Office-Based Medical Malpractice Claims: Study Examines Administrative and Clinical Systems Factors

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According to the CDC's National Center for Health Statistics, the number of visits to healthcare practitioner offices in the United States is estimated to be over a billion annually, including visits by over 83 percent of adults and almost 94 percent of children. Ensuring patient safety is the goal in each office encounter. As evidenced by medical malpractice claims, however, harmful errors can occur that lead to poor outcomes for patients.

The Doctors Company uses an evidence-based clinical coding taxonomy from Candello[1] in leveraging malpractice data to prevent future errors and improve practice. Learning from claims can assist in identifying possible weaknesses within healthcare practitioner offices.

Recent updates to the coding taxonomy enabled claim contributing factors to be linked with both the *service* (for example, family medicine) and the *role* (for example, attending physician). We are also able to add a new weighting factor to the coding taxonomy, *primary drivers*. Primary drivers are factors determined to be the most likely to have led to an error or claim.

Our study covered office-based medical malpractice claims closed from 2011 through 2022 with administrative and clinical systems factors. The aim of the analysis was to (1) describe the characteristics of the claims, (2) identify roles associated with them, and (3) determine the primary drivers.

(For this analysis we excluded office-based dental and oral surgery.)

Claim Characteristics

Table 1 provides overall findings for office-based claims with administrative and clinical systems factors. Most of the injuries were of medium severity. The top major allegations were diagnosis-related and medical treatment. Family medicine was the top primary responsible service. Organizational leadership and attending/consulting physician were the top two roles.

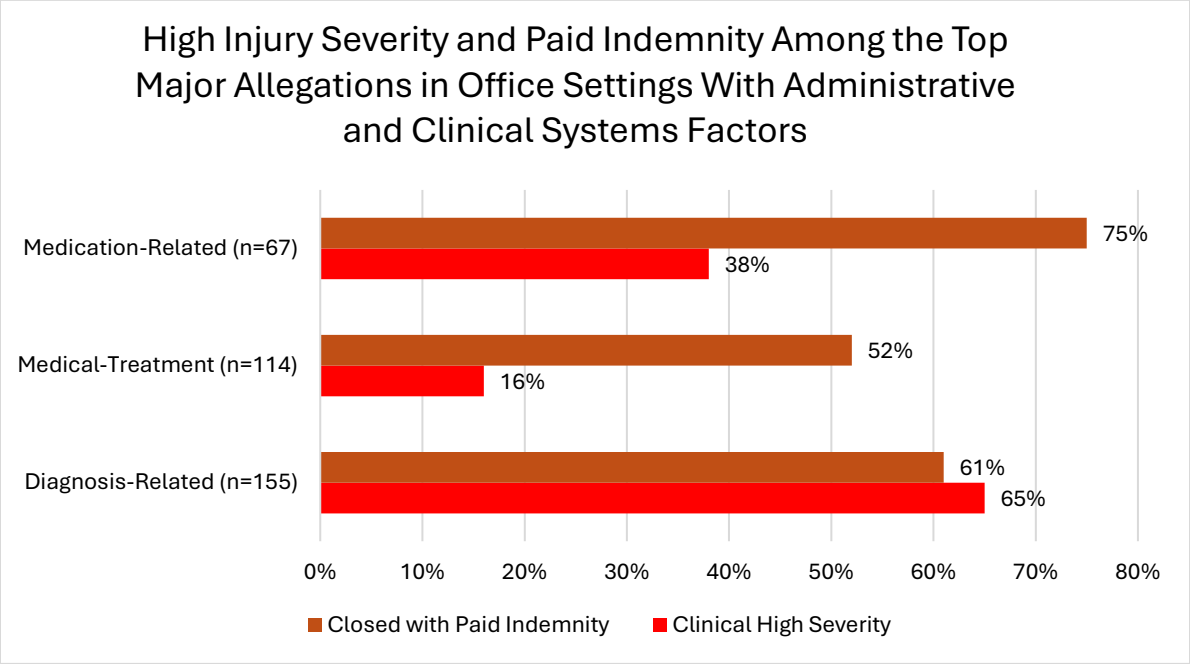
Table 1. Administrative and Clinical Systems Findings 2011–2022

