Primary Care Closed Claims Experience of Massachusetts Malpractice Insurers

Gordon D. Schiff, MD; Ann Louise Puopolo, RN, BSN; Anne Huben-Kearney, RN, BSN, MPA; Winnie Yu, MA, MBA; Carol Keohane, RN, BSN; Peggy McDonough, RN, BSN; Bonnie R. Ellis, RN, BSN; David W. Bates, MD; Madeleine Biondolillo, MD

IMPORTANCE Despite prior focus on high-impact inpatient cases, there are increasing data and awareness that malpractice in the outpatient setting, particularly in primary care, is a leading contributor to malpractice risk and claims.

OBJECTIVE To study patterns of primary care malpractice types, causes, and outcomes as part of a Massachusetts ambulatory malpractice risk and safety improvement project.

DESIGN, SETTING, AND PARTICIPANTS Retrospective review of pooled closed claims data of 2 malpractice carriers covering most Massachusetts physicians during a 5-year period (January 1, 2005, through December 31, 2009). Data were harmonized between the 2 insurers using a standardized taxonomy. Primary care practices in Massachusetts. All malpractice claims that involved primary care practices insured by the 2 largest insurers in the state were screened. A total of 551 claims from primary care practices were identified for the analysis.

MAIN OUTCOMES AND MEASURES Numbers and types of claims, including whether claims involved primary care physicians or practices; classification of alleged malpractice (eg, misdiagnosis or medication error); patient diagnosis; breakdown in care process; and claim outcome (dismissed, settled, verdict for plaintiff, or verdict for defendant).

RESULTS During a 5-year period there were 7224 malpractice claims of which 551 (7.7%) were from primary care practices. Allegations were related to diagnosis in 397 (72.1%), medications in 68 (12.3%), other medical treatment in 41 (7.4%), communication in 15 (2.7%), patient rights in 11 (2.0%), and patient safety or security in 8 (1.5%). Leading diagnoses were cancer (n = 190), heart diseases (n = 43), blood vessel diseases (n = 27), infections (n = 22), and stroke (n = 16). Primary care cases were significantly more likely to be settled (35.2% vs 20.5%) or result in a verdict for the plaintiff (1.6% vs 0.9%) compared with non–general medical malpractice claims (P < .001).

CONCLUSIONS AND RELEVANCE In Massachusetts, most primary care claims filed are related to alleged misdiagnosis. Compared with malpractice allegations in other settings, primary care ambulatory claims appear to be more difficult to defend, with more cases settled or resulting in a verdict for the plaintiff.
The spotlight for improving patient safety and malpractice risk is increasingly focusing on outpatient care. After several decades of relative neglect, outpatient safety issues, particularly in the primary care setting, are increasingly being recognized for both their magnitude and the risks that result from the increasing complexity of patients being treated in the outpatient setting, discontinuities, and increasing time and resource constraints. Many malpractice insurers now report that both the frequency and dollar amounts of outpatient claims exceed inpatient claims, with primary care offices and physicians frequently contributing to these outpatient claims. Even simple outpatient processes, such as following up on a test result or making a referral, given the enormous volume and problem-prone logistics, are increasingly being identified as significant challenges that can create malpractice exposure.

Although much of the energy for malpractice reform in the United States has been expended on reform of the legal system, directing efforts upstream toward better understanding and preventing problems clearly represents a needed component of efforts to decrease malpractice litigation and patient harm. Toward that end, the Agency for Healthcare Research and Quality has funded a series of projects, including one based in Massachusetts—the Proactive Reduction of Outpatient Malpractice—Improving Safety, Efficiency, and Satisfaction (PROMISES) Project. The PROMISES Project represents a collaboration of multiple stakeholders, including the Massachusetts Department of Public Health, leading Massachusetts academic and safety partners (Massachusetts Coalition for the Prevention of Medical Errors, Brigham and Women’s Hospital, the Institute for Healthcare Improvement, and Harvard School of Public Health), and the state’s 2 leading malpractice insurers—The Risk Management Foundation of the Harvard Medical Institutions (CRICO) and Coverys (formerly ProMutual Group), who together insure approximately 85% of the physicians in the state. As a part of this collaboration, the 2 insurers came together to share data from their malpractice cases. The aim was to identify practice and system issues found in malpractice cases to help inform the PROMISES Project improvement activities and to identify patient safety issues and interventions from which others could benefit. Although each insurer collects and analyzes its own litigation claims experience, we believed that pooling these data could give a broader statewide picture of the types of problems that lead to malpractice claims. In particular, we sought to examine the frequency, types of problems identified, problematic diagnoses, temporal trends, litigation outcomes, and priority areas for improvement that emerged from this aggregated statewide overview of claims experience.

