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Authors

Hwang, Richard

Park, Howard

Sheppard, William

et al.

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Delayed Diagnosis Is the Primary Cause of Sarcoma Litigation: Analysis of Malpractice Claims in the United States

Richard Hwang MD, Howard Y. Park MD, William Sheppard MD, Nicholas M. Bernthal MD

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Abstract

Background Sarcoma care is highly litigated in medical malpractice claims. Understanding the reasons for litigation and legal outcomes in sarcoma care may help physicians deliver more effective and satisfying care to patients while limiting their legal exposure. However, few studies have described malpractice litigation in sarcoma care.

Questions/purposes (1) What percentage of sarcoma malpractice cases result in a defendant verdict? (2) What is the median indemnity payment for cases that result in a plaintiff verdict or settlement? (3) What are the most common reasons for litigation, injuries sustained, and medical specialties of the defendant physicians? (4) What are the factors associated with plaintiff verdicts or settlements and higher indemnity payments?

Methods The national medicolegal database Westlaw was queried for medical malpractice cases pertaining to

sarcomas that reached verdicts or settlements. Cases from 1982 to 2018 in the United States were included in the study to evaluate for trends in sarcoma litigation. Demographic and clinical data, tumor characteristics, reasons for litigation, injuries, and legal outcomes were recorded for each case. A univariate analysis was performed to identify factors associated with plaintiff verdicts or settlements and higher indemnity payments, such as tumor characteristics, defendant's medical or surgical specialty, reason for litigation, and injuries sustained. A total of 92 cases related to sarcomas were included in the study, of which 40 were related to bone sarcomas and 52 were related to soft-tissue sarcomas. Eighty-five percent (78 of 92) of cases involved adult patients (mean age \pm SD: 40 ± 15 years) while 15% (14 of 92) of cases involved pediatric patients (mean age \pm SD: 12.5 ± 5 years).

Results Thirty-eight percent (35 of 92) of the included cases resulted in a defendant verdict, 30% (28 of 92) resulted in a plaintiff verdict, and 32% (29 of 92) resulted in a settlement. The median (interquartile range [IQR]) indemnity payment for plaintiff verdicts and settlements was USD 1.9 million (USD 0.5 to USD 3.5 million). Median (IQR) indemnity payments were higher for cases resulting in a plaintiff verdict than for cases that resulted in a settlement (USD 3.3 million [1.1 to 5.7 million] versus USD 1.2 million [0.4 to 2.4 million]; difference of medians = USD 2.2 million; $p = 0.008$). The most common reason for litigation was delayed diagnosis of sarcoma (91%; 84 of 92) while the most common injuries cited were progression to metastatic disease (51%; 47 of 92) and wrongful death (41%; 38 of 92). Malpractice claims were most commonly filed against primary care physicians (26%; 28 of 109 defendants), nononcology-trained orthopaedic surgeons (23%; 25 of 109), and radiologists (15%; 16 of 109). Cases were more likely to result in a ruling in

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Each author certifies that his institution waived approval for the reporting of this investigation and that all investigations were conducted in conformity with ethical principles of research.

R. Hwang, H. Y. Park, W. Sheppard, N. M. Bernthal, Department of Orthopaedic Surgery, David Geffen School of Medicine at UCLA, Los Angeles, CA, USA

R. Hwang (✉), Department of Orthopaedic Surgery, David Geffen School of Medicine at UCLA, 10833 Le Conte Ave., Los Angeles, CA 90095 USA, Email: rhwang@mednet.ucla.edu

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favor of the plaintiff or settlement if a delay in diagnosis occurred despite suspicious findings on imaging or pathologic findings (80% versus 51%; odds ratio 3.84 [95% CI 1.34 to 11.03]; $p = 0.02$). There were no differences in indemnity payments with the numbers available in terms of tumor type, tumor location, defendant specialty, reason for litigation, and resulting injuries.

Conclusions Many lawsuits were made against primary care physicians, nononcology-trained orthopaedic surgeons, or radiologists for a delayed diagnosis of sarcoma despite the presence of imaging or histologic findings suspicious for malignancy. Although previous studies of bone and soft-tissue sarcomas have not shown a consistent association between time to diagnosis and decreased survival, our study suggests that physicians are still likely to lose these lawsuits because of the perceived benefits of an early diagnosis.

Clinical Relevance Physicians can mitigate their malpractice risk while reducing delays in diagnosis of sarcomas by carefully reviewing all existing diagnostic studies, establishing closed-loop communication protocols to communicate critical findings from diagnostic studies, and developing policies to facilitate second-opinion consultation, particularly for imaging studies, with an experienced sarcoma specialist. Musculoskeletal oncologists may be able to help further reduce the rates of malpractice litigation in sarcoma care by helping patients understand that delays in diagnosis do not necessarily constitute medical malpractice.

Introduction

Medical malpractice litigation in the United States remains a major concern among physicians across all specialties. Each year, an estimated 7% of physicians across all specialties will face a malpractice claim, with approximately 20% of these claims resulting in an indemnity payment [16]. However, nearly 15% of physicians in high-risk specialties such as general surgery and orthopaedic surgery will face a malpractice claim, compared with less than 5% in low-risk specialties such as family medicine and pediatrics [16]. Because of the threat of litigation, more than 90% of physicians in high-risk specialties admitted to practicing “defensive medicine” [45]. In the United States, the practice of defensive medicine is estimated to cost the healthcare system USD 45 billion per year [26]. Given the high burden of medical malpractice litigation in the United States, there is increasing interest in understanding the reasons for litigation, the likelihood of a verdict in favor of the plaintiff, and the indemnity payment amounts of various conditions and procedures. Studies of medical malpractice in oncology and orthopaedic surgery have found that diagnostic and procedural errors are

frequently cited as the most common reasons for litigation in oncology, while procedural errors represent the vast majority of reasons for litigation in orthopaedic surgery [1, 2, 20-23, 24, 29, 35, 36, 42]. Analyses of medical malpractice claims have been used to advocate for medical liability reform with the hopes of reducing the volume and cost of malpractice litigation [18, 27, 33].

