Risk Management

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Faculty

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Faculty Disclosure

Contributing faculty, Lori L. Alexander, MTPW, ELS, MWC, has disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

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The division planners and director have disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

Audience

This course is designed for physicians, physician assistants, and nurse practitioners seeking to enhance their knowledge of risk management strategies, especially in the outpatient setting.

Accreditations & Approvals

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Our contributing faculty members have taken care to ensure that the information and recommendations are accurate and compatible with the standards generally accepted at the time of publication. The publisher disclaims any liability, loss or damage incurred as a consequence, directly or indirectly, of the use and application of any of the contents. Participants are cautioned about the potential risk of using limited knowledge when integrating new techniques into practice.

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Course Objective
With patient safety as the priority, risk management should focus on the avoidance of medical errors, as they are, along with inadequate informed consent, the most common assertions in malpractice claims in the United States. The purpose of this course is to provide healthcare professionals with the information necessary to engage in risk management practices, including a variety of proven strategies to avoid malpractice.

Learning Objectives
Upon completion of this course, you should be able to:

1. Define the most important issues and trends related to risk management and malpractice.

2. Define the key concepts in malpractice.

3. Outline malpractice-related laws, such as Good Samaritan laws, charitable immunity laws, and apology statutes.

4. Identify the most common underlying causes and characteristics of malpractice claims.

5. Describe the consequences of malpractice with respect to healthcare delivery and personal and professional effects on physicians.

6. Describe measures to enhance patient-physician communication, ensure appropriate disclosure of errors to patients, and guarantee adequate informed consent.

7. Develop efficient office processes to enhance documentation, diagnosis, test tracking, medication management, and other issues.

INTRODUCTION

Risk management in the healthcare professions refers to strategies designed to enhance patient safety, decrease the risk of malpractice claims, and minimize loss. Effective risk management is essential not only because of the inherent value of patient safety but also because of the high prevalence of malpractice claims, which exact great costs in terms of money, time, and personal and professional losses [1; 2].

Healthcare institutions implement interdisciplinary risk management programs to ensure that high-quality medical care is provided to patients and to reduce the risk of malpractice claims brought against the institution and/or its attending physicians and other healthcare professionals. While physicians in surgery and obstetrics/gynecology are most likely to be named in a malpractice suit, primary care physicians in private practice are very vulnerable to malpractice claims and often face greater professional and personal consequences of a malpractice suit [3; 4; 5]. Thus, this course primarily addresses risk management programs for healthcare providers in private practice.

The course begins with a definition of risk management, emphasizing the need for primary care physicians to establish risk management strategies in their practice. A definition of tort (personal-injury) law and several legal issues related to malpractice lay the foundation for a better understanding of such key concepts as medical negligence and the standard of care, adequate informed consent, and malpractice-related laws such as apology statutes, Good Samaritan laws, and charitable immunity laws. The focus is on the issues that cause the most common allegations in malpractice claims in the United States [6].

Descriptions of the common characteristics of malpractice claims and the consequences of malpractice are included to enhance healthcare professionals' understanding of the underlying causes and motivations of malpractice claims. Such an understanding can help physicians develop targeted risk management strategies and enhance patient safety, and a variety of proven strategies to avoid malpractice are discussed.

DEFINITION OF RISK MANAGEMENT

Risk management is a program of strategies to minimize the risk of harm to patients and to decrease the healthcare provider's exposure to liability. An effective risk management program includes both proactive and reactive components [7]. The proactive component consists of strategies to prevent adverse occurrences, and the reactive component includes strategies for responding to such occurrences (i.e., minimizing loss). Minimizing loss involves developing a process to handle a malpractice claim as efficiently as possible. Quality assurance is also an important factor in risk management, as improving the quality of medical care is the theoretical underpinning of avoiding malpractice [8].

The following are among the most important issues related to risk management [9]:

- Communication (with patients and among staff and other healthcare professionals)
- Missed appointments
- Follow-up on test results
- Documentation
- Management of medications
- Patient satisfaction
- Scope of practice
- Disruptive patients
- Patient termination
- Medical record retention

In addition, in 2014, the American Society for Healthcare Risk Management developed a holistic approach to risk management called enterprise risk management that includes traditional reactive strategies combined with proactive strategies. The following eight risk domains make up enterprise risk management [10]:

- Operational
- Clinical and patient safety
- Strategic
- Financial
- Human capital
- Legal and regulatory
- Technological
- Environmental- and infrastructure-based hazards

Surveys of medical office practices have shown that problems related to risk management are common across all physician specialties [5]. These problems warrant attention and improvement efforts not only because they are associated with a risk of malpractice but also because they have the potential for causing medical errors, which have been reported to be highly prevalent and highly preventable [11]. An overall understanding of malpractice and its key components is needed to provide a framework for defining and discussing effective risk management strategies.
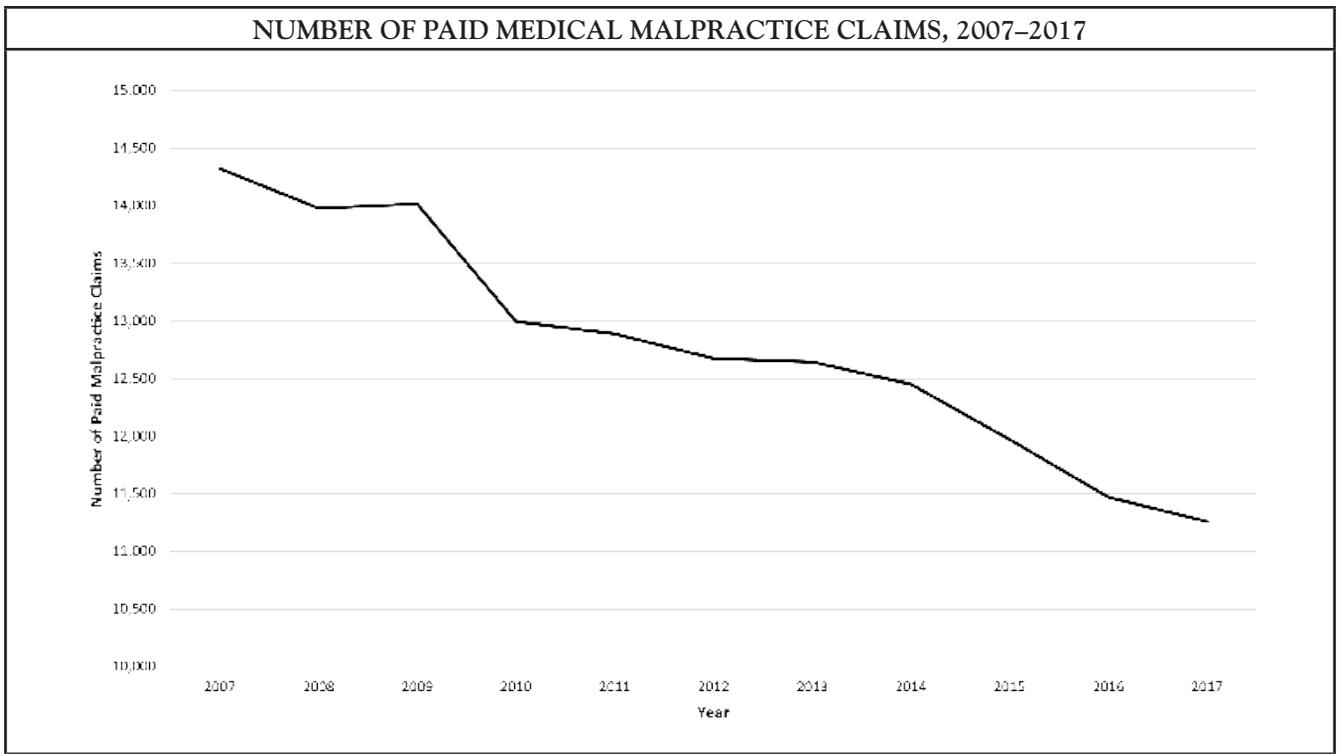
ANATOMY OF MALPRACTICE

Physicians are the primary target of malpractice. According to records of malpractice payments in 2021, 89.8% of payments were made in claims against physicians and dentists; professional nurses accounted for 3.3%, and all other healthcare practitioners constituted 6.9% [12]. In total, 34% of physicians have been sued, with 16.8% having been sued more than twice [13]. Lower quality of care does not appear to be the cause of most malpractice claims, as no significant differences have been found in quality between physicians who have and have not been sued [14].

For physicians in low-risk specialties (e.g., pediatrics, psychiatry), there is a substantial gap between physicians' perceived risk of malpractice and their actual risk, with physicians perceiving a much greater risk of malpractice than has been documented for their specialty [15; 16]. For example, in a survey regarding malpractice concerns, 62.5% of pediatric physicians agreed or strongly agreed that they were at risk, compared with American Medical Association (AMA) data that indicated 17.8% of pediatric physicians had ever been sued [13; 17]. Similarly, radiologists have estimated their risk of litigation within five years as 35%, which compares with an actual rate of approximately 10% [15]. By contrast, using the same datasets, physicians in high-risk specialties (i.e., obstetrics/gynecology and surgery) had a much closer concern/reality gap, with concern data showing 81% for obstetricians/gynecologists and 75.3% for surgical specialists, compared with a lifetime malpractice claim rate of 63.6% and 63.2%, respectively [13; 17].