Methods

Study Population

The study population was all closed outpatient general medicine malpractice claims for practices and physicians insured by CRICO and Coverys for the most recent period for which complete closed claims data were available (January 1, 2005, through December 31, 2009).

Data Collection Methods

Databases from the 2 insurers were queried for all claims closed during the study period that involved adult primary care physicians, specifically, general internists, family practitioners, and practices, including nonurgent clinics, correctional facilities, and some long-term care. Cases were selected by the year closed and the presence of one or more general medicine physicians, whether or not an indemnity payment was made by the insurer. All patient-identifying information was removed using contextual deidentification, and records were merged into a common SAS database for analysis (SAS Institute Inc). To further protect anonymity of patients and insurers, records of which malpractice insurer contributed the case to the merged data set were deidentified. Because the 2 insurers used somewhat different classification systems to categorize the potential process of care breakdowns, we chose one insurer’s (CRICO’s) scheme and manually recoded the other insurer’s data to produce a single classification scheme that identified where the alleged breakdowns in the processes of care occurred. The institutional review boards of the State of Massachusetts Department of Public Health and Brigham and Women’s Hospital approved this study.

Statistical Analysis

For each of the 5 years studied, we performed descriptive statistics of the numbers of closed claims, patient diagnoses (deidentified), physician(s) named, disposition of case (eg, settled, verdict for plaintiff, or verdict for defendant), classification of breakdowns in the process of care (eg, diagnosis or medication), and subclass of breakdown (eg, for diagnosis: history or physical examination, evaluation of symptoms, ordering of tests, or test interpretation) based on the insurers’ review of the claim. When more than one breakdown occurred, multiple codes were assigned. Statistical t tests comparing outcomes of primary care vs non–primary care cases were also performed using SAS statistical software (SAS Institute Inc).

Results

Pooling data from the 2 leading malpractice insurers’ closed claims in Massachusetts primary care settings alleging malpractice during the 5-year period 2005 through 2009 found a total of 551 claims. These 551 claims represent 7.7% of a total of 7224 cases (551 general medicine cases plus 6673 non–general medicine inpatient and outpatient cases) closed for the 2 insurers from January 1, 2005, through December 31, 2009. During this period, the insurers covered a mean of 3305 general medical staff or fellow physicians; a mean of 110 cases were closed per year, for an overall rate of 3.3 cases per year per 100 physicians covered. A total of 595 physicians were named in these 551 cases: 525 were named in 1 case, 53 in 2 cases, and 17 in 3 or more cases.

The 551 cases closed from January 1, 2005, through December 31, 2009, included cases in which the event occur-
ence year of the alleged malpractice dated back as far as 1989, with most alleged malpractice occurrences being in the decade preceding the date of closing of the claim (averaging 3 years from filing to closing the claim).

A total of 397 of 551 cases (72.1%) were diagnosis-related allegations, outnumbering medication-related and medical treatment-related allegations by factors of 6:3:1 and 10:1, respectively (Table 1). The annual numbers and distributions of these claims categories were remarkably consistent during the 5-year period.

