THE ROLE OF INFORMATION TECHNOLOGY IN AMBULATORY CARE PATIENT SAFETY

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“Mistakes are a fact of life. It's the response to the error that counts.”

—Nikki Giovanni (American poet, 1943- )

“I want to be sure I don’t make the wrong mistake”

—Yogi Bera

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EXECUTIVE SUMMARY

In this report, we review the evidence which addressed the impact of information technology (IT) on patient safety. We begin by first describing briefly the current chaotic nature of ambulatory care clinical information management. Most US physicians do not use any form of IT for ambulatory care clinical information management today, while in other Western English speaking countries the situation is very different. We describe where errors are known to occur in ambulatory care and their known prevalence, and review the extensive literature pertaining to the use of IT in hospital environments to improve patient safety, and discuss its relevance to ambulatory care.

Ambulatory care patient safety can be improved by simply improving the reliability of access to a patient’s medical record, and this is best done by creating a computer-based patient record, commonly known as an electronic medical record (EMR). When present, an EMR can provide alerts or reminders to prompt physicians to abide by a wide variety of care management rules or guidelines, and these are known to have a considerable effect on clinician decision making, and the effect decays when the reminders are removed. Such alerts or reminders may also be applied for specific disease state management, improved preventive care, more appropriate diagnostic testing, reducing redundant testing, and improving response time to abnormal results. EMR systems may also reduce the incidence of medication errors and improve interpretation of diagnostic tests through drug-drug interaction testing, and drug-lab interaction testing. Such systems may also provide immediate alerts to the clinician if a patient has a known drug allergy or other untoward reaction to a medication being considered for prescription. Even simple EMR systems can improve patient safety by producing a complete, coherent (appropriate dose, route, and frequency for selected drug), and legible prescription at the point of care.

We also describe how such systems may be used for adverse event detection and prevention in the inpatient environment and the possibilities for similar effects in the outpatient setting. We also describe how such systems are known to improve patient care monitoring and follow up of abnormal test results. We also describe how such systems may impact provider-provider communication in the referral process in ambulatory care, and provider-patient communication as well. Increasingly, patients experiencing the conveniences resulting from application of IT in other industries are coming to expect the same in healthcare: using EMR technologies can facilitate patient access to their medical record information and improve patient education, and involvement in their own healthcare.

The evidence is clear that IT can have a significant impact on patient safety in ambulatory care, yet appropriate technology has not been widely adopted in this delivery setting. To foster adoption, we belief key thorny policy issues must receive continued analysis. Providers and healthcare delivery systems need greater assurance that they can protect patient privacy, and data security and confidentiality, and not feel that they have assumed too much exposure by putting patient information ‘online’. Further work also needs to be done on standardization of a minimal set of data to support patient safety in
ambulatory care – to support the appropriate guidelines, alerts, reminders, and benchmark reports, and to support improved interoperability between disparate systems.

While the evidence would suggest there are a wide variety of opportunities for improving ambulatory care patient safety, we choose to focus our recommendations in several key areas in recognition of the need to incrementally change the fundamental nature of ambulatory care clinical practice: development of a national patient safety knowledge-base, development of national minimal standards for ambulatory patient safety, and development of standards for minimal patient communication in ambulatory care. We separate knowledge development activities from safe practice standards to allow each to be developed simultaneously. It is our belief that providing an economic incentive alone would foster alignment of organizational incentives, and be sufficient motivation for physicians, to promote adoption of IT in support of patient safety quickly. The healthcare technology marketplace is likely able to move with much more alacrity than the standards development process once incentives are in place.

Specific Recommendations

1. **No particular technology recommendation**

   We do not recommend at this time a mandate for widespread adoption of a particular technology to impact patient safety in ambulatory care. Rather, we suggest adoption of several key ambulatory care patient safety standards to drive technology adoption.

2. **Development of a National Patient Safety Knowledge-base**

   Two key activities should be undertaken immediately to create a national resource to support ambulatory care patient safety.

   2.1 **Definition of essential minimal data set for ambulatory patient safety**

   The first critical element of a national patient safety knowledge-based would be specification of the key data elements required in ambulatory practice clinical information systems to support safe care practices. Such a ‘data dictionary’ for patient safety should be a national priority of the first order.

   2.2 **Definition of essential guidelines for alerts or reminder systems in ambulatory care**

   Well known rule sets from academic centers have been created and found to be useful but it is difficult to export these rules to commercial systems. Creation of a validated public library of care rules would be very useful to the vendor community.

3. **Development of Ambulatory Care Safe Practice Standards**

   3.1 **No handwritten prescriptions**
We concur with the growing body of experts and professional agencies and societies which call for the elimination of the handwritten medical prescription. All prescriptions should be written with the benefit a computer for drug interaction assessment, appropriateness, completeness, and coherence of the prescription.

3.2 Compliance with selected care management guidelines

We call for widespread adoption of a minimal set of ambulatory care management guidelines, and suggest reimbursement be tied to compliance with these guidelines.

3.3 Routine communication to patients of all test results with explanation

We further recommend that the following be established as a standard of ambulatory care: patients are routinely informed of all of their laboratory results with a reasonable explanation of abnormal findings – similar to the manner in which customers are kept abreast of the status of their bank accounts from financial institutions.

4. Ambulatory care reimbursement reform to support patient safety

The cornerstone of our recommendations, however, is that the payer community apply pressure in the ambulatory practice sector, much like the Leapfrog Group is applying pressure in the inpatient setting (and possibly soon in the outpatient setting) for improved patient safety through differential reimbursement for providers adopting technology in support of patient safety, and demonstrated compliance with safe standard benchmarks.
INTRODUCTION

In this report, we review the problems associated with ambulatory care patient safety, and the potential role information technology may play ameliorating these problems. We begin with a brief overview of the current status of ambulatory care clinical information management highlighting current paper processes, and where errors occur in ambulatory care. Next, we discuss the effects information management technology (or simply ‘information technology’, IT) can have on patient care through improved information access, clinical decision support, alerts or reminders, and medication prescribing decision support and monitoring. We also describe the demonstrated effects of IT on disease management, and adverse drug event detection and reporting. Next, we provide a brief overview of the effect of IT on provider-to-provider, and patient-provider, communications.

