study of Health Professionals. <em>British Journal of General Practice</em>. 2004; 54:108-113.</td>
<td>did not have a system for managing appointments, leaving 336 for analysis.</td>
<td>A focus group of 29 participants (11 GPs, 10 receptionists, 7 practice managers, and 1 practice nurse) was held following survey collection to discuss findings.</td>
<td>• Patient symptoms were better… &lt;br&gt; • Patient overslept… &lt;br&gt; • Patient had transport difficulties… &lt;br&gt; • Patient unable to get there because of the weather… &lt;br&gt; • Appointment was at an inconvenient time,” among other factors.</td>
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<td>Kachalia A, Gandhi T, Puopolo A, et al. Missed and Delayed Diagnoses in the Emergency Department: A Study of Closed Malpractice Claims from 4 Liability Insurers. <em>Ann Emerg Med</em>. 2007; 49:196-105.</td>
<td>Claims involving missed or delayed diagnosis were defined as those alleging an error in diagnosis or testing that resulted in a delay in appropriate treatment or a failure to act or follow-up on diagnostic test results.”</td>
<td>The authors extracted data from random samples of closed claims. Patient medical records were retrieved for selected claims. The authors reviewed 429 claims involving delayed or missed diagnoses. This study focuses on a subset of 122 claims which pertain to diagnostic error allegations involving the ED.</td>
<td>Among other findings not related to patient contributions to errors, the authors identified errors that involved patient-related factors contributing to diagnostic error in 34 percent of the cases, which may be relevant for our purposes. Patient-related factors included: &lt;br&gt; • Patient non-adherence (10%), &lt;br&gt; • Complicated medical history (8%), &lt;br&gt; • Substance abuse (8%), &lt;br&gt; • Poor patient history provided (5%), and &lt;br&gt; • Language barrier (1%) among other factors.</td>
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<td>Kalichman SC, Rompa D. Functional health literacy is associated with health status and health-related knowledge in people living with HIV-AIDS. <em>J Acq Imm Def Synd Hum Retrovir</em>. 2000;25:337-344.</td>
<td>N/A</td>
<td>A community-recruited sample of 339 HIV-infected men and women</td>
<td>Surveys and interviews conducted that assessed functional health literacy, health status, AIDS-related disease and treatment knowledge, and health care perceptions and experiences. Medical records were available for chart abstraction of health status for a subsample of participants.</td>
<td>About 1 of 4 people living with HIV-AIDS demonstrated difficulty comprehending simple medical instructions and therefore lower health literacy. HIV-infected people with lower health literacy had lower CD4 cell counts, higher viral loads, were less likely to be taking antiretroviral medications, reported a greater number of hospitalizations, and reported poorer health than those with higher health literacy. In addition, after adjusting for years of formal education, lower health literacy was associated with poorer knowledge of one’s HIV-related health status, poorer AIDS-related disease and treatment knowledge, and more negative health care perceptions and experiences.</td>
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<td>Kaushal R, Goldmann D, Keohane C, et al. Adverse Drug Events in Pediatric Outpatients. <em>Ambul Pediatr</em>. 2007; 7:383-389.</td>
<td>“To determine rates and types of adverse drug events (ADEs) in the pediatric ambulatory setting.”</td>
<td>Medication errors: “errors in drug ordering, transcribing, dispensing, administering, or monitoring.”</td>
<td>1,788 Pediatric patients (aged 21 or younger) in six office practices in Greater Boston, MA, who had at least one office visit where they received a prescription between 7/2002 and 4/2003.</td>
<td>Data was collected from a variety of methods, including duplicate prescription review, surveys, and chart review.</td>
<td>The authors identified 57 preventable ADEs and 226 non-preventable ADEs. Among other findings not directly related to patient-error, the authors found that “40 (70%) of the preventable ADEs were related to parent drug administration.” None of the preventable ADEs were life threatening, although 8 (14%) were serious. “Rates of ADEs due to errors are comparable in children and adults despite less medication utilization in children.” Clinician reviewers concluded that “72% could have been potentially prevented by improved communication between the prescribing pediatric provider and patient, whereas 21% could have been prevented by CPOE with clinical decision support.”</td>
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"Medication errors: “errors in drug ordering, transcribing, dispensing, administering, or monitoring.” “A two-physician panel classified the severity, preventability, and ability to ameliorate [identified] ADEs.” Taxonomy used: “ADEs were rated in three categories according to the severity of injury: life-threatening, serious, or significant.” Measurement of error: Distribution of information into established categories."
