Diagnostic Accuracy:
Room for Improvement

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Diagnosis-related events are the single largest common root cause of medical professional liability claims.

INTRODUCTION

Each year in the United States, nearly 84% of adults and an astounding 93% of children will have contact with a healthcare professional because something ails them — they are injured or sick or experiencing out-of-the-ordinary health symptoms.[1] These patients and their caregivers are ultimately asking for two things — an accurate diagnosis and an appropriate treatment plan.

Diagnostic accuracy is far from simple. In fact, diagnosis-related events are the single largest root cause of medical professional liability claims. Arriving at a diagnosis is a process that is rife with pitfalls and variability and one that can trip up even the most skilled diagnosticians. To help improve diagnostic accuracy and patient safety, healthcare providers can benefit from fresh perspectives, data-driven insights, and new ways of thinking about the everyday activities that contribute to making an accurate diagnosis.

This special report provides insight into the root causes of diagnosis-related claims based on an analysis of 10,618 closed medical professional liability claims at Coverys across a five-year period (2013-2017).[*]

A FRESH APPROACH TO CLAIMS DATA

At Coverys, we refer to claims data as "signal intelligence." Our conclusions from analysis of the data are not absolute findings. Rather, they are hypotheses: signals from the past about where vulnerabilities existed and may still be at play. In fact, the past can and does predict the future, especially if we're not paying attention.

Typically, a fully investigated liability claim will contain valuable information, such as:

- Allegations of primary and secondary causes of the claim
- Patient health and demographic information
- Injury severity
- Physician specialty
- Risk management issues
- Location of the alleged error (e.g., office/clinic, ED/urgent care, lab/testing)
- The human and financial costs
- Expert reviews and opinions

Coverys uses this information to create evidence-based recommendations to mitigate risk.

*Unless otherwise indicated, statistics and other information in this publication were derived from this proprietary data.

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LEADING CAUSES OF CLAIMS

Diagnosis (Dx)-related failures are cited as the single largest root cause of claims, resulting in indemnity payments just slightly higher than the next five highest categories combined.

Legend: 🟥 % of Claims ◼️ % of Indemnity Paid

Diagnosis-related claims are the #1 most common root cause of claims

Category	% of Claims	% of Indemnity Paid
Diagnostic-Related	33%	47%
Surgical/Procedural	24%	18%
Medical Management	14%	9%
Medication-Related	9%	7%
Patient Environment/Safety	4%	2%
Obstetrics-Related	4%	8%
Patient Monitoring	3%	5%
Anesthesia-Related	3%	2%
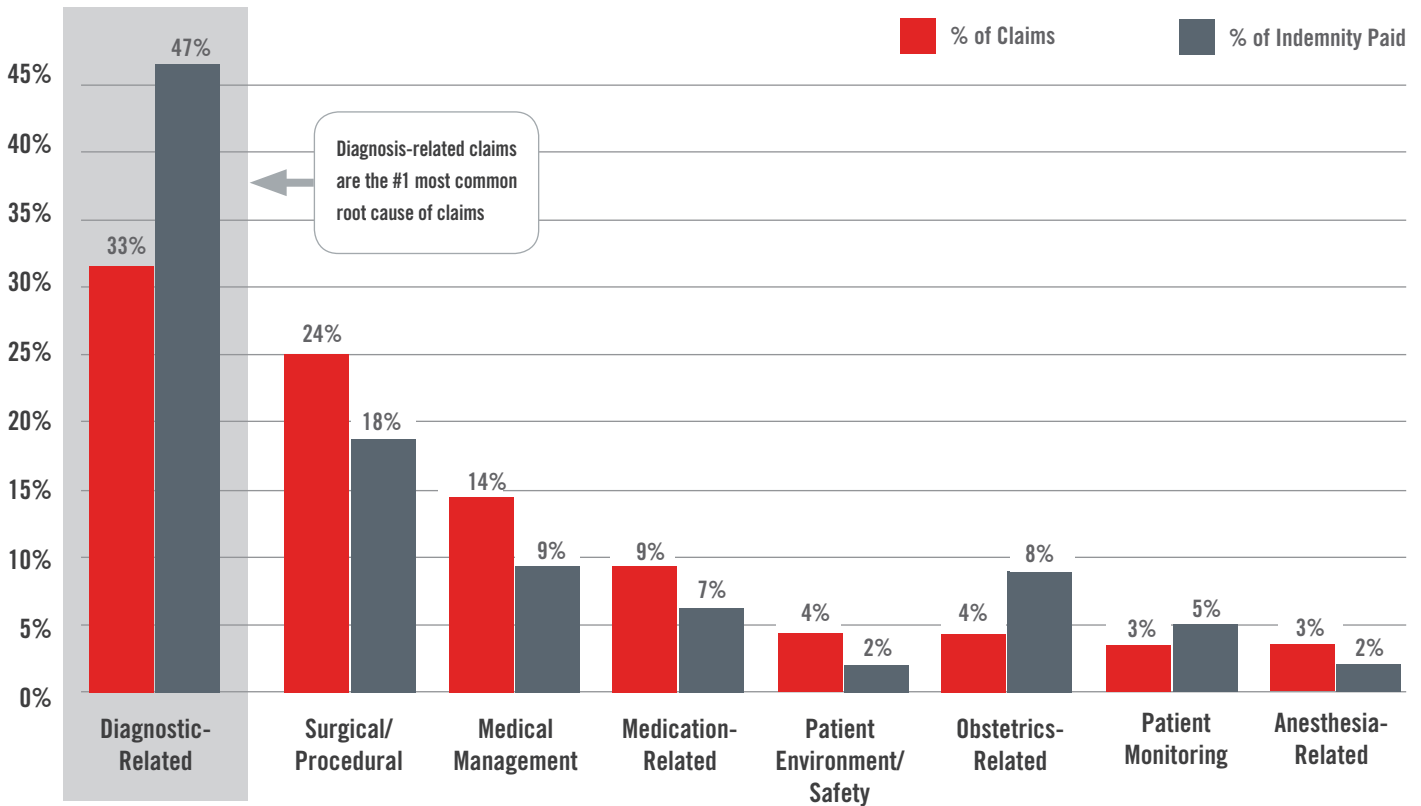
N = 10,618 closed claims between 2013-2017

53% of Dx-related claims include risk management issues involving poor clinical decision-making