To discuss the potential for IT in ambulatory care we describe the obstacles which must be overcome in various contexts for IT implementations (independent clinics, and the integrated delivery network), and what is practical now from a variety of perspectives. We also describe fundamental work which should be done to support the development and dissemination of a knowledge base for clinical information management systems in ambulatory care. Finally, we make recommendations about specific information technology which may be applied now in the ambulatory care setting to impact patient safety today.

CURRENT STATUS OF AMBULATORY CARE CLINICAL INFORMATION MANAGEMENT

The current status of ambulatory care clinical information management may be characterized as chaotic at best. It is generally acknowledged that clinical practice environments have been slow to adopt IT for a wide variety of reasons. One of the principle reasons is that the information environment in healthcare is exceedingly complex.

In routine primary care ambulatory clinical practice a physician may expect to see anywhere from 20-45 or more patients in a single day. For each of these, a clinical encounter note must be written, and typically a bill generated. For most patients one or more prescriptions are written, for many a lab test is ordered, and for a fraction a referral will be made, or a consultant’s report created. Making conservative assumptions about the volume of paperwork to be done, an ambulatory care practitioner today is completing approximately 20,000 forms per year, not including other billing paperwork that is usually done by administrative staff.

1 25 patients/d, 48 weeks practice/yr, 50% of patients require an average of 3 prescriptions, 50% of patients require at least one lab order, 10% of patients require a referral slip, 5% of patients require other paperwork (school/work note, disability form, etc.)
Anecdotal reports suggest that the average adult US citizen may have anywhere from 5-7 outpatient charts at any one time that are maintained independently by various care providers (primary care, sub-specialists, allied health providers, etc.). The number of charts created across the course of a person’s life may easily be 2-3 times this number. Rarely do these clinic charts share information effectively with hospital medical records; and, careful studies of information availability have found that physicians cannot find relevant information in the medical record from 10% to 81% of the time.

In the vast majority of ambulatory practice settings today, the medical record is maintained without the benefit of information technology. Recent industry estimates suggest the penetration of electronic medical record technology, or electronic prescribing, in ambulatory care is modest at best. A recent Harris Interactive survey found 15% of primary care physicians, and approximately 10% of sub-specialist physicians, may ‘sometimes’ use some form of automated clinical information management tool in any clinical setting, and anecdotal evidence suggests only three quarters of ambulatory practice settings have some form of practice management (billing) system in place. The potential for IT to improve many aspects of this workload is well understood. In addition, although the ambulatory practice environment is less well studied than the inpatient environment, it is clear that errors do occur in ambulatory practice and that IT could potentially reduce these errors.

Where Errors Occur In Ambulatory Care

The types of errors that occur in ambulatory care can be classified in many ways, either according to the stage of the process or to the type of process involved. Regarding stage, the first stage is initiation (prescribing a medication, ordering a test, or considering a specific diagnosis). The second stage relates to getting results back, including laboratory tests and radiological results. Monitoring includes communication about results and progress with the patient and represents the third stage. The fourth stage—closely related to the second—is tracking and acting on results; doing this well implies knowing what results are pending, and ensuring that appropriate follow-up steps are taken. Errors can occur at all these stages, although few data are available from the ambulatory setting about their relative importance. However, some data do suggest that monitoring is probably especially important outside the hospital compared to inside it, given the low levels of communication and surveillance.

Another way to classify errors relates to the process involved: medications, laboratory testing, radiology, diagnosis, or communication (including referral). Medication errors are clearly frequent in the outpatient setting. Laboratory errors and radiology errors appear less frequent but can be important, especially if an important result (for example, an abnormal mammogram) does not get appropriate follow-up. While few data are available regarding errors in diagnosis, they are probably quite important, though the boundaries of what constitutes an error may be less clear than in other domains.

Finally, errors in communication—both failure of physicians to contact each other and their patients, and failure of patients to contact their physicians when they are experiencing an important problem—likely represent a large proportion of errors resulting in injuries.
Summary

Clinical information management in the US ambulatory practice setting is still largely done with paper. A small minority of physicians use any form of information technology to support clinical information management, and errors are known to occur at a variety of stages of clinical decision making.

IT EFFECTS ON AMBULATORY CARE PATIENT SAFETY

Information Access

Simply having clinical information ‘online’ without any other form of clinical decision support may dramatically improve clinical decision making, utilization, and probably patient outcomes. Even if the chart is available, physicians may not be able to find relevant information as described above, and often the chart itself may not be available\(^{21-24}\). In an early study at Duke, simply having medical information accessible via computer resulted in an estimated $596 savings per year for geriatric patients\(^{25}\). In other studies in the outpatient setting, it is found that simply displaying test results\(^ {26,27}\) or predicting test results\(^ {28}\) can reduce test utilization. Even having access via wireless methods to only certain components of the medical record, such as laboratory results, can influence utilization and management\(^ {29}\).

Summary

While often not as well appreciated because it is generally assumed to be self-evident, simply improving access to the patient’s medical record may improve patient safety, and impact test utilization. It is clear in both inpatient and outpatient environments that using IT to put medical records online can dramatically improve record access for authorized users.

Clinical Decision Support

Though access to information is important, another major IT benefit is the potential for decision support. One of the major challenges to informatics in the coming years is to develop both acceptable and effective ways to make decision-support available to clinicians\(^ {30}\), and patients\(^ {31-36}\). Several kinds of decision-support are possible. For example, some situations are so straightforward that the computer can make an active suggestion with an alert or reminder\(^ {37,38}\). In other instances, the best approach may be a passive one, for example providing links that allow rapid access previous results, a clinical prediction rule, an algorithm, or a World Wide Web based information resource. “Structured ordering”, in which the physicians’ intentions are elicited at the time of ordering and then critiques or educational material is presented to help guide ordering, is another important method of decision-support in order entry\(^ {39,40}\).

