

Meeting the Challenge of Patient Safety in the Ambulatory Care Setting

Medical Group Management Association
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White Paper

TABLE OF CONTENTS

Executive Summary.....	3
Introduction.....	3
Evolution of Patient Safety.....	4
Moving Beyond Risk Management.....	5
Culture of Safety.....	5
Migrating Patient Safety From the Hospital to the Ambulatory Setting.....	7
Patient Safety in Ambulatory Surgery Center.....	7
Patient Safety in Office-Based Surgery.....	8
Patient Safety in the Physician Office.....	9
Policies and Procedures as Patient Safety Infrastructure.....	11
The Leadership Challenge.....	11
The Administrator as Chief Safety Officer.....	12
The Role of the Physician Leader.....	12
Other Members of the Patient Safety Leadership Team.....	13
Practice Assessment as a Change Event.....	13
Policies and Procedures to Support the Patient Safety Changes.....	14
Conclusion.....	15
References.....	16
Authors.....	18

EXECUTIVE SUMMARY

Until recently, most of the attention to patient safety and quality was focused on inpatient care. However, the last 20 years have seen rapid growth in the volume and complexity of procedures provided in ambulatory settings, so greater attention is now focused on ambulatory care and physician practices. Because healthcare is frequently delivered for episodic needs that involve multiple providers in several sites, the events that compose an episode of care are seldom “seamless.” Transitions between inpatient and ambulatory care as well as between different points in ambulatory care increase the risk of adverse events and shortfalls in quality of care. It has become increasingly clear that attention to safety and quality is required across the whole spectrum of care. Physicians and physician practices, which have responsibility for the patient across this spectrum of care, need to pay particular attention to these transitions and potential discontinuities in care.

The provision of care in many small and independent physician offices has presented a unique set of challenges to the leadership of these practices in terms of adapting patient safety practices that were originally developed for larger hospitals. This paper delves into these challenges and presents the policies and procedures used by the leadership to create patient safety infrastructures in the physician offices. The paper concludes with a section on practice assessment and change management that can lead a physician practice to consciously and candidly examine its patient safety record.

This paper is conceptual in nature in that it presents the patient safety developments over time and within the changing landscape of healthcare in the United States. It is also the precursor to an anticipated second paper in which the tools to improve patient safety in physician offices will be covered in some detail.

INTRODUCTION

While most ambulatory care is less technically complex than inpatient care, it is often logistically more complicated. An episode of ambulatory care often requires communication and

coordination among a number of clinicians, laboratories and imaging facilities, as well as the patient and the family, across different sites. This infrastructure frequently provides suboptimal support for coordinating and managing care. Another unique component of ambulatory care is reliance on the patient and/or the patient's family to seek treatment and carry out much of his or her own clinical management.

Patient safety has taken center stage in the healthcare debate since the publication of the Institute of Medicine (IOM) report, *To Err is Human* (Kohn, Corrigan, & Donaldson, 1999). The report highlighted the about 100,000 avoidable deaths that occur due to medical errors in hospitals in any given year. Much of the patient safety literature uses this watershed as the starting point of the patient safety movement in the United States.

This white paper traces the origins of the patient safety movement to early in the last century and notes the role played by physicians and practice administrators who were instrumental in setting standards for the provision of safe care in medical settings. It illustrates how patient safety has evolved and how the concepts have been adapted from the hospital setting into the ambulatory setting, where most healthcare is currently provided.

EVOLUTION OF PATIENT SAFETY

Physicians and administrators have played an important role in developing and implementing policies, procedures and standards related to patient safety. The Joint Commission, for instance, began in 1917 when the American College of Surgeons (ACS) created a hospital accreditation program (Joint Commission, 2009). Other prominent organizations such as the American Medical Association (AMA), the American Hospital Association (AHA) and the American College of Physicians (ACP) joined the board in 1952 (Sandrick, 2004). Similarly in 1979, in response to the growing complexity of care provided in the ambulatory setting, the Medical Group Management Association (MGMA) was a founding member of the Accreditation Association for Ambulatory Health Care (AAAHC, 2009). The accrediting organizations began as peer-based assessments of how quality patient care is delivered in safe environments.