Data Point	Case Count (Percentage)
Injury Severity	
Death/Fetal Death	94 (22%)
High	83 (19%)
Medium	190 (43%)
Low	69 (16%)
Top Major Allegation	
Diagnosis-Related	173 (39%)
Medical Treatment	126 (28%)
Medication-Related	68 (15%)
Surgical Treatment	33 (7%)
Top Primary Responsible Service	
Family Medicine	104 (24%)
Internal Medicine	53 (12%)
Orthopedic Surgery	23 (5%)
Plastic Surgery	22(5%)
Pain Medicine	20 (5%)
Top Roles*	
Organizational Leadership	162 (40%)
Attending/Consulting Physician	132 (33%)
Clerical Staff	42 (11%)
Medical Assistant	18 (5%)
Clinical Technician	14 (4%)
Physician Assistant (PA)	14 (4%)
Nurse Practitioner (NP)	13 (3%)

*Unspecified/undetermined not included.

Overall, we found a high percentage of claims with a paid indemnity (59 percent). However, claims with a diagnosis-related allegation had both a large percentage of high injury severity (65 percent) and paid indemnity claims (61 percent). Medication-related and medical treatment allegations had a lower high injury severity percentage (38 percent and 16 percent, respectively). Refer to Figure 1.

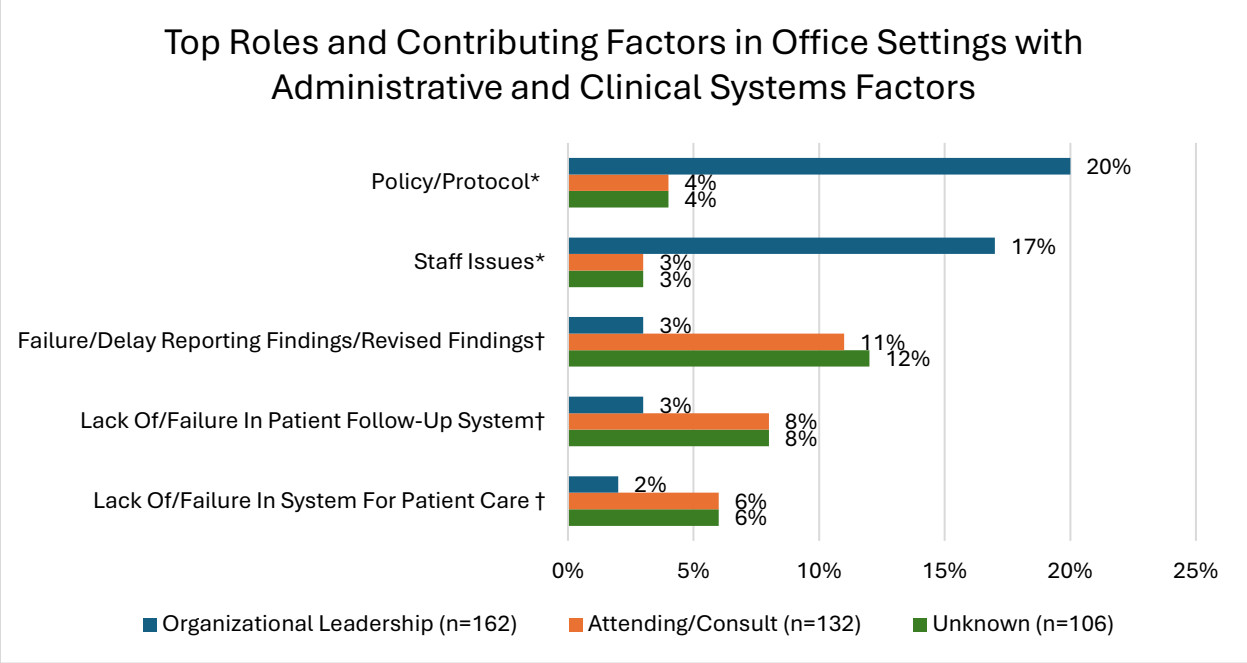
Figure 1. High Severity, Indemnity, and Major Allegations



Office Practice Roles

Overall, our analysis identified 20 different roles associated with office-based medical malpractice claims. Organizational leadership, which accounted for 40 percent of the roles in the analysis, was responsible for administrative matters, such as staff issues, policies, and protocols, while the attending or consulting physician (33 percent) had more accountability for clinical systems. The third most-common role was "unspecified or unknown," an indication that, based on the information available, the patient safety analyst was unable to determine which role was responsible for the contributing factor in the claim. Clerical staff accounted for 11 percent of the roles in the analysis. Physician assistants (PAs) and nurse practitioners (NPs) rounded out the top roles at 4 percent and 3 percent, respectively.