There are several important implementation details, most notably the trade-off between the requirement for rapid response time by users and time required to process decision-support software, particularly at peak loads\(^ {7,41}\). To date, computer-based physician order
entry has require more time than pen and paper methods. Physician acceptance of computer order entry depends critically on the system’s response time, so it is important that decision-support features do not appreciably slow it. Also, messages from decision-support features should be constructive and non-judgmental. Other benefits of computer order entry include the fact that the decision-support is immediately available to all physicians, may require little maintenance once in place other than knowledge maintenance, and can be continued indefinitely. Critical issues remaining to be solved for widespread adoption of clinical decision support systems for differential diagnosis and other more complicated aspects of medical cognition include development of a generalized framework for knowledge representation, and methods of inference which may account for patient preferences and other utility considerations. But most importantly, clinical decision support at order entry allows immediate feedback to physicians at the time they write orders, because to be optimally effective, an intervention should occur as close in time to the event as possible. However, a recent study showed that the beneficial effects of computerized reminder systems deteriorated over time. Further research needs to determine how to ensure more sustainable effects.

Summary

The evidence is clear that physicians respond favorably to decision support provided by clinical information management systems. Such systems may simply improve access to relevant clinical information or knowledge, or may support diagnostic and therapeutic clinical decision making. To be optimally effective, decision support must be provided to the clinician in the course of the clinical workflow.

Alerts & Reminders

Computer-generated alerts or reminders at the point of care are one of the most well documented means to effect behavior change in providers. Many studies have shown that practice lags behind best evidence in the inpatient and outpatient settings. Preventive care services such as mammograms, pap smears, and influenza vaccinations have clearly specified guidelines. However, absolute rates of compliance are low and many opportunities are missed. One study showed that mentioning a particular preventive service to a patient of appropriate age and gender is likely to occur at a third of visits or fewer. Even when patients report that the visit was for a physical exam or routine check-up, indicated preventive services were prescribed less than 50% of the time. Another example of poor guideline compliance comes from national guidelines for routine diabetes care. In a study by Weiner, et al., data from over 97,000 elderly diabetic patients were evaluated and, within a one-year period, only 16% of the patients had a hemoglobin A1c level, only 46% had an ophthalmologic examination, and only 55% had total cholesterol measurements. Another recent study showed that among qualifying patients, 78% were out of compliance with the national cholesterol guidelines.

Reminders at the point of care in the clinical workflow have been shown to affect provider behavior, improve compliance with good practices, and decrease unnecessary utilization. For example, immediate feedback with the computer was twice as effective as
delayed for improving compliance with preventive care protocols. Other studies have found providing an inference about expected abnormal test results can influence test ordering. Reminders can improve patient follow up as well. For example, with reminders, follow up of patients with newly discovered high-blood pressure increases from 25-84 percent. Also, reminders can impact test utilization by simply indicating the presence of a recent test. For example, the computer can inform the physician when a test has been ordered that is clearly unnecessary or redundant (e.g. a second urine culture in 24 hours), or a medication has been ordered to which a patient is allergic.

Review of the effectiveness of various methods of guideline dissemination shows the most predictable impact is achieved when the guideline is delivered through computer-based, patient-specific reminders that are integrated into the clinician’s workflow. Several studies have demonstrated that information technology can improve care. Preventive care is an area where adherence to guidelines has been well studied. A meta-analysis of the effectiveness of computer-based reminder systems in the use of preventive care measures in ambulatory settings demonstrated that computer reminders were effective. Shea and colleagues estimated that with a baseline compliance rate of 50% among practitioners, computerized reminders would increase the compliance rate to 64%.

Alerts or reminders can impact management of specific conditions, or individual disease management. Reminders for diabetes care have received extensive analysis. Two recent studies evaluating computerized diabetes management programs showed an improvement in adherence to recommended guidelines by providing reminders at the time of the patient-doctor interaction. Lobach et al. showed that physicians, who were on average 18-21% compliant with a “reasonable” set of guidelines without interventions, improved to 32% with reminders. Also, Nilasena et al. demonstrated that physicians at their hospital were 36% compliant at baseline and achieved 53% compliance with computerized reminder interventions. Computerized reminders showed significant improvements but still did not achieve high absolute rates of compliance.

However, these computerized reminder interventions were not tightly integrated with a functioning EMR so that the full capability of what is possible with information technology remains to be determined. A study using the Regenstrief record evaluated the impact of displaying computerized guidelines for patients with congestive heart failure. The data from this study are still being analyzed but many valuable lessons were learned during the study about implementing sophisticated guidelines, particularly guidelines about drug therapies. A recent study with reminders based on an outpatient EMR evaluated the impact of giving reminders about preventive measures, drug substitutions, drug-disease suggestions, and diabetes reminders. The reminders were more effective for some providers than others, and broadly speaking their impact was positive. Tang has designed a system which presents web-based guidelines to an EMR user at the point of care, in the appropriate context for clinical decision support. Rollman disseminated a depression guideline via a commercially available EMR. Further work, however, needs to be done to assess how optimally to incorporate guideline knowledge into clinical systems, and into the clinical workflow.
Critical laboratory results also occur commonly in inpatients and delays in physician response are common. One study showed that using an inpatient computerized alerting system to notify physicians of critical lab results reduced the time until an appropriate treatment was ordered by 38%. Similar benefits would be expected in the outpatient setting, especially since delays in obtaining test results are likely to be more common due to testing being performed off-site.

Decision support can also be used to improve test or lab ordering. One study evaluated the appropriateness of random samples of inpatient and outpatient serum digoxin levels. Among inpatient levels, only 16% (95% C.I. 11-20%) were appropriate. Of the 130 outpatient levels, 52% (95% C.I. 44-61%) were appropriate. Another study evaluated the appropriateness of thyroid testing in outpatient clinics of an academic medical center. Initial thyroid testing for screening was a thyroid-stimulating hormone (TSH) alone in only 73% of patients, despite literature recommendations supporting TSH alone as a suitable strategy. Follow-up often involved either unnecessary testing or did not include indicated testing. Computer-based interventions to improve the ordering of lab tests could potentially save substantial resources without missing important clinical results.