54% of Dx-related claims are high-severity cases, and 36% result in death

36% of Dx-related claims stem from outpatient (office setting) locations

TOP DX-RELATED ALLEGATIONS

Vulnerabilities in the diagnostic process can begin with the first patient visit and continue all the way through to the follow-up phase after evaluation, testing, and treatment.
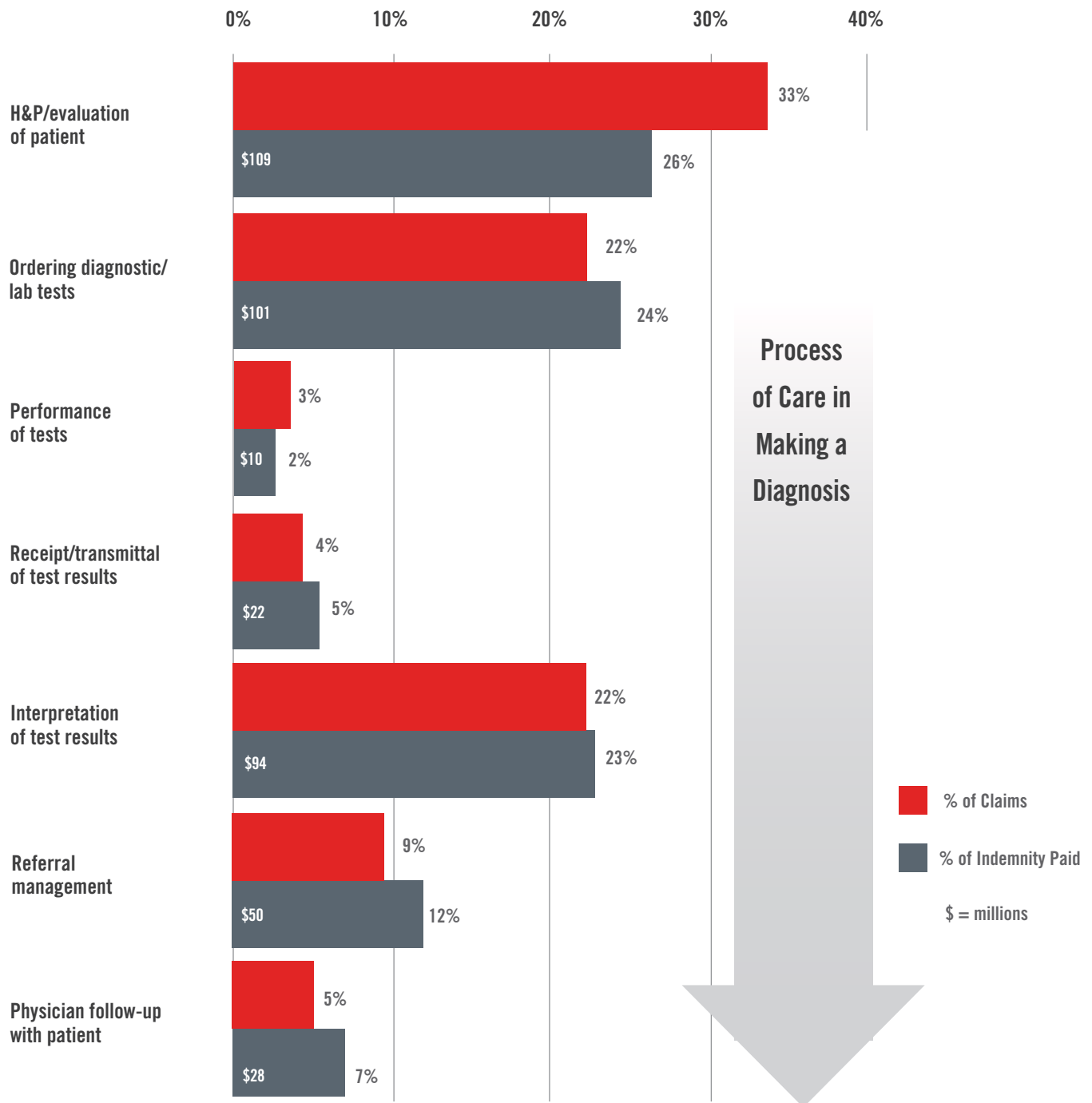
H&P/evaluation of patient
- 33% (% of Claims)
- $109 — 26% (% of Indemnity Paid)

Ordering diagnostic/lab tests
- 22% (% of Claims)
- $101 — 24% (% of Indemnity Paid)

Performance of tests
- 3% (% of Claims)
- $10 — 2% (% of Indemnity Paid)

Receipt/transmittal of test results
- 4% (% of Claims)
- $22 — 5% (% of Indemnity Paid)

Interpretation of test results
- 22% (% of Claims)
- $94 — 23% (% of Indemnity Paid)

Referral management
- 9% (% of Claims)
- $50 — 12% (% of Indemnity Paid)

Physician follow-up with patient
- 5% (% of Claims)
- $28 — 7% (% of Indemnity Paid)

Process of Care in Making a Diagnosis

Legend:
- % of Claims
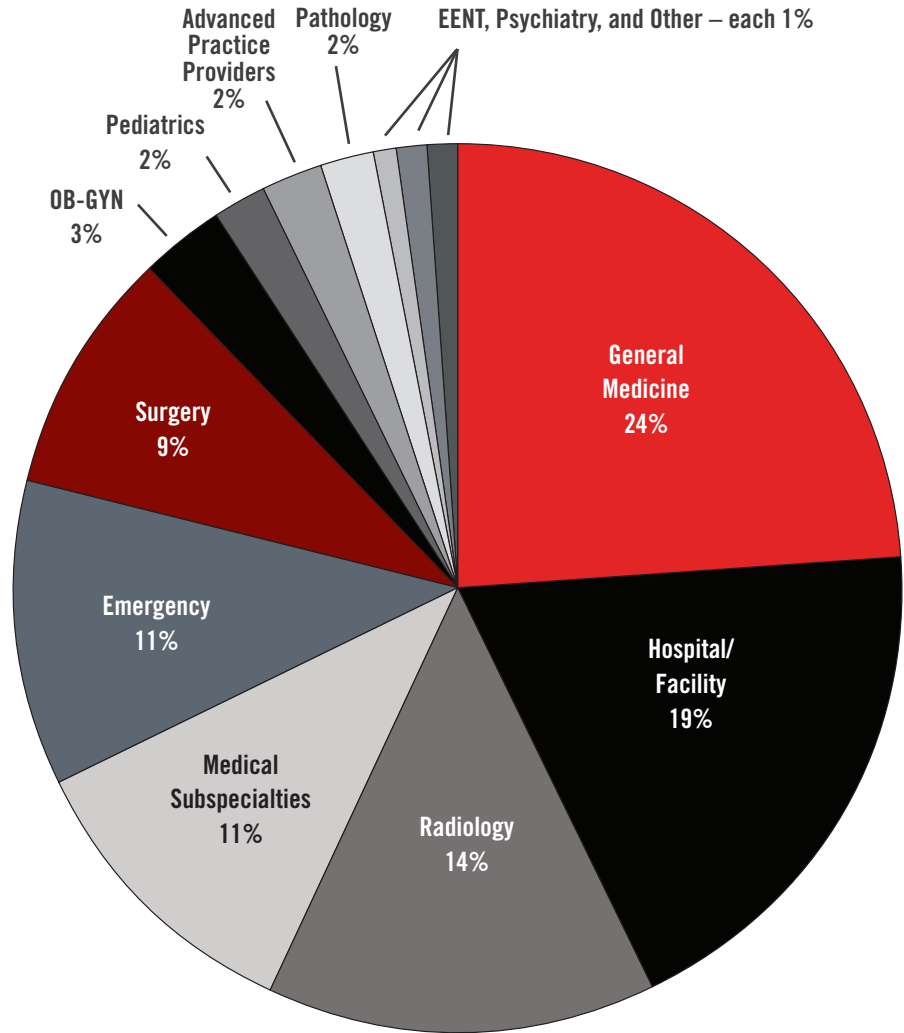- % of Indemnity Paid
- $ = millions

Note: Allegation columns are presented in the order in which the diagnosis process typically takes place to help highlight where the process breaks down.

N = 3,466 closed claims between 2013-2017 with a diagnosis-related allegation

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CLAIMS BY PROVIDER TYPE

The majority of diagnosis-related claims stem from general medicine (internal, family, etc.) and hospital/facility-related claims, followed by radiology, medical subspecialties (e.g., gastroenterology, cardiovascular disease, neurology, infectious disease, hospitalist), emergency medicine, and others.
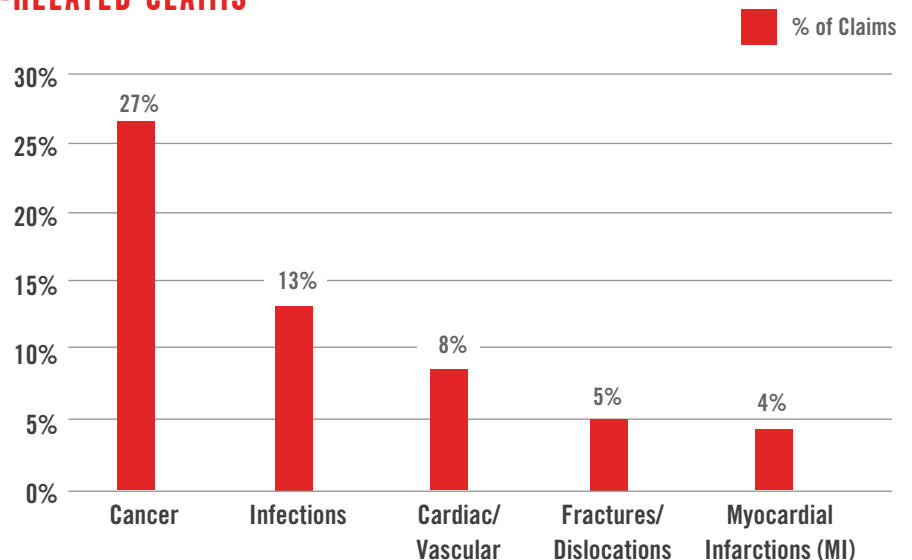
Advanced
Practice
Providers
2%

Pathology
2%

EENT, Psychiatry, and Other — each 1%

Pediatrics
2%

OB-GYN
3%

Surgery
9%

General
Medicine
24%

Emergency
11%

Hospital/
Facility
19%

Medical
Subspecialties
11%

Radiology
14%

N = 3,466 closed claims between 2013-2017 with a diagnosis-related allegation

TOP CONDITIONS IN DIAGNOSIS-RELATED CLAIMS

Of the 3,466 closed claims from 2013-2017 with diagnosis-related allegations, claims involving cancer were the most prevalent, followed by infections, cardiac/vascular conditions, fractures/dislocations, and myocardial infarctions.