Table 2 gives the final diagnoses for cases. Allegations regarding failure to diagnose or delay in diagnosis of cancer predominated, followed by failure or delay in diagnosis of diseases of the heart, blood vessels, infection, and cerebrovascular disease. Two-thirds of the cancer-related delayed diagnosis cases (129 of 190 [67.9%]) were 1 of 4 cancers—colorectal, lung, prostate, and breast cancer. Each of these leading cancers had a somewhat different pattern and frequency of various breakdown points in the diagnostic process (Tables 3, 4, and 5). Issues in evaluation of symptoms and signs dominated breast cancer, whereas ordering and following up tests had a larger role in prostate cancer. Among the 56 cases of colorectal cancer with a diagnosis-related major allegation, 9 patients (16.1%) were 49 years or younger, with 3 (5.4%) being 39 years or younger (Table 5).

The Figure illustrates the disposition of the closed cases, comparing differences between general medicine and non-general medicine cases, as well as different outcomes in diagnosis cases vs medication-related cases. Although overall most claims were dropped, denied, dismissed, or received a verdict in favor of the defendant, we found significant differences in the rates of cases settled in general medicine cases vs non-general medicine, particularly for those alleging diagnostic error. Ambulatory cases were significantly more likely to be settled (35.2% vs 20.5%) or result in a verdict for the plaintiff (1.6% vs 0.9%) compared with non-general medical malpractice claims ($P < .001$). Because insurers often chose to settle cases that, on their experts’ reviews, they considered more difficult to defend, this significantly higher percentage suggests these cases might have had more obvious negligence, leading the malpractice insurer to negotiate a settlement with the plaintiff.

Allegations of negligence in cases in which medication-related process issues were identified were much less frequent than diagnostic malpractice, but nevertheless drug treatment was the major issue in 68 cases. Considering the physician’s role in ordering medications, only 11 cases (16.2% of the medication-related cases) had problems in the ordering stage, whereas 34 (50.0% of the medication cases) identified “monitoring and administration” as the problematic step in the medication use process.

### Discussion

As part of a malpractice improvement collaborative project in Massachusetts, the state’s 2 leading malpractice insurers pooled their primary care claims data to give an unprecedented look at statewide litigation experience. There were more than 100 such claims each year alleging malpractice in primary care offices, most of which are related to diagnostic errors, with cancer being the leading diagnosis alleged to be missed or delayed.

Pooling data from 2 different types of insurers (not for profit vs for profit) covering different types of practices (largely academic vs private practices) and geographic areas (clustered around Boston vs distributed across the state) gave a more complete picture and illustrated the commonalities of these types of practices. Although the confidentiality agreement that permitted this data pooling collaborative precludes separate analyses and/or direct comparisons of the 2 insurers, the findings are comparable to what each has reported regarding their individual experiences. These findings include a substantial percentage of cases and settlement dollars arising in outpatient and primary care settings with a predominance of diagnosis errors—data similar to those of other published studies. Compared with earlier studies,$^{5,6,14,15}$ diagnostic errors were even more common, with colorectal cancer replacing breast or other cancers as the most common alleged delayed cancer diagnosis. Both insurers conduct comprehensive physician practice risk evaluations and have found that the cases we document in our study also track closely with the types of process errors identified in such evaluations.
Adding weight and urgency to the need to address such issues was our finding that outpatient primary care in general and diagnostic cases in particular were more likely to be settled or result in a verdict for the plaintiff (Figure). This finding suggests that these cases may be harder to defend based on their malpractice insurers’ review of the case or that a court ruled in favor of allegations of substandard care, which occurred in 36.8% of the primary care diagnosis cases vs 21.4% of all other non–general medicine cases ($P < .001$).

Although we did not have access to other variables related to the settlement of these cases (ie, settlement decision-making factors unrelated to the actual medical care), this finding suggests there may be a higher rate of preventable adverse outcomes and/or identifiable failures to deliver an optimal standard of care in these cases.