**Summary**

Currently, there is relatively poor compliance with accepted guidelines of care and guidelines for monitoring and testing. Computerized reminders and decision support have significant potential to improve these compliance rates. In addition, computerized alerting can quicken provider response to abnormal test results.

**Medication Prescribing**

Adverse drug events (ADEs) and medication errors are common in the inpatient setting. Fewer data exist in the ambulatory setting, but several recent studies have increased our understanding of the frequency of these outpatient events. In one study, a cross-sectional chart review and patient survey of primary care patients in 11 ambulatory clinic sites was done. Eighteen percent of patients reported problems or symptoms related to their medications. Among the ADEs detected by chart review, patients had had a previously documented allergy to the medication in 11%, and 4.5% required hospitalization. These data suggest that drug complications in the ambulatory setting are common and can be serious and preventable.

A prospective study of 4 outpatient clinics using prescription review and patient survey identified adverse drug events in 25% of patients and medication errors in 9% of prescription. Of these, almost half had potential to harm patients. Of the 182 ADEs, 25 (14%) were serious, 21 (12%) preventable, 50 (27%) ameliorable, and 11 (6%) both serious and preventable or ameliorable.

While many strategies for preventing medication errors and ADEs have been proposed, the evidence supporting their efficacy is, with some exceptions, limited. Bates et al. showed that implementation of a physician order entry system resulted in a 55% decrease in the serious medication error rate, and others have found that delivery of
Computerized decision-support for antibiotics reduced costs and improved outcomes. Computerization of prescribing with accompanying decision-support seems likely to be important in all settings, although its yield and the most important types of decision-support are likely to vary by setting.

One study assessed the impact of basic computerized prescribing on medication errors, potential ADEs, and ADEs in the outpatient setting. Basic computerized prescribing at two study sites included printed prescriptions and required fields, but the programs contained few defaults or checks for allergies and drug interactions. Prescriptions from these computerized sites contained significantly fewer medication errors (7% vs 15%, p<0.0001) and rule violations (32% vs 40%, p<0.0001). However, potential ADE rates and ADE rates were not significantly different.

Physician reviewers judged that computerized medication ordering with appropriate decision support could potentially have prevented 92 of 159 (58%) of the medication errors and 47 of 81 (57%) potential ADEs. The majority of medication errors could have been prevented with requiring complete prescriptions (44 of 92, 48%), frequency checking (20 of 92, 22%), and dose checking (13 of 92, 14%). Requiring complete prescriptions and dose checking were much more important for handwritten sites. More advanced decision support would also have prevented a third of preventable ADEs. Other advantages of computerized prescribing systems include the ability to reduce transcription and verbal orders by automatically sending prescriptions to pharmacies and to improve the upkeep of accurate medication lists in the medical record.

**Summary**

The evidence suggests medication prescribing errors in the ambulatory care setting are common, serious, and can be prevented. Simple alerts about pre-existing drug allergy could dramatically impact medication errors due to allergy. The impact of more advanced computerized decision support for drug interactions, dose, frequency, route, and prescription completeness, could also dramatically impact medication errors in the ambulatory care setting.

**Medication appropriateness and monitoring**

Many guidelines have been developed regarding when to treat and which drugs are most cost-effective. However, the effect of these guidelines on physician behavior is limited. Both under use and overuse are problems; for example, many patients status post myocardial infarction do not receive beta-blockers, while expensive medications are commonly given when less expensive drugs would be as effective, and drugs are often given for uncertain or inappropriate indications. One study demonstrated widespread inappropriate antibiotic use for colds, upper respiratory tract infections, and bronchitis nationwide. This inappropriate use of medications, both in terms of under use and overuse, can have a substantial impact on patient safety, both in terms of potential disease aversion and unnecessary ADEs.
A study was also done to evaluate the use of cholesterol-lowering drugs in a large outpatient population, the range and variation of monitoring, and the impact of monitoring. Monitoring for safety of statin lipid-lowering medications varied widely, despite guidelines, and intensity was not higher for patients at highest risk.

These studies suggest that physicians have trouble following monitoring guideline recommendations and could benefit from decision-support. One study to improve appropriateness and monitoring of medications through computerized decision support showed that compliance with various protocols for medications and monitoring increased from 22% to 51%. Another study demonstrated that a computer screen displaying an adaptation of the Center for Diseases Control guidelines for appropriate vancomycin at the time of physician order entry resulted in 32% fewer orders. This type of intervention should be amenable to the outpatient setting, especially for medications such as antibiotics.

**Summary:**

Medication errors and ADEs are common and preventable in the outpatient setting. Computerized prescribing with advanced decision support has potential to substantially reduce these error and ADEs, as well as improve appropriateness of prescribing and monitoring.

**Adverse Event Detection & Reporting**

Perhaps the primary reason that the “hidden epidemic” of medical injury has received so little attention until recently is that most institutions use spontaneous reporting to detect adverse events in general and ADEs in particular. However, spontaneous reporting is ineffective, identifying only 1 in 20 ADEs. Efforts to increase the frequency of spontaneous reporting have had only a minor impact.

To reduce the rate of a problem, it is essential to be able to measure its frequency on a routine basis. One possibility is improved reporting systems that are quick and easy to use. Several groups are currently developing and studying the impact of such web-based reporting systems in the inpatient and outpatient settings, and anecdotal evidence exists that these systems can increase reporting by 8-10x. Integration of these reporting systems into electronic medical records and routine work flow could be particularly useful to facilitate reporting. In addition, prompted reporting has been shown to improve the frequency of spontaneously reported events and could be implemented in the outpatient setting. Inpatient and outpatient pharmacies also have the ability to track interventions they make to prevent medication errors, and this is an underutilized resource.