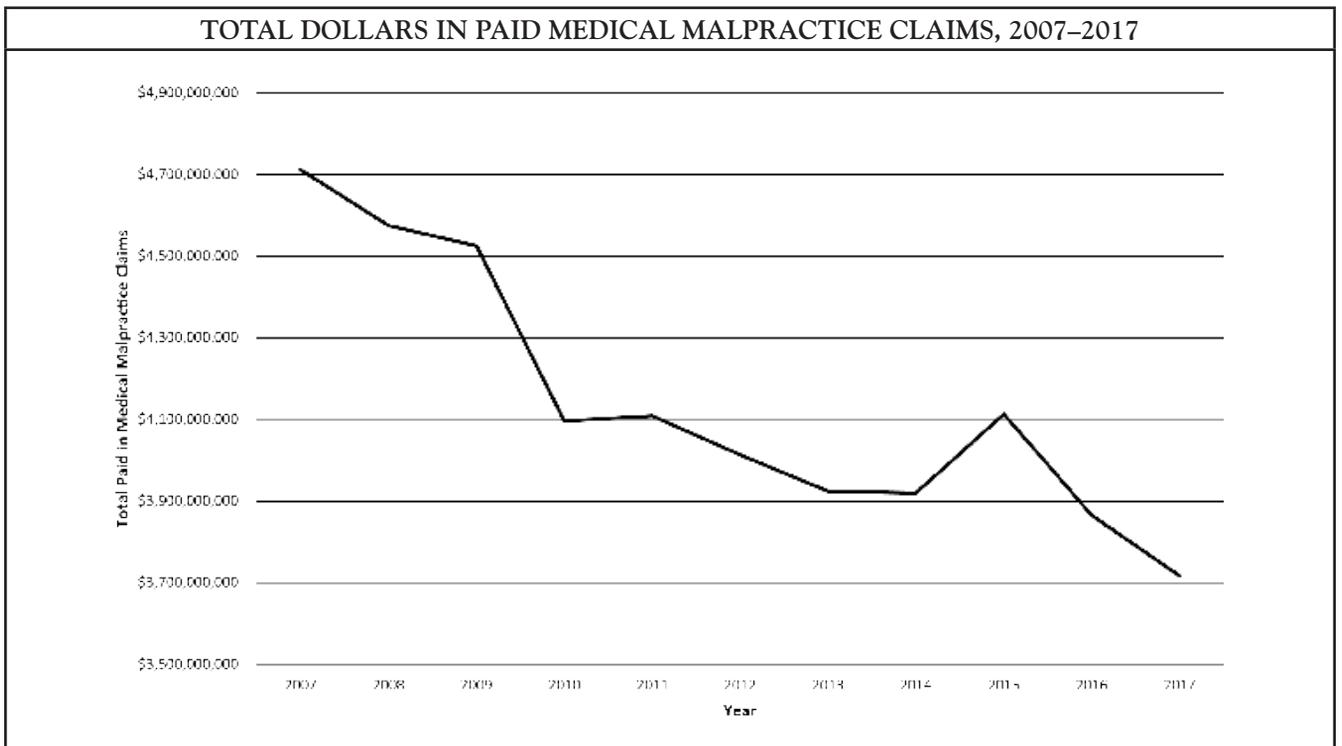| ANNUAL PAID MALPRACTICE CLAIMS ACCORDING TO SPECIALTY, 1992–2014		
Specialty	Total Paid Claims[a]	Mean Payment
Obstetrics and gynecology (includes surgery)	20,060	$432,959
Family medicine	18,349	$290,698
Internal medicine	17,174	$318,071
General surgery	12,981	$298,625
Orthopedics (includes surgery)	10,641	$258,763
Radiology	9,079	$333,422
Emergency medicine	8,007	$309,411
Anesthesiology	7,892	$377,499
Pediatrics	5,799	$413,974
Cardiology (includes surgery)	5,378	$365,029
General practice	4,435	$231,622
Ophthalmology	4,044	$244,039
Urology (includes surgery)	3,631	$23,290
Otolaryngology	3,226	$282,822
Plastic surgery	3,156	$189,219
Psychiatry	3,115	$238,909
Gastroenterology	2,881	$349,013
Neurosurgery	2,797	$469,222
Pathology	2,372	$411,529
Thoracic surgery	2,179	$380,402
Neurology (nonsurgical)	2,156	$431,049
Otorhinolaryngology	1,081	$282,822
Dermatology	1,717	$189,065
Colon and rectal surgery	549	$337,976
[a]Includes physicians with more than one paid claim.		
Source: [5]		Table 1

The risk of malpractice varies among medical specialties and typically increases with the frequency with which procedures are performed and with a greater potential for catastrophic injury [5; 18]. The rates of malpractice claims against family medicine and internal medicine physicians have historically been low, but the rates have increased since the late 1990s [19]. According to paid claims between 1992 and 2014, family medicine and internal medicine were the specialties with the second and third leading number of claims (behind obstetrics/gynecology), with 18,349 and 17,174 paid claims, respectively (**Table 1**) [5]. It has been estimated that the typical family physician can expect to be sued about once every 7 to 10 years [20]. One study noted that by 65 years of age, 75% of physicians in low-risk specialties faced a malpractice claim, compared with 99% of physicians in high-risk specialties. It should be noted, however, that more than 75% of these malpractice claims do not result in indemnity payment [21]. In an analysis of overall paid malpractice claims between 1992 and 2014, it was found that the rate of paid claims decreased by 55.7%; however, the mean payment amount increased by 23.3% (**Table 1**) [5].

NUMBER OF PAID MEDICAL MALPRACTICE CLAIMS, 2007–2017

Source: [12]

Figure 1

TOTAL DOLLARS IN PAID MEDICAL MALPRACTICE CLAIMS, 2007–2017

Source: [12]

Figure 2

Overall rates of medical malpractice claims declined between 2010 and 2020. The same trend occurred in the number of paid malpractice claims and the average compensation (*Figure 1* and *Figure 2*) [12]. In 2020, 9,401 malpractice claims were paid in the United States, with the compensation totaling more than $3.4 billion [12]. It has been argued that malpractice claims represent a substantial factor in rising healthcare costs. However, estimates for 2010 demonstrate that the total costs related to malpractice claims (compensation plus administrative costs) represented only 0.23% (range: 0.13% to 0.33%) of the $2.8 trillion (range: $2.6 trillion to $3 trillion) spent on health care in the United States that year [22; 23].

The average compensation varies widely according to geography, type of injury, and physician specialty. In 2021, the average compensation ranged from $202,552 (North Dakota) to $318,213 (New York) [12]. Total compensation also varies considerably. In 2021, compensations in New York State accounted for 17% of all payments that year in the United States, and the top six states (New York, Pennsylvania, New Jersey, Illinois, Florida, and California) accounted for more than half of all 2021 compensation payments [12]. Claims payments are typically lowest for "insignificant injury" (average of $35,500 in 2019) and highest for quadriplegia, brain damage, or lifelong care (average of $1,094,848 in 2019) [24]. Of 24 specialties, general and family medicine ranks 18th in mean compensation (approximately $290,698) and internal medicine ranks 14th (approximately $318,071) [5].

Malpractice draws a great deal of attention by the public at large, but the actual number of malpractice claims that are filed is lower than the number of individuals who seek legal advice about a medical issue, and the number of claims that are won is still lower. One study found that in closed claims in 2015, 68% were dropped, dismissed, or withdrawn.

In addition, only 7% of claims were decided by a trial verdict, and of these, 88% were won by the defendant [25]. Additionally, a 2021 survey of physicians with a malpractice claim indicated that the result of the lawsuit was settled before trial (33%); dismissed within first few months (13%); verdict in physician's favor (10%); ongoing or in process (7%); dismissed prior to settling (6%); dismissed by court (6%); dismissed prior to trial (6%); voluntarily dismissed by plaintiff prior to trial (6%); verdict in plaintiff's favor (2%); and settled at trial (2%) [4].

The primary goals of the U.S. medical malpractice system are to compensate individuals who have been harmed through medical negligence, to hold a responsible individual accountable, and to provide deterrence to unsafe medical practices or medical errors [8; 26]. (The AMA defines a medical error as an "unintended act or omission, or a flawed system or plan, that harms or has the potential to harm a patient" [27].) According to the 2000 landmark Institute of Medicine report, *To Err is Human: Building a Safer Health System*, 44,000 to 98,000 deaths are caused by medical errors in U.S. hospitals each year, with more than 7,000 of those deaths attributable to medication errors [11]. In addition, a national survey conducted in 2017 indicated that 21% of patients personally experienced a medical error, and 31% have personally been involved in the care of someone who has experienced an error. Combined, 41% of individuals surveyed experienced or were involved in a medical error [28]. However, the true number of adverse outcomes attributable to medical errors or negligence is difficult to determine. In a large study of hospital discharge records and malpractice claims, researchers determined that only 17% of claims involved an injury caused by medical negligence and that there were 7.6 times as many negligent injuries as there were claims, with only 2% of negligent injures resulting in claims [29].

A later study of 1,452 closed malpractice claims demonstrated that 37% did not involve a medical error, and the findings of another study indicated that more than three-quarters of 26,126 malpractice claims against primary care physicians were not considered to involve negligence [2; 3]. A separate analysis of four major studies on lethal medical errors indicated that in 2013 there were 251,454 preventable deaths due to medical error [30]. However, this was quickly debated and an estimate of 174,901 preventable deaths was given after adjusting for perceived biases [31]. In either case, medical error was still found to be the third leading cause of death in the United States [30; 31]. These results show the difficulty in determining the true number of medical errors and indicate that most patients who sustain a medical injury as a result of medical negligence do not sue and that a substantial number of claims do not involve negligence, which leaves the primary goals of the malpractice system unmet [2; 29; 32; 33]. Calls for reform of the malpractice system have been made in light of these findings, and several organizations, including the AMA, have taken steps toward medical liability reform, with the goal of creating an accurate and fair liability process, while ensuring patient access to physicians and a full range of healthcare services [25].

KEY CONCEPTS IN MALPRACTICE

Medical malpractice is processed in the civil court system or according to tort law. Overall, the civil court system provides a mechanism for an individual or group to recover damages when a tort (derived from the French word for "wrong") is committed against a person or property. Torts are classified as either intentional or negligent. Several intentional torts may be committed by physicians, including assault and battery (e.g., operating on a patient without informed consent), false imprisonment (e.g., forcing a patient to stay in the office until a bill is paid), and fraud (e.g., claiming cure when the physician knows cure is not possible) [34]. A negligent tort involves the omission or commission of an act that a reasonably prudent person would or would not do under given circumstances [35].

The statutes of limitations for medical malpractice vary according to the state, with many states having statutes that vary by cause of action and special rules for minors. In general, a medical claim must be filed within 1 to 5 years after the malpractice occurred or after the alleged injury was discovered if it was not immediately evident.

Standard of Care and Medical Negligence

In a medical malpractice case, the plaintiff has the burden of establishing the appropriate standard of care and demonstrating that the standard of care has been breached. The standard of care is primarily defined by other practitioners with similar qualifications, who provide expert testimony about how they would have managed an individual's care under the same or similar circumstances [36]. In general, expert testimony is based on the physician expert's knowledge, skill, experience, and training and may be supplemented by published literature, practice guidelines, and surveys of practitioners [36]. The focus is whether the physician's actions met or breached the standard of care and, if the latter, whether the plaintiff was harmed as a result of the breach [36].