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<td>Keating NL, Gandhi TK, Orav EJ, Bates DW, Ayanian JZ</td>
<td>To understand how patients' characteristics and experiences are related to trust in specialist physicians.</td>
<td>N/A</td>
<td>Surveyed patients who had a new patient visit with a cardiologist, neurologist, nephrologist, gastroenterologist, or rheumatologist practicing in hospital-based practices</td>
<td>We used multivariable models to assess associations of patients' characteristics and experiences with trust.</td>
<td>Most patients reported good experiences, and 79% reported complete confidence and trust in the specialist. Black patients were less trusting than white patients (risk ratio [RR], 0.5; 95% confidence interval [CI], 0.2-0.8). Patients were more trusting if they reported that the consultant listened (RR, 1.8; 95% CI, 1.0-2.5), received as much information as they wanted (RR, 1.6; 95% CI, 1.1-1.9), were told what to do if problems or symptoms continued, got worse, or returned (RR, 1.4; 95% CI, 1.2-1.5), were involved in decisions as much as they wanted (RR, 1.5; 95% CI, 1.2-1.8), and spent as much time as they wanted with the specialist (RR, 1.8; 95% CI, 1.3-2.2).</td>
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<td>Keating NL, Green DC, Kao AC, Gazmararian JA, Wu VY, Cleary PD</td>
<td>To assess the relationships between outpatient problem experiences and patients’ trust in their physicians, ratings of their physicians, and consideration of changing physicians</td>
<td>N/A</td>
<td>Patients (N=2,052; 58% response) insured by a large national health insurer.</td>
<td>Telephone survey during 1997. Measurements were patient trust, overall ratings of physicians, and having considered changing physicians.</td>
<td>Most patients (78%) reported at least 1 problem experience. In multivariable analyses, each problem experience was independently associated with lower trust (all P &lt;.001) and 5 of 6 with lower overall ratings (P &lt;.001). Three problem experiences were independently related to considering changing physicians: physicians not always giving answers to questions that are understandable (odds ratio [OR], 2.0; 95% confidence interval [CI], 1.3 to 3.0), not always taking enough time to answer questions (OR, 3.3; 95% CI, 2.2 to 5.2), and not always giving enough medical information (OR, 4.0; 95% CI, 2.4 to 6.6).</td>
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<td>Kim, EY, Han HR, Jeong S, Kim K, Park H, Kang E, Shin HS, Kim MT. Does knowledge matter? Intentional medication nonadherence among middle-aged Korean Americans with high blood pressure. <em>J Cardiovasc Nurs.</em> 2007 Sep-Oct; 22(5): 397-404.</td>
<td>To examine predictors of intentional and unintentional nonadherence to antihypertensive medication regimens and their relationships to blood pressure outcomes.</td>
<td>N/A</td>
<td>445 Korean Americans with high blood pressure enrolled in trial at baseline. 208 of these were on antihypertensive medications and included in the analysis.</td>
<td>A cross-sectional analysis performed to assess the factors affecting nonadherence to antihypertensive medication regimens.</td>
<td>Approximately 53.8% of the subjects endorsed 1 or more types of nonadherent behaviors. After controlling for demographic variables, multivariate analysis revealed that a greater number of side effects from the medication (adjusted odds ratio [OR], 1.19; 95% confidence interval [CI], 1.07 to 1.33) and a lower level of HBP knowledge (adjusted OR, 0.89; 95% CI, 0.79 to 0.99) were significantly associated with intentional nonadherence. Unintentional nonadherence was less strongly associated with the study variables examined in the analysis.</td>
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<td>Lowry KP, Dudley TK, Oddoen EZ, Bosworth HB.</td>
<td>To examine associations between patient characteristics, including reported adverse effects, and both intentional and unintentional nonadherence among 588 hypertensive patients.</td>
<td>Baseline data from a clinical trial, the Veterans' Study To Improve the Control of Hypertension, were examined. Intentional and unintentional nonadherence were assessed using a self-report measure.</td>
<td>Participants were presented with a list of adverse effects commonly associated with antihypertensive medication and asked to indicate which symptoms they had experienced. Logistic regression analyses were used to examine adjusted associations between patient characteristics and type of nonadherence.</td>
<td>Approximately 31% of patients reported unintentional nonadherence and 9% reported intentional nonadherence. Non-white participants, individuals without diabetes mellitus, and individuals reporting ≥5 adverse effects were more likely to report intentional nonadherence than their counterparts. Individuals with less than a 10th-grade education and non-white participants were more likely to report unintentional nonadherence than their counterparts. When symptoms of increased urination and wheezing/shortness of breath were reported, patients were more likely to report intentional and unintentional nonadherence compared with those who were adherent. Unintentional nonadherence was also associated with reports of dizziness and rapid pulse.</td>
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<td>Lemer C, Bates D, Yoon C, et al. The Role of Advice in Medication Administration Errors in the Pediatric Ambulatory Setting.* J Patient Saf. 2009; 5:168-75. *Based on abstract</td>
<td>To consider the &quot;effect of advice from medical professionals on medication safety.&quot;</td>
<td>1,685 pediatric patients in six office practices in Greater Boston, MA.</td>
<td>Data was collected from parental interviews, review of duplicate prescriptions, and chart review. “Descriptive analysis was followed by a multivariable analysis to determine which factors influenced the occurrence of reported medication administration errors.”</td>