Inpatient tools have been developed that allow routine identification of ADEs in an ongoing automatic way. In 1991, Classen et al. published information about a computerized ADE monitor that identifies signals suggesting that an ADE is present. Such signals can be followed up by a trained reviewer who can then determine whether an ADE is present. Based on the rules in this study, Bates et al. developed a similar
monitor, and showed that it can identify approximately half the ADEs identified by chart review, at much lower cost \(^91\). One community hospital implemented a similar ADE monitor and identified opportunities to prevent patient injury at a rate of 64/1000 admissions \(^94\). Also, Bowman and Carlstedt used the Regenstrief Medical Record System to create a computerized inpatient ADE detection system \(^92\). Compared to a “gold standard” of chart review, the monitor had 66% sensitivity and 61% specificity, with a positive predictive value of 0.34.

These prior studies demonstrated markedly enhanced ADE detection rates as compared with voluntary reporting systems. While such computerized monitors are not yet widely used, they offer an efficient approach for monitoring the frequency of ADEs on an ongoing basis. Little has been done, however, to translate these kinds of monitoring systems to the outpatient setting. One of the major reasons for this is that, unlike hospitalized patients, outpatient clinical information is often not computerized as described above. Even if computerized data are available, key pieces of information may reside in disparate systems, potentially in multiple locations, and under the purview of different business entities. Therefore, development of automated systems to identify ADEs in these settings is more difficult.

As computerized outpatient records become more common, the techniques learned in the inpatient setting will be translatable to the outpatient setting. One group developed a computerized monitor that allows detection of ADEs in outpatients using a computerized outpatient medical record \(^95\). The detection application looked for newly recorded allergies, ICD-9 codes likely to be associated with ADEs, laboratory values suggesting the presence of an ADE, and drug-symptom combinations within notes suggesting that an ADE may be present (e.g. ACE inhibitor and cough). The computer program identified 25,056 incidents, which were associated with an estimated 867 ADEs in 864 patient visits. Therefore, computerized search programs can successfully detect ADEs, and free-text searches were especially useful.

**Summary:**

Detection of adverse events, particularly those related to medications, is critical for subsequent quality improvement initiatives. Computerized spontaneous reporting systems and computer monitor methodology are both promising ways to detect outpatient events.

**Population Surveillance, Tracking and Follow-Up**

Clinicians are responsible for tracking and follow-up of an increasing number of results from ancillary studies. This problem is exacerbated due to increasing patient volumes resulting from managed care pressures. Paper-based or memory-based methods for tracking laboratory results are prone to error. This is perhaps no more evident that in the area of abnormal pap smear follow-up, where loss-to-follow-up rates have ranged from 30% to 50% \(^96,97\).

In addition, as patients have become better informed about health care, they have developed higher expectations for follow-up \(^98,99\). Evidence from malpractice litigation
also suggests that incomplete follow-up of test results is an important issue\textsuperscript{100}: more than $\frac{1}{4}$ of diagnosis-related malpractice cases can be attributed to failure in the follow-up system. In response to these concerns, the National Committee for Quality Assurance (NCQA) has proposed missed follow-up of abnormal test results as one of its outcome measures to be included in the new HEDIS criteria.

A number of factors have been postulated as the root causes of this problem: physicians may be short on time or lack the necessary support staff; paper-based systems may fail; patients may not understand the follow-up plan; physicians and patients may forget about the follow-up plan; and physicians may not know what the appropriate follow-up plan is. There is a relatively large literature on efforts to increase patient adherence with recommendations for further evaluation of abnormal pap smears or breast cancer screening. However, very little literature on the follow-up of test results exists.

In one study\textsuperscript{18}, documentation of transmitting results to patients and documentation of follow-up plans for abnormal mammograms, pap smears, and cholesterol tests were examined. Significant deficiencies were found. For example, on average 47% of records had no documentation of results transmitted to patients (mammogram 44%, pap smears 50%, cholesterol 45%) and 20% of records had no documentation of follow-up of abnormal results (mammogram 16%, pap smears 7%, cholesterol 35%).

This study also used the Picker ambulatory survey to assess patient reports with testing, including understanding need for tests, how to get test results, and having test results explained in the way they could understand\textsuperscript{18}. Patient satisfaction with testing appeared to be associated with the documentation of communication with the patient. Among patients to whom results were transmitted, 86% reported satisfaction with the testing scale, compared to 72% of those without such documentation ($p<0.05$). Those with a documented follow-up plan in the record were more likely to be satisfied with testing (85%), compared to 75% for patients without a follow-up plan in the record ($p<0.05$). This study emphasizes the deficiencies that exist in documentation and communication of test results and in the follow-up of abnormal results. Another study showed that direct mailing of pap results to patients improved follow-up\textsuperscript{101}.

Another study looked at the frequency of ADEs in the post-discharge period and found that 19% of patients experienced an adverse event after discharge (includes medication-related and non-medication related)\textsuperscript{102}. Of these, 12% were preventable or ameliorable.

Medication reconciliation is also an area fraught with possibilities of error. Inpatients are often transferred multiple times to multiple units during a hospitalization, often transferred to outside facilities (rehab, nursing homes) and then subsequently to home. At each transfer, new medication orders may be written, and the potential to omit or duplicate certain therapies is high. Systems that can streamline this process and facilitate transfer of medication information from outpatient systems to inpatient systems, as well as pharmacy systems, could reduce these opportunities for hand-off errors.

**Summary:**
Information systems can play an important role in improving tracking, follow-up, and communication, of results. Such systems can collect the data of interest, present the data to the clinician in an organized manner, provide easy links to other relevant patient data and guidelines, and facilitate communication with the patient. Further research needs to be done to determine the best way to develop and implement these kinds of tracking and follow-up systems for clinicians, and to determine reliable and appropriate means of communication to patients.

Electronic Communication

We divide our discussion of the impact of information technology on communications into two parts: effects on communications within and between clinics, and effects on provider-patient communications.

Clinic communications

The referral process is the critical communication link between primary care and subspecialty care for outpatients. Ideally, a referral communication should include a specific goal or question, pertinent clinical information, and the referring physician’s initial assessment. Feedback from the specialist should occur soon after the consultation visit so that continuity of care is not disrupted. However, evidence from physician surveys indicates that neither the initial communication nor feedback from the specialist occurs reliably. This breakdown in physician-to-physician communication has led to delayed diagnoses, polypharmacy, increased litigation risk, and unnecessary testing.