According to tort law, four elements must be established for a ruling of malpractice [35; 37]:

- Duty: The physician owed a duty to meet a particular standard of care.
- Breach of duty: The physician failed to perform the owed duty.
- Causation: There is a causal connection between the physician's failure and the patient's injury.
- Damages: An injury occurred for which monetary compensation is adequate relief.

These elements must be shown by a "preponderance of the evidence," defined as more than 50% probability, a lower standard than the "beyond a reasonable doubt" used in criminal law [36; 38]. Malpractice cases are decided on the basis of what a "jury is likely to think is fact" rather than actual fact [39; 40].

A duty is owed if there is an active patient-physician relationship at the time of alleged injury [35]. This relationship is defined as any service given by a provider to an individual, whether in the provider's office, in an emergency department, or within a telephone discussion [35]. Breach of duty can be claimed if the healthcare provider does not meet a relevant standard of care or there is an obvious error (e.g., retained surgical instruments). Causation requires that the plaintiff establishes that the physician's negligence led to the stated injury; an association can be interpreted as causation by a jury who may be sympathetic to the plaintiff [35]. Damages sustained by the patient are compensatory and/or punitive. Compensatory damages consist of compensation for directs costs, such as for lost earnings and medical expenses (current and future), as well as compensation for indirect costs, such as pain, emotional distress, and loss of consortium. Punitive damages are awarded to a plaintiff when the physician's actions are found to be intentionally harmful or grossly negligent [35].

Informed Consent

The informed consent law in medicine was originally developed from battery, an intentional tort [37]. The definition of battery as unwanted physical touching of the body by others was extended to include a treatment provided by a physician without a patient's consent [37]. Battery was also applied to cases in which the procedure performed was substantially different from the one for which consent was given, in which the procedure exceeded the scope of the consent, or in which the procedure was performed by a physician other than the one to whom consent was given [37]. Cases of medical informed consent are now classified as negligence, carrying with it the burden to prove the four elements for liability [37; 41].

The primary goal of informed consent is to protect patients by requiring that physicians provide a balanced discussion of a proposed procedure/treatment as well as of the alternative options, so patients can make informed medical decisions [37]. Informed consent was once required only for invasive procedures but the scope of procedures has expanded to include complex treatments (e.g., radiation therapy, chemotherapy), and a separate written consent is required for the use of anesthesia (general, spinal/epidural, or regional) in some states [6; 41; 42].

The informed consent discussion should focus on the expected benefits, the risks involved with the procedure/treatment, and the feasible alternatives [6; 41]. The adequacy of the disclosure of risks is defined differently among states. In most states, a "professional standard" is applied, which means that adequate disclosure is defined as what a reasonable medical practitioner would disclose in a similar situation; in other states, a "lay standard" is applied, with adequate disclosure defined as what a reasonably prudent individual would want to know before consenting to the particular procedure/treatment [6]. In general, physicians must disclose all severe risks, such as death, paralysis, or loss of an extremity, regardless of the likelihood of the event. Less severe events should be disclosed if they are frequent, whereas nominal risks do not need to be disclosed if they are not frequent [37; 41].

The Centers for Medicare and Medicaid Services (CMS) mandates that all medical records (inpatient and outpatient) contain completed written informed consent forms for all procedures and treatments [42]. In 2007, CMS also issued new interpretive guidelines for informed-consent documentation in patients' medical records. According to these guidelines, informed consent is defined as, "the patient or patient representative is given (in a language or means of communication he/she understands) the information, explanations, consequences, and options needed in order to consent to a procedure or treatment" [42].

MALPRACTICE-RELATED LAWS

Several laws have been established to provide healthcare professionals specific types of protection against legal liability. These laws, which include Good Samaritan laws, charitable immunity laws, and apology statutes, vary by state.

Good Samaritan Laws

Good Samaritan laws, also known as volunteer protection laws, were enacted to protect individuals from being sued as a result of voluntarily rendering emergency aid to an injured person [43; 44]. A "volunteer" can help an injured person on the grounds of implied consent, but if the person is conscious and can respond, first asking permission to help him or her is recommended [43]. In most states, a person is not legally obligated to provide first aid (unless it is part of a job description), but when such aid is provided, the person giving aid has a duty to be reasonably careful [43]. Good Samaritan laws protect a volunteer against legal liability in the event he or she makes an error during the provision of emergency care [43]. Some Good Samaritan laws may hold the volunteer liable if he or she does not act to assist during an emergency. Whether the volunteer chooses to act or not, the important consideration is to act in a manner that will not render the volunteer liable [43].

Charitable Immunity Laws

Charitable immunity laws are designed to protect physicians and other healthcare professionals who volunteer their services in free health clinics and other community initiatives to provide health care to uninsured individuals. These laws also differ from state to state, but they act to either raise the negligence standard of care (from simple negligence to gross negligence) or indemnify volunteer healthcare professionals with liability protection as if they were government employees [45]. Some state laws have elements of both approaches.

Requiring evidence of gross negligence (defined as "willful," "wanton," or "reckless" negligence) makes it more difficult to prove medical negligence [46]. States that indemnify volunteer healthcare professionals as government employees have a legal defense fund to cover defense costs and monetary damages; in some cases, there is an established limit on the total amount of compensation that can be paid [46]. Thus, such indemnification, also known as the State Tort Claims Act, can help to limit loss. In addition to state statutes, federal legislation also protects healthcare professionals who provide free health care.

The Volunteer Protection Act of 1997 provides protection against liability for a volunteer clinician "acting within his or her scope of duties in a nonprofit organization" [45]. This law also limits punitive damages to cases in which there is clear and convincing evidence of willful or criminal misconduct or conscious, flagrant indifference to the rights or safety of the individual harmed [45]. All states had laws limiting liability of certain volunteers at the time the Volunteer Protection Act was adopted, and these laws are not preempted if they provide additional protections [47].

Although state and federal charitable immunity laws do not guarantee that a malpractice claim will not be filed, the laws appear to have limited the number of malpractice claims, as physicians in volunteer settings are rarely targets of malpractice claims [46].

Apology Statutes

Apology statutes are designed to promote disclosure of medical errors by protecting physicians who apologized for an error. According to these laws, expressions of apology made after a medical error are excluded from evidence in a malpractice suit. There are two types of apology statutes [48]:

- Sympathy only: protects a physician's expression of sympathy, regret, and condolence

- Admission of fault: protects a physician's admission of fault and error (in addition to expressions of sympathy, regret, and condolence)

Massachusetts was the first state to enact an apology law, in 1986. Since then, apology laws have been enacted in 39 states and the District of Columbia. These states have enacted one of the two types of apology statutes, but the majority of states have adopted the sympathy only law [48; 49; 50; 51]. As of 2022, six states have provisions that specifically relate to accidents [51]. However, physicians are often skeptical of apologizing for potential error or adverse outcomes. In a 2021 survey of physicians with malpractice suits, 79% indicated that apologizing would not have made a difference, while only 2% indicated that it would have [4].

CHARACTERISTICS OF MALPRACTICE CLAIMS

Closed malpractice claims have been used in a host of studies to gain a better understanding of the specific factors associated with claims. Data on medical malpractice claims are found in three primary sources, and each source provides slightly different types of data. The most comprehensive source of claims information is the National Practitioner's Data Bank (NPDB), maintained by the U.S. Department of Health and Human Services [12]. The Health Care Quality Improvement Act of 1986 requires that all payments in settlement of malpractice claims must be reported to this system. The drawback to this source is that only claims that have been paid are included. Another source is the Medical Professional Liability (MPL) Association (formerly Physician Insurers Association of America) data sharing project. The MPL Association is a trade association of more than 50 medical malpractice insurance companies that represent more than two-thirds of private practice physicians and 2,500 hospitals, and the data represent approximately 25% of the medical malpractice claims in the United States at a given time [52]. The MPL Association includes both paid and unpaid claims, and queries on physician specialty can be carried out. The third source is Jury Verdicts on Westlaw; this source has limited value, as the number of malpractice claims that are decided by jury verdict is small [53].

Studies of malpractice claims have provided valuable information on the most common underlying causes of alleged injuries/events (also known as "medical misadventures") and the diagnoses at highest risk for malpractice. Additional studies have identified a wide variety of factors that motivate individuals to file a malpractice claim. Understanding the risk factors and patient motivators for malpractice can help physicians develop risk management strategies that address the most common issues related to patient safety.

Underlying Causes

Diagnostic error (misdiagnosis or missed or delayed diagnosis) is the most common allegation in malpractice claims, noted in 22% to 78% of all claims [2; 3; 5; 16; 54; 55]. In a study of 307 claims alleging diagnostic error in the ambulatory setting, researchers found that 59% of the claims involved a diagnostic error that harmed the patient [56]. Among the errors that caused harm, 59% caused serious harm and 30% caused death [56]. Another study analyzing paid claims noted that there was a substantial difference in paid claims for diagnostic errors among specialties. The percentage of paid claims for which diagnostic error was alleged was highest among pathology (87%) and radiology (83.9%), and lowest among anesthesiology (3.5%) and plastic surgery (4.3%) [5].

Although "failure in judgment" is usually a contributing factor for diagnostic errors, most errors involve several contributing factors [57; 58; 59]. The origins of diagnostic errors are multifaceted and may involve communication problems, system-related problems (e.g., lack of supervision, workload, technology issues), physician-related factors (e.g., stress, fatigue, hurriedness), patient-related factors, or a combination of any of these [56; 57; 60; 61]. Researchers have narrowed the diagnostic process down to seven stages, with diagnostic errors occurring in one or more of these stages [61]:

- Access and presentation
- History taking/collection
- Physical exam
- Testing
- Assessment
- Referral
- Follow-up

One study in the primary care setting noted that diagnostic process breakdown most frequently occurred during the patient-practitioner clinical encounter (78.9%), which includes errors in history-taking (56.3%), examination (47.4%), and/or ordering diagnostic tests for further work-up (57.4%). Other areas of process breakdown included referrals (19.5%), patient-related factors (16.3%), follow-up and tracking of diagnostic information (14.7%), and performance and interpretation of diagnostic tests (13.6%). A total of 43.7% of cases involved more than one of these processes [62].