<td>The majority of adverse drug events in the study population were due to parent medication administration errors. “Advice from both office and pharmacy was assessed to be poor in quality and limited in provision.” “Healthcare providers most often failed to offer information.” “57% of families who did not receive information were not presented with information, rather than refusing it.” “Multivariate analysis did not demonstrate that advice …reduced the rate of medication errors. However, taking more than 1 medication at an age younger than 5 years were correlated with risk of a medication administration error.”</td>
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<td>Lokker N, Sanders L, Perrin E. et al.</td>
<td>&quot;[T]o examine caregiver understanding of the age indication of over-the-counter cold medication labels and identify factors, associated with caregiver understanding.&quot;</td>
<td>182 caregivers of infant children were recruited from pediatric clinics at three institutions between 9/1/2006 and 10/16/2007. The mean &quot;education level was 12.5 years, and 99% had adequate literacy skills, but only 17% had &gt;ninth grade numeracy skills.&quot;</td>
<td>Study participants were surveyed regarding use of infant over-the-counter medications which specifically advised consulting a physician before using for children aged &lt;2. Study participants numeracy and literacy levels were tested using instruments.</td>
<td>&quot;Misunderstanding of over-the-counter cold products is common and could result in harm if medications were given inappropriately.&quot; &quot;Up to one-third of caregivers reported having previously used at least one of the OTC cold or cough products.&quot; &quot;When examining the front of the product label, 86% of the time parents thought these products were appropriate for use in children &lt;2 years of age.&quot; &quot;More than 50% of the time, parents stated that they would give these over-the-counter products to a 13-month-old child with cold symptoms.&quot; &quot;Of note, some caregivers in [the] study indicated that they would give the OTC products because of previous product endorsement from their physician. Two previous healthcare provider surveys have suggested that as many as one-half of physicians surveyed have recommended using OTC cold products in children &lt;12 months of age.&quot;</td>
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| Metlay J, Hennessy S, Localio A, et al. Patient Reported Receipt of Medication Instructions for Warfarin is Associated with Reduced Risk of Serious Bleeding Events. *J Gen Intern Med.* 2008; 23:1589-94. | "To identify whether patient report of receipt of medication instructions and markers of complex care (multiple physicians, recent hospitalization) predict the risk of serious bleeding for older adults on warfarin." | N/A | 2,268 low-income elderly members of the Pennsylvania Pharmacy Assistance Contract for the Elderly (PACE) Programs who were identified as new or continuing warfarin users during the sampling period 5/1/2002-5/31/2003. | Participants were followed for 24 months. Patients were interviewed at the start of the study and again 12 months later. Hospitalizations were identified through the Pennsylvania Healthcare Cost Containment Council. The authors identified 126 hospitalizations within the cohort due to warfarin-related bleeding over the two-year study follow-up period. Three events resulted in patient death. "Patients who reported receiving medication instructions from either a physician or nurse plus a pharmacist had a 60% reduced rate of subsequently experiencing a serious bleeding event over the next two years."
| | | | | |
| | | | | "Having >4 physicians proving medication prescriptions over the last 3 months and filling prescriptions at 0.1 pharmacy over the last 3 months were independently associated with increased bleeding rates."
<p>| | | | | This study adds to the literature by &quot;demonstrating that if patients do not recall receiving instructions on the proper way to use warfarin, they are at increased risk of suffering a serious warfarin-related bleeding event&quot; through patient-admistration errors. |</p>
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<td>Neal R, Hussain-Gambles M, Allgar V, et al. Reasons for and Missed Appointments in General Practice in the UK: Questionnaire Survey and Prospective Review of Medical Records. BMC Family Practice. 2005; 6:47.</td>
<td>To “determine the reasons for missed appointments and whether patients who miss an appointment subsequently consult their general practitioner.”</td>
<td>N/A</td>
<td>122 adult patients who missed appointments over three weeks in 2001 across seven general practices in West Yorkshire, U.K.</td>
<td>Study period were mailed a survey; 122 responded. Patients were asked to indicate why they missed their appointments and what could be done to help them keep appointments. Medical records were reviewed to determine the date of the patient’s next appointment.</td>
<td>Patients who miss appointments tend to cite practice factors and their own forgetfulness as the main reasons for doing so, and most attend within three months of a missed appointment.” The majority of respondents indicated that they forgot the appointment (n=89). Several respondents indicated that the appointment was at an inconvenient time (n=81), that it was difficult to cancel the appointment (n=81), that they were too ill to attend (n=84), or had family obligations (n=80). 57 (47%) of patients agreed to a medical record review. “Of these, 52 (91.2%) patients subsequently consulted within three months of the index consultation. “One-third were in the first week and over half were within three weeks.”</td>
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<td>Sarkar U, Fisher L, Schillinger D. Is self-efficacy associated with diabetes self-management across race/ethnicity and health literacy? Diabetes Care. 2006;29:823-829.</td>
<td>To examine the relationship between diabetes self-efficacy and self-management behavior in an urban, diverse, low-income population with a high prevalence of limited health literacy.</td>