Referral letters are the standard communication medium of consultations, and have been the focus of prior research. Ninety percent of generalists and consultants agree that referral requests should include a statement of the medical problem, current medications, and specific clinical question. However, while 98% of referrals contain patient background information, only 76% state an explicit purpose for the referral. This discrepancy may explain why in 14% of inpatient consultations, the referring physician and consultant disagree on the reason for the consultation.

In the outpatient setting, the interaction between referrer and specialist is presently inadequate and a source of dissatisfaction. Sixty-three percent of primary care physicians in one system were dissatisfied with the referral process. Reasons most often cited were late consultation reports, redundancy in the current referral process, and the time required to create an adequate referral note. Forty percent of PCP’s had not received feedback from the consulting specialist 2 weeks after the initial evaluation. The problem of late or missing feedback has not automatically resolved with the advent of new communication technologies. In 1980, physicians received follow up information from consultants in 62% of cases while 18 years later the follow-up rate is reported at 55%.

Specialists are likewise dissatisfied with the referral process. In one study, 48% stated the information from the referring physician was untimely, while 43% felt the content of the referral request was inadequate. Their primary concern was the failure of referring...
physicians to include a specific question and pertinent past medical history in the request. This missing information may be a substantial drain on physician time and office resources.

Little research has been done to study systematic changes to the referral process that could improve these deficits in communication. Computerizing the referral process and substituting electronic messaging for paper-based communications could help solve the problem of insufficient information exchange. Implementing referrals within a networked environment could facilitate communication between primary care physicians and specialists by making it easier to send a complete referral letter and more quickly receive feedback. Computerized referral templates could require necessary data elements, and unlike paper-based forms, can enforce those requirements. Coded information already stored within the electronic medical record could be automatically included in the communications, eliminating time-consuming data re-entry. Referral messages also could be routed to multiple recipients, ensuring that the clinical process and managed care approval process proceed in tandem without physician intervention. Finally, the status of referrals on multiple patients could be tracked in a central location, so that primary care providers (PCP) can more quickly know when a specialist’s evaluation is complete.

Summary:

Poor communication has led to pervasive dissatisfaction among providers and likely results in sub-optimal care and substantially increased costs. Electronic communications have the potential to improve clinical care and physician satisfaction with the referral system, by facilitating the transfer of appropriate and relevant clinical information between providers. These systems need to be developed and implemented in order to determine their impact.

Patient communications

Improving patient education about their medications, patient understanding of their plan of care, and patient access to their physicians are all important aspects of patient safety. In one study, outpatients were significantly less likely to report a drug complication if they had been advised of side effects beforehand. In another study of outpatient ADEs, 39% of ADEs were ameliorable, defined as an ADE whose severity could have been substantially reduced if different actions had been taken. Ameliorable ADEs were attributed to physicians’ failure to act on results of symptom monitoring (62%) and patients’ failure to inform their physician of problems (38%). Therefore education about medications and improved patient-provider communication about problems when they occur are important issues to address.

Healthcare consumers are flocking to the Internet in advance of clinicians to find second opinions, and general health resources. Patient involvement in their plan of care, including preventive health screening and follow-up of abnormal test results is a critical piece of improving compliance with guidelines. With the widespread adoption of electronic mail and use of the Internet, e-mail communications between providers and
patients may potentially improve information exchange \(^{31}\), and ultimately impact healthcare outcomes.

**Summary:**

Improved provider-patient communication impacts patient understanding of their health, medications, and care management. Information technology including the Internet and electronic mail may improve patient communications and education.

**Conclusions**

The evidence is clear that IT can have a significant impact on patient safety in the inpatient care delivery setting. Clinical information management systems improve provider access to relevant patient information, improve test ordering practices and reduce redundant test ordering, improve medication prescribing, and may prevent certain medication errors. Reminder and alerting systems may modify provider behavior at the time of clinical decision making, improve compliance with practice guidelines, and impact disease and population management. IT can support improved provider-patient communications and patient education. These effects have been demonstrated in a handful of leading academic medical centers committed to IT adoption and assessment of the impact of these technologies.

While there is less direct evidence in the outpatient environment for similar effects it may be expected that many of the effects will be borne out there as well. While the characteristics and attributes of information management in the outpatient environment are different than the inpatient environment \(^{5}\), many of these IT effects will still apply. In fact, other effects may be demonstrable in the outpatient environment which are not demonstrable in the inpatient environment. Nevertheless, to advance the patient safety agenda in ambulatory care, we believe certain obstacles must be addressed, and incentives created to foster technology adoption in this environment.

**NEXT STEPS FOR AMBULATORY PATIENT SAFETY**

Given that IT has the potential to greatly improve patient safety in ambulatory care, how might these technologies be applied? What are the obstacles to overcome before IT can be effectively applied broadly to outpatient care? The answers to these questions depend largely on the organizational context from which they are asked. It is beyond the scope of this report to review the determinants of organizational readiness, or motivation, for adoption of IT in ambulatory care settings. However, certain barriers and obstacles are fairly well understood and will be briefly reviewed here. It is our belief that providing an economic incentive alone would foster alignment of other organizational incentives, and be sufficient motivation for physicians to adopt IT in support of patient safety quickly.

**What Obstacles Need to be Overcome**

**Incentives for Technology Adoption**
While the healthcare IT marketplace generally appreciates the need for improved clinical information management to support patient safety and clinical efficiency, there is not yet widespread adoption of EMR technology. Clinicians generally understand that EMRs can improve their patient care, but to date have resisted adoption because of costs of the technology, a perception that the technology would not meet their needs, and the complexity of implementation and customization in their clinical environment. In the context of continued healthcare organizational turmoil, continued healthcare cost inflation, shrinking physician incomes, and smaller healthcare profit margins, it is not surprising healthcare providers are taking a ‘wait and see’ attitude before making considerable technology investments.