Medication errors and adverse drug events represent 6.3% of malpractice claims, and the adverse event has been considered to be preventable in approximately 28% to 73% of claims [63; 64; 65]. Most medication errors do not cause adverse events, but when they do, serious harm may be the result; 38% to 46% of adverse drug events were reported to be life-threatening or fatal [63; 64].

A variety of other underlying causes have been identified, including delayed or inappropriate treatment, failure to supervise or monitor the case, improper performance of procedure, failure/delay in referral, and failure to recognize complications of treatment [2; 3; 57; 66; 67]. In one analysis of 369 closed claims, 659 risk management/patient safety events were identified; most events were issues related to diagnosis (58%) [67]. Other allegations were related to medical treatment (23%); improper medication management (9.5%); ordering errors (2.2%); insufficient patient monitoring (1.6%); and miscellaneous (5.7%) [67].

Diagnoses

The leading diagnoses-related allegations have varied somewhat across studies. One analysis of internal medicine malpractice found that 79% of allegations were failure to diagnose, with the remainder due to delay in diagnosis [67]. Of the failures to diagnose, 29% were cardiovascular disorders, 26% were infections, 18% were neoplasms, 10% were neurologic disorders, and 9% were gastrointestinal disorders [67]. Of the diagnostic delays, 40% were neoplasms, 18% were infections, 16% were gastrointestinal disorders, 16% were neurologic disorders, and 2% were cardiovascular disorders. In another study of claims settled between 1985 and 2000, acute myocardial infarction was the leading diagnosis (5%), followed by lung, breast, and colon cancer (each accounted for 3% of claims) and appendicitis (2%) [3]. Another study of missed diagnoses in the primary care setting found that more than 35% of missed diagnoses were conditions common in primary care, including pneumonia (6.7%), decompensated congestive heart failure (5.7%), acute renal failure (5.3%), cancer (primary) (5.3%), and urinary tract infection or pyelonephritis (4.8%) [62]. Diagnostic errors are also a predominant source of emergency department allegations (37%) [68]. A 2010 study identified the most common conditions associated with emergency department claims, with fractures (6%), acute myocardial infarction (5%), and appendicitis (2%) topping the list [68].

In a review of 307 claims of diagnosis error in an ambulatory setting, cancer accounted for 59% of the missed or delayed diagnoses; breast cancer was the leading type of cancer (24%), followed by colorectal cancer (7%), and skin, gynecologic, and hematologic cancers (4% each) [56]. Other diagnoses frequently missed or delayed according to that review were infection (5%), myocardial infarction (4%), and fractures (4%) [56].

SPECIFIC REASONS INDIVIDUALS GIVE FOR FILING A MALPRACTICE CLAIM
Problems with patient-physician communication
Poor relationship with the healthcare provider
Desire for information about what happened
Feeling of not being informed
Desire to prevent situation from happening to another person
Unmet expectations or unwanted outcomes
Desire for accountability/revenge
Suspicion of cover-up
Feeling of not being appropriately referred
Financial need
Pain and suffering
Advice from another (knowledgeable friend or acquaintance or healthcare provider)
Television ad for law firm
Source: [18; 57; 69; 70; 71]   *Table 2*

Patient Motivations

Given that a high number of malpractice claims do not involve a medical injury, other factors must motivate patients and families to sue [18; 69]. Patient motivations for malpractice have been extensively studied, and a wide variety of motivations have been identified (**Table 2**) [18; 57; 69; 70]. In general, these motivations are not related to financial need but rather to problems with patient-physician communication or the patient-physician relationship and unmet expectations of the patient [69]. The overwhelming majority of patients and families say they just want information about what happened, and many wish to prevent the situation from happening again [18; 69; 71].

CONSEQUENCES OF MALPRACTICE

Malpractice exacts a substantial cost on healthcare delivery, physicians, and patients. The fear of litigation alone (real or perceived) has led many physicians to reconsider their profession. For example, the risk of litigation has prompted one-third of radiologists to consider leaving the field of breast imaging [15]. Fear of malpractice also influences physicians' practice behaviors, primarily through the use of defensive medicine. The legal process involved with a malpractice claim takes physicians away from patient care and their families, a burden that is heightened by the amount of time required for resolution of a case.

Defensive Medicine

The threat of malpractice—real or perceived—has been shown to affect clinical decision making, prompting many physicians to practice so-called defensive medicine, or care based primarily on avoidance of litigation rather than on defined clinical need [4; 16; 72; 73]. Defensive medicine has been defined in two categories: "assurance behavior" or "avoidance behavior" [8; 16]. Assurance behavior, referred to as "positive defensive medicine," involves excessive ordering of tests and hospitalization of patients and referrals for consultations; avoidance behavior, referred to as "negative defensive medicine," involves decreasing the delivery of high-risk services or declining to treat high-risk patients [8; 16; 17; 25; 72; 74; 75].

The use of defensive medicine has been evaluated among general practitioners as well as several physician specialties and has been found to be widely prevalent [25]. Surveys of urologists have shown that 77% have practiced defensive medicine, with 58% to 60% saying they had considered referring difficult cases and/or limiting the scope of their practice because of the threat of malpractice [8].

Neurologists with higher malpractice concerns were found to order more tests in clinical scenarios related to seizures and Alzheimer disease [17]. A survey of defensive practices among 1,028 neurosurgeons found that 72% ordered additional imaging studies, 67% ordered additional laboratory tests, 66% referred patients to consultants, and 40% prescribed medication. Forty-five percent of respondents reported eliminating high-risk procedures from their practices [76]. Among emergency physicians, the fear of malpractice accounted for significant variability in decision making, especially with regard to individuals with chest pain, and was associated with the increased use of diagnostic tests and the increased hospitalization of low-risk patients [74]. These findings are consistent with those from broad samples of physicians. In a survey of 824 physicians in six high-risk specialties (i.e., emergency medicine, general surgery, orthopedic surgery, neurosurgery, obstetrics/gynecology, radiology), 93% of respondents reported practicing defensive medicine, and a survey of 2,416 physicians, conducted by Mount Sinai School of Researchers, found that 91% of physicians said they practiced defensive medicine [75; 77]. A national survey of 1,214 orthopedic surgeons showed that 96% reported having practiced defensive medicine by ordering imaging, laboratory tests, specialist referrals, or hospital admissions to avoid potential malpractice liability [78].

All of these studies and surveys have shown that assurance behaviors are more common than avoidance behaviors, with the most frequent practice being the excessive ordering of tests, especially imaging studies [17; 74; 75]. For example, in the survey of physicians in high-risk specialties, 92% of respondents reported ordering more tests, performing more diagnostic procedures, and referring more patients for consultation [75]. Approximately 42% of the respondents said they had recently limited their practice to eliminate procedures with a high risk of complications or had avoided patients with complex medical problems or who were perceived as litigious [75]. A 2015 study that included more than 24,000 physicians, evaluated data from acute care hospital admissions in Florida from 2000 to 2009 [79]. Across specialties, greater average spending by physicians was associated with reduced risk of incurring a malpractice claim. For example, among internists, the probability of an alleged malpractice incident ranged from 1.5% with spending at $19,725 to 0.3% with spending at $39,379. In six of the specialties evaluated, a greater use of resources was associated with a statistically significantly lower subsequent rate of alleged malpractice incidents [79].

Both types of defensive medicine have several important implications for health care and healthcare costs. Unneeded testing may be associated with false-positive results and treatment complications, and limitations in physician services can lead to unmet care needs [17; 73]. The financial cost of defensive medicine is difficult to quantify, primarily because of the challenges in identifying and measuring assurance and avoidance behaviors. Physician expectations about the benefits and harms of interventions also may be a contributing factor. One systematic review sought to assess clinicians' expectations of the benefits and/or harms of any treatment, test, or screening test [80]. Following a comprehensive search of four well-known databases, the authors included a total of 48 articles in their review: 20 focused on treatment, 20 on medical imaging, and 8 on screening. Of these, the majority (67%) assessed only harm expectations. Among the studies that compared benefit expectations with a correct answer (total of 28 outcomes), most participants provided correct estimation for only 3 outcomes (11%). Among the studies that compared expectations of harm with a correct answer (total of 69 outcomes), most participants correctly estimated harm for only 9 outcomes (13%) [80]. Inaccurate perceptions about the benefits and/or harms of interventions contribute to suboptimal clinical management choices and increased costs. A 1994 study estimated the cost of defensive medicine to be between $5 and $15 billion in 1991 U.S. dollars [72]. A study published

in 2010 found that annual overall medical liability costs are an estimated $55.6 billion, or 2.4% of total healthcare spending [80].

Personal and Professional Effects

A malpractice claim has a profound impact on a physician in terms of time, psychologic effects, and reputation. The average length of time between the date of an incident and closure of the claim is approximately four to five years [1; 2; 4; 70]. During this time, the physician is distracted with the malpractice defense and the legal process robs time from personal and professional activities.

Malpractice litigation has a negative psychologic effect on a physician because of its threat to personal integrity and honor. In general, physicians share personality traits that render them particularly vulnerable to malpractice litigation in which fault must be established [81]. These traits include self-criticism, exaggerated sense of responsibility, and vulnerability to guilt [82]. Physicians may experience loss of self-esteem and engage in self-questioning (e.g., "What did I do wrong?" or "What could I have done better?") [70; 83]. In addition, the adversarial nature of litigation contradicts the normal work environment of a physician. As a result, approximately 80% to 95% of physicians have reported emotional distress during the process of malpractice litigation [84; 85]. This distress affects not only the physician but also his or her family and office staff [70]. A physician's reaction to a malpractice claim has been described as beginning with a sense of shock, outrage, or dread, followed by feelings of intense anger, frustration, isolation, and inner tension [81]. In a study of physicians with a malpractice claim, 54% indicated that they were very surprised by the claim, 32% were somewhat surprised, and 14% were not surprised [4]. In cases in which there is clearly a negative outcome, the physician may also feel a substantial amount of guilt. Among the most common reactions to malpractice are [85; 86]:

- Adjustment disorder symptoms (20% to 50%)
- Major depressive disorder symptoms (27% to 39%)
- Onset or exacerbation of physical illness (2% to 15%)

A malpractice suit may also cause negative professional effects. In addition to the time spent away from the practice to defend a claim, a physician's and/or practice's reputation can be damaged by a claim, regardless of the outcome of the litigation [83]. In a 2021 survey of physicians who have had a malpractice lawsuit, 48% indicated changes to their practice. Among these changes were lack of trust in patients or treating them differently (24%); leaving the practice setting (7%); changing insurer (3%); and/or purchasing more insurance (2%) [4]. In addition, 29% of physicians surveyed felt that the lawsuit negatively affected their medical career [4]. A malpractice suit may also have implications on licensing and credentialing [70]. In general, patterns in the type of adverse events and the severity (amount) of payment to resolve the claim are the focal points for licensing boards and credentialing bodies [6]. Availability and cost of liability insurance may also be concerns; the frequency and severity of claims influence insurance underwriting, but a favorable settlement will weigh positively in the risk evaluation of the insurer [6].