Sarcoma care represents an area with potential for high malpractice risk given the challenges associated with sarcoma diagnosis and treatment. Sarcomas are a relatively rare diagnosis affecting both pediatric and adult patients, representing 20% of pediatric and less than 1% of adult solid malignant cancer diagnoses in the United States [5]. For sarcomas in pediatric and adult patients, diagnosis delays are common, despite efforts to improve timely diagnosis and referrals to musculoskeletal oncology specialists [4, 15, 17, 37-39, 46, 49]. Limb-sparing surgeries have replaced amputation as the mainstay of sarcoma surgical treatment over the past few decades due to advances in imaging, surgical technique, implants, and systemic therapies [6, 11, 25]. Complications of limb-sparing surgery and reconstruction, such as inadequate surgical margins, neurovascular injury, infection, and limb-length discrepancies, may prompt malpractice litigation against the patient’s surgeon. Patients may attribute poor outcomes such as local recurrence, subsequent amputation, metastasis, and death to errors in surgical or medical treatment and perceive these errors as medical malpractice. Currently, we are aware of only one study on sarcoma malpractice claims in the United States [28], which found that nearly 90% of claims cited delayed diagnosis as a reason for litigation, while fewer than 10% of cases cited treatment related errors as a reason for litigation, despite the complexity of and potential for complications in sarcoma treatment. However, it remains unclear how these delays in diagnosis occurred, such as failure to order appropriate diagnostic studies, missed diagnoses on imaging, or misinterpretation of lesions on imaging or pathology as benign. Without additional information on the nature of the delays in diagnosis prompting malpractice litigation, it is difficult for physicians to implement changes in their practice to improve patient care while reducing malpractice risk. With the current available data on sarcoma litigation, physicians may feel compelled to practice defensive medicine by ordering potentially unnecessary advanced imaging studies or biopsies to minimize their litigation risk [28]. Thus, more information is needed on sarcoma litigation to help identify potential areas to improve patient safety, avoid medical errors, and reduce malpractice risk. We sought to identify these potential areas of improvement by analyzing a large national medicolegal database to capture additional sarcoma malpractice claims [28].

Specifically, we asked: (1) What percentage of sarcoma malpractice cases result in a defendant verdict? (2) What is

the median indemnity payment for cases that result in a plaintiff verdict or settlement? (3) What are the most common reasons for litigation, injuries sustained, and medical specialties of the defendant physicians? (4) What are the factors associated with plaintiff verdicts or settlements and higher indemnity payments?

Materials and Methods

We searched the national medicolegal database Westlaw (Thomson Reuters, New York, NY, USA) for medical malpractice cases involving sarcoma litigation. Westlaw is a large subscription-based online legal research tool containing 40,000 databases of publicly available state and federal court records in the United States. Westlaw is one of the largest collections of legal records for cases that have proceeded to trial or court arbitration, although reporting of cases by judges and court systems is not mandatory. Each case in Westlaw contains in-depth case summaries, court documents such as expert witness statements, and details of the plaintiffs and defendants, which provides a greater depth of information that is not typically available in other legal databases. Westlaw does not contain records of cases that were settled privately outside of court or were dismissed before trial; however, these cases may represent claims for actions considered grossly negligent and indefensible or claims considered frivolous lawsuits. Westlaw has been used in numerous other medicolegal studies, but has not yet been used for sarcoma litigation [2, 14, 22, 34, 42, 47]. Large privately owned databases managed by insurance associations have been used in medicolegal studies for other conditions and represent another potential source of data for sarcoma litigation; however, these databases typically contain coded data using standardized definitions which limits the depth of information for each case [1, 23, 24, 35, 36]. LexisNexis is a legal database similar to Westlaw and has been used previously to examine sarcoma litigation [28]; however, we chose to use Westlaw to avoid redundancy and for the depth of information available from court documents. In the absence of a single centralized, comprehensive database of all malpractice claims in the United States, Westlaw represents one of the best publicly available data sources. To identify relevant medical malpractice cases involving sarcoma litigation, we queried Westlaw using the search terms “malpractice” AND “sarcoma” OR “osteosarcoma” OR “chondrosarcoma” OR “Ewing’s” OR “histiocytoma” OR “fibrosarcoma” OR “rhabdomyosarcoma” OR “angiosarcoma” OR “liposarcoma” OR “malignant peripheral nerve sheath” OR “bone cancer” OR “bone tumor.”

Cases were identified from the “Jury Verdicts and Settlements” section of Westlaw, spanning the entire database from 1982 to 2018. Sarcoma cases spanning this 36-year period were included to capture potential trends in

the reasons for litigation, injuries sustained, proportion of plaintiff verdicts and settlements, and indemnity payments, which may reflect the advances in sarcoma diagnosis and management during this period. All cases were then reviewed for inclusion in the study. All bone and soft-tissue sarcoma cases were considered for inclusion. Cases involving head or neck, uterine, intra-abdominal, or retroperitoneal sarcoma locations were excluded from the study because these tumors are less commonly treated by musculoskeletal oncologists.

Patient demographics, diagnosis and treatments, reason for litigation, injuries, defendant specialty, and case characteristics were recorded for each case identified from the Westlaw query. Cases were grouped into geographic regions as defined by the United States Census Bureau (West, Midwest, Northeast, South) [48]. Data were abstracted from the case summaries and court documents available in Westlaw by a single author (RH). For each case, only the reasons explicitly listed as the plaintiff’s reasons for litigation and injuries sustained were recorded. All cases included in the study explicitly cited at least one reason for litigation and at least one injury sustained. Reasons for litigation were classified into distinct categories, including delayed diagnosis, failure to obtain informed consent, excessive or inappropriate surgery, surgical error, inadequate surgery or biopsy, chemotherapy error, or improper postoperative management.

For cases citing a delayed diagnosis as a reason for litigation, we recorded whether the delay in diagnosis occurred despite the presence of imaging or histologic findings suspicious for malignancy. This information was recorded only if explicitly cited within the available case summary and/or court documents, as Westlaw does not contain radiologic or histopathologic studies and reports for review. This information was explicitly documented for 79 of the 84 cases which cited delayed diagnosis as a reason for litigation. For the five cases in which this information was not available, these cases were excluded from the univariate portion of the analysis. Examples included failing to identify a suspicious lesion on imaging, misdiagnosing a lesion on imaging as likely benign, or misdiagnosing a biopsied lesion as a benign lesion. This distinction was made to identify cases that may be less defensible given the presence of diagnostic evidence of the patient’s malignancy that should have prompted further work-up.

Injuries sustained as a result of a defendant’s alleged negligence were also classified into distinct categories, including pain and suffering, permanent weakness or sensory deficits, nerve injury, surgical-site infection, limb loss requiring more extensive treatment than would have otherwise been performed (for example, surgery, chemotherapy, or radiation therapy), worse prognosis (without death

or progression to metastatic disease), progression to metastatic disease, or death.