12%
of Dx-related claims involved patients with heart or vascular conditions, including missed MI.

■ % of Claims

Condition	%
Cancer	27%
Infections	13%
Cardiac/Vascular	8%
Fractures/Dislocations	5%
Myocardial Infarctions (MI)	4%

N = 3,466 closed claims between 2013-2017 with a diagnosis-related allegation

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PROCESS VULNERABILITIES

Arriving at an accurate and timely diagnosis can require numerous steps and involve many practitioners. Every step matters and can be vulnerable to patient safety risks. The costs — human and financial — are highest in the first two steps where listening, communicating, and data interpretation are key.

DIAGNOSTIC PROCESS — KEY STEPS AND RISKS

HISTORY & PHYSICAL
(Evaluation of the Patient)

Risks include failure to:
- Obtain a complete patient history
- Obtain a complete family history
- Review history notes in the patient record, if applicable
- Conduct a relevant and thorough physical exam

33% of claims
26% of indemnity paid

DIAGNOSTIC/LAB TESTING STEPS*

*For the purposes of examining the diagnostic journey as a process, we have included ordering, performance, receipt/ transmittal, and interpretation of tests as one comprehensive phase in the overall process.

Risks include failure to:
- Choose and order the appropriate diagnostic/lab tests
- Properly perform tests (including handling of specimens)
- Receive or transmit test results
- Communicate clearly and efficiently between lab and radiology professionals and the ordering physician and other relevant providers
- Accurately interpret test results
- Clearly communicate results to the patient
- Repeat tests or order additional diagnostics

52% of claims
55% of indemnity paid

REFERRAL MANAGEMENT

Risks include failure to:
- Appropriately hand off or refer a patient to a specialist
- Obtain a report from the specialist that includes the diagnosis, prognosis, and recommended next steps
- Communicate the specialist's findings to the patient
- Ensure the patient comes back for follow-up with the referring physician to close the loop
- Properly document notes and lab results from the specialist into the patient's health record

9% of claims
12% of indemnity paid

PHYSICIAN FOLLOW-UP WITH PATIENT

Risks include failure to:
- Maintain and document adequate connections over time with the patient (via phone, email, portal, and in person) to find out how the patient is doing since initial diagnosis
- Seek information about any new symptoms
- Evaluate and document the effectiveness of treatment(s), and any possible next steps

5% of claims
7% of indemnity paid

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There is no more vulnerable step in the diagnostic process than the performance of a patient history and physical.

RETHINKING THE DIAGNOSTIC PROCESS

As we examine the diagnostic episode of care, we discover not just compelling data, but stories and trends. There are vulnerabilities at every step. In the following analyses, we dig deeper into the process outlined on page 5 to share key statistics, real case studies, and risk management recommendations from Coverys experts. It's estimated that 10-20% of all medical diagnoses are inaccurate.[2] We believe predictable vulnerabilities seen in actual claims can help pinpoint actions and interventions that can improve diagnostic accuracy. Providers and organizations who take the insights of this report to heart can be a powerful force for improvement.

HISTORY & PHYSICAL: RISKS & RECOMMENDATIONS

The diagnostic journey begins, quite literally, with "hello" and can get easily derailed during the history (patient and family) and physical examination (H&P) of the patient. As previously noted, 33% of diagnostic-related claims and 26% of associated indemnity payments allege a breakdown in decision-making occurred during patient evaluation. This is an important place for physicians to focus their efforts when it comes to improving diagnostic accuracy. The H&P was identified as a key problem area in 26% of indemnity payments.

CASE STUDY

Consider the case of a patient in his early 50s who presented to an urgent care center with several severe symptoms, including bilateral jaw pain and numbness in his arm. He also mentioned having recently had some flu-like nasal symptoms. After a brief assessment and a positive flu test, the patient was sent home with a flu diagnosis and instructions to rest and take Tylenol for his pain. Hours later, he died of acute myocardial infarction.

This case underscores the vital role of a thorough history and physical in arriving at a timely and accurate diagnosis. The healthcare provider in this case had been treating a great number of patients with flu and therefore went into the patient evaluation inclined to a narrow diagnostic focus and failed to elicit an adequate patient medical history and family history. It was only later discovered that three members of the patient's immediate family had experienced serious or fatal heart disease and that the patient suffered from other conditions that predisposed him to sudden coronary death.

Risk Management Recommendations:

- Develop a policy for performing an H&P that requires obtaining and documenting specific elements of the patient's and family's history and of the patient's physical examination.

- Implement the use of a H&P template to serve as a checklist when performing the physical examination.

- Establish a routine for updating family history regularly. Reminders and prompts in the EHR will help establish consistent attention.

One-third of all diagnostic-related claims in our study reflect missed opportunities early in the diagnostic process, before and during the establishment of a differential diagnosis. Using decision-making tools and conversation checklists to improve the H&P process can help to ensure relevant patient factors are captured.

![COVERYS℠]

More than half of all diagnosis-related claims in our study indicate a breakdown in testing-related steps.

DIAGNOSTIC/LAB TESTING STEPS: RISKS & RECOMENDATIONS

Logistics in healthcare can be fraught with vulnerability. Ordering the right tests, having them properly performed, and transmitting and receiving results with the appropriate sense of urgency to all relevant providers in a complete, clear, and timely manner is no easy set of tasks to coordinate. Everything from lost specimens to unclear reporting of results can occur. For many patients, the middle part of their diagnostic journey includes testing and processing of test results. And much can go wrong when sending a patient or a patient's specimens to a lab.

When taken together, the four discrete phases of testing (ordering, performance, receipt/transmittal, and interpretation) trigger a disturbing 52% of diagnosis-related claims and 55% of indemnity payments.

CASE STUDY

Two weeks after spinal fusion surgery, a female patient in her 40s had a bulging fluid collection at the incision site. Her neurosurgeon referred her to interventional radiology, where fluid was drained and sent to the microbiology lab for routine Gram stain and C+S. Two hours later, the Gram stain result was available in the hospital's computerized system. It was positive for white blood cells and Gram positive cocci in pairs. The result was not telephoned to any of the patient's providers but was flagged in the hospital's computerized system to the attention of the interventional radiologist and the patient's neurosurgeon. Neither of these providers accessed these results.

The culture eventually grew Staph aureus, and the patient began leaking copious amounts of purulent fluid from the wound and felt systemically ill. She was taken to the ER and then to the OR by her neurosurgeon, where a large purulent hematoma was drained, and where a large epidural fluid collection was noted consisting of CSF and hematoma. A small tear in the thecal sac was found and repaired. The patient required multiple debridement and washout procedures and required a prolonged course of wound care treatment.

Issues surrounding the way the patient's specimen was labeled, as well as communication breakdowns and lack of clarity around the hospital's "critical value" policy, resulted in the lab results not being treated as STAT. Both physicians expected either a phone call or a fax to alert them to critical values, which they never received; the interventional radiologist didn't tell the neurosurgeon that he aspirated turbid yellow/brown fluid (possibly indicating infection), and the neurosurgeon failed to communicate the intent of the test and the STAT nature of it to the interventional radiology team.

Risk Management Recommendations:

- Provide decision support tools to assist providers in ordering proper diagnostic tests.

- Implement a protocol for obtaining and documenting patient specimens that includes using two identifiers, such as name and date of birth; methods for labeling and filing specimens; communicating test results to the ordering practitioner and, if applicable, to the consultants and patient; and time frames for practitioner review of all results.

- Implement a process for patients to obtain outstanding test results and the name and contact information of whom to call for clarification.