<td>N/A</td>
<td>Spanish and English to patients with type 2 diabetes at two primary care clinics at a public hospital.</td>
<td>Oral questionnaire. We measured self-efficacy, health literacy, and self-management behaviors using established instruments. We performed multivariate regressions to explore the associations between self-efficacy and self-management, adjusting for clinical and demographic factors. We tested for interactions between self-efficacy, race/ethnicity, and health literacy on self-management.</td>
<td>The study participants were ethnically diverse (18% Asian/Pacific Islander, 25% African American, 42% Latino/a, and 15% white), and 52% had limited health literacy (short version of the Test of Functional Health Literacy in Adults score &lt;23). Diabetes self-efficacy was associated with four of the five self-management domains (P &lt; 0.01). After adjustment, with each 10% increase in self-efficacy score, patients were more likely to report optimal diet (0.14 day more per week), exercise (0.09 day more per week), self-monitoring of blood glucose (odds ratio 1.16), and foot care (1.22), but not medication adherence (1.10, P = 0.40). The associations between self-efficacy and self-management were consistent across race/ethnicity and health literacy levels.</td>
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<td>Schillinger D, Bindman A, Wang F, Stewart A, Piette J. Functional health literacy and the quality of physician-patient communication among diabetes patients. Patient Educ Couns. 2004;52:315-323.</td>
<td>To examine the relationship between functional health literacy (FHL) and the quality of clinician–patient communication.</td>
<td>N/A</td>
<td>This study performed within the context of a larger study examining the relationship between FHL and diabetes Outcomes. 408 English- and Spanish-speaking diabetes patients were enrolled</td>
<td>Trained bilingual research assistants interviewed patients in clinic prior to their appointment. To measure functional health literacy, we used an abbreviated version of the short-form Test of Functional Health Literacy in Adults (s-TOFHLA, 14-point font), English and Spanish versions. We enrolled 408 English- and Spanish-speaking diabetes patients to examine whether patients with inadequate FHL report worse communication than patients with adequate FHL.</td>
<td>In multivariate models, patients with inadequate FHL, compared to those with adequate FHL, were more likely to report worse communication in the domains of general clarity (adjusted odds ratio [AOR] 6.29, P &lt; 0.01), explanation of condition (AOR 4.85, P = 0.03), and explanation of processes of care (AOR 2.70, P = 0.03). Poor FHL appears to be a marker for oral communication problems, particularly in the technical, explanatory domains of clinician–patient dialogue.</td>
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<td>Schenker Y, Karter AJ, Schillinger D, Warton EM, Adler NE, Moffet HH, Ahmed AT, Fernandez A. The impact of limited English proficiency and physician language concordance on reports of clinical interactions among patients with diabetes: the DISTANCE study. Patient Educ Couns. 2010 Nov;81(2):222-8. Epub 2010 Mar 11.</td>
<td>To assess the association of limited English proficiency (LEP) and physician language concordance with patient reports of clinical interactions.</td>
<td>N/A</td>
<td>8638 Kaiser Permanente Northern California patients with diabetes.</td>
<td>Cross-sectional survey of 8638 Kaiser Permanente Northern California patients with diabetes. Patient responses were used to define English proficiency and physician language concordance. Quality of clinical interactions was based on 5 questions drawn from validated scales on communication, 2 on trust, and 3 on discrimination.</td>
<td>Respondents included 8116 English-proficient and 522 LEP patients. Among LEP patients, 210 were language concordant and 153 were language discordant. In fully adjusted models, LEP patients were more likely than English-proficient patients to report suboptimal interactions on 3 out of 10 outcomes, including 1 communication and 2 discrimination items. In separate analyses, LEP-discordant patients were more likely than English-proficient patients to report suboptimal clinician-patient interactions on 7 out of 10 outcomes, including 2 communication, 2 trust, and 3 discrimination items. In contrast, LEP-concordant patients reported similar interactions to English-proficient patients.</td>
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<td>Schillinger D, Grumbach K, Piette J, et al. Association of health literacy with diabetes outcomes. <em>JAMA</em>. 2002;288:475-482.</td>
<td>To examine the association between health literacy and diabetes outcomes among patients with type 2 diabetes.</td>
<td>N/A</td>
<td>408 English- and Spanish-speaking patients who were older than 30 years and had type 2 diabetes identified from the clinical database of 2 primary care clinics of a university-affiliated public hospital in San Francisco, Calif.</td>
<td>Cross-sectional observational study. Participants were enrolled and completed questionnaires between June and December 2000. We assessed patients' health literacy by using the short-form Test of Functional Health Literacy in Adults (s-TOFHLA) in English or Spanish.</td>
<td>After adjusting for patients' sociodemographic characteristics, depressive symptoms, social support, treatment regimen, and years with diabetes, for each 1-point decrement in s-TOFHLA score, the HbA(1c) value increased by 0.02 (P = .02). Patients with inadequate health literacy were less likely than patients with adequate health literacy to achieve tight glycemic control (HbA(1c) &lt; or = 7.2%; adjusted odds ratio [OR], 0.57; 95% confidence interval [CI], 0.32-1.00; P = .05) and were more likely to have poor glycemic control (HbA(1c) &gt; or = 9.5%; adjusted OR, 2.03; 95% CI, 1.11-3.73; P = .02) and to report having retinopathy (adjusted OR, 2.33; 95% CI, 1.19-4.57; P = .01).</td>