To evaluate trends in sarcoma litigation from 1982 to 2018, cases were stratified based on the year that the verdict or settlement was reached. Cases were grouped by decade (1982 to 1989, 1990 to 1999, 2000 to 2009, and 2010 to 2018) and by cases during the first half of the study period (1982 to 1999) versus the second half of the study period (2000 to 2018). The reasons for litigation, injuries sustained, proportion of cases resulting in plaintiff verdicts and settlements, and indemnity payments were compared between these periods. Cases were pooled due to the small sample sizes.

Case Characteristics

We identified 242 medical malpractice cases from the initial Westlaw search parameters. After excluding duplicates and cases not related to sarcoma litigation, we included 92 medical malpractice cases in the study (Table 1). Forty-three percent (40 of 92) of cases involved bone sarcomas and 57% (52 of 92) involved soft-tissue sarcomas (Table 2). Eighty-five percent (78 of 92) of cases involved adult patients (mean age \pm SD: 40 \pm 15 years) while 15% (14 of 92) of cases involved pediatric patients (mean age \pm SD: 12.5 years \pm 5), and 47% (43 of 92) of cases involved patients who were women. Tumors were located in the upper

Table 1. Characteristics of cases included in the study (n = 92)

Factor	Value
Age (years) ^a	
Adult (n = 78)	40 \pm 15
Minor (n = 14)	12.5 \pm 5
Total	35 \pm 17
Percentage of women	47% (43)
Location of tumor	
Upper extremity	13% (12)
Lower extremity	57% (52)
Axial/pelvis	23% (21)
Unknown	7 (8%)
Tumor types	
Bone sarcomas	43% (40)
Soft-tissue sarcomas	57% (52)
Year of case verdict/settlement	
1982 to 1989	8% (7)
1990 to 1999	34% (31)
2000 to 2009	35% (32)
2010 to 2018	18% (17)
Unknown	5% (5)

^aData are presented as mean \pm SD.

Table 2. Histologic subtypes of tumors included in the study (n = 92)

Sarcoma subtypes	% (n)
Bone sarcomas	43% (40)
Osteosarcoma	13% (12)
Ewing sarcoma	16% (15)
Chondrosarcoma	7% (6)
Unspecified	8% (7)
Soft-tissue sarcomas	57% (52)
Alveolar soft part sarcoma	1% (1)
Angiosarcoma	1% (1)
Clear cell sarcoma	1% (1)
Dermatofibrosarcoma	1% (1)
Epithelioid sarcoma	2% (2)
Fibrosarcoma	1% (1)
Leiomyosarcoma	1% (1)
Liposarcoma	8% (7)
Malignant fibrous histiocytoma	5% (5)
Malignant peripheral nerve sheath tumor	2% (2)
Myxoid sarcoma	1% (1)
Rhabdomyosarcoma	4% (4)
Spindle cell sarcoma	1% (1)
Synovial cell sarcoma	8% (7)
Unspecified	18% (17)

extremity in 13% (12 of 92), lower extremity in 57% (52 of 92), axial skeleton/pelvis in 23% (21 of 92), or unspecified in 8% (7 of 92) of cases. Claims were filed in 23 states and 62 counties in the United States (Table 3). Claims were most prevalent in California (16%; 15 of 92), New York (16%; 15 of 92), and Massachusetts (12%; 11 of 92).

Statistical Analyses

We analyzed variables using descriptive statistics. We performed a univariate analysis to identify factors associated with a case outcome in favor of the plaintiff (plaintiff verdict or settlement) and higher monetary awards. The factors analyzed were: age, gender, tumor type (bone versus soft tissue sarcoma), tumor location (axial/pelvis versus extremity), defendant specialty, reason for litigation, injury sustained, and length of delay in diagnosis. Statistical analyses were performed using R version 3.4.4 (R Core Team, Vienna, Austria). A bivariate analysis of case characteristics and outcomes was performed using Fisher's exact test or a chi-square test. Differences in indemnity payments by case characteristics were analyzed using the Mann-Whitney U test, given the nonparametric distribution of monetary awards. The effects of age and length of delay

Table 3. Geographic distribution of cases included in the study (n = 92)

State/county	Number of cases	Percent
California	15	16
Los Angeles	8	9
Marin	1	1
Orange	3	3
San Bernardino	1	1
San Diego	1	1
Unspecified	1	1
New York	15	16
Bronx	1	1
Broome	1	1
Cayuga	1	1
Kings	1	1
Nassau	2	2
New York	1	1
Putnam	1	1
Queens	1	1
Richmond	2	2
Suffolk	3	3
Westchester	1	1
Massachusetts	11	12
Middlesex	1	1
Norfolk	1	1
Plymouth	1	1
Suffolk	3	3
Worcester	1	1
Unspecified	4	4
Florida	9	10
Duval	2	2
Escambia	1	1
Hillsborough	1	1
Miami-Dade	1	1
Orange	1	1
Palm Beach	1	1
Pinellas	1	1
Unspecified	1	1
Pennsylvania	8	9
Lackawanna	1	1
Lehigh	1	1
Luzerne	1	1
Montgomery	1	1
Philadelphia	3	3
York	1	1
Ohio	5	5
Cuyahoga	3	3
Stark	1	1

Table 3. continued

State/county	Number of cases	Percent
Summit	1	1
Connecticut	3	3
Litchfield	1	1
New Haven	1	1
Unspecified	1	1
Michigan	3	3
Oakland	1	1
Ottawa	1	1
Wayne	1	1
New Jersey	3	3
Essex	1	1
Monmouth	1	1
Union	1	1
Texas	3	3
Bexar	2	2
El Paso	1	1
Washington	3	3
Skagit	1	1
Spokane	1	1
Unspecified	1	1
Illinois	2	2
Cook	2	2
Missouri	2	2
Boone	1	1
St. Louis City	1	1
Alabama	1	1
Jefferson	1	1
Alaska	1	1
Anchorage	1	1
District of Columbia	1	1
District of Columbia	1	1
Iowa	1	1
Scott	1	1
Kansas	1	1
Sedgwick	1	1
Maryland	1	1
Anne Arundel	1	1
Minnesota	1	1
Kandiyohi	1	1
New Mexico	1	1
Bernalillo	1	1
Oregon	1	1
Coos	1	1
South Dakota	1	1
Minnehaha	1	1

Table 4. Proportion of cases resulting in a defendant verdict, plaintiff verdict, or settlement (n = 92)

Case verdict	All years n = 92 % (n)	1982-1989 n = 7 % (n)	1990-1999 n = 31 % (n)	2000-2009 n = 32 % (n)	2010-2018 n = 17 % (n)
Plaintiff	30% (28)	43% (3)	29% (9)	34% (11)	24% (4)
Settlement	32% (29)	29% (2)	29% (9)	34% (11)	18% (3)
Defendant	38% (35)	29% (2)	42% (13)	31% (10)	59% (10)

in diagnosis on case outcome and monetary awards were evaluated using simple logistic regression and simple linear regression, respectively. Statistical significance was established at $p < 0.05$. All monetary values were adjusted to 2017 USD using the Bureau of Labor Statistics Consumer Price Index.