Figure 2. Top Roles and Contributing Factors



*Administrative Factor.
†Clinical Systems Factor.

Primary Drivers

Three of the top five office-based claims primary drivers were administrative in nature, including two related to policy and protocol. One primary driver was related to an established policy and a failure to adhere to it. Yet, the opposite administrative problem arose with the need for a policy or protocol. Often, this concern occurred when clinical systems failed, particularly in communications about test results or follow-up appointments when expectations about actions to be taken (that is, who, what, when, and how) were unclear. Refer to Table 2.

Table 2. Primary Drivers: Administrative and Clinical Systems Findings 2011–2022

Primary Driver	Overall Percentage
Policy/protocol not followed*	14%
Patient did not receive initial or revised test results†	13%
Need for policy/protocol*	12%
Staff training/education*	11%
Lack of or failure in patient follow-up system for new findings†	10%
Failure or delay in scheduling or performing recommended test†	6%
Nosocomial infection†	6%
Failure/delay in reporting incidental test finding†	5%
Clinician did not receive test results (other)†	5%
Failure in system for patient follow-up after missed consult/referral†	5%

*Administrative Factor.
†Clinical Systems Factor.

Risk Mitigation

This study illustrates that diagnosis-related claims had a large percentage of high injury severity compared with other types of claims. Additionally, primary drivers around policies and protocols and staff training were prominent. The following case example illustrates these findings:

> A patient with morbid obesity (BMI >42) came to the family medicine practitioner complaining of a rash. The patient's blood pressure was recorded as 172/115. The practitioner did not comment on the patient's blood pressure in notes about the visit. About four months later, the patient returned to review a sleep study. The patient's blood pressure reading of 210/132 was entered into the record by the medical assistant. The practitioner noted that no physical was done because this visit was scheduled for discussion of the sleep study. There was no documentation of discussion between the medical assistant and the practitioner or with the patient regarding the elevated blood pressure. One week later, emergency services were called to the patient's home for stroke symptoms that included expressive aphasia. The patient, whose blood pressure was 220/140, was taken to the hospital and diagnosed with an ischemic stroke. As a result, the patient has mild cognitive impairment with word-finding difficulties, anxiety, and depression, and now takes anticoagulants. Although practitioners are expected to read the patient's record, no policy was in place requiring medical assistants to alert the practitioner when a patient has an abnormally high blood pressure reading. Questions also arose about whether the practice's medical assistant training included an emphasis on the importance of informing the practitioner about a patient's abnormal blood pressure. This claim was settled.

Policies and Protocols

Evidence-based policies and protocols can be effective risk mitigation strategies as they promote patient safety and quality of care, address compliance with state and federal laws, foster effective communication and decision-making among the healthcare team, promote standardization, and provide for a safe work environment. Policies differ from protocols in that a policy is a formal requirement established by an organization. Policies are necessary for an organization's day-to-day functioning and operations because they set the standards for patient care and consistency in clinical and administrative processes (e.g., when terminating a patient-practitioner relationship). Protocols are step-by-step instructions on how a process should be carried out (e.g., telephone triage by licensed and trained clinical staff).

Policies and protocols must be reviewed and approved by clinical leadership and administration and updated regularly to reflect any changes in statutes, regulations, and standards of patient care. Educating and training clinicians and staff is of paramount importance, as is record keeping. Retain previous versions of policy and protocol documents. If an adverse event occurs. having a record of the policies and procedures in place at that time is helpful in defending a malpractice claim or disciplinary action against the practitioner or practice.

Although policies and protocols can serve as effective mitigation strategies, they can also be a liability for the clinician and office practice. Policies and protocols that are poorly written, outdated, or not followed can create risk exposure and result in patient harm.

For unlicensed medical assistants and clerical staff, having clearly written policies and protocols that establish the role's scope of practice and responsibilities is vital, especially when handling patient phone calls. Provide written protocols for unlicensed staff taking initial telephone calls, such as obtaining basic information on the patient's name, current medications, allergies, and reason for the call. The information is then passed to a licensed practitioner for review and further action as required. The licensed practitioner can then follow up with the patient to communicate the advice or recommended care and document the contact in the patient record.

Clinical protocols should be written and approved by practice leadership. The protocols should address the types of information that unlicensed staff may provide to patients without licensed practitioner consultation and specify which situations require consultation with a physician or advanced practice clinician before giving telephone advice to a patient.