The risk of negative physical and psychologic outcomes during and after a medical malpractice claim has been termed medical malpractice stress syndrome; it presents similarity to post-traumatic stress disorder. Strategies to ensure emotional and physical health due to the consequences of medical malpractice stress syndrome include increasing social support systems, replacing the mystery surrounding litigation with knowledge, and seeking the appropriate medical and psychiatric help [87].

AN EFFECTIVE RISK MANAGEMENT PROGRAM

When developing an office-based risk management program, a physician should address the underlying causes, diagnoses, and patient motivators that have been identified most often in malpractice claims, especially as they pertain to his or her medical specialty. Surveys of medical office practices have shown that, across all physician specialties, the most common problems related to risk management include [5]:

- Ineffective process to track diagnostic test results/consults
- Incomplete or poor documentation
- Failure to review patients' medications and provide education on taking prescribed medications

The following elements are essential for an effective risk management program:

- Optimum patient-physician communication
- Mandate for informed consent
- Appropriate and complete documentation
- Establishment and maintenance of efficient office processes
- Quality assurance program
- System for evaluating practice behaviors
- Continued development of diagnostic and technical skills

OPTIMUM PATIENT-PHYSICIAN COMMUNICATION

The lack of effective patient-physician communication has been noted to be perhaps the second leading cause of malpractice [18; 70]. In one study, communication problems were noted by patients in 70% of malpractice depositions [88]. In addition, problems with patient-physician communication have been reported to contribute significantly to patient dissatisfaction, which is commonly a precursor to a malpractice claim [89]. The quality of the patient-physician relationship affects many areas within a risk management program, including diagnosis, patient satisfaction, disclosure of errors, informed consent, and medication management.

Effective communication also serves to build rapport, to strengthen mutual trust, and to demonstrate the physician's respect of the patient's preferences and culture, which can help avoid malpractice claims [90]. In contrast, ineffective patient-physician communication can lead to anger, misunderstandings, and unrealistic expectations, all of which have been associated with malpractice claims [33; 91]. Improved patient-physician communication may mitigate the harm from medical errors in some cases and may also help reduce the frequency of future errors [48]. Thus, optimizing patient-physician communication and strengthening the patient-physician relationship is a priority in managing risk.

Optimum patient-physician communication involves ensuring that patients are adequately informed, which includes addressing the patient's literacy level and cultural context, ensuring that patients are satisfied with their care, and alerting patients about errors in a timely manner.

Adequately Inform Patients

Physicians with a history of malpractice claims have been described by their patients as not providing enough information about their condition, prognosis, medication side effects, and alternative treatment options [92]. This information is necessary to enable individuals to be active participants in their healthcare decisions. Physicians should also educate patients about realistic outcomes, as surveys have demonstrated a gap between individuals' perceived outcomes and realistic outcomes [7]. As examples, patients have reported that the pain or complications related to a procedure or surgery were not expected, and women have overestimated by 100-fold the value of screening mammography in reducing breast cancer-related mortality [92; 93].

ENHANCING THE PATIENT-PHYSICIAN RELATIONSHIP
Introduce yourself to new patients.
Listen attentively, without interrupting.
Avoid acting rushed, and provide adequate time to talk to each patient.
Explain plans for treatment and follow-up.
Use language the patient can understand—avoid jargon and provide interpreter services, if necessary.
Apologize for any delays in the office schedule.
Remain within your scope of care and competence, providing timely referrals if necessary.
Encourage patients to write down their questions before they come to the office.
Do not guarantee the outcome of a treatment.
Provide educational resources for patients, asking them their preference for media format.
Ask the patient about his or her preferred level of involvement in decision making (and document this in the patient's record).

Source: [37; 90; 95]   *Table 3*

To help ensure that individuals are adequately informed about their health and care, the Partnership for Clear Health Communication launched the Ask Me 3 campaign. This patient education initiative is designed to encourage patients to understand the answers to three basic questions [94]:

- What is my main problem?
- What do I need to do?
- Why is it important for me to do this?

If a patient does not ask these questions, the physician should emphasize the importance of understanding the answers. Educational resources for patients are available at the Institute for Healthcare Improvement/National Patient Safety Foundation website, https://www.npsf.org.

Several other strategies have been recommended as ways to strengthen communication and enhance the patient-physician relationship (*Table 3*) [37; 90; 95].

Consider Literacy and Cultural Context

Communicating effectively and establishing rapport are more challenging when the patient's literacy level is low or his or her primary language differs from that of the practitioner. Misunderstandings can lead patients to think that a poor health outcome or adverse event is the result of physician error rather than related to the lack of a clear understanding.

Health literacy, the ability to understand health information and make informed health decisions, is integral to good health outcomes [96]. Yet, the National Assessment of Adult Literacy estimated that only 12% of adults have "proficient" health literacy and 14% have "below basic" health literacy [97]. Rates of health literacy are especially low among ethnic minority populations and individuals older than 60 years of age [96]. Compounding the issue of health literacy is the high rate of individuals with limited English proficiency. According to U.S. Census Bureau data from 2019, more than 65.9 million Americans speak a language other than English at home, with approximately 25.6 million of them (8.4% of the population) speaking English less than "very well" [98].

Physicians should assess their patients' literacy level and understanding and implement interventions as appropriate. It has been suggested that when patients are first evaluated, they should be asked what language is spoken at home and if they speak English "very well" (if the healthcare professional is English-speaking) [99]. In addition, physicians should ask what language patients prefer for their medical care information, as some prefer their native language even though they have said they can understand and discuss symptoms in English [99].

Physicians should use plain language in their discussions with patients who have low literacy or limited English proficiency. They should ask them to repeat pertinent information in their own words to confirm understanding [100]. Reinforcement with the use of low-literacy or translated written educational materials is helpful.

"Ad hoc" interpreters, such as family members, friends, and bilingual staff members, are often used instead of professional interpreters for a variety of reasons, including convenience and cost. Physicians should check with their state's health officials about the use of ad hoc interpreters, as several states have laws about who can interpret medical information for a patient [101]. Even when allowed by law, the use of a patient's family member or friend as an interpreter should be avoided, as the patient may not be as forthcoming with information and the family member or friend may not remain objective [101]. Children should especially be avoided as interpreters, as their understanding of medical language is limited and they may filter information to protect their parents or other adult family members [101]. Individuals with limited English language skills have actually indicated a preference for professional interpreters rather than family members [102].

Most important, perhaps, is the fact that clinical consequences are more likely with ad hoc interpreters than with professional interpreters [103]. A systematic review of the literature showed that the use of professional interpreters facilitates a broader understanding and leads to better clinical care than the use of ad hoc interpreters, and many studies have demonstrated that the lack of an interpreter for patients with limited English proficiency compromises the quality of care and that the use of professional interpreters improves communication, utilization, clinical outcomes, and patient satisfaction with care [104; 105]. The importance of professional interpreters to effective communication and patient safety has been recognized by the development of The National Board of Certification for Medical Interpreters, founded in 2010 by the International Medical Interpreters Association [106].

When professional interpreters are not feasible or available, bilingual staff members may be used, and their adherence to several principles can enhance their effectiveness [101]:

- Use the universal form of the language when possible
- Avoid assuming the role of interviewer or decision-maker
- Allow the patient to lead the discussion
- Translate everything (without additions, deletions, or changes to meaning)
- Translate in a way to convey the patient's cultural context
- Meet the patient before the interaction to be translated
- Meet with the physician before the visit, to develop a structure to the interaction
- Seek continuing education to improve interpretation skills

Physicians should encourage their bilingual staff members to enhance their interpretation skills. Resources for such training include the Cross Cultural Health Care Program and the National Council on Interpreting in Health Care.

When no professional or ad hoc interpreters are available, physicians may be able to obtain an interpreter from a community organization. In addition, several translation businesses offer fee-based interpretation over the phone or Internet. Many of these businesses also provide translation of documents. Partnering with healthcare plans and hospitals can help identify the best services for your practice [100].

If a patient refuses to use an interpreter, the physician should emphasize to the patient and family the importance of accurate interpretation and understanding on both sides of the patient-physician discussion. A referral to a physician who speaks the patient's primary language may be appropriate [100].

The AMA offers several health literacy resources for healthcare professionals on its website, and the U.S. Department of Health and Human Resources offers valuable information on cultural competency from the Health Resources and Services Administration (HRSA) and the Office of Minority Health. The HRSA also offers a free online course, "Unified Health Communication 101: Addressing Health Literacy, Cultural Competency, and Limited English Proficiency." Another resource is Diversity Rx, a joint initiative of the Resources for Cross Cultural Health Care and the Center for Health Equality at Drexel University School of Public Health.

Issues related to literacy and interpretation should be noted in the patient's record to provide documentation of the physician's assessment of understanding.

Strive to Achieve and Maintain Patient Satisfaction

Patients who have experienced harm from a medical error are less likely to file a malpractice claim if they consider their physician to be caring or compassionate; in contrast, patients who are dissatisfied with their physician are more apt to file a claim [33; 107]. Thus, making efforts to ensure that patients are satisfied with their care is another integral aspect of a risk management program.

Patients are satisfied when they feel as if they receive sufficient attention from healthcare professionals. Patients of physicians with prior malpractice claims have reported feeling rushed and ignored, being given explanations and advice that were inadequate, and having shorter office visit times than patients of physicians with no malpractice history [108]. A study of primary care physicians and their patients showed that physicians with no history of malpractice differed significantly from those with previous claims in terms of the use of facilitation statements, the amount of information given to orient the patient to the office visit, and the use of humor [107]. In addition, the length of a routine office visit was a significant predictor of a malpractice claim [107].