Results

Percentage of Cases Resulting in a Defendant Verdict

Among the malpractice cases, 38% (35 of 92) resulted in a defendant verdict, 30% (28 of 92) resulted in a plaintiff verdict, and 32% (29 of 92) resulted in a settlement (Table 4). There were no differences in the proportion of cases resulting in a defendant verdict between any two decades, or after pooling cases from 1982 to 1999 versus 2000 to 2018 (data not shown). Similarly, there were no differences after stratifying cases by geographic region (data not shown).

Median Indemnity Payments in Plaintiff Verdicts or Settlements

Sixty-two percent (57 of 92) of cases resulted in a payment to the plaintiff. The median indemnity payment for plaintiff verdicts and settlements was USD 1.9 million (interquartile range [IQR] USD 0.5 to USD 3.5 million). Median (IQR) indemnity payments were higher for cases resulting in a plaintiff verdict than for cases that resulted in a settlement

(USD 3.30 million [1.12 to 5.69 million] versus USD 1.16 million [0.42 to 2.42 million]; difference of medians = USD 2.14 million; $p = 0.008$) (Table 5). The highest indemnity payment for a plaintiff verdict was USD 28.64 million, while the highest indemnity payment for a settlement was USD 12.31 million (Fig. 1). Median (IQR) indemnity payments were USD 0.45 million (0.30 to 3.51 million) from 1982 to 1989, USD 1.08 million (0.48 to 2.76 million) from 1990 to 1999, USD 2.28 million (1.20 to 5.25 million) from 2000 to 2009, and USD 4.34 million (2.03 to 8.40 million) from 2010 to 2018 (Fig. 2). Median (IQR) indemnity payments were higher from 2000 to 2018 compared with 1982 to 1999 (USD 2.42 million [1.45 to 5.48 million] versus USD 0.79 million [0.43 to 3.01 million]; difference of medians = USD 1.63 million; $p = 0.01$) (Table 5). This difference persisted even after excluding the outlier plaintiff verdict award of USD 28.64 million (USD 2.28 million [1.41 to 4.79 million] versus USD 0.79 million [0.43 to 3.01 million]; difference of medians = USD 1.49 million; $p = 0.02$). There were no differences in indemnity payments after stratifying cases by geographic region (data not shown).

Most Common Reasons for Litigation, Injuries Sustained, and Medical Specialties of Defendants

The most common reason for sarcoma litigation was delayed diagnosis (91%; 84 of 92 cases) (Table 6). Thirty-one percent of these cases (26 of 84) resulted in a plaintiff verdict, 31% (26 of 84) resulted in a settlement, and 38% (32 of 84) resulted in a defendant verdict. Thirty-six

Table 5. Indemnity payments (in USD million) for plaintiff verdicts compared with settlements and for cases from 1982 to 1999 versus 2000 to 2018 (adjusted to 2017 USD using the Consumer Price Index)

Case verdict	Median (USD million) (IQR)	Difference of medians (USD million)	p value ^a
All cases			
Plaintiff	3.30 (1.12 to 5.69)	2.14	0.008
Settlement	1.16 (0.42 to 2.42)		
Year of verdict/settlement			
1982 to 1999	0.79 (0.43 to 3.01)	1.63	0.01
2000 to 2018	2.42 (1.45 to 5.48)		

^aMann-Whitney U test.

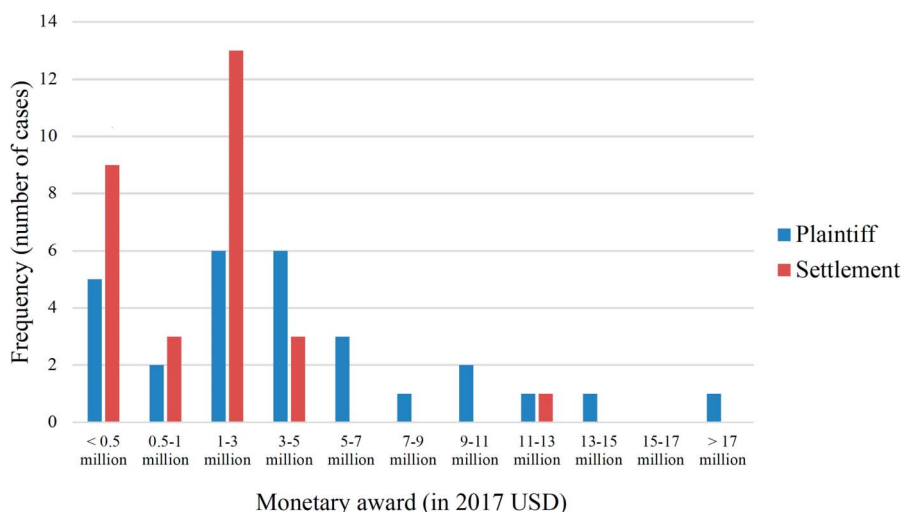


Fig. 1 This histogram shows monetary awards for plaintiff verdicts and settlements (in 2017 USD).

percent (30 of 84) of the cases citing delayed diagnosis as a reason for litigation alleged the defendant failed to diagnose the patient’s sarcoma in a timely manner, despite imaging or histologic findings suggestive of sarcoma. In contrast, allegations of delayed diagnosis were made in 58% (49 of 92) of cases against the defendant physician for

failing to diagnose the patient’s sarcoma in a timely manner based on the patient’s symptoms or physical examination findings alone. Cases cited delays in diagnosis ranging from 1.5 months to 65 months, with a median (IQR) delay of 9.5 months (5 to 16) for bone sarcomas and 12 months (8 to 25) for soft-tissue sarcomas. The shortest delay in diagnosis to result in either a plaintiff verdict or settlement was 1.5 months. Two cases cited delays of 2 months and another two cases cited delays of 3 months. Of the 84 cases citing a delay in diagnosis, 18% (15 of 84) cited a delay of 6 months or less. Only 9% (8 of 92) of the cases cited negligent treatment (defined as a surgical error, excessive surgery, inadequate surgery, or chemotherapy error) as a reason for litigation; one case cited surgical error because of negligent performance of lymph node dissection, one case cited excessive surgery in which limb amputation was performed instead of a limb-sparing procedure, one case cited inadequate surgery resulting in positive margins requiring re-excision, and five cases cited chemotherapy errors related to incorrect dosing or improper management of side effects. There were no differences in the reasons for litigation after stratifying the cases based on the decade of the verdict or settlement or after stratifying the cases based on the geographic region (data not shown).