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<td>Sorensen L, Stokes J, Purdie D, Woodward M, and Roberts M. Medication Management at Home: Medication-Related Risk Factors Associated with Poor Health Outcomes. <em>Age and Aging</em>. 2005; 34:626-632.</td>
<td>“To determine the association between medication-related risk factors and poor patient health outcomes from observations in patients’ homes.”</td>
<td>204 general practice patients living at home in Queensland, Victoria, New South Wales, and Western Australia identified by GPs as being at risk of medication-related poor health outcomes.” Participants selected because they met one or more of the following criteria: Taking 5 or more regular medications, taking 12 or more doses per day, had 3 or more medical conditions and were suspected to be non-adherent with medication regimens by GPs, among other factors.</td>
<td>Study was a part of a randomized control trial of multi-disciplinary domiciliary medication reviews. Patients who agreed to participate were given questionnaires to collect demographic information. Information was obtained from GPs regarding the patient’s health and adverse drug events experienced in the past three months. Patient home visits were then conducted between 9/2/1999 and 2/5/2000. Home visits were conducted by pharmacists (87.3%) and GPs (12.7%). A proforma was used to guide the capture of observations and impressions and to capture data on all the patient’s medications found in the home.”</td>
<td>The average age of participants was 72.4 years; the average quantity of medications taken per person was 9.9. However, an average of 14.7 medications were found in homes. “…Patients were frequently confused by generic and trade names (114 patients) while poor adherence was reported by 107.” “No medication administration routine was found for 56 (27.5%), 43 (21.1%) hoarded medications, 43 (21.1%) retained discontinued medication repeats, 40 (19.6%) had expired medications, and 17 (8.3%) stored their medications in multiple locations.” “Some 68 (33%) patients risked therapeutic duplication (actual or possible) and some patients had more than one duplicated set of items.” “In multivariate analysis, patients who had greater numbers of medications in the home were more likely to have therapeutic duplication, hoarding, have greater severity of illness.” “Logistic regression showed that patients storing their medication in multiple locations were 4.2 times more likely to have recently experienced worsening of their health.” Overall, recent worsening of health status was seen in 55 (27%) of patients and 51 (25%) of patients experienced an adverse drug event (ADE) over the preceding three months. “…”Expired medication and poor adherence were also associated with poor health outcomes, however, not independently.”</td>
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<td>Wahls T and Peleg I. Patient and System-Related Barriers for the Earlier Diagnosis of Colorectal Cancer. <em>BMC Family Practice</em>. 2009; 10:1-9.</td>
<td>To identify patient factors that may contribute to diagnostic delays or failure to offer/complete colorectal cancer (CRC) screening.</td>
<td>N/A</td>
<td>150 CRC cases diagnosed between 1/1/2000-3/1/2007 in the Rural Veterans Administration Healthcare System that met established study criteria.</td>
<td>A variety of data sources were used, including progress notes, orders, and pathology, laboratory, and imaging results.</td>
<td>Among other findings not related to patient factors, the authors found that patient factors contributed to missed diagnoses. “In total, 97 (65%) of the cases had missed opportunities for early diagnosis, and 57 (38%) had patient factors that likely contributed to the diagnostic delay or apparent failure to screen/offer to screen.” The most frequently identified patient-factors included “patient declined evaluation” (n=16), “appointment no-shows” (n=9).</td>
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<td>Weech-Maldonado R, Morales LS, Spritzer K, Elliott M, Hays RD.</td>
<td>This study examines whether parents' reports and ratings of pediatric health care vary by race/ethnicity and language in Medicaid managed care.</td>
<td>The data analyzed are from the National Consumer Assessment of Health Plans (CAHPS) Benchmarking Database 1.0 and consist of 9,540 children enrolled in Medicaid managed care plans in Arkansas, Kansas, Minnesota, Oklahoma, Vermont, and Washington state from 1997 to 1998.</td>
<td>Data were analyzed using multiple regression models. The dependent variables are CAHPS 1.0 ratings (personal doctor, specialist, health care, health plan) and reports of care (getting needed care, timeliness of care, provider communication, staff helpfulness, plan service). The independent variables are race/ethnicity (white, African American, American Indian, Asian, and Hispanic), Hispanic language (English or Spanish), and Asian language (English or other), controlling for gender, age, education, and health status.</td>
<td>Racial/ethnic minorities had worse reports of care than whites. Among Hispanics and Asians language barriers had a larger negative effect on reports of care than race/ethnicity. For example, while Asian non-English-speakers had lower scores than whites for staff helpfulness (beta = -20.10), timeliness of care (beta = -18.65), provider communication (beta = -17.19), plan service (beta = -10.95), and getting needed care (beta = -8.11), Asian English speakers did not differ significantly from whites on any of the reports of care. However, lower reports of care for racial/ethnic groups did not translate necessarily into lower ratings of care.</td>
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<td>Yin H, Mendelsohn A, Wolf M, et al. Parents Medication Administration Errors: Role of Dosing Instruments and Health Literacy. Arch Pediatr Adolesc Med. 2010; 164:181-186.</td>
<td>“To assess parents liquid medication administration errors by dosing instrument type and to examine the degree to which parents health literacy influences dosing accuracy.”</td>