Accreditation became formalized with the Social Security Amendment of 1965, which stated that organizations accredited by the Joint Commission on Accreditation of Hospitals

(JCAH), an earlier incarnation of the Joint Commission, also met the Medicare conditions of participation by hospitals. Many state licensing bodies also demanded accreditation, further formalizing what was in essence a voluntary activity at its inception. In 1982, Medicare began paying for procedures performed in ambulatory surgery centers and made accreditation a requirement for those wanting to participate in the Medicare program.

As accreditation became formalized, the concept of peer-based assessment of patient safety and quality of care largely gave way to the more reactive movement of meeting standards. Practice administrators and physicians had little role in developing these standards, with factors such as litigation and risk management playing a large role in this progress (Berenson, 2005; Smith, 2005). The malpractice mindset encourages an approach to patient safety that is largely reactive to “sentinel events” and “incident reports.” It replaces ongoing administrative oversight of standard medical practice with more clinical activity to alleviate risk.

MOVING BEYOND RISK MANAGEMENT

Typical risk management involves minimizing financial and public relations damage related to an actual or potential medical legal action. While this process is an important aspect of any healthcare business, legal actions related to medical errors can also lead to the prevention of similar errors in the future. Analyzing near-misses and errors for trends can reveal areas of weakness and provide the opportunity for improvement of processes or systems before another error occurs. Performing an in-depth, root-cause analysis of serious events provides the foundation for building new processes that incorporate safety mechanisms. These mechanisms can help reduce and prevent future harm to patients.

CULTURE OF SAFETY

Traditionally, it was assumed that physicians primarily determined the quality of care. Over the past several decades, it has become increasingly clear that the safety and quality of patient care depend both on the decisions and actions of clinicians as well as the reliability and effectiveness of processes and systems in the physician practice. In fact, the greatest potential gains in patient safety may result from improving the infrastructure of information management, communication and coordination of care. These processes and systems are the responsibil-

ity of clinicians as well as managers and administrative staff, and include both clinical processes (e.g., clinical decision-making) and clinical support processes (e.g., management of information). Administrators and clinicians need to establish a culture within the practice that encourages working in partnership to establish and maintain these systems.

Organizational culture is typically a vague group of ideals that may be difficult to define. Krause and Hidley (2009) define culture as “a distinct, observable and measurable set of attributes that we know to be predictably related to exposure to hazards in the working interface and thereby to the presence or absence of preventable adverse events.” They go on to describe the working interface as any area where treatment occurs or where healthcare workers accomplish their jobs. In the ambulatory setting, examples include the exam room in the physician’s office, laboratory, community pharmacies, medical transportation and patient homes. It becomes very difficult to control the culture in all of these diverse locations and promote safety regardless of where the medical interaction occurs.

Establishing a culture that not only embraces but rewards reporting also encourages personnel to report errors or near-misses (Elder, McEwen, Flach, & Gallimore, 2008). Developing feedback loops so staff and providers understand the connection between reporting and the processes that are improved is important to establish a culture of reporting (Kaprielian, Østbye, Warburton, Sangvai, & Michener, 2008). Many organizations today rely on reporting by staff to learn about breaches or potential breaches in safety.

While the approach to patient safety has changed over time, the complexity of care provided in the ambulatory environment continues to increase (Hammons, Piland, Small, Hatlie, & Burstin, 2003). As the majority of healthcare provision has migrated from an inpatient to an outpatient setting, patient safety and quality-of-care issues have followed.

To explore how to assess and improve quality and safety, leaders in the field have focused on six dimensions of the processes and outcomes of care as identified by the Institute of Medicine in its report, *Crossing the Quality Chasm: A New Health System for the 21st Century* (IOM, 2001).

- Healthcare must be safe.
- Healthcare must be effective.
- Healthcare should be patient-centered.

- Healthcare should be timely.
- The healthcare system should be efficient.
- Healthcare should be equitable.