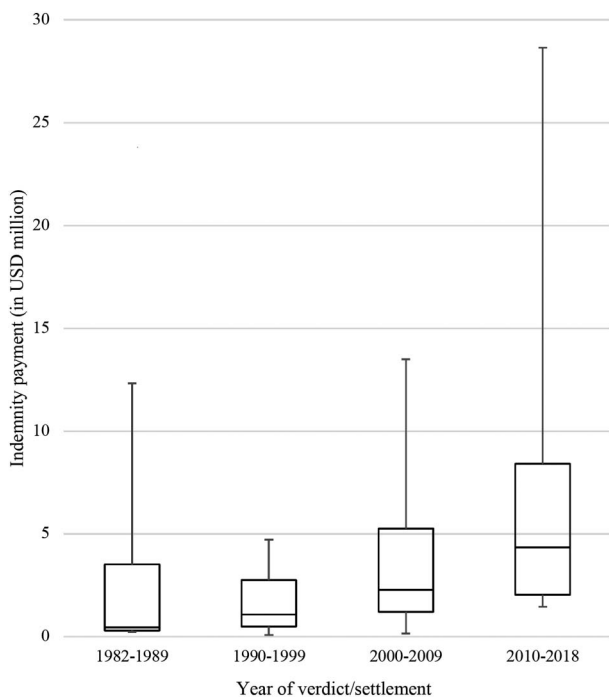


Fig. 2 This box and whisker plot shows the indemnity payments (in USD million) for plaintiff verdicts and settlements stratified by decade (adjusted to 2017 USD using the Consumer Price Index). Horizontal line denotes median. Box denotes interquartile range. Whisker denotes minimum and maximum amounts.

The most common injuries cited were progression to metastatic disease (51%; 47 of 92 cases) and death (41%; 38 of 92 cases) (Table 7). Because of the defendant’s alleged negligence, patients often reported having to undergo more extensive treatment than would have otherwise been performed (30%; 28 of 92 cases). Many of these cases cited limb loss owing to the defendant’s negligence (21%; 19 of 92 cases). The distribution of injuries did not differ after stratifying by decade of the verdict or settlement (data not shown). Cases often cited multiple injuries.

Table 6. Reason for sarcoma malpractice litigation (n = 92 cases)

Reason for litigation	Plaintiff % (n)	Settlement % (n)	Defendant % (n)	Total (n = 92) % (n)
Delayed diagnosis (n = 84)	31% (26)	31% (26)	38% (32)	91% (84)
Without imaging or histologic findings (n = 49)	22% (11)	29% (14)	49% (24)	53% (49)
With imaging or histologic findings (n = 30)	43% (13)	37% (11)	20% (6)	33% (30)
Unspecified (n = 5)	40% (2)	20% (1)	40% (2)	5% (5)
Negligent chemotherapy treatment (n = 5)	40% (2)	40% (2)	20% (1)	5% (5)
Failure to obtain informed consent (n = 3)	33% (1)	0% (0)	67% (2)	3% (3)
Surgical error (n = 1)	0% (0)	100% (1)	0% (0)	1% (1)
Inadequate surgery or biopsy (n = 1)	0% (0)	100% (1)	0% (0)	1% (1)
Negligent postoperative management (n = 1)	0% (0)	0% (0)	100% (1)	1% (1)
Excessive or inappropriate surgery (n = 1)	0% (0)	0% (0)	100% (1)	1% (1)

Defendant characteristics were available for 75 of the 92 malpractice cases identified in this study. A total of 109 defendants were named in these 75 malpractice claims (Fig. 3). Primary care physicians (26%; 28 of 109 defendants), nononcology-trained orthopaedic surgeons (23%; 25 of 109), and radiologists (15%; 16 of 109) were the most common defendants in malpractice claims. Only 5% (5 of 109) of defendants were oncology fellowship-trained physicians, all of whom were medical oncologists. There were no malpractice claims against oncology fellowship-trained surgeons.

Factors Associated with Plaintiff Verdicts or Settlements and Higher Indemnity Payments

Cases were more likely to favor the plaintiff (plaintiff verdict or settlement) if a delay in diagnosis occurred despite imaging or histologic findings suggestive of sarcoma than those in which there were no imaging or histologic findings (80% versus 51%; OR 3.84 [95% CI 1.34 to 11.03]; $p = 0.02$)

Table 7. Complaints or injuries as a result of alleged negligence (n = 92 cases)

Injury due to negligence	% (n)
Progression to metastatic disease	51% (47)
Death	41% (38)
Required more extensive surgery, chemotherapy, or RT	30% (28)
Limb loss	21% (19)
Pain or suffering	16% (15)
Worse prognosis (without death or metastasis)	15% (14)
Weakness or sensory deficit (such as numbness, tingling)	3% (3)
Infection	2% (2)
Nerve injury	1% (1)

RT = radiation therapy.

(Table 8). There was no difference in the percentage of cases favoring the plaintiff for soft tissue compared with bone sarcomas, extremity compared with axial or pelvis tumors, cases against primary care physicians, cases against orthopaedic surgeons, negligence resulting in more extensive treatment, negligence resulting in limb loss, negligence resulting in progression from localized to metastatic disease, and negligence resulting in wrongful death (Table 8). There was no difference in the indemnity payment amounts for soft tissue compared with bone sarcomas, extremity compared with axial or pelvis tumors, cases against primary care physicians, cases against orthopaedic surgeons, whether the delay in diagnosis occurred despite imaging or histologic findings suggestive of sarcoma, negligence resulting in more extensive treatment, negligence resulting in limb loss, negligence resulting in progression from localized to metastatic disease, and negligence resulting in wrongful death (Table 9). Patient age, gender, and length of delay in diagnosis were not associated with defendant verdicts or monetary award amounts (data not shown).