Pressure for improved patient safety is being applied in the inpatient setting by leading healthcare purchasers. Selected payers, and health care systems, are now experimenting with providing a reimbursement differential as incentive for adoption of this technology. The Leapfrog Group has been leading the way in this regard\textsuperscript{115}. The NY Times\textsuperscript{116} reported on Nov. 1, 2001 that Verizon, IBM, and PepsiCo had joined with Empire Blue Cross/Blue Shield to provide an incentive for New York hospitals to adopt Leapfrog patient safety standards that include technology such as physician order entry. The payer will provide 4\% premium (based on charges) to hospitals that adopt the standards by Jan. 1, 2002, and progressively lesser premiums if adopted by 2003, or 2004. While this focuses on the inpatient environment with an indemnity insurance plan, it points to an interesting idea to stimulate adoption of technology in support of patient safety.

In the ambulatory care setting, there is less pressure from payers to date for adoption of IT to support patient safety. In one setting, however, an experienced and expert EMR user has documented a variety of ways that a clinics’ use of EMR has lead to clinic savings and quality improvements\textsuperscript{117}. These insights, supported by data from the EMR, have allowed this clinic to improve his capitation rates through a differential payment for improved formulary compliance. In this case, (for additional detail see:\textsuperscript{118}) taking national statistics showing estimated savings of $0.30 pmmp for each 1\% increase in generic or formulary compliance, an incentive program was developed whereby each provider would be credited $0.10 pmmp for every 1\% increase in generic usage or formulary compliance. If this percent exceeds 5\% in any given year, then $0.15 pmmp would be credited.

Similar incentives for improved patient safety, or compliance with accepted guidelines for healthcare maintenance, if widely applied by healthcare payers, could have a profound effect on ambulatory care technology adoption. Already many primary care physician salaries and managed care contracts are tied to physician or clinic performance on these types of guidelines. For example, in the Partners Community Healthcare, Inc. (PCHI), affiliated community physicians will receive bonus payments based upon their attainment of benchmark compliance rates for specific interventions or practices\textsuperscript{119}. For example, adult physicians attaining a 75\% compliance rate with Pap Smear, 70\% with Mammography, and a composite benchmark for diabetes care (all based upon HEDIS measures) would receive an $1.00 pmmp for each benchmark attained. To comply with these goals, physicians will have to produce practice-based reports documenting their
compliance. The easiest way to do so would be with an electronic medical records system with reporting capabilities.

**Patient Privacy, Data Security and Confidentiality**

Beyond lack of sufficient financial incentives, many clinicians and healthcare systems are not yet sure how to deal with their own and their patients’ concerns surrounding patient privacy and the security and confidentiality of patient data. Regrettably, due to several well publicized security breaches in which private information was wrongfully disclosed, and the well publicized continuing debate on protection of confidentiality and user identity on the World Wide Web, most clinicians and health care systems are also unsure of how to proceed. Clarity deriving from the Healthcare Insurance Portability and Accountability Act (HIPAA) of 1996, and the DHHS rules and regulations emerging on the issue of protected health information should help, but the nation as a whole is still wrestling with appropriate boundaries for patient privacy and data confidentiality weighed against improved patient safety and healthcare delivery efficiencies.

**Data Standardization**

Even if clinicians and healthcare delivery systems have sufficient incentive to adopt new technologies and are confident they would not suffer increased liability exposure from information management using these tools, the field of medical informatics has not yet standardized all of the data types across the spectrum of clinical and administrative healthcare information systems. Nevertheless, one of the leading pundits in the field argues correctly that we have sufficient standards now for basic representation and exchange of healthcare using existing standards for clinical messaging via HL-7, and existing codes for an individual’s healthcare problems (ICD-9-CM), tests and procedures (CPT), and laboratory results (LOINC).

While HIPAA goes a long way in the Administrative Simplification Subsection to specify the standards for administrative, pharmaceutical, and billing transactions, and information exchange, it regrettably not as strong in specifying a comparable set of standards for patient medical record information. The NCVHS report on Uniform Data Standards for Patient Medical Record Information of July 2000 provided guiding principles for selecting standards for patient medical record information but did not set standards; these are expected in a follow on report to be delivered 18 months after the first report. In the absence of a nationally mandated standard for such information, even at the most basic level, vendors of clinical information management systems are left to their own devices to meet the users perceived needs. Vendors often do not go so far as considering data standardization for the broader context of healthcare; rather they are often limited by their own somewhat myopic view of their needs for an individual clinic or delivery system (see testimony of Dr. Middleton before the NCHVS on patient medical record information for additional discussion).

**Interoperability**
Given the lack of data standardization, physicians’ clinics, or even healthcare delivery systems, are typically unable to electronically exchange clinical information. Administrative transactions are for the most part standardized, and are readily exchanged between small and large healthcare delivery systems, and payers, thanks to ASC X12N EDI standards. Further work is being done under the rubric of HIPAA to refine and extend the ASCX12N standards framework, and work is being done on the NCPDP framework for pharmaceutical claims data exchange, but critical work needs to be done on defining a minimal essential data set for patient clinical data. Such a data set would be defined by analysis of the literature to determine the intersection of information needs for patient safety alerts or reminders and care management protocols for key conditions.

**Recommendations**

While the evidence would suggest there are a wide variety of opportunities for improving ambulatory care patient safety, we choose to focus our recommendations in several key areas in recognition of the need to incrementally change the fundamental nature of ambulatory care clinical practice: development of a national patient safety knowledge-base, development of national minimal standards for ambulatory patient safety, and development of standards for minimal patient communication in ambulatory care. We call for reimbursement reform in ambulatory practice to provide the incentive for clinicians and healthcare delivery systems to adopt technologies to support patient safety. Appropriate financial incentives will drive adoption of these technological innovations. We separate knowledge development activities from safe practice standards to allow each to be developed simultaneously. Pointedly, we do not make any particular technology recommendations. We discuss these recommendations each in turn.

**No technology recommendations**

We do not recommend at this time a mandate for widespread adoption of a particular technology to impact patient safety in ambulatory care. It would be presumptuous to do so in the current marketplace – there is no single technology which by itself broadly addresses many ambulatory care patient safety issues, and to do so would be contrary to the typical American approach of letting the private sector respond to opportunity. The technology landscape also changes dramatically and quickly, and it is impossible to predict with any certainty which technologies will be widely favored and persist in their use, vs. those which may be passing fads. Nevertheless, given the fractured nature of the current US healthcare delivery system, and in the absence of strong incentives for technology adoption, we believe several activities and new standards for ambulatory practice may be usefully pursued and promulgated. Given the appropriate incentives were put in place, current technologies would be widely adopted and profoundly impact ambulatory care patient safety.