MIGRATING PATIENT SAFETY FROM THE HOSPITAL TO THE AMBULATORY SETTING

Care provided in the inpatient hospital setting is by its very nature different from that provided in outpatient settings. The patient usually has a longer stay in inpatient settings, being admitted for certain kinds of serious treatments and therapies that are best provided in a setting where the patient is monitored by automation and healthcare providers. The patients may have less autonomy in such settings not only because of treatment protocols but also because their role in their own care is often more passive rather than active (Wachter, 2006). In contrast, care provided in ambulatory settings is episodic in nature, and the patient plays an important role through adherence and self-management at home. Thus, while providing safe care is an important aim for either setting, the approaches taken to achieve safer care need to take into consideration the similarities as well as the differences between providing hospital-based versus outpatient care (Hammons, et al., 2003).

PATIENT SAFETY IN AMBULATORY SURGERY CENTER

One of the earliest ambulatory surgical centers (ASC) was opened in Phoenix, Ariz., by Drs. Reed and Ford in 1970. Initially, the focus was on a limited number of procedures that could be safely performed without admission to a hospital and the resulting overnight stay. Although 85 percent of the procedures performed on adults were under general anesthesia, after 60,000 procedures, not one patient from the Phoenix SurgiCenter had a cardiac- or hypothermia-related complication. The hospital transfer rate was 0.2 percent (Dawson & Reed, 1980).

Although early ASCs were able to exhibit safety characteristics similar to hospitals, their growth remained slow. Medicare coverage for procedures performed in ASCs was not approved until 1982. There were only 2,462 Medicare-approved facilities in the United States at that time. By 2007, the number of Medicare-approved ASCs had grown to 4,964, or over 101 percent growth

in 10 years, with most being for-profit ASCs (96 percent) and located in urban areas (88 percent) (MEDPAC, 2008).

By most objective criteria, ASCs tend to provide safer care than that provided in hospital outpatient surgical settings. Care-associated infections, often a major patient safety concern in hospitals, have historically been exceptionally low in ASCs when compared to the hospital outpatient department (Fleisher, Pasternak, Herbert, & Anderson, 2004). This is not to suggest that ambulatory surgery centers are entirely free of patient safety threats; while generally assumed to be a safer site of service for ambulatory surgery, patient safety breakdowns periodically fill the headlines. For example, in February 2008, an endoscopic ambulatory surgical center located in Nevada may have exposed up to 40,000 patients to hepatitis C due to unsafe sedation practices (Labus, et al., 2008a, 2008b).

Safer environments do not necessarily equate to better patient safety in and of themselves. Administrative oversight and enforcement of safe practices as outlined in policies and procedures, as well as follow-up with periodic self-assessment, establishes the vigilance required to maintain a high level of patient safety.

PATIENT SAFETY IN OFFICE-BASED SURGERY

While the patient safety and quality of care provided in ambulatory surgery centers benefited from standards first established in hospitals, office-based surgery (OBS) operated for many years without sound regulation, and, in some cases, patient safety suffered. In the absence of regulations, the office surgical settings were often not required to verify the provider's training, surgical proficiency and malpractice coverage. The unregulated environment of office-based surgery led one researcher to call office surgery "the wild, wild, west of health care" (Quattrone, 2000).

Data collection in an unregulated environment is problematic because data repositories are limited in scope or do not exist at all. While actual surgical volumes in OBS were assumed to be increasing, by the year 2000, only five states had any regulatory framework related to OBS practices; these were New Jersey (1998), Rhode Island, Pennsylvania, California (all 1999) and Florida (2000). The level and detail of specific regulation varied by state, but each included some reporting requirement (Sutton, 2001).

Using the data collected during the first two years of regulation, a comparative analysis of patient outcomes for surgeries performed in ASCs and physician offices in the state of Florida (April 1, 2000, to April 1, 2002) identified a tenfold increase in adverse incidents and death in the office setting versus the ASC setting (Vila, Soto, Cantor, & Mackey, 2003). Other researchers have asserted that the reporting structure used to generate data in the Florida study underestimated the total number of procedures completed in the office setting and inflated the rates of death and adverse events (Hancox, Venkat, Coldiron, Feldman, & Williford, 2004; John G. Hancox, et al., 2004). The implication is that the variation in state reporting systems lends itself to these kinds of variations in findings.