Discussion

Medical malpractice litigation represents a substantial emotional and financial burden for physicians in the United States, particularly those in high-risk specialties such as oncology and surgery [16]. Sarcoma care has evolved over the past several decades due to increased availability of advanced imaging modalities and the shift towards limb-sparing surgeries [6, 11, 25]. Before this study, only one study of sarcoma litigation in the United States had been published of which we are aware, which found that delayed diagnosis was the most common reason for litigation despite these advances in sarcoma care [28]. Without additional information on the nature of the delays in diagnosis, physicians may feel compelled to practice defensive medicine by ordering potentially unnecessary tests to

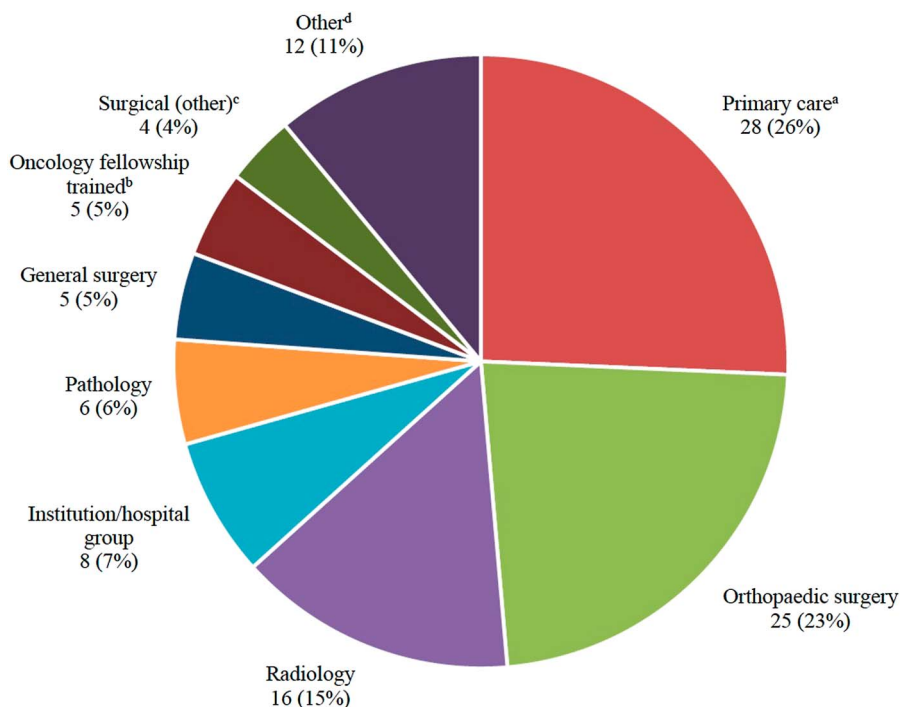


Fig. 3 This pie graph shows the specialties of defendants named in sarcoma medical malpractice claims (n = 109); ^ainternal medicine: 14; pediatrics: 2; family medicine: 12; ^bmedical oncology: 5; orthopaedic oncology: 0; surgical oncology: 0; radiation oncology: 0; ^cneurosurgery: 2; vascular surgery: 1; plastic surgery: 1; ^dneurology: 3; emergency medicine: 2; OBGYN: 2; pulmonology: 1; dermatology: 1; podiatry: 2; chiropractor: 1. A color image accompanies the online version of this article.

minimize their risk of litigation. Thus, we conducted the present study to further explore the factors associated with sarcoma malpractice litigation with the hope of identifying areas to improve patient safety while reducing malpractice risk. Our study found that sarcoma litigation results in high indemnity payments, with most cases involving nononcology-trained physicians due to delayed diagnosis of the patient’s sarcoma. These delays occurred despite the presence of imaging or histologic findings suspicious for malignancy in approximately one-third of all sarcoma claims and were less likely to result in a defendant verdict. Our study findings suggest that physicians can mitigate their malpractice risk while reducing delays in sarcoma diagnosis by carefully reviewing all existing diagnostic studies, establishing protocols to communicate critical findings from diagnostic studies, and maintaining a low threshold for seeking a second-opinion consultation or referral to an experienced sarcoma specialist.

Limitations

There are several potential limitations to our study. We used the publicly available Westlaw legal database, one

of the largest national legal databases commonly used for medicolegal research. There is a potential selection bias when using databases such as Westlaw because reporting of cases to the database is voluntary and may not identify all sarcoma cases that proceeded to trial during the study period. Many cases may have been dismissed before trial, such as frivolous claims without sufficient justification, while others may have settled out of court before trial, such as malpractice claims that were grossly negligent and thus poorly defensible by the defendant physician or claims involving smaller monetary awards [40]. Therefore, the cases in our study should be considered a subset of all sarcoma claims, specifically those that were deemed to have sufficient basis for trial involving higher monetary claims, which may be of greater relevance for physicians hoping to identify methods to improve patient care while reducing malpractice liability. Potentially relevant case details, such as the presence of warning symptoms (such as nighttime pain), specific physical examination findings (like the presence of an enlarging mass, or tumor size), and availability of a sarcoma specialist for referral or second-opinion consultation, were not included in the study because these details were not always available

Table 8. Factors associated with plaintiff verdicts or settlements (defendant versus plaintiff verdict or settlement)

Factor	Defendant % (n)	Plaintiff/settlement % (n)	OR (95% CI)	p value
Tumor type				
Bone sarcoma (n = 40)	30% (12)	70% (28)	0.54 (0.23 to 1.29)	0.16
Soft tissue sarcoma (n = 52)	44% (23)	56% (29)		
Tumor location				
Axial/pelvis (n = 21)	24% (5)	76% (16)	0.40 (0.13 to 1.23)	0.13 ^a
Extremity (n = 64)	44% (28)	56% (36)		
Defendant specialty				
Non-primary care (n = 67)	33% (22)	67% (45)	0.45 (0.18 to 1.15)	0.09
Primary care (n = 25)	52% (13)	48% (12)		
Non-orthopaedic surgery (n = 70)	39% (27)	61% (43)	1.10 (0.41 to 2.97)	1.0 ^a
Orthopaedic surgery (n = 22)	36% (8)	64% (14)		
Reason for litigation				
Delayed diagnosis without imaging or histologic findings (n = 49)	49% (24)	51% (25)	3.84 (1.34 to 11.03)	0.02 ^a
Delayed diagnosis with imaging or histologic findings (n = 30)	20% (6)	80% (24)		
Injury due to negligence				
No effect on treatment (n = 64)	39% (25)	61% (39)	1.15 (0.46 to 2.90)	0.76
Required more extensive treatment (such as surgery, chemotherapy, radiation therapy) (n = 28)	36% (10)	64% (18)		
No limb loss (n = 73)	42% (31)	58% (42)	2.77 (0.84 to 9.16)	0.11 ^a
Limb loss (n = 19)	21% (4)	79% (15)		
Localized disease (n = 45)	47% (21)	53% (24)	2.06 (0.88 to 4.86)	0.10
Progression to metastatic disease (n = 47)	30% (14)	70% (33)		
No death (n = 54)	37% (20)	63% (34)	0.90 (0.38 to 2.12)	0.81
Death (n = 38)	39% (15)	61% (23)		

^aFisher's exact test.

for each case because of the variability of case reporting. In addition, medical records such as clinic notes, imaging reports, and histologic reports were not available in Westlaw. Review of these records may have revealed additional factors associated with sarcoma malpractice risk that were not identified in our study.