Staff Training

Educating practitioners and staff on policies and protocols should occur during new staff orientation, practitioner onboarding, and whenever new policies and protocols are created or updated. It is essential that temporary staff also receive training. The practice manager should retain records of all staff training as the documentation can be subpoenaed as evidence in the event of litigation. The absence of staff knowledge and compliance with policies and protocols can significantly hinder the defense during a malpractice action. Refer to your state laws on record retention, as state laws may vary regarding how long training records must be kept.

Laboratory, Diagnostic Test, and Consultation Systems

Medical office practices need to have effective written policies and protocols that address closing the loop on clinical labs, diagnostic tests, and consultations; communicating results to patients; and following up on appointments. It is easy for busy practices to divert from standard operating procedures. Ultimately, this can result in delayed care and treatment and poor outcomes for patients.

Closing the loop on clinical labs, diagnostic tests (including pathology), and consultations includes a process and standardized workflow for reconciling tests/consults ordered with results received. EHRs may provide automation for some steps in the tracking process. Practitioners and staff should not, however, rely solely on individual alert inboxes for tracking outside test results. Periodic randomized chart audits or scheduled patient record reviews can be helpful in monitoring the test/consultation tracking process.

Passively waiting for test/consult results or waiting on a return appointment by the patient can lead to significant delays in treatment if tests/consults are not received in a timely manner. Avoid the "no news is good news" approach. Instruct patients to contact the office if they do not receive their results within a certain time frame. It is also recommended that the patient be scheduled for an in-person follow-up appointment to discuss the test results and treatment plan.

Risk mitigation strategies include the following actions:

- Implement a test/consult tracking log or an alpha system of retaining copies of outstanding requisitions in the file until results are reconciled. A date-based accordion file can also be used.
- Run EHR reports routinely to reconcile ordered tests/consults against results received.
- Assign specific staff to proactively manage outstanding test/consult results.
- Include documentation of practitioner instructions to staff for applicable test management.
- Act on all outstanding tests/consults not received within the specified time frame by contacting the patient, testing center, and/or consultant.
- Ensure practitioner sign-off and date (electronic signature or manually) on all test/consult reports to ensure review prior to filing/scanning into the patient record.
- Include a plan of care and document patient nonadherence with plan of care.
- Use the functionality of the EHR when possible to track all tests and consults regardless of the method of ordering and receipt of results. Options may include creating a special computerized provider order entry (CPOE) order for manual test and consult requests or using the calendar function.
- Consider the AMA STEPS Forward Pre-Visit Laboratory Testing process.

Reaching out to patients about missed appointments is important for maintaining continuity of care and preventing lost chances for treatment. Follow-ups can be accomplished through phone calls, patient portals, and certified letters. In an emergency when the patient cannot be reached, contact the patient's emergency contact. Document the patient's record with all attempts to contact the patient.

Nosocomial Infections and Compounded Medications

In our analysis, nosocomial infections were a primary driver in 6 percent of the claims. In some cases, infections arose from contaminated compounded medications. Some of the claims alleged a lack of transparency and consent about the use of compounded medications.

Compounding medications may be essential for some patients. If you are compounding medications in your office, or using or prescribing compounded medications, verify that the compounding facility follows applicable standards and regulations. Inform patients that the medications are not approved by the FDA and explain what non-FDA approval means. Contact your malpractice insurance carrier to check whether compounding medications or using compounded medications are covered under your policy.

Find more information about compounding medications from these sources:

- U.S. Food and Drug Administration, Compounding and the FDA: Questions and Answers
- U.S. Food and Drug Administration, Human Drug Compounding
- U.S. Pharmacist, Pros and Cons of Pharmacy Compounding

Conclusion

This analysis provides insight into the characteristics of office-based medical malpractice claims with administrative and clinical systems as contributing factors. We discovered that over 20 different roles—from attending physicians, to organizational leadership, to the clerical staff—contributed in some way to the claim. Most of the claims were based on allegations of errors in diagnosis or medical treatment and involved patient harm with a medium injury severity. Administrative and clinical systems risks can be mitigated using policies and protocols, staff training, and tracking systems for laboratory and diagnostic tests and consultations.

Reference

1. CRICO-Candello Clinical Taxonomy Manual, V4.0, 2021. Copyrighted by and used with permission of Candello a division of The Risk Management Foundation of the Harvard Medical Institutions Incorporated, all rights reserved. As a member of the Candello community, The Doctors Company participates in its national medical malpractice data collaborative.