<td>300 parents of children visiting a public hospital pediatric clinic in New York, NY.</td>
<td>Interviews were held with study participants (parents). Parents were observed administering medication using a variety of tools to assess accuracy. Tools included dosing cups, dosing spoon, droppers, and oral syringes. One dosing cup had calibration markings and the other had etched markings. One oral syringe had a bottle adapter and the other did not.</td>
<td>“Dosing errors by parents were highly prevalent with cups compared with droppers, spoons, or syringes.” 30.5% of study participants (parents) using the cup with printed markings and 50.2% of participants using the cup with etched markings administered doses accurately. “Large dosing errors (&gt;40% deviation) were made by 25.8% of parents using the cup with printed markings and 23.3% of parents using the cup with etched markings.” “Compared with the oral syringe, cups were associated with increased odds of making large dosing errors.” “Limited health literacy was associated with making a dosing error.”</td>
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<td>Zwaan L, Bruijne M, Wagner et al. Patient Record Review of the Incidence, Consequences, and Causes of Adverse Events. Arch Intern Med. 2010; 170:1015-1021.</td>
<td>To explore &quot;diagnostic adverse events (DAEs) across all medical specialties to determine their incidence and to gain insight into their causes and consequences by comparing them with other AE types.”</td>
<td>40 Dutch hospitals were invited to participate in the study; 21 hospitals took part.</td>
<td>Trained physicians reviewed 7,926 randomly selected patient records in 21 hospitals in the Netherlands. Patients were either deceased or had been discharged in 2004. Taxonomy used: Eindhoven Classification Model. Measurement of error: Distribution of identified DAEs into established categories; statistical analysis was used to compare incident rates and consequences.</td>
<td>Most of the study pertained to DAEs occurring in hospitals. The authors did identify DAEs that involved patient-related causes, such as treatment adherence, which is relevant for our purposes. The authors found that “patient related causes... occurred significantly less in DAEs vs. other AE types (30 % vs. 44.9%).”</td>
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## VI. Research on Patient Roles in Ambulatory Safety

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| Britten N, Stevenson F, Barry C, Barber N, and Bradley C. Misunderstandings in Prescribing Decisions in General Practice: Qualitative Study. *BMJ*. 2000; 320:484-488. | "To identify and describe misunderstandings between patients and doctors associated with prescribing decisions in general practice." | 20 general practitioners practicing in mid- and southeast England. 35 adult patients (18+ years) were recruited by the GP’s respective practices. | Information for the study was obtained through a variety of means. The patient’s consultation was audiotaped. Semi-structured interviews were held with patients and providers (independently) before and after the consultation. During the interviews respective parties were asked to describe their experiences, expectations, their relationship with their doctor/patient and their satisfaction level. Information was subsequently transcribed and coded using qualitative techniques. | Analyses show that misunderstandings took place in the majority of consultations (28 of 35). Identified categories of misunderstanding included:  
   a) “Patient information unknown to doctor;  
   b) Doctor information unknown to patient;  
   c) Conflicting information given;  
   d) Disagreement about attribution of side effects;  
   e) Failure of communication about doctor’s decision;  
   and f) Relationship factors.”  
   “Overall, 26 of the 35 patients received prescriptions; 5 patients received unwanted prescriptions, 3 did not receive a prescription they wanted, 3 did not obtain another wanted action, such as a referral; 14 did not receive desired information or reassurance; 4 did not have their prescriptions dispensed; and 7 did not take their medicine as intended by the doctor. Only 8 of those whose expectations were not met expressed dissatisfaction with the consultation.”  
   The causes of misunderstandings stemmed from  
   a) Through lack of exchange of relevant information in both directions,  
   b) As a result of conflicting... |
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<td>c) When the patient failed to understand the doctor's diagnostic or treatment decision, and d) Form actions taken to preserve the doctor-patient relationship.&quot; Consultations do not reflect shared decisionmaking because patients frequently did not voice concerns and doctors operated from faulty assumptions regarding patient preferences.</td>
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| Tarn D, Heritage J, Paterniti D, et al. Physician Communication When Prescribing New Medications. *Arch Intern Med.* 2006; 166:1855-1862. | To “describe and assess the quality of physician communication with patients about newly prescribed medications.” | N/A | The study focused on practitioners and their patient in two healthcare systems based in Sacramento, CA, including 16 family physicians, 18 internists and 11 cardiologists. | The authors audiotaped and transcribed patient office visits and surveyed both patients and providers between 1/1999-11/1999. | “When initiating new medications, physicians often fail to communicate critical elements of medication use.”

“Physicians stated the specific medication name for 74% of new prescriptions and explained the purpose of the medication for 87%.”

Potential adverse events were discussed for 35% of medications and how long to take the medication for 34%.

“Physicians explicitly instructed 55% of patients about the number of tablets to take and explained the frequency of timing of dosing 58% of the time.”