Another limitation is that there may be geographic factors that influence malpractice risk and likelihood of successfully defending a claim, such as variations in local liability environments and cultural or socioeconomic factors, which we are unable to account for in our study. Nevertheless, when stratified by geographic region (West, Midwest, Northeast, South), there were no differences in the percentage of cases resulting in a plaintiff verdict, settlement, or defendant verdict; indemnity payment amounts; or in the reasons for litigation. We have listed the states and counties for all of the sarcoma cases included in our study (Table 3), and physicians practicing in areas not

represented in our study should consider this potential limitation when interpreting our findings.

Next, cases over a period of nearly four decades were included in our study to capture potential trends over time. Inclusion of older cases may be considered a potential limitation, as these cases may be less applicable to physicians today given changes in legal practices and medical care over time. However, these cases provide insight as to how sarcoma litigation may have changed, and our findings reveal that delayed diagnosis remains the primary reason for litigation despite advances in sarcoma care. Attorney and court fees are often not included in cases with a result favoring the defendant, and thus the total cost of litigation reported in our study likely underestimated the true cost of sarcoma litigation.

Finally, our statistical analyses may be underpowered, given the relatively small number of cases. Sarcomas are relatively rare, which may contribute to the small number of cases identified in our study. LexisNexis has been

Table 9. Indemnity payments (in USD million) for plaintiff verdicts and settlements (adjusted to 2017 USD using the Consumer Price Index)

Factor	Median (USD million) (IQR)	Difference of medians (USD million)	p value ^a
Tumor type			
Bone sarcoma	1.41 (0.45 to 3.33)	0.62	0.51
Soft-tissue sarcoma	2.03 (0.72 to 4.34)		
Tumor location			
Axial/pelvis	1.20 (0.39 to 2.94)	0.75	0.44
Extremity	1.95 (0.67 to 3.41)		
Defendant specialty			
Non-primary care	1.87 (0.53 to 3.51)	-0.32	0.75
Primary care	1.55 (0.65 to 3.61)		
Non-orthopaedic surgery	1.87 (0.56 to 3.30)	0.08	0.51
Orthopaedic surgery	1.95 (0.67 to 4.99)		
Reason for litigation			
Delayed diagnosis without imaging or histologic findings	1.87 (0.72 to 4.48)	-0.53	0.37
Delayed diagnosis with imaging or histologic findings	1.34 (0.45 to 2.94)		
Injury due to negligence			
No effect on treatment	1.94 (0.73 to 3.35)	-0.32	0.85
Required more extensive treatment (such as surgery, chemotherapy, radiation therapy)	1.62 (0.47 to 4.24)		
No limb loss	1.90 (0.62 to 4.10)	-0.03	0.88
Limb loss	1.87 (0.43 to 3.33)		
Localized disease			
Progression to metastatic disease	1.91 (0.51 to 4.50)	-0.26	0.84
No death	1.65 (0.58 to 3.32)		
Death	1.87 (0.54 to 4.13)	0.15	0.79
Death	2.02 (0.76 to 3.30)		

^aMann-Whitney U test; IQR = interquartile range.

previously used to examine sarcoma litigation [28], therefore, we chose not to include cases from this database to avoid redundancy. We specifically chose to use Westlaw due to the depth of information available for each case and the availability of court documents. Additional cases could be identified using other databases, such as those managed by privately-owned databases from insurance associations, and combined with the data in our study [1, 23, 24, 35, 36]. By increasing the sample size, future studies may reveal associations between other factors, such as injury severity, and plaintiff verdicts and indemnity payments. However, these databases typically contained coded data using standardized definitions, which may limit the ability to identify other clinically relevant factors, and may not have a sufficient number of cases because of the relative rarity of sarcomas. Because there are no databases containing all malpractice claims filed in the United States, legal databases such as

Westlaw may be the best-available resource of public legal records.

Percentage of Cases Resulting in a Defendant Verdict

We found that sarcoma malpractice claims resulted in a defendant verdict in approximately one-third of cases, with most cases resulting in a plaintiff verdict or settlement (Table 4). Among cases that went to trial, slightly fewer cases were decided in favor of the plaintiff than the physician defendant. These percentages did not change over the past four decades (Table 4). These findings are comparable to previously published results on sarcoma malpractice claims [28]. In the absence a centralized database containing all sarcoma malpractice lawsuits, our data and the previously published results on the percentages of defendant verdicts in sarcoma litigation represent the best-

available estimates at this time. Physicians faced with a sarcoma malpractice claim can use this information to estimate the probability of successfully defending the claim if they proceed to trial. Given that physicians only successfully defended half of the cases which proceeded to trial, many physicians may not feel that the time, effort, and cost of defending the claim is worth the relatively high risk of losing in court. Therefore, many physicians may use this information to justify settling the claim rather than attempting to defend the claim in court. Future studies should use other sources of legal data to capture sarcoma cases that may not have been previously identified.

Median Indemnity Payments in Plaintiff Verdicts or Settlements

The median (IQR) indemnity payment for plaintiff verdicts and settlements was USD 1.9 million (0.5 to 3.5 million); we also found that verdicts favoring the plaintiff resulted in a higher median indemnity payments than settlements did, which is consistent with prior analyses of malpractice claims in the United States [40]. Compared with all paid malpractice claims in the United States, sarcoma litigation is costly with a median indemnity amount above the 90th percentile of all payments [27, 33, 41]. Sarcoma malpractice indemnity payments were higher over the last two decades compared with the preceding two decades (Table 5), consistent with nationwide analyses of malpractice claims across all specialties [27, 33, 41]. The reasons for litigation, injuries sustained, and proportions of cases resulting in a plaintiff verdict or settlement in our study did not differ when stratified by decade and thus are unlikely to explain the observed increase in indemnity payments over time. Given the high malpractice costs combined with rising indemnity payments, physicians facing a sarcoma-related malpractice claim may feel pressured to settle the claim rather than attempt to defend their actions to avoid the potentially high indemnity payment associated with a plaintiff verdict. These findings highlight the importance of ensuring the timely diagnosis of sarcomas to avoid the costly consequences of sarcoma-related litigation.