In the absence of voluntary peer-based assessment for patient safety and the quality of care, no options exist to monitor the care provided in the office-based surgical environment other than state regulation. By the end of 2007, 19 states had passed legislation outlining the regulation of office-based surgical operations.

PATIENT SAFETY IN THE PHYSICIAN OFFICE

Physician offices present a unique set of issues related to patient safety. The average American will visit a physician office four times during the course of one year (Webster, et al., 2008). Sandars and Esmail (2003) report that errors occur from 5 to 80 times per 100,000 primary care encounters, with the majority of these errors related to missed diagnoses and delayed treatments. Episodic care is another factor that contributes to medical errors in a primary care setting such as physicians' offices represent (Jacobson, Elwyn, Robling, & Jones, 2003). Some other factors that contribute to the occurrence of adverse events in the ambulatory setting include the difficulty of coordinating care across different healthcare facilities, physician-patient communication, patient self-management and medication errors (Gandhi, et al., 2000; Gandhi, et al., 2003; Kaprielian, et al., 2008; Poon, et al., 2004; Woods, Thomas, Holl, Weiss, & Brennan, 2007).

Providing staff with needed training and ensuring that the staff is competent to perform assigned tasks is the first step to ensuring that high-quality care is being provided. Many small offices do not have the resources available to send staff to continuing education courses and workshops. Staff training may only consist of on-the-job training performed by the person cur-

rently completing the task within the office. While much can be learned in these situations, there is also the opportunity for bad habits to be passed from the trainer to the trainee when true competency is not assessed. Hospitals are required to maintain licensure and meet regulatory requirements providing a degree of safety to patients. Many physician offices are not governed by standard regulatory bodies and are infrequently audited for processes. Lacking the incentive of regulations and standards makes many physician offices reluctant to initiate change. A lack of infrastructure support also contributes to safety issues in the office setting (Webster, et al., 2008). Physician office leadership can mitigate the lack of external pressures to provide safe care by utilizing self assessment tools to determine areas of risk and minimizing exposure to these risks.

Obtaining true informed consent is another area where the physician office can play an increasingly important role because the majority of discussions regarding procedures and surgeries initially take place in this setting. Simply asking patients to sign a consent form once they appear for previously discussed surgery (in inpatient or outpatient settings) does not provide for adequate education; it does not provide the needed information for the patient to understand treatment options, risk, and benefit. Taking the time to explain and discuss these issues in the primary care setting, prior to the signing of the consent, can save time and regrets later.

Patient harm can also happen through a lack of privacy, confidentiality or disclosure issues in the physician office setting because it is where most routine, maintenance visits happen. Trust in the healthcare provider can be broken when patients hear “hallway” conversations about other patients or themselves through the closed exam room door. These types of conversations constitute HIPAA violations and are subject to regulations surrounding this law. The diversity of issues covered in this section highlight the distinct nature of the care provided in physician offices and the potential for patient harm during the provision of care. The lack of standards and an assumption of patient safety can result in serious patient injury in this setting no less than in the settings where invasive procedures may be performed.

These concerns, combined with a relative dearth of externally imposed standards and incentives, have led many physician and administrator leaders of medical practices to institute their own policies and procedures in order to set quality standards and mitigate patient risk of harm in the provision of medical care. However, not all medical practices have been so proactive and many continue to harbor unsafe processes.

POLICIES AND PROCEDURES AS PATIENT SAFETY INFRASTRUCTURE

The policies and procedures developed within a physician office allow for an orderly and uniform approach to patient safety. The responsibility to develop and implement these policies and procedures falls to the leadership and management of the medical practice. Most physician offices use a team approach, drawing from the resources within the organization to assist in the development and implementation of a patient safety regimen.