Patient satisfaction can be enhanced by improving service throughout the office. Physicians should assess every aspect of the office, including the waiting room, front desk staff and procedures, billing and scheduling, and staff interactions, to ensure that patients receive a positive experience throughout the office [70]. After these aspects have been assessed, ways to improve service should be discussed with all staff members and service should be assessed in an ongoing manner [70].

Assigning a staff member to receive and review complaints and address them in a timely manner can help mitigate patient dissatisfaction [70]. In addition to helping to address a patient's concern, handling a complaint also provides evidence of efforts to address the situation should a claim be presented [70]. Documenting complaints and their resolution can also serve as an important aspect of a quality assurance program [70].

STATEMENTS ENDORSING DISCLOSURE	
Organization	**Statement**
American Medical Association	Code of Medical Ethics (8.6 Promoting Patient Safety) Patients have a right to know their past and present medical status, including conditions that may have resulted from medical error. Open communication is fundamental to the trust that underlies the patient-physician relationship, and physicians have an obligation to deal honestly with patients at all times, in addition to their obligation to promote patient welfare and safety. Concern regarding legal liability should not affect the physician's honesty with the patient. Individual physicians who have been involved in a (possible) medical error should: • Disclose the occurrence of the error, explain the nature of the (potential) harm, and provide the information needed to enable the patient to make informed decisions about future medical care. • Acknowledge the error and express professional and compassionate concern toward patients who have been harmed in the context of health care. • Explain efforts that are being taken to prevent similar occurrences in the future. • Provide for continuity of care to patients who have been harmed during the course of care, including facilitating transfer of care when a patient has lost trust in the physician.
National Quality Forum	Safe Practice 7 Following serious unanticipated outcomes, including those that are clearly caused by systems failures, the patient and, as appropriate, the family should receive timely, transparent, and clear communication concerning what is known about the event.
Source: [27; 121]	*Table 4*

Disclose Errors

Numerous studies have shown that patients prefer full disclosure of a medical error and want details about how the error occurred, what the consequences are (including financial costs), and what measures are being taken to prevent the same error from occurring again [71; 109; 110; 111; 112; 113; 114]. Disclosure of errors has been linked to many benefits, including increased patient satisfaction, greater trust with the physician, and higher likelihood of a patient's positive experience, all of which are related to a lower likelihood that a patient will sue [48]. Physicians have indicated that they want to apologize for errors, but in practice, a substantial number of physicians have admitted that they did not disclose an error [110; 115; 116]. In addition, in a national survey of individuals who had experienced a medical error, only 32% said that the involved healthcare professional had disclosed the error [28].

Physicians and ethicists have long acknowledged that physicians have an ethical and moral obligation to disclose errors [71; 117]. However, for many years, defense lawyers have advised physicians to avoid apologizing to a patient for an adverse event for fear that the apology would be used as an admission of wrongdoing [109; 113; 115; 118]. This approach is changing. Several professional associations and patient safety organizations have established statements endorsing disclosure (**Table 4**) [27; 119; 120; 121; 122]. Legislation has also addressed disclosure, with some states requiring that hospitals notify a patient (or patient's family) about a "serious event" in writing within a specific amount of time after the event [114]. The Sorry Works! Coalition was established in 2005 and has become the leading advocacy group for disclosure, apology (when appropriate), and compensation (if necessary) after adverse medical events [123]. Sorry Works! notes four basic facts every physician should know about disclosure [123]:

- Disclosure benefits doctors as well as nurses, hospitals, and insurers.
- Successful disclosure depends on overall good communication, informed consent, and excellent customer service.
- An empathetic apology should be provided immediately after an adverse event.
- After apologizing, the healthcare professional should immediately call a risk manager, insurance company, or defense counsel.

As discussed, apology statutes now protect physicians and other healthcare professionals who apologize, but not all states have enacted apology statutes, and the statutes vary across states. In addition, the majority of physicians are unfamiliar with their state statutes. Physicians are encouraged to talk to their state medical associations and legal counsel to determine how best to comply with their state's apology statute.

Most physicians are uncomfortable with disclosing errors and, because they have not received formal training in how to conduct such a discussion, they are unclear about how much information to provide and what words and phrases to use [118; 124]. As a result, physicians who disclose errors often provide minimal information and express incomplete apologies [111; 113]. Guidelines have been developed to help physicians disclose errors in a way that provides patients (and family) with the information they desire [122; 125; 126]. These guidelines recommend:

- Disclose the error as soon as possible; do not wait for the patient (or family) to ask.
- Be prepared for strong emotions.
- Tell what you know; focus on what happened and the possible consequences.
- Accept responsibility for the outcome, but avoid attributions of blame.
- Express apology and regret.

- Outline a plan of care to address the harm and to prevent recurrence.
- Offer to get second opinions, when appropriate.
- Suggest a family meeting (with the option of having lawyers present).
- Document the disclosure discussion.
- Offer to have follow-up meetings if the patient desires.

The impact of full disclosure on malpractice liability is unclear [113; 118]. Early reports of full-disclosure policies at two institutions (the University of Michigan and the Lexington Veterans Affairs Medical Center, Kentucky) indicated that such policies can reduce the number of malpractice claims, increase the number of settled claims, and decrease legal expenses [89; 127]. Studies in which individuals are presented with clinical scenarios or vignettes involving adverse events have also suggested that patients would be less likely to sue if physicians provided disclosure and an apology [71; 111; 112; 117; 128]. However, there is no conclusive evidence demonstrating that disclosing errors decreases the likelihood of litigation [109; 118]. Some have argued that uniform disclosure of errors may actually lead to an increase in malpractice claims [89].

MANDATE FOR INFORMED CONSENT

Informed consent requires patients to sign a document stating that they understand the risks and benefits of a procedure or treatment plan and alternative treatment options. However, the principle of informed consent extends beyond the signed form. The process of informed consent helps patients assume an active role in healthcare decision making and aids in the management of patients' expectations, both of which can reduce the likelihood of a malpractice claim [129].

DISCUSSION POINTS FOR INFORMED CONSENT
Diagnosis (if known)
Nature and purpose of treatment or procedure
Potential risks of proposed treatment
Expected benefits of proposed treatment
Probability of a good outcome with the proposed treatment
Potential problems during recovery
Estimated time to return to normal activities
Availability of alternative treatment options
Risks and benefits of alternative treatment options (including no treatment or procedure)
Likely results if no treatment is given

Source: [41; 129]   *Table 5*

Essential elements of the informed consent conversation include the diagnosis, the proposed procedure or treatment plan and its potential risks and expected benefits, the risks and benefits of any alternative treatment options, the typical recovery process, and the expected long-term and short-term effects (***Table 5***) [41; 129]. In addition, physicians should tailor the informed consent discussion to a patient's unique situation, noting risks that may be applicable to a patient because of his or her medical history or current comorbidities [42].

In a study to assess the levels of knowledge of patients, more than 80% of patients were satisfied with an informed consent discussion about pending surgery and considered themselves to be fully informed, but more than half could not list a single potential complication related to the surgery [130]. A patient's dissatisfaction with an informed consent discussion is most likely to surface only if an adverse event occurs after the treatment was given. Because of the gap between what is told and what is remembered, a patient may think that an adverse event is the result of inadequate informed consent or negligent care [131].

Given the challenge of knowing whether a patient has understood the informed consent discussion, physicians should take several efforts to enhance understanding. Asking the patient to read a sec-tion of the informed consent form aloud enables the physician to assess the patient's literacy level [42]. Physicians should plan sufficient time to speak with the patient and should present information in easy-to-understand language. Patients should be encouraged to ask questions and to take an active role in decision making [131]. Lastly, the patient should be asked to describe a section or sections of the form in his or her own words to demonstrate the level of understanding. Physicians should have consent forms translated into languages spoken by any large percentage of their patient population [42].

Informational resources in a variety of media may be helpful as a supplement to the discussion. These resources help emphasize realistic expectations and address different learning preferences; as such, they have been shown to enhance understanding, especially for patients with low educational levels [70; 132; 133]. A systematic review of 55 trials on decision aids indicated that they increase patients' involvement and are more likely to lead to informed values-based decisions, but the size of this effect has varied across studies [134]. An updated review that included 105 trials indicated that decision aids are more likely to lead to improved patient knowledge and improved perception of the risks involved [135].

If time allows, it is reasonable to let patients consider a decision made after signing an informed consent form [37]. Giving a patient 24 to 48 hours to think about the risks and benefits can reinforce the validity of the informed consent [37]. If a patient withdraws consent, it should be documented in the medical record, with the date and time of withdrawal.

Documenting the informed consent discussion in the patient's record and including the signed informed consent form in the record decreases the probability of a successful malpractice case against the physician [37]. A signed informed consent form is not automatic protection; patients can argue that the risks were discussed by a healthcare professional other than the physician who performed the treatment or that they did not understand the risks.

ESSENTIAL INFORMATION TO DOCUMENT
Full date (month, date, year) and time of the encounter
Updated patient problem list
Medication list (including over-the-counter drugs and supplements)
Informed consents
Thorough patient history (including experience with drugs or alcohol, and psychologic or social issues)
Drug allergies and sensitivities
Physician's advice
Diagnosis (including thought process and list of possible diagnoses if uncertain)
Physical examination findings (especially changes or absence of abnormality)
Changes in the clinical course of a condition
All tests ordered or recommended
All discussions with the patient
All telephone conversations with the patient
All test results
Follow-up plan
Patient's refusal of care or noncompliance with medications, treatment, or scheduled follow-up or appointments (and the physician's efforts to educate the patient about the risks of noncompliance)
Reports of consultations, with dates and times
Results of all testing, including the dates they were ordered, interpreted, and reviewed
Notes regarding patient dissatisfaction and the response of the physician or other staff

Source: [9; 83; 137; 138]   *Table 6*

APPROPRIATE AND COMPLETE DOCUMENTATION

The patient's medical record is a legal document that reflects the care provided to a patient, and it serves as the basis of defense against malpractice claims and other types of lawsuits [9]. As such, it is crucial for physicians to document all encounters and patient information carefully and accurately [9]. Experts indicate that no amount of documentation is too much, especially in situations at high risk for malpractice claims because of the patient's diagnosis or the physician's specialty [83]. Careful, complete documentation provides proof that the physician did the right thing and demonstrates that the physician gave logical thought and consideration to the case [83; 95].