REFERRAL MANAGEMENT: RISKS & RECOMMENDATIONS

Coordination of medical care can be complex. When a patient needs to see multiple clinicians, the patient carries a heavy responsibility for communicating with the various clinicians involved in their treatment and translating the sometimes conflicting or confusing information they share. And clinicians themselves face challenges in communicating with one another across facilities with electronic health record (EHR) systems that don't properly integrate. It's a high-stakes version of the "telephone game" with numerous opportunities for things to go wrong.

Of the diagnosis-related claims examined in the Coverys study, 9% were attributed to issues with referral management. The ordering physician and the radiologist or lab professional must have a strong, open line of communication, where nothing is left to misinterpretation or chance. And yet, it's common for these collaborating professionals to barely know one another.

CASE STUDY

Consider a Coverys claim in which two physicians both felt that it was the other practitioner's job to order a biopsy after the performance of an ultrasound; each doctor trusted the other would do it without further discussion. Neither encouraged the patient to pursue a biopsy, and the diagnosis of cancer was delayed by eight months.

A lack of thoughtful processes and clear communications channels will jeopardize the chances of an accurate and timely diagnosis.

Risk Management Recommendations:

- Develop a consultation policy that includes criteria for a provider to consider when deciding whether to obtain a consultation, when a consultation must be obtained, and when a consultant must directly manage the patient (such as requiring an infectious disease provider to manage Zika patients). *Then hardwire this policy into the EHR flow and care.*

- Develop and embed into the physicians' work flow processes for all transitions which require communication and documentation of specific patient status information, including a current medication list.

- Commit to process improvements for obtaining reports from specialists that include the diagnosis, prognosis, and recommended next steps; a method to document those findings in the medical record; and a means to communicate them to the patient.

- Implement a chain-of-command policy that outlines the process for anyone to escalate patient treatment differences to an ultimate decision-maker. Train and reward for adherence to this process.

- Develop a follow-up process for patients who have been referred to a specialist, and include in that process patient contact, as well as follow-up appointment with the primary care provider.

Failure to follow up can be a major contributor to delayed, missed, or inaccurate diagnosis.

PHYSICIAN FOLLOW-UP: RISKS & RECOMMENDATIONS

Each time a patient leaves the exam room, another is soon to enter. And with doctors feeling as busy and over-scheduled as they have ever been, it's not surprising that physicians can overlook the sometimes consequential step of following up with a patient days, weeks, or months after their appointment.

But when it comes to arriving at an accurate diagnosis, it is sometimes essential to check back with a patient to see what has happened, what has changed, and how they are feeling. Likewise, the patient should be instructed to call the physician if new or concerning symptoms arise. In order to truly know what ails a patient, an update on symptoms or the effectiveness of the prescribed treatment can be crucial. Cases involving allegations about inadequate physician follow-up with the patient account for 5% of claims and 7% of indemnity paid in the Coverys study.

CASE STUDY

A female patient in her 50s presented to the ER with nausea and abdominal pain. Her cardiac workup was negative, and an abdominal ultrasound revealed stones in the gallbladder, as well as a sizable cystic lesion adjacent to one of her kidneys. She was admitted to the hospitalist service and ultimately had laparoscopic cholecystectomy. She didn't return for surgical follow-up, and she was never told about the lesion on her kidney.

Two years later, her primary care physician palpated a firm abdominal mass during a routine physical exam. Ultrasound revealed a large kidney mass, now more than double the size it was when she was seen for the gallbladder pain. She was diagnosed with perinephric leiomyosarcoma with extensive metastases and died from complications of metastatic disease five years later. This case was described as a "perfect storm scenario" where neither the interpreting radiologist, the PA from the emergency department, the general surgeon, nor the hospitalist followed up on the finding from the ultrasound obtained in the ED. The patient's primary care provider never had direct involvement in the patient's hospital admission and never received records from the ED visit or the surgery. At least four providers failed to notify the patient, and one another, of a cystic lesion that ultimately ended the patient's life.

Risk Management Recommendations:

- Provide the patient with written instructions that describe the diagnosis, expected results, side effects, or new symptoms that could arise and require attention; who to contact if they have questions or concerns; and suggested follow-up care with providers, as well as appropriate contact information.

- Ensure the patient's primary care provider receives a copy of all instructions provided to the patient, as well as test results and information on follow-up appointments.

- Consider various methods for patients to communicate, such as secure patient portals, email, and a designated line for patients to call to report concerns and ask questions.

(Continued)

- Develop a call-back system for patients with certain high-risk presentations to determine whether symptoms have subsided and instructions have been followed.

- Engage the patient. Assign them the job of reporting back key symptoms. Be clear about what they should be on the lookout for.

TOP RISK MANAGEMENT CATEGORIES IN DX-RELATED CLAIMS

■ % of Claims

Category	%
Clinical Judgment	53%
Clinical Systems	16%
Communication	9%
Documentation	7%
Behavior-Related	5%
Administrative	4%
Electronic Health Record-Related	2%
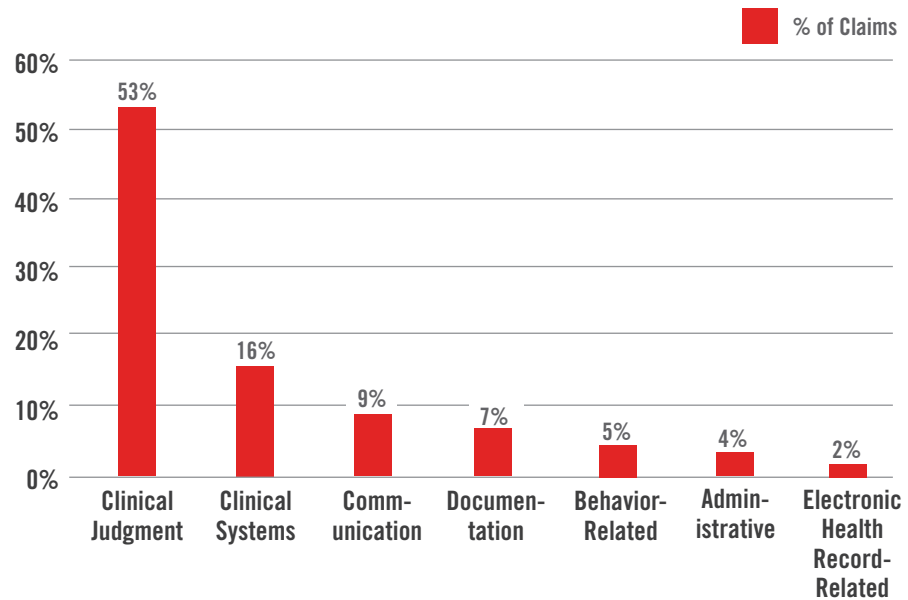
N = 3,466 closed claims between 2013-2017 with a diagnosis-related allegation

"Thanks to impressive advances in quality control procedures, diagnostic errors in the modern age are rarely the result of an error in the analytical test itself. Most laboratory-related errors now originate from the preanalytical and postanalytical phases, namely issues related to the physician ordering and interpreting the test result." [2]

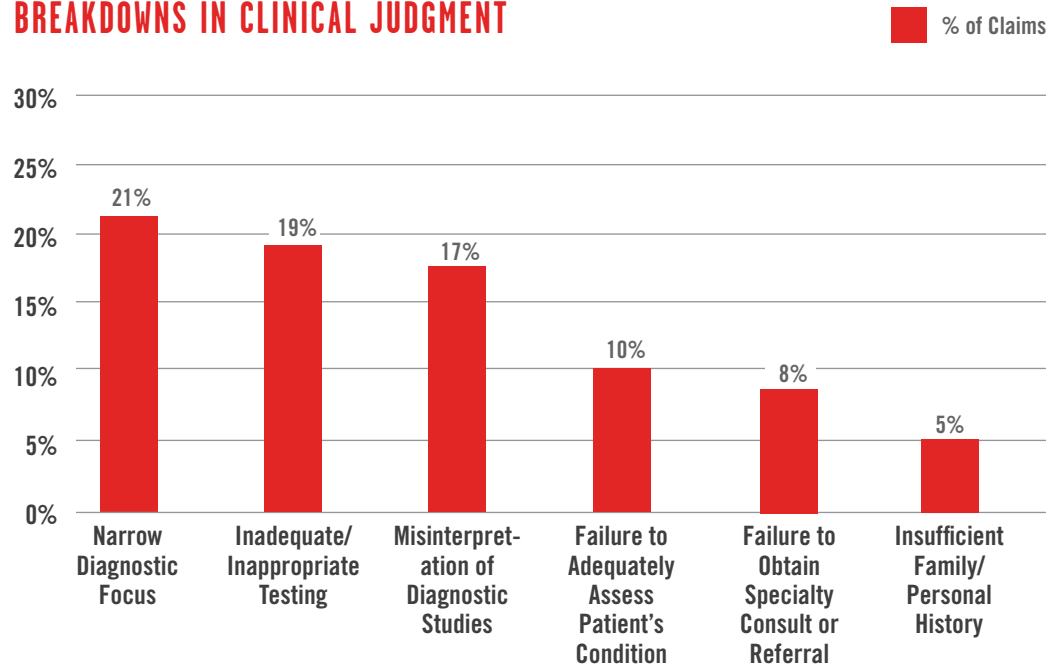**— Mark L. Graber, MD, President, Society to Improve Diagnosis in Medicine**

THE DIAGNOSTIC JOURNEY

In diagnostic cultures where practitioners rely on teams of peers, diagnostic focus is broader.