Achieving consensus as to what standards are to be used for patient safety policies and procedures is often an important organizational decision. Adherence to evidence-based standards can minimize bias and help to create robust guidelines. Once these standards are adopted, they can serve as a benchmark to measure the degree of variance, which, while expected, should be infrequent and not of a high degree.

One of the key roles of the practice administrator, in conjunction with the clinicians, is to monitor, report and take corrective action as needed when variance from established patient safety policies and procedures is observed. Since no two physician offices are exactly alike, no one “generic” set of patient safety policies and procedures are an exact fit for all medical practices. By seeking input from those whose are involved in direct patient care, the practice’s administration can help to make expected standards more clinically specific and tailored to their organization.

In the absence of externally based standard-setting bodies, the policies and procedures instituted by the physician office leadership become the de facto standards by which safe and high-quality medical care is provided to patients.

THE LEADERSHIP CHALLENGE

Who in the physician office practice is in the best position to serve as the arbiter of patient safety? While some would argue the clinician because of his or her training and the fact that he or she “lays hands” on the patient, others would argue that the administrator is best suited to this role by having an overview of the entire organization and its processes. Neither answer is in-

correct; ideally, a combination of the two may be best for most practices.

THE ADMINISTRATOR AS CHIEF SAFETY OFFICER

The administrator should certainly play a role in patient safety leadership in the practice. The administrator is in a unique position to collaborate with and support the practice's physician leadership in providing strategic direction to the organization. The administrator can foster teamwork between clinical and administrative staff. The administrator can also institute changes to ensure effective patient care and safety, as well as improve practice performance.

However, the administrator's role cannot be performed alone. As stated above, he or she should promote patient safety as part of a strong physician/administrator team. The administrator's involvement in overseeing business operations, financial management, human resource management, information management, organizational governance, patient care systems, quality management, and risk management make him or her the ideal person to team with the physicians in promoting a culture of patient safety in the organization (MGMA, 2009a, 2009b, 2009c, 2009d, 2009e, 2009f, 2009g, 2009h). In *The Physician/Administrator Team – An optimal model for leading medical practices*, Kaplan and Patterson note, "A physician/administrator team leadership model is uniquely suited to meet the demands of medical group practices in today's environment. The diverse requirements of the industry, the blurring of lines between clinical and financial issues and the quantity and complexity of work requires a team approach" (2002).

THE ROLE OF THE PHYSICIAN LEADER

The physician's role is to help the leadership team develop evidence-based decision-support tools to assist and guide decisions within the office, to help ensure quality outcomes, to provide measurable standardization and to provide the ability to assign role accountability among the team providing patient care. "For too long, there has been little evidence-based guidance for physicians on what constitutes quality care and safe processes in the office setting," Nancy Elder, MD, MSPH, notes (ECRI, 2009). The physician can help lead the team through defining what quality and safety is within the unique confines of the practice they are leading. Although themes such as medication safety, infection control, environmental concerns, etc., are common among most practices, the physician leader can help define and direct the role of the clinical

team within the medical practice, therefore helping to reduce the blurred lines between various patient safety issues.

OTHER MEMBERS OF THE PATIENT SAFETY LEADERSHIP TEAM

Nurses, nursing assistants, medical assistants, lab technicians, etc., are all a part of the care-delivery team. The team may be developed by the physician's and the administrator's collaborative efforts, but the champions are the team members that put the effective processes to work on a daily basis. The team approach requires good communication skills and the sharing of information and ideas. If everyone on the team knows what they are responsible for, and there are good policies, procedures and assessment tools available, then patient risk can be minimized and safe and effective care provided within the physician office. The support of other staff in the practice can be invaluable when the administrator does not have a clinical background. Other staff can serve as content experts for developing and monitoring the policies and procedures that are needed for an effective patient safety program.

As noted before, patient safety is as much, if not more, an internally driven activity in physician offices than it is an externally mandated one. Given this, assessment of patient safety and change management within the physician office become an important activity in the roster of tasks needed to achieve patient safety.