Although notable cases of wrong site surgery or lethal medication errors may capture the newspaper headlines, most primary care cases seem to be due to failures in more routine yet high-volume outpatient office processes. Most failures were in diagnosis (mostly cancer) and can be pinpointed to just 3 broad areas of outpatient activity: (1) obtaining and regularly updating a comprehensive patient and family history, physical examination, and evaluation of symptoms; (2) ordering (or failure to order) diagnostic or laboratory tests; and (3) managing referrals and following up with the patient. It would appear that a finite number of safeguards could be put in place to prevent and/or mitigate these errors, which, in turn, could have a major effect on patient safety and malpractice. Testing such measures as (1) structured methods for reliably obtaining and updating patient or family history (including patient self-completed data) and physical examination records, (2) use of differential diagnosis reminders and checklists, and (3) implementation of more reliable test ordering and follow-up strategies, along with methods for ensuring specialty referral and follow-up and improved documentation in these 3 realms, offers avenues to address shortcomings found in these cases. Optimally designing electronic medical records to more reliably and efficiently facilitate reengineering these functions and testing their effectiveness represents a priority for preventing future malpractice. The PROMISES Project has been testing various strategies, in part based on the insights from this overview of high-risk areas and processes in primary care. Our collaborative has emphasized a systematic practice-wide team approach aimed at 3+1 target areas for improving (1) test, (2) referral, and (3) medication management, plus overarching communication improvement strategies.

Electronic health records can be powerful tools for ensuring that follow-up of some abnormal test results occurs. However, the results of some tests, such as prostate-specific antigen, are much easier to track than others, such as nodules found incidentally on chest radiographs or new biopsy results that indicate malignant neoplasms, which may not be coded in ways that enable decision support. Furthermore, many electronic health records do not include robust tools that make it easy for physicians to ensure that important follow-up has occurred. Better approaches for all these areas and approaches that practices can use to ensure complete follow-up for key abnormalities, which may leverage but go beyond health information technology, will be valuable.

This study has several noteworthy and somewhat unexpected findings. One is the low percentage of diagnostic error cases related to receipt and transmittal of test results, which occurred in only 23 diagnostic error cases (5.8%). Experience had suggested that this is a particularly vulnerable step, especially because it is most readily identified retrospectively and thus more easily targeted for malpractice claims. As noted previously, the relative scarcity of claims related to alleged errors in the medication ordering step, at least compared with issues in the medication monitoring stage, is also
Figure. Disposition of Closed Cases

Comparison of the differences between general medicine and non–general medicine cases and the different outcomes in diagnosis cases vs medication-related cases. There were 551 Risk Management Foundation of the Harvard Medical Institutions (Controlled Risk Insurance Company [CRICO]) and Coverys outpatient malpractice cases closed from 2005 through 2009 that named general medicine staff or fellow physicians (excluding hospitalists) and excluding emergency department locations.

This analysis should be interpreted with several caveats and limitations. As noted above, retrospective closed malpractice claims reviews give only a partial picture of problems and safety risks, capturing what has often been called the “tip of the iceberg.” Closed malpractice claims overlook cases with process failures that have no, or less serious, adverse outcomes that are often undetected or do not lead a patient to file a claim. Our present study, although designed to give a comprehensive and representative picture of our entire state’s experience, does not include a few self-insured practices and institutions. Furthermore, given the large number of academic institutions and affiliated practices in Massachusetts, ours may not be representative of other states nationally. The cases and trends are inherently not fully current with contemporary practices, given the lag period from the time a problem occurs and

Abbreviations: PCP, primary care physician; PSA, prostate-specific antigen.

*See Table 3 for operational definitions.