**Development of National Patient Safety Knowledge-base**

Two key activities should be undertaken immediately to create a national resource to support ambulatory care patient safety.
Definition of essential minimal data set for ambulatory patient safety

The first critical element of a national patient safety knowledge-based would be specification of the key data elements required in ambulatory practice clinical information systems to support safe care practices. This would include identification of key data elements to support clinical decision support systems, as well as outcomes analyses, or other population analyses (e.g. to create clinical dashboards). Specifying this set of critical data elements with appropriate attributes, allowable code source (ICD, LOINC, ASTM, etc.), and, if necessary, appropriate controlled medical terminology, would allow vendors of clinical systems to be sure these data elements were represented in their products to support the implementation of the next critical element: guidelines for alerts or reminders in ambulatory care. Such a ‘data dictionary’ for patient safety should be a national priority of the first order.

Definition of essential guidelines for alerts or reminder systems in ambulatory care

While commercial software vendors may use medication knowledge-based available from such companies as First Databank, and Cerner/Multum, there is no commercial source of essential guidelines for alerts or reminder systems knowledge. Well known rule sets from academic centers \(^{124-127}\) have been created and found to be useful but it is difficult to export these rules even with the Arden Syntax to commercial systems \(^{128}\). Creation of a validated library of care rules, even without much attention to the representation of the knowledge, would be very useful to the vendor community. Vendors could then implement these rules in their systems in the manner appropriate for their system. While this may decrease the differentiation between vendors in this one regard, it would certainly lead quickly to improved patient safety. Vendors would still require their products to have the ability to customize rules based on the local situations of each of their customer implementations. Most vendors view the knowledge engineering required to create and maintain such a knowledge-base as beyond their commercial purview – they are not the appropriate authority to create such a resource. Most customers of clinical systems view having at least a starter set of useful clinical rules from a validated knowledge-base, yet this is not available from either the vendor or any other source. Thus, there is a chicken and egg problem. National leadership is called for to move us beyond this conundrum.

Development of minimal ambulatory care safe practice standards

No handwritten prescriptions

Many recognized experts, organizations and institutes are calling for widespread adoption of computer-based provider order entry (CPOE) soon. These include the Institute for Safe Medication Practices (ISMP), National Coordinating Council for Medication Error Reporting and Prevention, and the American Society of Health –System Pharmacists. Outpatient CPOE could start with prescriptions as a reasonable first step \(^{129}\). This is feasible with a wide variety of currently available commercial technology. See figure 1 for a screen shot from a commercially available EMR prescription writing system.
We suggest that healthcare purchasers could apply pressure for the adoption of technology to support electronic prescribing in the ambulatory practice environment. Providers could meet this requirement by use of a handheld (PDA) system for generating prescriptions, a desktop (self contained) EMR system, a client-server EMR system, or a web-hosted EMR system. We believe, however, that to fully support ambulatory care patient safety initiatives, the clinical information management tool must at a minimum provide access to a longitudinal medical record containing a patient’s problem list, medication list, laboratory data, and allergies. This level of functionality is consistent with most commercially available desktop or client/server EMR packages, and web-hosted EMR applications, but not PDA-based prescription writing systems.

**Compliance with selected care management guidelines**

After reducing medical error due to medication prescribing, we suggest purchasers apply pressure to ensure providers’ compliance with selected care management guidelines, for example preventive care guidelines, and perhaps selected conditions recommended by the IOM Report Crossing the Quality Chasm[^130], or as described above in Partners Community Healthcare, Inc. Demonstration of compliance would most readily be served by adoption of clinical information management technology such as EMRs that support creation of practice profile reports. Such a reporting requirement would not be supported by use of a prescription writing system alone. See figure 2 for a screen shot of preventive care reminders presented in a commercially available EMR system.

**Clinical Communications**

We further recommend that the following be established as a standard of ambulatory care: patients are routinely informed of all of their laboratory results with a reasonable explanation of abnormal findings – similar to the manner in which customers are kept abreast of the status of their bank accounts from financial institutions. Such a standard would necessitate dramatically improved provider-patient communications, and would provide two independent means to be sure no abnormal test results were ever lost to follow-up: the provider, and the patient. This standard could be served by providing routine paper-based reports to patients of relevant healthcare information, or more simply allowing patient’s secure access to their online medical records once established, as is done with ‘online banking’ today.

**Ambulatory care reimbursement reform to support patient safety**

A cornerstone of our recommendations, however, is that the payer community apply pressure in the ambulatory practice sector, much like the Leapfrog Group is applying pressure in the inpatient setting (and possibly soon in the outpatient setting) for improved patient safety. It is beyond the scope of this report to determine the form and mechanism of such reimbursement reform under all payment systems. However, financial incentives are essential to prompt action by clinicians and healthcare delivery systems in the current climate.
CONCLUSION

The evidence for improving patient safety with the use of information technology in the ambulatory practice environment would suggest that immediate gains in safety can be had with adoption of electronic prescription writing systems with medication interaction decision support, and alerts or reminders for preventive care and condition-specific care management. While the technology is sufficiently mature to improve patient safety it is not yet widely adopted in ambulatory practice settings. In addition, since this is an incremental approach, systems that include results tracking, improved clinic and patient communication features, and adverse event reporting are all features that should be considered for immediate adoption. Financial incentives from payers are necessary to motivate providers and healthcare delivery systems to adopt technology in support of patient safety. While today’s technologies can have an impact, additional work needs to be done to increase the knowledge-base for such clinical decision support systems and make it widely available.
FIGURES

Figure 1. Prescription writing in an EMR (Courtesy Medscape, Inc.)
Figure 2. Alerts and Reminders in an EMR (Courtesy Medscape, Inc.)
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