Most Common Reasons for Litigation, Injuries Sustained, and Medical Specialties of Defendants

The most common reason for sarcoma litigation was delayed diagnosis, and this was cited in more than 90% of cases (Table 6). Most cases were made against primary care physicians, non-oncology-trained orthopaedic surgeons, and radiologists, claiming that the delay in diagnosis was responsible for progression to metastatic disease and/or death. Although the general belief that an

earlier diagnosis of cancer is associated with improved outcomes, numerous studies of bone and soft-tissue sarcomas have failed to demonstrate a clear correlation between delayed diagnosis and decreased disease-free survival or overall survival [38, 39, 50]. Despite these findings, patients perceive these delays in diagnosis as malpractice and attribute subsequent negative outcomes to these delays. Musculoskeletal oncologists could play a role in reducing malpractice litigation by counseling patients to help them understand that a delay in diagnosis does not necessarily constitute malpractice. Although claims related to surgical errors and complications are the most common reasons for litigation for other orthopaedic conditions, only a small number of cases in our study cited these as a reason for litigation [2, 10, 22, 24, 41, 42]. The reason that few cases cited negligent surgical treatment of sarcomas may be partially because of the known, inherent risks of surgery. Positive margins during tumor resection are a known risk of surgery, particularly for patients undergoing limb-salvage surgery. Therefore, failure to obtain clear margins may not necessarily constitute a deviation from the standard of care. Alternatively, cases related to surgical errors simply may not be captured by the study database. Sarcoma treatment is typically performed at tertiary care sarcoma centers, which are frequently large academic institutions. These institutions may be more likely to settle malpractice claims privately rather than proceed to court. Evaluation of claims data from individual malpractice insurers, which include cases settled privately, may be necessary to identify claims related to sarcoma surgery.

Factors Associated with Plaintiff Verdicts or Settlements and Higher Indemnity Payments

Cases were more likely to conclude in favor of the plaintiff if a delay in diagnosis occurred despite imaging or histologic findings suggestive of sarcoma compared with those in which there were no imaging or histologic findings; we identified no other factors associated with a plaintiff verdict, though we may have been underpowered on some of these analyses (Table 8). Given that this was cited in one-third of all cases and nearly half of all cases which resulted in an indemnity payment, efforts to reduce these occurrences can dramatically reduce sarcoma malpractice risk. However, there are potentially other factors associated with a plaintiff verdict or higher indemnity payments that were not captured in our study, as complete medical records were not available for review. Future studies should attempt to obtain complete medical records to identify other modifiable risk factors to reduce sarcoma related malpractice risk.

Evidence-based Recommendations and Conclusions

Malpractice litigation involving sarcomas is likely to result in a legal outcome in favor of the plaintiff, with high monetary awards. Many lawsuits were made against primary care physicians, nononcology-trained orthopaedic surgeons, or radiologists for a delayed diagnosis of sarcoma despite the presence of imaging or histologic findings suspicious for malignancy. Although previous studies of bone and soft-tissue sarcomas have not shown a consistent association between time to diagnosis and decreased survival, our study suggests that physicians are still likely to lose these lawsuits because of the perceived benefits of an early diagnosis.

Based on these findings, we believe that the following recommendations can help improve timely diagnosis of sarcomas while reducing medical liability risk. First, physicians should carefully review all available diagnostic studies and reports. Many sarcoma claims in our study were made against the treating physician and/or radiologist for failing to detect suspicious findings such as abnormal calcifications. In many cases, patients were asymptomatic from their tumor and these imaging studies were performed for unrelated symptoms. As a result, the treating physician and/or radiologist may have focused on the region corresponding to the patient's symptoms without recognizing the presence of suspicious findings in a separate area on the imaging study. Primary care physicians and orthopaedic surgeons who interpret their own in-office radiographs without relying on a formal radiologist interpretation must ensure that they are thoroughly evaluating the entire imaging study beyond the particular area of clinical concern to avoid missing these incidental findings. Although the utility and cost-effectiveness of radiology interpretation of routine in-office imaging has been questioned, some of these lesions may have been detected if the imaging studies had been reviewed by a radiologist [3, 12, 30, 44].

Second, physicians and healthcare institutions must establish closed-loop communication protocols for communicating critical findings identified on diagnostic studies. In some cases, diagnosis delays occurred because recommendations by the radiologist or pathologist for additional work-up were not adequately communicated to the treating physician. In these cases, the treating physician typically failed to read the final radiology or pathology report. Orthopaedic surgeons and other physicians who routinely interpret their own in-office imaging studies, but who also obtain a formal radiologist interpretation for these studies, should ensure that all final radiology reports are reviewed for actionable findings, such as an incidental finding of a musculoskeletal tumor and recommendations for additional work-up. Despite efforts to improve communication of actionable findings, up to one third of these findings may go

unnoticed by ordering physicians [13, 43]. Interventions designed to facilitate closed-loop communication between the radiologist or pathologist and the ordering physician can help ensure receipt of critical findings [19].

Lastly, physicians and institutions should develop policies for seeking second-opinion consultation, particularly for imaging studies, with an experienced sarcoma specialist. Many cases in our study cited misdiagnosis of the sarcoma as a benign lesion on either imaging or histopathologic studies. Correctly diagnosing sarcomas can be challenging due to the relative rarity and heterogeneity of musculoskeletal tumors. Musculoskeletal tumors are frequently misdiagnosed on imaging by radiologists, particularly general radiologists who may have limited experience evaluating musculoskeletal tumors [8]. Developing a standardized policy of second-opinion radiology consultation for all bone and soft tissue tumors by a musculoskeletal radiologist could improve diagnostic accuracy and reduce malpractice risk [8]. Biopsies of suspected sarcomas should be performed at a multidisciplinary sarcoma center and examined by an experienced sarcoma pathologist to minimize misdiagnosis risk [31, 32]. Development of clinical practice guidelines for evaluating bone and soft tissue masses could help physicians identify when to refer patients to a sarcoma center, particularly in the absence of clear warning signs. Guidelines in the United Kingdom and Europe recommend referral of all soft tissue masses which are enlarging, painful, or > 5 cm to a sarcoma center for further evaluation [7, 9]. Although similar guidelines have not been established in the United States, physicians should consider these guidelines and maintain a low threshold for referral to a sarcoma center. Once patients are referred to a musculoskeletal oncologist, these specialists may be able to help further reduce the rates of malpractice litigation in sarcoma care by helping patients understand that delays in diagnosis do not necessarily constitute medical malpractice.

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