PRACTICE ASSESSMENT AS A CHANGE EVENT

Assessment of patient safety measures within the medical practice should occur before any changes are initiated. This process will provide an initial knowledge base or guide, especially if there is no existing infrastructure for safety in the organization. A gap analysis will help the organization identify specific areas that need improvement. Through these efforts, the administrator can begin to understand the current status vis-à-vis patient safety before any change is introduced. "As an administrator and a medical practice leader, you must set the standards and the tone for patient safety in your organization," stated William Jessee, MD, FACMPE, President and Chief Executive Officer of the Medical Group Management Association (Jessee, 2008).

POLICIES AND PROCEDURES TO SUPPORT THE PATIENT SAFETY CHANGES

The development and implementation of patient safety policies and procedures within a medical organization inevitably involves change. This change may be met by resistance or noncompliance by certain clinical or administrative staff. The arguments may be as simple as “if it is not broken, then why fix it” or “we have been doing this the same way for years without any problems,” etc. One tool an administrator may use to address these arguments is to refer to clinical evidence as the basis for the patient safety policies and procedures.

As stated earlier, care provided in physician offices is becoming increasingly diverse and complex. These characteristics place greater emphasis on communication and teamwork as key requirements for achieving and maintaining high levels of patient safety. In organizing and managing patient safety, the administrator must know the limitations of his or her medical/procedural knowledge. By involving physicians and key clinical staff members in developing and implementing patient safety policies and procedures (“the patient safety team”), the administrator gets “buy-in” to the process from these individuals.

After the administrator and patient safety team complete formulating patient safety policies and procedures for the practice, these should be reviewed by the entire organization prior to adoption. A sufficient period should be allotted for this final review with adequate time for the administrator and patient safety team to answer questions and provide additional information as needed. Such a process has the potential to explicate unclear policies and to create a shared purpose and understanding of the practice’s role in providing safe care.

The process of implementing patient safety policies and procedures is critical to their initial effectiveness. Proper planning, communication and training of staff are key elements in a successful implementation. The involvement of the administrator and patient safety team are essential to this implementation process. The implementation also marks the start of the ongoing process of evaluating the effectiveness of the patient safety policies and procedures. It is recommended that a three-month period elapse before any policy and procedural changes are made, with the exception of those that are obviously in error or pose a threat to patient safety. During this period, the clinical evidence that the policies and procedures were based on can be reviewed in order to address objections that may arise.

Patient safety is an evolving process – as must be the creation and implementation of patient safety policies and procedures. Ongoing evaluation and measurement of the effectiveness of adopted patient safety processes, comparative to internal and/ or external benchmarks and clinical evidence, is an important part of this evolutionary process.

CONCLUSION

Patient safety has been an integral topic within the broad scope of the healthcare delivery system in the US, beginning with its initial development in the hospital setting. Since the exceptional growth and availability of advanced medical technologies in the latter half of the last century, the trend in the US has been decreasing inpatient hospital admissions and increasing volumes of outpatient services, including surgeries. This has led to the importance of patient safety within the ambulatory care setting. Since there are not as many robust regulations in this setting, it is essential for physician practices to develop their own patient safety cultures in order to ensure the wellbeing and health of their patients, as well as to avoid errors and potential legal suits due to malpractice.

In the ambulatory setting, it is the practice administrator's role, in conjunction with physicians and other clinicians, to create a culture that encourages the establishment and maintenance of patient safety procedures. The practice administrator has substantial responsibility for the people, processes and systems in these locations. The administrator is uniquely suited to work as the chief patient safety officer, in tandem with the physician leaders of the practice, to create and promote a culture of safety. Other members of the patient safety team, such as nurses, medical assistants and lab technicians, can put the safety processes into motion on a daily basis. If everyone on the team knows what they are responsible for and that there are good policies, procedures and assessment tools available, then patient risk can be minimized while safe and effective care is provided within the physician office.

This manuscript outlines the evolution of patient safety and its eventual development away from a focus solely on risk management to the creation of patient safety teams, which serve as collaborative resources to adequately implement, drive and evaluate patient safety within the practices. The importance of unity within the administrative and the clinical staff in

this process of achieving the goals of patient safety cannot be stressed enough.

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