Clinical judgment can be impaired for a variety of reasons, not the least of which is that the diagnostic journey can be a lonely, rushed, and sometimes overly confident affair. In diagnostic cultures where practitioners rely on teams of peers, diagnostic focus is broader, over-reliance on previous diagnosis is more likely to get challenged, the ordering and interpretation of tests can be improved by multiple minds and checkpoints, and the speed with which consultations can occur is accelerated. In addition to hardwiring team collaboration into the diagnostic process, another major opportunity to improve diagnosis is by committing to continuous education through CME opportunities that can broaden diagnostic focus and even expand professional networks to include additional specialists for consultation and referral.

BREAKDOWNS IN CLINICAL JUDGMENT

■ % of Claims

	%
Narrow Diagnostic Focus	21%
Inadequate/Inappropriate Testing	19%
Misinterpretation of Diagnostic Studies	17%
Failure to Adequately Assess Patient's Condition	10%
Failure to Obtain Specialty Consult or Referral	8%
Insufficient Family/Personal History	5%

N = 1,840 closed claims between 2013-2017 with a diagnosis-related allegation and a clinical judgment risk management issue

CLINICAL SYSTEMS: WHERE THEY'RE WORKING, WHERE THEY'RE BREAKING DOWN

When it comes to the top risk management categories among diagnostic-related claims, cases involving clinical systems failures are second only (in percentage of claims) to failures in clinical decision-making.

As a whole, practitioners are doing a good job of screening patients to identify disease. And physicians and their colleagues are, by and large, coordinating patient care effectively when the patient is on-site in their presence and able to advocate for themselves. But our data seems to show an "out of sight, out of mind" blind spot. It's all too easy to drop the ball after patients leave the building, and healthcare providers and systems are left to properly manage specimens, reports, and reminders to follow up. Providers are being challenged to serve more patients in less time and somehow not misstep when it comes to all these critical clinical systems. Never has there been a more important time for automated processes, reminder technologies for physicians and other staff, and for empowered, proactive patients.

Top Clinical Systems Issues	% of claims
Failure to manage patient's follow-up care	17%
Insufficient studies (e.g., imaging)	16%
Results or specimens lost, misfiled, or physician unaware of results	13%
Lack of coordination of care	10%
Failure to inform patient of test results	8%
Failure to promptly review studies/results	6%
Patients seeing multiple physicians	6%
Premature discharge	5%

N = 550 closed claims between 2013-2017 with a diagnosis-related allegation and a clinical systems risk management issue

ELECTRONIC HEALTH RECORDS (EHRs) AND DIAGNOSTIC ACCURACY

Technology in medicine is improving and saving lives each day. In an era of surgical robots, electronic pills, and 3D-printed medical devices, even the unsung heroes of health information technology, like EHRs, are doing their part to improve patient safety. During previous periods, Coverys claims data revealed a great deal more vulnerability when it came to process issues like referral management and receipt/transmittal of test results. But thanks to the widespread use of EHRs in the past several years, we've seen a reduction in these process-based issues. Additionally, EHRs can give providers reliable access to a patient's complete health information, often right in the exam room where the history and physical is conducted. According to a HealthIT study, 94% of providers now report that patient health records are available at the point of care.[3] This comprehensive picture can help providers diagnose patients' problems sooner and more accurately. Of the Coverys claims that cited an EHR issue, 58% had an injury severity considered high — a category that includes death.
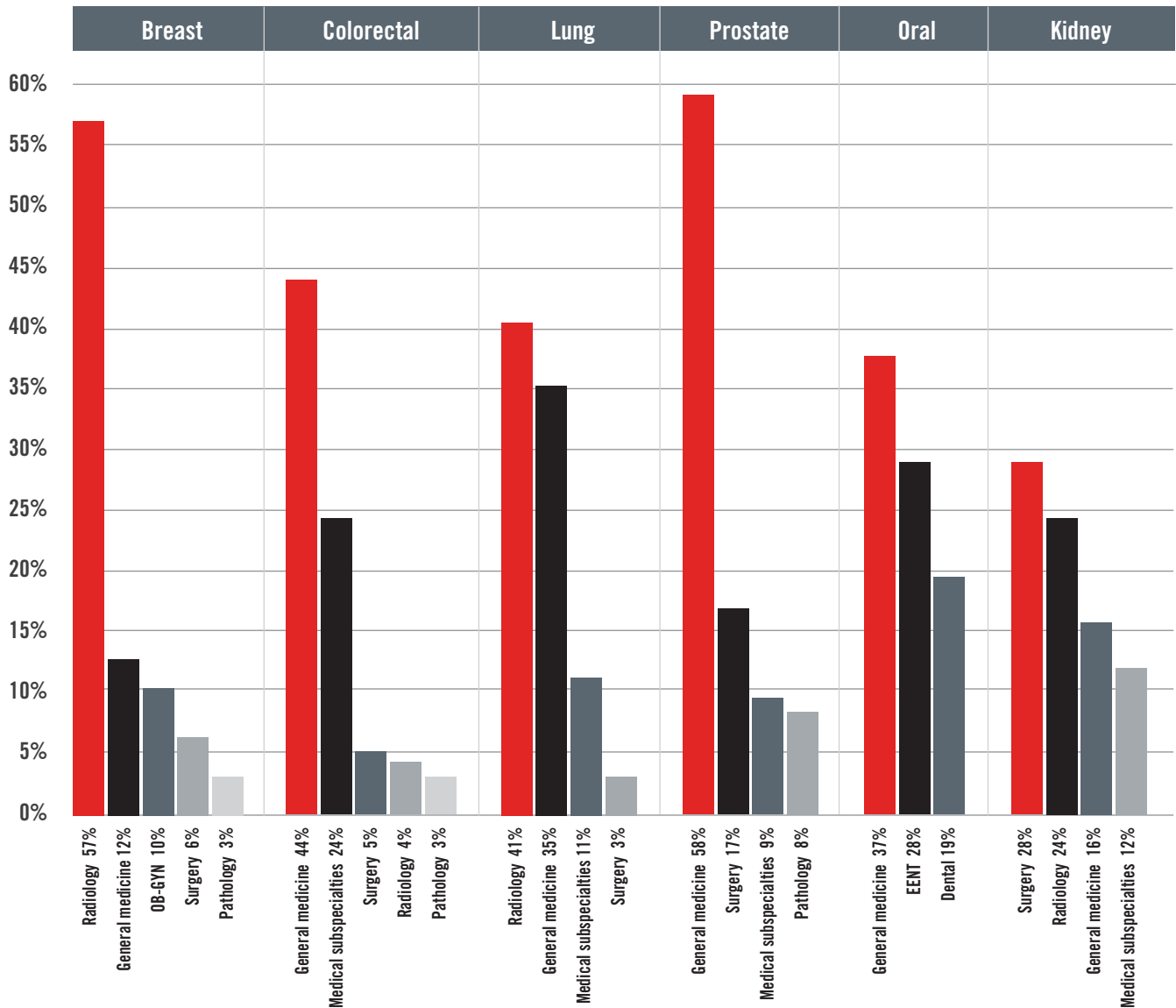
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Support to Help Make the Right Diagnosis

It's not that doctors don't know everything; it's that they can't know everything. That's why clinical decision support tools can make a world of difference when timely and accurate diagnoses count the most. VisualDx® — which is available to Coverys policyholders — has been implemented at 1,500 hospitals and is in use at half of all medical schools. It leverages the innate human ability to recognize visual patterns by combining high-quality, peer-reviewed medical images and concise, actionable information to support busy physicians in the accurate recognition and management of disease.