“This might contribute to misunderstandings about medication directions or necessity and, in turn, lead to patient failure to take medications as directed.” |
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<td>Davis T, Wolf M, Bass P, et al. Low Literacy Impairs Comprehension of Prescription Drug Warning Labels. J Gen Intern Med. 2006; 21:847-851.</td>
<td>&quot;To examine whether adult patients receiving primary care services at a public hospital clinic were able to correctly interpret commonly used prescription warning labels.&quot;</td>
<td>The study included 251 adults (aged 18 or older) patients who were waiting to be seen at the Primary Care Clinic of the Louisiana State University Health Sciences Center in Shreveport in July 2003. 70% of participants were female and 66.1% were African American. Participants were aged 18-86; the mean age was 47.2 years.</td>
<td>Structured interviews were conducted with participants. Among other things, participants were asked to explain what eight prescription drug warning labels meant to them. Literacy assessments were conducted using the Rapid Estimate of Adult Literacy in Medicine (REALM) instrument. Taxonomy used: &quot;Patient literacy was classified either as low (6th grade and below), marginal (7th to 8th grade), or functional (9th grade and higher).&quot; Measurement of error: Information was analyzed using STATA</td>
<td>&quot;Patient literacy was limited; 29.5 were reading at or below a sixth-grade level (low literacy) and 31.1% were reading at the seventh- to eighth-grade level (marginal literacy).&quot; &quot;Patients with low literacy had difficulty understanding prescription medication warning labels.&quot; &quot;Patients of all literacy levels had better understanding of warning labels that contained single-step versus multiple step instructions.&quot; &quot;...[L]ow literacy is related to limited understanding and misinterpretation of warning labels, and, therefore, may be a factor in unintentional nonadherence and therapeutic failure.&quot; &quot;Incomplete understanding of labels may be an unrecognized contributor to [hospitalizations from misuse of prescription medications].&quot;</td>
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<td>Davis T, Woolf M, Bass P, et al. Literacy and Misunderstanding Prescription Drug Labels. Ann Intern Med. 2006; 145:887-894.</td>
<td>“To examine patients’ abilities to understand and demonstrate instructions found on container labels of common prescription medications.”</td>
<td>395 adult (18 or older) patients who were waiting to be seen at outpatient primary care clinics in Shreveport, LA; Jackson, MI, or Chicago, IL, in July 2003 or July 2004.</td>
<td>Structured interviews were conducted with participants to obtain socio-demographic information. Participants were shown five actual prescription bottles (with labels) and asked about how to take the information. Participants literacy was tested using the Rapid Estimate of Adult Literacy in Medicine (REALM) test</td>
<td>“Patient literacy was limited; 19% read at or below a sixth-grade level (low literacy), and 28.6% read at the seventh- to eighth-grade level (marginal literacy).” “Correct understanding of the five labels ranged from 67.1% to 91.1%” “Almost half (46.3%) of patients misunderstood one or more of the prescription label instructions, and the prevalence among patients with adequate, marginal, and low literacy was 37.7%, 51.3% and 62.7%, respectively.” The majority (51.8) of incorrect patient responses reflected an error in dosage, and 28.2% stated the wrong dose frequency.” “Patients at all literacy levels were more able to read label instructions than to demonstrate the correct number of pills to be taken.”</td>
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<td>Persell S, Osborn C, Richard R, et al.</td>
<td>“To assess the relationship between health literacy, patient recall of antihypertensive medications, and reconciliation between patient self-report and the medical record.”</td>
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<td>119 adult (18 or older) hypertension patients at three community health center clinics in Grand Rapids, Michigan.</td>
<td>Interviews and formal literacy assessments (using short form Test of Functional Literacy in Adults) were conducted with participants.</td>
<td>“Limited health literacy was associated with a great number of unreconciled medications.”</td>
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<td>Limited Health Literacy is a Barrier to Medication Reconciliation in Ambulatory Care. J Gen Intern Med. 2007; 22:1523-1526.</td>
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<td>Only 31% of participants had adequate health literacy.</td>
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<td>Participants were asked to list their current blood pressure medications.</td>
<td>Of the participants with inadequate health literacy, “60% could not name any antihypertension medications and nearly two-thirds named no antihypertension medication that was recorded in their medical record.”</td>
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<td>Participants medical records were also reviewed to determine the accuracy of their response.</td>
<td>“Patients with inadequate health literacy were less able to name any of their antihypertensive medication compared to those with adequate health literacy (40.5% vs. 68.3%).”</td>
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<td>“Agreement between patient reported medications and the medical record was low – 64.9% of patients with inadequate and 37.8% with adequate literacy had no medications common to both lists.”</td>
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<td>Flores G, Barton Laws M, Mayo S, et al. Errors in Medical Interpretation and Their Potential Clinical Consequences in Pediatric Encounters. <em>Pediatrics</em>. 2003; 111:6-14.</td>
<td>“To determine the frequency, categories, and potential clinical consequences of errors in medical interpretation.”</td>
<td>Pediatric patient encounters involving a Spanish translator in an urban hospital outpatient care clinic in Massachusetts.</td>
<td>The authors audio-taped patient encounters involving a Spanish language translator.</td>
<td>Bilingual transcripts for 13 clinical encounters (474 pages) were prepared from the recorded material by a “professional transcriptionist fluent in both English and Spanish.”</td>
<td>“Errors in medical interpretation are common, averaging 31 per clinical encounter, and omissions are the most frequent type.”</td>
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<td>Transcripts were subsequently reviewed for accuracy three separate times, “once by a bilingual physician whose first language is English, a second time by a bilingual sociologist whose first language is English, and a third time by a bilingual physician whose first language is Spanish.”</td>
<td>Bilingual transcripts for 13 clinical encounters (474 pages) were prepared from the recorded material by a “professional transcriptionist fluent in both English and Spanish.”</td>
<td>“396 interpretation errors were found in transcripts of 13 patient encounters, with an average of 21 per encounter.”</td>
<td>“The most common error type was omission (52%), followed by false fluency (16%), substitution (13%), editorialization (10%), and addition (8%).”</td>