Table 5. Illustrative Patients From Primary Care Closed Claims Cases

<table>
<thead>
<tr>
<th>Case Summary</th>
<th>Breakdown or Delay in Steps in Care Process*</th>
<th>Test result follow-up</th>
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<tbody>
<tr>
<td>A 28-year-old man presented to a PCP with intermittent rectal bleeding. Physical examination revealed no hemorrhoids, but the patient had a guaiac-positive stool sample. Fifteen subsequent office visits during the next 2 years without follow-up on this problem. The patient finally was referred to gastroenterologist 28 months from time of first PCP visit, and a diagnosis of rectal carcinoma was made.</td>
<td>Physical examination or evaluation Referral Test result follow-up</td>
<td>Follow-up Referral</td>
</tr>
<tr>
<td>A 61-year-old man had a PSA of 5.95 at the time of first PCP visit. Eighteen months later, the PSA was 5.33 and no rectal examination was performed. Seven months later, the PSA was 7.03. Physician’s plan to recheck in 4-6 weeks, but family member who is physician made referral to urologist for biopsy. Diagnosis of prostate cancer with involvement of seminal vesicles.</td>
<td>Physical examination or evaluation Test result interpretation Test result follow-up</td>
<td>Follow-up Referral</td>
</tr>
<tr>
<td>A 69-year-old woman had a family history (younger sister) of lung and colon cancer. At the initial visit, no documentation of stool guaiac or discussions of colorectal screening. Four months later, the patient presented with abdominal pain, guaiac-negative stool sample, and a normal hemoglobin level. Three subsequent visits for abdominal pain, treated with a histamine-2-blocker, and for Helicobacter pylori. During the next 15 months, multiple appointments were scheduled and rescheduled by the patient with several missed appointments. Four months later, the patient had a visit for a tooth problem, 9 kg (20-lb) weight loss, and decreased hemoglobin level recorded but not addressed. Two months later, the patient presented to the emergency department with further weight loss and was found to have multiple pulmonary nodules and cecal mass with metastases to liver and lung.</td>
<td>Physical examination or evaluation Test result follow-up</td>
<td>Follow-up Referral Patient adherence</td>
</tr>
<tr>
<td>A 54-year-old woman with a 2-pack-per-day smoking history. Preoperative chest radiography ordered by the neurosurgeon before discectomy for a herniated disc noted a 2.5-cm new mass in the right lung; follow-up imaging was recommended by the radiologist in the report. Day surgery center nurse noted in medical record that patient’s PCP was called with abnormal radiograph report, although both the PCP and surgeon denied receiving calls about the report. One year later, a chest radiograph ordered for right-side chest pain identified a 5-cm mass. Adenocarcinoma of the lung was diagnosed, and the patient died 1 year later of lung cancer.</td>
<td>Test result follow-up</td>
<td></td>
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Abbreviations: PCP, primary care physician; PSA, prostate-specific antigen.

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the filing of a malpractice claim, in addition to the time that elapses from the filing to the closing of claims (which was required for enrollment in our study). Because the taxonomy for classifying the cases differed somewhat between the 2 insurers, we had to map the cases to fit a unified schema. Because the data shared were not the detailed legal files but only limited case summaries, additional granular analysis of the cases was impossible, which limited more in-depth review of these cases. Thus, this high-level look does not permit an in-depth analysis of exactly how and why many of the errors occurred.

A review of statewide malpractice claims experience for primary care physicians and practices revealed that such cases represent a substantial malpractice burden. Failure or delays in diagnosis, particularly for breast, lung, colorectal, and prostate cancers, represented the leading cases, each with its own patterns of problems. Targeting routine outpatient practice processes that create vulnerabilities to adverse patient outcomes and malpractice claims represents a priority for preventing these problems and lawsuits because, compared with other malpractice cases in other settings, they seem more difficult to defend.

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Author Affiliations: Division of General Internal Medicine and Primary Care, Department of Medicine, Brigham and Women’s Hospital, Boston, Massachusetts (Schiff, Bates); Center for Patient Safety Research and Practice, Division of General Internal Medicine and Primary Care, Department of Medicine, Harvard Medical School, Boston, Massachusetts (Schiff, Bates); The Risk Management Foundation of the Harvard Medical Institutions (Controlled Risk Insurance Company), Cambridge, Massachusetts (Puopolo, Yu, Keohane); CVS Caremark Corporation, Woonsocket, Rhode Island (Puopolo); Coverys Corporation, Boston, Massachusetts (Huben-Kearney, McDonough, Ellis); Signature Healthcare, Brockton, Massachusetts (Huben-Kearney); Massachusetts Department of Public Health, Boston (Biondolillo).

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Study concept and design: Schiff, Puopolo, Keohane, Bates.
Acquisition of data: Schiff, Puopolo, Yu, McDonough, Ellis.
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