LEARN MORE AT: Coverys.com/VisualDx

visualDx®

## DIAGNOSIS-RELATED CANCER ALLEGATIONS BY SPECIALTY TYPE

Breast	Colorectal	Lung	Prostate	Oral	Kidney

Breast: Radiology 57%, General medicine 12%, OB-GYN 10%, Surgery 6%, Pathology 3%

Colorectal: General medicine 44%, Medical subspecialties 24%, Surgery 5%, Radiology 4%, Pathology 3%

Lung: Radiology 41%, General medicine 35%, Medical subspecialties 11%, Surgery 3%

Prostate: General medicine 58%, Surgery 17%, Medical subspecialties 9%, Pathology 8%

Oral: General medicine 37%, EENT 28%, Dental 19%

Kidney: Surgery 28%, Radiology 24%, General medicine 16%, Medical subspecialties 12%

N = 548 closed claims between 2013-2017 with a diagnosis-related allegation of a missed or delayed cancer

DIAGNOSTIC ACCURACY: CANCER

The top four missed cancers represent 58% of cancer claims and 54% of indemnity payments.
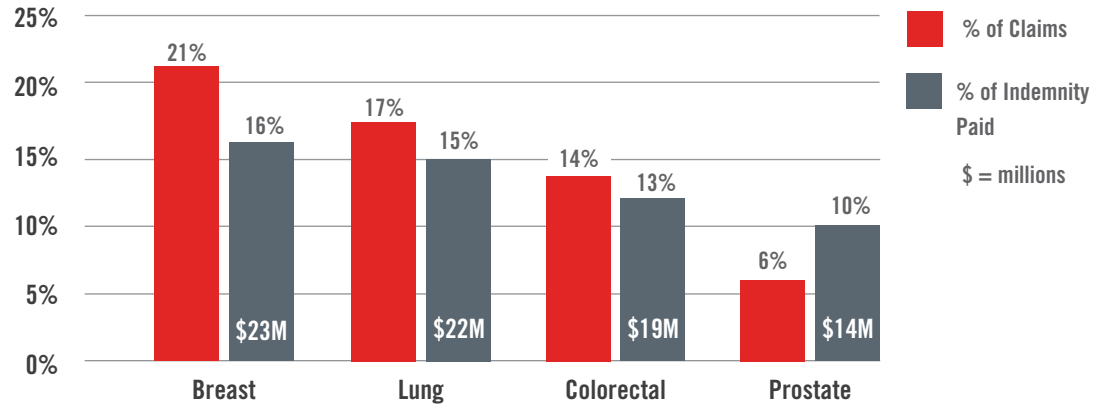
N = 945 closed claims between 2013-2017 with a missed or delayed cancer diagnosis allegation

MISSED AND DELAYED DIAGNOSIS OF CANCER

Among malpractice claims that allege a diagnostic failure, the largest number involve a missed or delayed diagnosis of cancer. And for as long as we have been analyzing claims at Coverys, the top four cancers involved in such claims have always been breast, lung, colorectal, and prostate, though the exact order periodically shuffles. The data continues to reveal interesting trends.

Breast and lung cancers:

• The majority of claims alleging diagnostic failure were filed against radiology practitioners.

• The leading clinical judgment issue was deemed to be misinterpretation of diagnostic studies (47% of lung cancer claims and 44% of breast cancer claims). We believe that poorly written diagnostic/radiology reports are a major contributing factor to this trend; such reports are unclear and in need of a bullet-point lead-in that tells a clear story and specific action steps for the ordering provider.

Colorectal, lung, prostate, and oral cancers:

General medicine practitioners are the focus of most allegations involving these cancers. They are pulled into these cases largely because of their role as the overall manager of the patient's care.

Not surprisingly, the types of cancer mostly likely to have a missed or delayed diagnosis, according to our data, are many of the very same cancers that are on the rise in the United States in general.[4] In 2016, the highest number of new cancer cases among men were cancers of the prostate, lung and bronchus, and colon and rectum, while the largest number of new cancers in women were cancers of the breast, lung and bronchus, and colon and rectum — the exact top four cancers involved in allegations of diagnosis-related failure.

THE ROLE OF RADIOLOGY IN CANCER DIAGNOSIS

The vast majority of claims related to breast cancer and lung cancer allege that the specialist with the most accountability was the radiologist.

More than half of diagnosis-related claims involve an allegation about something that went wrong during one of the testing steps, specifically diagnostic studies that involve radiology and the presence of cancer. The vast majority of claims related to breast cancer and lung cancer allege that the specialist with the most accountability was the radiologist. This finding from our study of five years of claims data was the most surprising. When it comes to thoughtful risk management efforts underway at U.S. hospitals, the focus has been largely on patient-facing specialties like general medicine and surgery. We are left wondering whether radiology professionals have gotten the support and focus they need. The good news is that there are proactive steps a facility can and should take to ensure diagnostic accuracy and effective radiology report writing.

The quality improvement processes that provide honest feedback to radiologists on the accuracy of their reads may not be as robust as they ought to be. This may lead radiologists to conclude their accuracy rate is higher than it is. Also, when radiologists are unsure of their interpretation, there may not be decision support tools in place or an avenue to obtain a second opinion without embarrassment or retribution. This needs to be addressed by changing the culture of healthcare organizations. Further, ongoing provider education on common and unusual diagnostic pitfalls may be lacking. This is especially important for high-risk diagnoses.

Teleradiology has provided a valuable service for some facilities that cannot support an in-house radiologist around the clock. This modern and alternative approach to resourcing for radiology can, however, contribute to missed diagnoses if film and transmission quality are suboptimal.

In the end, sometimes a sound diagnosis and an optimal outcome for the patient comes down to the writing and communication skills of the radiologist and/or the ability of the ordering provider to interpret sometimes confusing information. Radiology reports that contain many possibilities but no definitive diagnostic information are frustrating for the ordering provider to understand and do not aid in developing a plan of care. This problem is further compounded when the report includes disclaimers and multiple recommendations without a sound basis to implement them. Methods to address these vulnerabilities are addressed in our recommendations below.

Risk Management Recommendations:

- Revisit peer review practices to ensure they include how to measure and communicate periodic evaluation of clinical outcomes and compliance with established quality indicators and when performance may warrant closer review.

- Implement over-read or second-evaluation processes that occur on an ongoing basis with feedback given to radiologists.

- Provide decision support tools to assist a provider in achieving diagnostic accuracy.

(Continued)

- Develop criteria for when a second read of a film must be performed and the stated time frame for completion.

- If teleradiology is practiced in the facility, conduct regular testing for film and transmission quality.

- Develop standardized report templates that require specific elements, such as conditions suspected, conditions that have been ruled out, and the probable diagnosis and recommendations. Include a bullet-pointed "summary of findings" at the beginning of the report template (this will benefit the ordering physician).

- Forbid the inclusion of disclaimers or language such as "dictated but not read."

How might we re-engineer the diagnostic culture so that we have an ability to calibrate confidence and accuracy? Imagine how patient safety and provider risk might improve if there was a way for physicians to differentiate between "I'm positive," "I'm fairly certain," and "It's a mystery."

DIAGNOSTIC ACCURACY: CARDIAC AND VASCULAR ISSUES

Cardiac and vascular issues represent 8% of diagnosis-related claims. When taken together, heart problem (non-MI), myocardial infarction (MI), and thrombosis/clot/emboli were involved in 12% of diagnosis-related claims. These issues were almost as frequent (12% vs. 13%) in our study as infections (pneumonia, sepsis, MRSA, sinusitis, etc.) and were more frequent than fractures/dislocations (a historically common condition in diagnosis-related claims). These heart and vascular issues can be difficult to diagnose because the symptoms can vary from patient to patient and can mimic symptoms for other common ailments. Because these issues are so often fatal, it's important that diagnostic testing be thorough and timely and that practitioners obtain a complete patient and family history, which can shed light on startling situations. This type of situation is illustrated in the case study outlined on page 6, where only *after* the patient died did a full history become clear, and a medical expert opined that the patient was tailor-made for sudden cardiac death.