Despite the importance of complete medical records, surveys of office practices have shown that documentation is frequently incomplete or poor, with the most often lacking elements being [136]:

- Updated problem list
- Discussion of medications
- Allergies
- Informed consent process
- Physician signature (to indicate review)

Physicians should ensure that all essential information is documented in every patient's record (*Table 6*) [9; 83; 137; 138]. In addition, the record should include written instructions that were provided to the patient. Documentation should be clear, objective, specific, and dated. The use of abbreviations should be limited to those that are approved.

Problems exist with both paper and electronic medical records. Paper records are often found to be illegible, and electronic medical records are frequently used inconsistently by the physicians within a practice [136]. Practices with electronic medical records should have a reliable backup system as well as a disaster recovery program [9]. A physician should never alter a medical record after a claim has been filed [9; 83].

ESTABLISH AND USE EFFICIENT OFFICE PROCESSES

Most medical errors have been found to be related to faulty systems rather than incompetence, which means that improving office and practice routines can help physicians avoid adverse outcomes [60]. Efficient office processes and procedures enhance the quality of patient care while decreasing the risk for medical error.

Electronic health records are increasingly being used in hospitals and office-based practices. Since 2009, the percentage of clinicians and hospitals using electronic health records has almost doubled, from 46% in 2009 to 88% in 2019 [139]. Preliminary data suggest that physicians who use electronic health records are less likely to have paid malpractice claims [140]. However, the effect of electronic health records on the quality of care and the potential for mitigating malpractice is unclear. One study of electronic health record-related malpractice claims found that 50% of claims were caused by system factors such as failure of drug or clinical decision support alerts, and 58% of claims were caused by user factors, such as copying and pasting progress notes [141]. In addition, a 2018 survey of physician attitudes toward electronic health records showed that 69% felt that the clerical aspect of updating records takes valuable time away from their patients, and 49% felt that using an electronic health records detracts from their clinical effectiveness [142]. Regardless of whether an office is paper-based or technology-based, the most important systems that should be established are standardized procedures and tools for improving diagnosis, ordering and tracking tests, and managing patient's medications.

Standardized Procedures

Each task in a physician practice should be standardized to ensure that the task is carried out accurately and efficiently each time, regardless of who is performing the task [142; 143; 144]. The use of standardized procedures helps to avoid errors related to lapses in staff members' memory or to the use of new staff. Following a standardized approach to each patient ensures consistent, high-quality care for all patients. This approach is also helpful in the event the physician does not provide comprehensive documentation for a visit. For example, if a physician forgets to document a breast examination during a female patient's annual physical examination but uses a standardized approach that includes this examination for all women during an annual physical examination, the physician can confidently describe the care given despite the lack of documentation [95].

Establishment of standardized procedures should begin with evidence-based protocols or standing order sets for chronic diseases and vital sign checks for all patients, regardless of the nature of the visit. Flowcharts, checklists, templates, and/or automatic alerts or reminders can help ensure that standardized procedures are carried out [143; 144].

Diagnosis

Given that missed or delayed diagnosis is the leading basis of malpractice suits, enhancing diagnostic accuracy is imperative. As stated earlier, diagnostic errors are usually the result of several breakdowns in the diagnostic process [56]. Physicians should develop risk management strategies that focus on the most common breakdowns in the diagnostic process. Thus, physicians should ensure that they:

- Obtain a thorough history
- Perform a comprehensive physical examination
- Order and track diagnostic tests appropriate for a patient's signs and symptoms
- Create a proper follow-up plan

- Seek additional interpretation of diagnostic tests if results are uncertain or inconclusive or seem incongruous with the patient's condition

Reviews of malpractice claims, as well as a systematic review of the literature, have shown that diagnostic errors are most often involved with atypical or nonspecific presentations, rarity of the disease, or masking comorbidities [59; 83]. For example, claims related to myocardial infarction are often associated with no history of cardiac problems, a normal electrocardiogram, and atypical signs and symptoms [83]. Similarly, malpractice claims related to breast cancer often involve younger women (average age: 45 years). Physicians should take care not to exclude diagnoses because of nontraditional presentations or low prevalence of a condition.

An inappropriate or inadequate follow-up plan has been alleged in nearly one-half of claims of misdiagnosis [56; 61]. Failure to follow-up has often involved a lack of follow-up after abnormal testing, an uncertain diagnosis, or referrals [56; 95]. In addition to providing guideline-based follow-up, physicians should seek ways to improve scheduling procedures, to check patient compliance with testing and referrals, and to track test results.

Most physicians are not aware that they need help in making accurate diagnoses, which means that automatic strategies, such as clinical decision support integrated into electronic health records, may be most helpful [56; 145]. Other effective interventions include electronic prompts in response to input of certain data and automated systems for tracking test results and scheduling follow-up [56].

Documentation of the differential diagnosis in the patient's record will reflect the physician's thought process in determining a diagnosis, which can be helpful if a malpractice claim is made [83]. This is especially important for diagnoses at high risk for malpractice, such as cancer (especially breast cancer) and myocardial infarction. The patient's report of symptoms should be carefully documented, as well as all tests ordered, the patient's compliance with screening and testing, and scheduled follow-up visits.

Test Ordering and Tracking

Laboratory and/or imaging studies are often an integral aspect of determining a definitive diagnosis, and inadequacies in managing test results can be an important factor in enhancing the timeliness and accuracy of diagnoses. Inadequate test tracking is an important factor in medical errors, with studies of primary care patients indicating that 15% to 54% of medical errors are related to test processes [146].

Ordering and tracking test results is a complex process, and the volume and variety of tests ordered within a practice add to the challenge. Four principle steps are involved in managing patients' test results [144; 147]:

- Tracking tests until the results have been received
- Notifying patients of test results
- Documenting that patients were notified
- Ensuring that patients with abnormal results receive the recommended follow-up care

A literature review indicated that there is no clearly defined method for tracking results that is effective and efficient at each of these steps, but a task flow can be created from some "good processes" that have been defined (**_Figure 3_**) [148; 149]. Studies have shown that most physician practices do not have an established protocol for managing test results, and the processes used to track test results vary widely, even within a single multiphysician practice [146; 148; 149]. In fact, the most common finding in a survey of office practices (across a broad range of specialties) was the lack of an effective tracking system for test results [136]. In one study, 92% of physicians said that each physician in their group practice used a different method for reporting lab results, with 61% using different processes for different types of tests [148].

TASK FLOW FOR EFFECTIVE TEST TRACKING
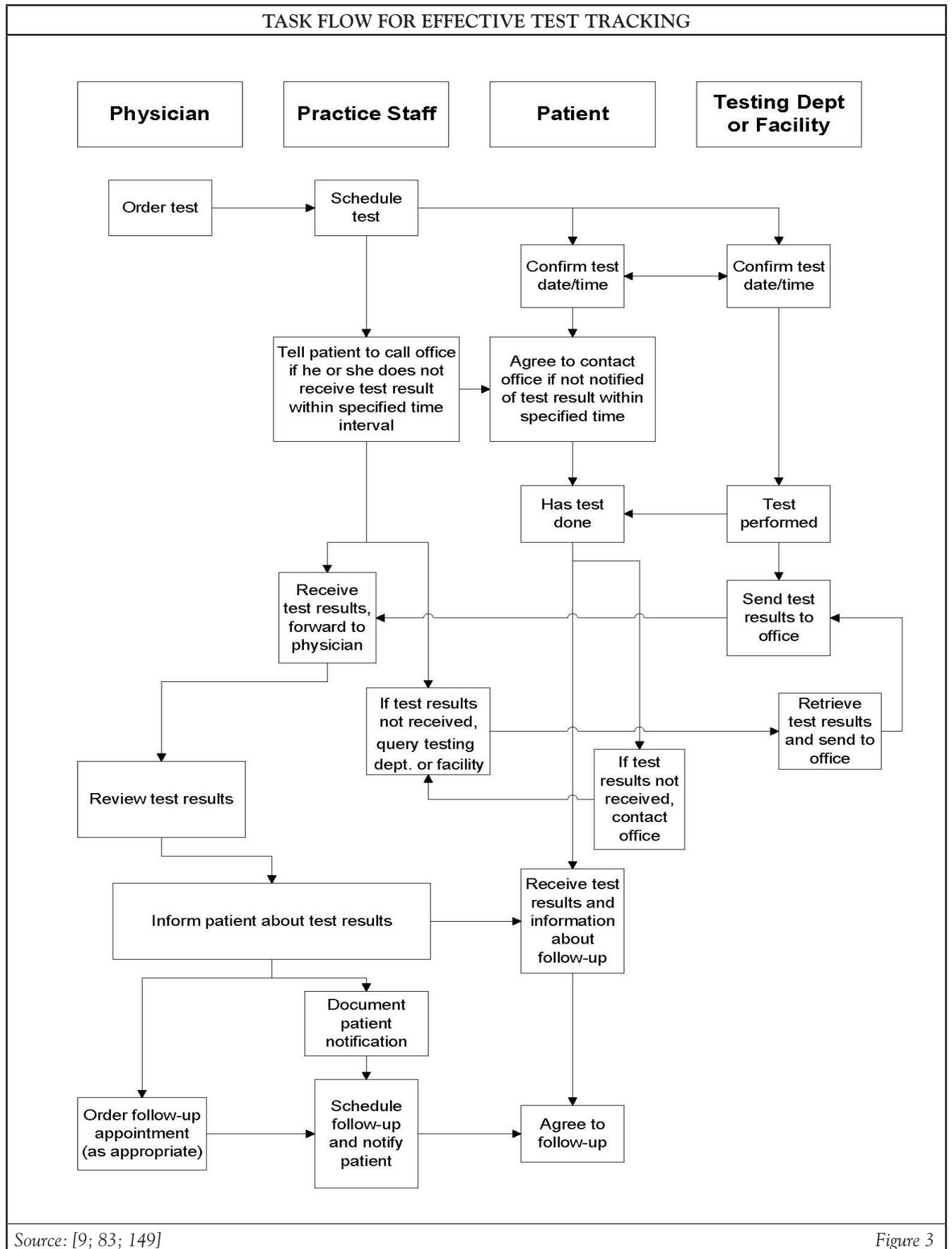
The lack of a clearly defined system for tracking or managing test results has led to high rates of failure to inform patients of test results and delays in notifying patients. The most common problems are a lack of a consistent system to verify that the physician has reviewed the results and communicated them to the patient and the practice of notifying patients only when the results are abnormal [136]. According to one study, 7% to 26% of patients with test results were not informed of the results (or did not have documentation of notification) [149]. In another study, patient notification was documented in 58% to 85% of charts, but rates were lower for documentation of the physician's response to the result (47% to 84%) and for follow-up after abnormal results (28% to 55%) [136; 142; 146]. As noted, prompting through electronic health record systems may help alleviate this issue [142].