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<td>“63 percent of all errors had potential clinical consequences, with a mean of 19 per encounter.”</td>
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<td>“Errors of clinical consequence included: 1) Omitting questions about drug allergies; 2) Omitting instructions on the dose, frequency, and duration of antibiotics and rehydration fluids; 3) Adding that hydrocortisone cream must be applied to the entire body, instead of only to facial rash; 4) Instructing a mother not to answer personal questions; 5) Omitting that a child was already swabbed for a stool culture; and 6) Instructing a mother to put amoxicillin in both ears for treatment of otitis media.”</td>
<td>“Errors of clinical consequence included: 1) Omitting questions about drug allergies; 2) Omitting instructions on the dose, frequency, and duration of antibiotics and rehydration fluids; 3) Adding that hydrocortisone cream must be applied to the entire body, instead of only to facial rash; 4) Instructing a mother not to answer personal questions; 5) Omitting that a child was already swabbed for a stool culture; and 6) Instructing a mother to put amoxicillin in both ears for treatment of otitis media.”</td>
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<td>Karliner L, Perez-Sable E, and Gildengorin G. The Language Divide:</td>
<td>To ascertain clinicians experience using and satisfaction with interpreters.</td>
<td>158 clinicians (105 physician residents, 45 attending physicians, and 8 nurse</td>
<td>Participating clinicians completed a questionnaire regarding their most recent</td>
<td>“Clinicians reported communication difficulties affecting their ability to understand symptoms and treat disease, as well as their ability to empower patients regarding their healthcare.”</td>
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<td>The Importance of Training in the Use of Interpreters for</td>
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<td>practitioners) at 3 academic outpatient settings in San Francisco.</td>
<td>patient encounter that involving an interpreter.</td>
<td>70% of participating clinicians reported that they had difficulty eliciting exact symptoms; 40% reported difficulty explaining treatments; 51% reported difficulty eliciting patient preferences.</td>
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<td>RISK FACTORS FOR PATIENT ERROR</td>
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<td>Metlay J, Cohen A, Polsky D, et al. Medication Safety in Older</td>
<td>“To identify the current state of medication taking practices of community-</td>
<td>4,955 low-income elderly members of the Pennsylvania Pharmacy Assistance Contract</td>
<td>Prospective cohort study. PACE members who met the study criteria and agreed</td>
<td>“Almost a third of the subjects reported not receiving any instructions on the use of their medications,” which places them at risk of self-caused medication-administration errors.</td>
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<td>Adults: Home-Based Practice Patterns. J Am Geriatr Soc. 2005; 53:</td>
<td>dwelling older adults.”</td>
<td>for the Elderly (PACE) and PACE Needs Enhancement Tier (PACE-NET) Programs.</td>
<td>to participate had an introductory interview as well as two annual follow-up</td>
<td>40% of participants indicated that they did not have a method of organizing their medication regimens.</td>
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<td>976-982.</td>
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<td>“Five groups were identified for sampling: new users of warfarin, chronic</td>
<td>interviews. In addition, they agreed to share pharmacy claims data and future</td>
<td>“Based on the prescriptions filled at the time of enrollment, 48% of the subjects enrolled were taking warfarin, 41% digoxin, and 11% phenytoin.”</td>
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<td>users of warfarin, new users of digoxin, chronic users of digoxin, brand new</td>
<td>hospitalization data.</td>
<td>“More than half of the subjects received their usual medical care in a</td>
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<td>and chronic users of phenytoin combined.”</td>
<td>During the interviews, participants were asked about where they obtain</td>
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<td>information about their current medications and practices for taking and</td>
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<td>organizing their medications at home.</td>
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### VI. Patient Roles in Ambulatory Safety Research

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| Sorensen L, Stokes J, Purdie D, Woodward M, and Roberts M. Medication Management at Home: Medication-Related Risk Factors Associated with Poor Health Outcomes. *Age and Aging.* 2005; 34:626-632. | “To determine the association between medication-related risk factors and poor patient health outcomes from observations in patients’ homes.” | 204 general practice patients living at home in Queensland, Victoria, New South Wales, and Western Australia identified by GPs as being at risk of medication-related poor health outcomes.” Participants were selected because they met one or more of the following criteria:  
  - Taking five or more regular medications; | Interviews were conducted between 5/1/2002-6/30/2003. | Study was a part of a randomized control trial of multi-disciplinary domiciliary medication reviews.  
Patients who agreed to participate were given questionnaires to collect demographic information.  
Information was obtained from GPs regarding the patient’s health and adverse drug events experienced in the past | The average age of participants was 72.4 years; the average quantity of medications taken per person was 9.9. However, an average of 14.7 medications were found in homes.  
“...Patients were frequently confused by generic and trade names (114 patients) while poor adherence was reported by 107.”  
“No medication administration routine was found for 56 (27.5%), 43 (21.1%) hoarded medications, 43 (21.1%) retained discontinued medication repeats, 40 (19.6%) had...
### VI. Patient Roles in Ambulatory Safety Research

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<td>• Taking 12 or more doses per day; • Had three or more medical conditions; and • Were suspected to be non-adherent with medication regimens by GPs, among other factors.</td>
<td>three months. Patient home visits were then conducted between 9/2/1999 and 2/5/2000. Home visits were conducted by pharmacists (87.3%) and GPs (12.7%).</td>
<td>expired medications, and 17 (8.3%) stored their medications in multiple locations. “Some 68 (33%) patients risked therapeutic duplication (actual or possible) and some patients had more than one duplicated set of items.” In multivariate analysis, patients who had greater numbers of medications in the home were more likely to have therapeutic duplication, hoarding, have greater severity of illness.” Logistic regression showed that patients storing their medication in multiple locations were 4.2 times more likely to have recently experienced worsening of their health.” “…Expired medication and poor adherence were also associated with poor health outcomes, however, not independently.”</td>
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