ENABLING AND EMPOWERING PHYSICIANS AND PATIENTS TO DO BETTER, TOGETHER

It's unrealistic to imagine a world in which every diagnosis is made accurately the first time and is made in an optimally timely manner. But there are things that can be done — individually and as healthcare organizations — to enable and empower physicians and patients to work more effectively together in the quest for diagnostic accuracy. Here are some important questions to consider:

- How might we re-engineer the diagnostic culture so that we have an ability to calibrate confidence and accuracy? Imagine how patient safety and provider risk might improve if there was a way for physicians to differentiate between "I'm positive," "I'm fairly certain," and "It's a mystery." In most practices and hospitals, there is no standardized or safe way to document a provider's degree of uncertainty.

- What kind of structures, consultation practices, and processes could be put in place for cases in which there is a high degree of uncertainty around a diagnosis?

- What can be done to improve communication between and among medical teams, especially including the lab, radiology, and the provider who will make the ultimate differential diagnosis?

(Continued)

- What does an enhanced role look like for the patient? Imagine a culture in which a physician tells the patient, "Your test results should be posted to the online portal by the end of the week. These are the two numbers I'm most interested in examining. If you end up seeing the results before I do, go ahead and look at those numbers, and call me if you'd like to talk."

- How might the frequency of medical professional liability claims be reduced if patients felt they could speak up when they think their diagnosis (or lack thereof) is off the mark? Today, most physicians get very little feedback from patients when a diagnosis is wrong. Typically, patients take their business elsewhere to seek a second (or third or seventh) opinion, or they do nothing. The relationship goes quiet. Often, doctors get served with lawsuits many years later and are shocked with the news that they got it wrong when it came to diagnostic accuracy.

DIAGNOSTIC ACCURACY AND LOCATION: INPATIENT VS. OUTPATIENT SETTINGS
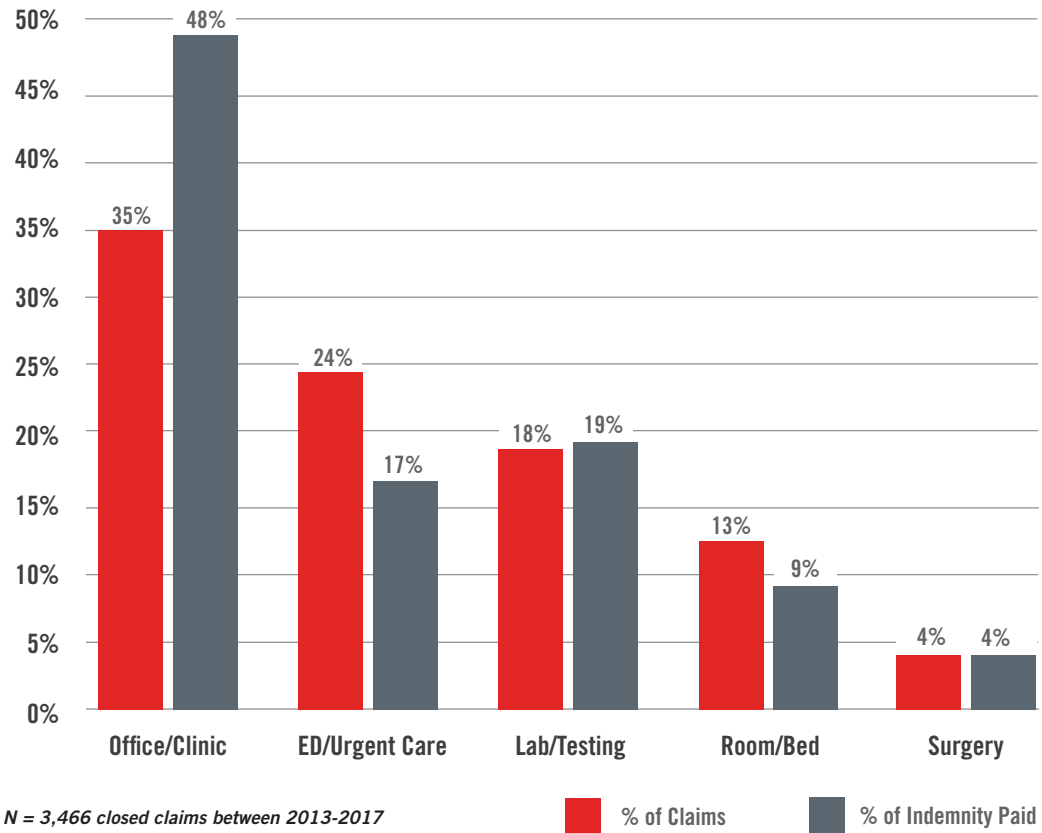
35% of diagnostic errors occur in non-ED outpatient settings

Coverys claims data show that 35% of diagnostic errors occur in physician offices and clinics. When compared to other top locations for diagnostic responsibility — like the emergency department or urgent care, lab/testing, room/bed, or surgery — these settings carry the largest burden for such claims. It is difficult to determine the exact cause(s) for this finding. It could be that office settings often do not have personnel dedicated to auditing compliance with published practice guidelines as hospitals do. Failure to measure compliance with these guidelines makes it difficult to determine which practice patterns contribute to better patient outcomes. Even if physician offices do review this information, the volume of information may not be large enough in small medical practices to be considered credible data on which to base treatment decisions.

Another element that should be considered is that peer review may not be as robust in a small practice for a number of reasons. All the providers may be similarly trained and approach diagnoses the same way; every provider in the practice may not feel comfortable offering alternatives to another provider; finally, there are typically no expert resources within an office practice that can provide guidance, as there are in a hospital setting that is well-resourced with quality and risk management personnel and a physician hierarchy that can be accessed to influence practice patterns. Patient populations that lack resources necessary to adhere to a treatment regimen (such as health insurance coverage, reliable transportation, literacy skills/English proficiency, etc.) face additional challenges.

Finally, the practice may not have access to clinical decision support tools that can assist in diagnosing and help inform the appropriate treatment during the first patient encounter. Inpatient settings more frequently have these tools, in addition to personnel who can offer a second opinion and alerts within their computer ordering entry systems that recommend treatment and prohibit ordering contraindicated treatment.

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TOP LOCATIONS FOR DX-RELATED CLAIMS

N = 3,466 closed claims between 2013-2017

Legend: ■ % of Claims ■ % of Indemnity Paid

Bar chart data:
- Office/Clinic: 35% of Claims, 48% of Indemnity Paid
- ED/Urgent Care: 24% of Claims, 17% of Indemnity Paid
- Lab/Testing: 18% of Claims, 19% of Indemnity Paid
- Room/Bed: 13% of Claims, 9% of Indemnity Paid
- Surgery: 4% of Claims, 4% of Indemnity Paid

Risk Management Recommendations:

- Explore clinical decision support tools available and use claims data to justify investing in one or more of these tools.

- Obtain national, state, and regional statistics on practice guidelines that are available for the diagnoses treated within the clinic or practice.

- Collect and compare clinic or practice data and clinical outcomes with the data obtained.

- As a practice, determine which of the practice guidelines should be followed, will be tracked, and how feedback will be shared with each provider.

- Ask local hospitals if they can provide data and expert resources to review certain types of cases and outcomes.

- If specific populations are treated within the practice or clinic, identify barriers to medical regimen adherence and explore opportunities with available community resources to address barriers.

- Review state peer review protections and immunity provisions.

THE EMERGENCY DEPARTMENT AND ITS ROLE IN DIAGNOSTIC RISK

The emergency department (ED) and urgent care facilities, when taken together as a category, represent the location type with the second highest incidence of diagnostic-related claims (24% of claims and 17% of indemnity paid). As such, we suggest specific risk management recommendations for improving diagnostic accuracy in these more high-risk and often high-chaos settings.

53% of diagnostic-related claims include risk management issues involving poor clinical decision-making

Emergency departments and urgent care facilities present unique issues for the providers who work in them, not the least of which is that treating patients is an exercise in providing care to a stranger. Physicians have no ongoing relationship with most of the patients they see in these settings. More challenging yet are patients who arrive in the ED unable to speak for themselves and with no reliable historian accompanying them. These issues are compounded by the fact that ED providers are working in an environment in which they have to make immediate and often lifesaving decisions with little or no information and where patient hand-offs are rapid and impersonal.