Physicians recognize the inadequacy of test results tracking. When surveyed, most physicians have expressed dissatisfaction with their practice's process for tracking test results. These surveys have indicated that only 15% to 41% of physicians said they were satisfied with how test results were managed in their offices [142; 150; 151]. Physicians were most likely to be satisfied when they actively tracked test orders to completion and/or used tools to help set priorities for workflow and generate letters to patients [151].

The optimum process for managing test results will vary according to a practice's specific needs and resources, especially technology. A focus on patient safety and a willingness to embrace technology throughout a practice are important factors in establishing and maintaining an effective test tracking system [146]. In the past, several practices have established systems in which staff log ordered tests in a notebook or date-defined card boxes, check them off when test results come in and again when the physician signs off on the results, and note when the patient has been notified [83; 144]. Although this system is effective, automated systems that perform the same tasks are more reliable and are less labor-intensive, a factor especially important in large practices [144]. Electronic clinical reminders are more efficient, and systems can be programmed to provide alerts when a test result is due or a patient should return for follow-up care [150]. Creating templates of patient notification letters for the most common tests is also helpful [144]. Also available are telephone and web-based programs that allow patients to obtain their test results; privacy is ensured with the need for a password, and some programs enable the physician to include specific comments to the patient [144].

Given the high risk of malpractice claims in association with various types of cancer, physicians should also be thorough in their approach to recommending screening tests. Follow-up should be done to ensure that the patient has had the screening and has been notified of the results. If the patient refuses to have screening despite the physician's recommendation and explanation of the risks, the refusal should be clearly documented in the patient's medical record [83].

Because appropriate follow-up after abnormal test results is often lacking, a test tracking system must involve a consistent process for scheduling follow-up visits. Failure to follow-up on abnormal mammography and ultrasound are common assertions in malpractice claims [83]. In addition, studies have shown that at least 20% to 36% of women do not receive guideline-directed follow-up after abnormal findings on mammography or Pap tests [152; 153; 154]. Failure to follow-up on suspicious findings on lung radiographs or computed tomography scans has also been noted [66].

Medication Management

Management of patients' medications is a frequent problem in medical office practice and a common basis for malpractice claims [63; 64; 136]. As noted earlier, a substantial proportion of medication errors and adverse drug events are considered to be preventable [63; 64].

STRATEGIES FOR AVOIDING MEDICATION ERRORS
Perform a thorough examination before prescribing medication or renewing a prescription (especially opioids).
Review medication list with the patient (including all over-the-counter medications, dietary supplements, herbal remedies, vitamins, etc.) at each visit and during transitions of care (e.g., hospital to outpatient).
Give a written medication list to the patient; the list should include the name of the drug, its purpose, the dosage, the directions for use, and side effects.
Discuss how and when the patient should take the medication.
Review the side effects of a new medication, as well as potential drug-drug or drug-food interactions, and tell the patient what to do if side effects or interactions occur.
Review the role of the medication in the overall context of the patient's health.
Establish guidelines to manage prescription calls and refills and record the calls with the date and time in the patient's chart.
Inform the pharmacist about the patient's comorbidities, allergies, and weight when calling in a prescription.
If providing medication samples, record the lot number in the patient's record (in case of a recall of the medication).
When administering a medication:
• Double check the vial or bottle label against the order.
• Ask the patient if he or she has an allergy to the medication, even if no drug allergies are noted in the medical record.

Source: [9; 158]   *Table 7*

In the office and outpatient setting, preventable medication errors occur primarily in the prescribing and monitoring stages [64; 155; 156]. Prescribing errors were identified in up to 11% of prescriptions written in the primary care setting and were typically related to dosage errors [57; 157]. Prescribing errors have also frequently involved the use of inappropriate drugs [64; 156]. Inadequate monitoring has caused a wide variety of adverse effects, such as electrolyte/renal imbalance, bleeding, gastrointestinal toxicity, and neuropsychiatric events, and often requires hospitalization of the patient [64; 155]. Other common medication-related errors are a failure to prescribe prophylactic agents when appropriate (as for patients taking nonsteroidal anti-inflammatory agents or anticoagulants) and drug-drug interactions [57; 155].

Studies and reviews of malpractice claims have identified several drug classes that are most often associated with preventable medication errors: antibiotics, antidepressants or antipsychotic agents, cardiovascular drugs, anticoagulants, analgesics, hypoglycemic agents, and diuretics [63; 64; 155]. As with most medical errors, preventable medication errors are most frequently caused by system deficiencies [63]. Electronic prescribing systems have not been found to reduce the number of prescribing errors; for example, handwriting legibility issues have now been replaced by e-prescribing issues, such as selecting the wrong box in a dropdown menu [156; 157]. General medication errors are still common. A 2014 observational study found that the most frequent prescribing errors were wrong drug quantity (40%), wrong duration of therapy (21%), wrong dosing directions (19%), and wrong dosage formulation (11%) [157]. Several strategies can help physicians avoid medication errors (**Table 7**) [9; 158].

QUALITY ASSURANCE PROGRAM

Risk management should also involve a quality assurance program in which the efficiency and outcomes related to policies and procedures are evaluated on an ongoing basis. All staff should be encouraged to provide feedback on ways to improve care; patient complaints can also provide opportunities for improvements [9]. In addition, physicians should evaluate their practice behaviors to identify evidence of defensive medicine to help eliminate variations in care and promote better patient outcomes.

It is also important to create an environment in which patient safety is emphasized. Physicians should provide leadership within the practice, encouraging teamwork, offering feedback on performance, and providing access to necessary training and continuing education for all staff [9].

OTHER ISSUES

Other issues that should be addressed in a risk management program are the scope of practice, termination of the patient-physician relationship, and retention of medical records.

Scope of Practice

All staff should perform only those tasks that are within the scope of their job descriptions, licensure, or certification [9]. In addition, staff should operate or maintain medical equipment or devices only if they have received appropriate training and have been certified (if required).

Termination of Relationship

Physicians should have a standardized procedure for dismissing patients (i.e., terminating the patient-physician relationship when the patient presents insurmountable problems, such as unresolved issues with missed appointments, abusive treatment of staff, or threatening behavior) [159]. It is recommended that a physician dismiss a patient who has filed a malpractice suit [69; 159].

When terminating a patient-physician relationship, the physician should send a letter to the patient, notifying him or her that the relationship will be terminated by a specific date, typically 30 days from the date of the letter [159]. The letter should be sent by certified mail with a return receipt requested to ensure appropriate delivery. A copy of the letter and the return receipt should be kept in the patient's medical record. Physicians should not refill a patient's prescription beyond the date of termination [9; 159]. Physicians are not obligated to help patients find another physician, but assisting with the transfer of medical records demonstrates an interest in facilitating continuity of care, which may be helpful in the event of litigation [159].

Retention of Medical Records

Most state and federal laws regarding mandatory retention times for medical records apply to hospitals rather than office-based practices. In the absence of state or federal laws, state medical boards and medical associations have recommended retention times [160]. It is recommended to retain medical records indefinitely, but if not, they should be kept for at least 10 years, and some associations recommend 25 years [160]. Medical records should be destroyed appropriately, and an inventory of all destroyed records should be kept.

CONCLUSION

Although overall paid medical malpractice claims have decreased since the early 2000s, the number of claims against primary care physicians increased during that time. The association of malpractice and medical errors is complex. Large studies have shown that malpractice claims often do not involve a negligent injury and that most patients who do sustain an injury due to negligence do not file a claim. These findings indicate that factors other than true medical error are motivators for a malpractice claim. A wide variety of motivators have been identified, the most common being inadequate patient-physician communication.

Thus, physicians should protect their liability not only through patient safety efforts but also through enhancement of patient-physician communication and the patient-physician relationship.

The threat of malpractice—whether real or perceived—has a negative effect on physicians personally and professionally and ultimately adversely affects healthcare delivery, primarily through the use of defensive medicine. An effective risk management program helps physicians ensure patient safety and avoid the time and stress associated with litigation. The most effective risk management strategies are those that address specific issues identified in studies of closed malpractice claims and surveys of office practices.

Studies of malpractice claims have shown that diagnostic error (missed or delayed diagnosis) is the leading underlying cause of claims and is most often related to cancer (especially breast cancer) and myocardial infarction. Diagnostic errors are usually the result of several contributing factors rather than faulty judgment alone, and the most common breakdowns in the diagnostic process have been failure to order an appropriate diagnostic test or to create a proper follow-up plan. Surveys of medical office practices have shown that the most common risk management-related problem is an ineffective process for tracking diagnostic test results. As such, an effective system for ordering and tracking tests, including follow-up plans for abnormal results, is an essential component of a risk management program. Other essential components include a mandate for informed consent, appropriate and complete documentation, establishment and maintenance of efficient office processes, a quality assurance program, a system for evaluating practice behaviors, and continued development of diagnostic and technical skills of the physician and other healthcare professionals in the practice.

As noted, perhaps the most important element of a risk management program is optimum patient-physician communication. The quality of patient-physician communication and the patient-physician relationship affects many areas within a risk management program, including diagnosis, patient satisfaction, disclosure of errors, informed consent, and medication management. Effective communication also serves to build rapport, foster trust, avoid misunderstandings, and ensure realistic patient expectations, all of which have been shown to be associated with a lower risk of malpractice claims. Improved patient-physician communication may mitigate the harm from medical errors as well as help reduce the frequency of future errors.

RESOURCES

**American Medical Association
Code of Medical Ethics**
https://www.ama-assn.org/delivering-care/ethics

**American Medical Association
State Medical Liability Reform**
https://www.ama-assn.org/practice-management/
sustainability/state-medical-liability-reform

Diversity Rx
http://www.diversityrx.org

**Institute for Healthcare Improvement
and National Patient Safety Foundation**
https://www.npsf.org

**National Council on Interpreting
in Health Care**
https://www.ncihc.org

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