About 48% of diagnostic-related ED closed claims included allegations of patient evaluation, followed by 26% that alleged issues with ordering tests. More than 50% of diagnostic-related ED closed claims showed the highest level of severity, a category that includes death. Key risk management issues in order of priority involved clinical decision-making (53%), clinical systems (13%), and communication (8%).

As with all the areas of diagnostic risk we've explored, a complete set of risk recommendations is beyond the scope of this report. But such a list is available to Coverys policyholders in our Health Care Facilities Manual, Emergency Services Chapter. Below are a few recommendations that address the key issues seen in diagnostic-related Coverys claims data.

Risk Management Recommendations:

- Ensure that patient evaluation occurs on an ongoing basis during the ED or urgent care episode by requiring documentation of patient status at certain prescribed intervals.

- Implement clinical decision support tools to assist providers in the diagnostic process, such as practice guidelines for high-risk presentations, clinical decision applications, and a dedicated radiologist and pharmacist to assist with diagnosis and treatment.

- Implement a chain-of-command policy to address situations in which there is a difference of opinion on patient treatment, and embed that policy into the work flow.

- Commit to process improvements based on a policy and template for communication of information during transitions in patient care, such as admissions, transfers, and discharges.

- Provide patients with written discharge instructions in laymen's terms that include the diagnosis, treatment provided, symptoms that require action and which actions to take, referral information for more definitive testing, medications and their expected response, and other pertinent information.

- Develop a protocol to manage communication of outstanding test results to the patient, primary care provider, and consultants, and hardwire those practices into everyday behavior.

HEALTH INSURANCE COMPANIES AND THEIR IMPACT ON DIAGNOSIS

Our insured providers continue to express concern over health insurers' approval processes for tests and procedures. They report that the approvals are not consistent, often delay the diagnostic process, and, at times, appear arbitrary. When national practice guidelines are in place for a particular diagnosis, most practitioners do not quarrel with those that are supported by credible data (like in the case of steps to follow for a suspected heart attack). However, physicians are frustrated by approvals that require several interim steps before moving to what the practitioner feels is the most efficient test or procedure that will provide the most accurate results. Those extra steps and the frustration they cause — for patient and provider alike — add complexity and confusion, which can negatively impact diagnostic accuracy.

Risk Management Recommendations:

- Document the patient's medical record thoroughly regarding discussions with the patient, recommendations and the basis for them and any supporting data or studies, and the risks associated with other alternatives.

- Scan copies of insurance company denials into the patient medical record, and advise the patient to contact the insurance company. They may have influence as the consumer.

- Provide the patient with the option to obtain the test or procedure at their own cost and document the conversation.

- Track repeated denials for the same request. Ask for evidence-based rationale. Send any evidence you have that supports approving the test or procedure that was denied.

FINAL RECOMMENDATIONS FOR MANAGING RISK AND IMPROVING PATIENT SAFETY

Throughout this report, we have provided data-driven recommendations for reducing risk and improving diagnostic accuracy as it relates to various key processes, care locations, and practice areas, including:

- The patient history and physical (page 6)

- Diagnostic/lab testing steps (page 7)

- Referral management (page 8)

- Physician follow-up (page 9)

- Radiology (page 15)

- Outpatient settings (page 17)

- The emergency department (ED) and urgent care facilities (page 19)

- Working in compliance with health insurance protocols (page 20)

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Constantly innovate and organize when it comes to processes, checklists, and protocols that should always be adhered to.

Following is a list of recommendations that apply broadly to the phenomena of diagnostic errors in U.S. medicine — regardless of where you practice, how you practice, and what you practice.

- **Honestly examine diagnostic culture and other influences that create overconfidence** in medical diagnoses. How do production pressures, diagnostic uncertainty, and threats to the self-image of each provider — in the face of admitting uncertainty of a diagnosis — lead to overconfidence and erroneous, delayed, or missed diagnoses?

- **Document any uncertainty in the EHR** — once a diagnosis is reached, if there is still a degree of uncertainty (e.g. the patient is presenting in an unusual way, their symptoms don't quite match what one would expect, diagnostic tests are inconclusive, etc.), document this to alert other team members that the final diagnosis is evolving. This could potentially prevent subsequent providers from becoming anchored in a diagnosis that is less than certain.

- **Find ways to include the patient in the decision-making** that leads to a differential diagnosis. Change the way you talk to patients during consultations (such as positioning your assessment as a "working diagnosis" rather than a definitive answer) and encourage them to actively examine test results and other information in online portals; an engaged patient is typically a safer patient. And when something does go wrong, a patient who feels cared for, engaged, and honestly communicated with is less likely to pursue litigation. Remember that transparency and disclosure on your part can quell anxieties and frustrations among patients for whom a complete or timely diagnosis eludes the professionals.[5]

- **Constantly innovate and organize when it comes to processes, checklists, and protocols.** And know you don't always have to reinvent the wheel when it comes to proven best practices. Take, for example, the "Get with the Guidelines" guides from the American Heart Association on stroke, heart failure, resuscitation, and AFIB.[6] Find other similar guidelines to help support and advise you.

- **Keep your location in mind.** Reaching an accurate and timely differential diagnosis in the emergency department may require different processes, skills, and talents than doing so in an outpatient setting. When it comes to diagnostic accuracy, the path to getting there involves different roads.

- **Use technology and decision-support tools** to the extent that they are available to you.

- **Information is everything, and if it's not centralized and easily found, it's virtually useless.** Implement resources and tools to support the centralization of patient intelligence that the entire care team can leverage.

- **Remember that communication is at the root of diagnostic accuracy.** Seek ways to include more formal and concentrated training on communications skills for all providers.

- **Ongoing education, in all areas, is key** — especially when it comes to emerging discoveries or diseases for which the incidence is suddenly on the rise. You cannot know what you do not know, so continuing medical education about diagnoses that are foreign to you is a first line of defense against diagnostic inaccuracy.

- **Be conscious of all that is working against you in seeking a diagnosis**. There are financial incentives for not continuing to look for the right diagnosis — the hunt can be expensive and arduous. And patients are prone to diagnosis fatigue and can eventually give up, accepting their health challenges as the new normal. Encourage patients to come back if they aren't getting better, to ask more questions, and to share more details and hunches about their symptoms. Accept the realities that finding the right diagnosis can sometimes be hard, but don't accept defeat.

- **Slow down when you can.** The pressure around time-limited patient appointments is real, but you and your patients deserve the few extra moments it can take to reason more fully through a clinical diagnosis.

CONCLUSION

It has been estimated that 10-20% of all diagnoses are inaccurate.

It is the doctor's job to diagnose, again and again. The magnitude of the responsibility is staggering. Each year in the U.S., patients will make 125.7 million hospital outpatient visits and 884.7 million physician office visits.[7]

The issue of diagnostic inaccuracy is no small matter. Among our own insured providers at Coverys, diagnosis-related events are the single largest common root cause of medical professional liability claims. On a national scale, it has been estimated that 10-20% of all diagnoses are inaccurate.[8] Yet while we should be turning our attention to this phenomenon, especially because some of these diagnostic inaccuracies have grave results, it's important to acknowledge that doctors are getting it right more often than not.

Indeed, there is much that can be done by providers and healthcare organizations to increase diagnostic accuracy. And there is much cause for hope. While arriving at a timely and accurate diagnosis for every single patient may not always be possible, it is always the goal. It is our sincere hope that the stories in our claims data provide not just a startling dose of reality, but also a dose of optimism and insight. We encourage you to view this data as signals to effect change that will ultimately improve safety for patients and practices. As you continue to identify trends and lessons in our numbers and in your own, we anticipate that you'll gain a renewed sense of vigilance and commitment to your patients as you fight to get it right when it comes to understanding what ails them.

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Unless otherwise noted, statistics and information in this publication were derived from an analysis of 10,618 closed medical professional liability claims at Coverys across a five-year period (2013-2017).

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For more information about the root causes of claims, access the Coverys interactive Risk Analytics Dashboard at https://dashboard.coverys.com

Case studies and other patient examples shared in this publication are derived from actual liability claims, with identifying details removed or altered to protect the anonymity of patients, families, practitioners, and healthcare organizations.

This report includes general risk management guidelines for informational purposes only and may not reflect the most current legal or medical developments. The information is not intended, and must not be taken, as legal or medical advice.