

Malpractice Claims Associated with Medication Management for Chronic Pain

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ABSTRACT

Background: Medication management is an integral part of chronic pain management. Prompted by an increase in the role of medication management in anesthesia chronic pain liability, we investigated the characteristics of malpractice claims collected from 2005 to 2008.

Methods: After Institutional Review Board approval, we compared medication management claims with other chronic pain claims from the American Society of Anesthesiologists Closed Claims Database of 8,954 claims. Claims for death underwent in-depth analysis.

Results: Medication management represented 17% of 295 chronic non-cancer pain claims. Compared with other chronic pain claims, medication management patients tended to be younger men ($P < 0.01$) with back pain. Most patients were prescribed opioids (94%) and also additional psychoactive medications (58%). Eighty percent of patients had at least one factor commonly associated with medication misuse and 24% had ≥ 3 factors. Most claims (82%) involved patients who did not cooperate in their care (69%) or inappropriate medication management by physicians (59%). Death was the most common outcome in medication management claims (57% vs. 9% in other chronic pain claims, $P < 0.01$). Factors associated with death included long-acting opioids, additional psychoactive medications, and ≥ 3 factors commonly associated with medication misuse. Alleged addiction from prescribed opioids was the complaint in 24%. Appropriateness of care and payments was similar for medication management *versus* other chronic pain claims.

Conclusions: Most anesthesia malpractice claims for medication management problems involved patients with a history of risk behaviors commonly associated with medication misuse. Malpractice

claims arising from medication management had a high proportion of deaths with both patient and physician contributions to the outcome.

What We Already Know about This Topic

- ❖ Opioid prescribing is common in chronic pain management, yet legal claims relating to such prescribing by anesthesiologists have not been reviewed

What This Article Tells Us That Is New

- ❖ In a review of the American Society of Anesthesiologists Closed Claims Database from 2005–2008, medication management represented 17% of claims in chronic pain
- ❖ Malpractice claims in this area involved opioid prescribing, especially in young men with back pain, were commonly associated with patient and physician contribution, and often involved death

CHRONIC pain is a complex heterogeneous group of conditions associated with psychologic and social dysfunction, chronic disability, and large healthcare costs. Medication management is considered integral to the management of chronic pain.^{1–3} Categories of medications for which there is well-established evidence of analgesic efficacy include acetaminophen, nonsteroidal antiinflammatory agents, tricyclic antidepressants, specific anticonvulsants, and opioids.^{2,4} Other adjunctive medications for chronic pain include antipsychotics,⁵ centrally acting muscle relaxants for either acute low back pain⁶ or nonspecific low back pain,⁷ and benzodiazepines.⁴ Nationally, opioid analgesics have been regarded as the mainstay of treatment for pain related to surgery and trauma since 1992⁸ and for cancer pain since 1994.⁹ Use of opioid analgesics in chronic noncancer pain has been more controversial, but a national consensus that some patients may benefit from use of these agents emerged in the late 1990s.^{10**}

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** Federation of State Medical Boards of the United States, Inc.: Model Guidelines for the Use of Controlled Substances for the Treatment of Pain. Adopted May 1998. Available at: <http://www.nsmadocs.org/pdf/ModelGuidelines.pdf>. Accessed October 21, 2009.

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Our previous review of 284 malpractice claims for chronic pain management from 1977 to 1999 in the American Society of Anesthesiologists (ASA) Closed Claims database found that 2% of claims were associated with medication management.¹¹ A subsequent interim review indicated that medication management claims increased to 8% of claims from 1995 to 2004.¹² Prompted by the increase in the role of medication management in anesthesia liability, we performed an in-depth analysis of recent claims for medication management for chronic pain in the ASA Closed Claims Project database. We explored mechanisms of injury and patterns of liability in these claims.

Materials and Methods

The ASA Closed Claims Project is a structured evaluation of adverse anesthetic outcomes obtained from the closed claims files of 36 professional liability insurance companies in the United States. The data collection process has previously been described in detail.^{13,14} We noted an increase in chronic pain claims since the 1990s, with no change in database inclusion or exclusion criteria during this time period. Hence, a revised Institutional Review Board approved form designed specifically to collect detailed information on chronic pain management was used for reviewing closed chronic pain management malpractice claims collected from 2005 onward. Each closed chronic pain management claim file was reviewed by a practicing anesthesiologist who completed the standardized form and narrative summary. Information was recorded concerning patient characteristics, treatment details, sequence of events, critical incidents, mechanism of injury, clinical manifestations of injury, outcomes, and standard of care. Specific medication management details included drugs (class, name, dose, and route of administration) and any addictive or aberrant behaviors of the patient (including history of depression, suicide attempts, substance use and abuse, escalating doses, missed appointments, failed urine tests, diversion activities, and others). More than half (55%) of the files were reviewed by anesthesiologists who practice chronic pain management. Forms and summaries completed by the on-site anesthesiologist reviewer were subsequently reviewed by three pain management anesthesiologists (D.F., J.R., and E.M.) before incorporation into the database. The current analysis involved chronic pain claims collected from 2005 to 2008 from the ASA Closed Claims database of 8,954 claims.

Pain locations were identified by the on-site reviewer and grouped into the following categories: back (including lumbar or thoracic), neck (including cervical pain), lower extremities (including foot or hip pain), headache, pelvis, bladder or urinary tract pain, shoulder(s), upper extremities (including hand pain), multiple concurrent or unspecified sites, and other. Pain occurring in more than one of these groups was classified as pain in multiple sites. Pain occurring in a single group such as lower extremity pain in both feet was classified as a single site of pain.

Medications were classified by drug class as opioids or other psychoactive medications. Nonopioid psychoactive medications included antidepressants, anticonvulsants, antispasmodics, centrally acting muscle relaxants, sedatives/hypnotics (barbiturates, benzodiazepines, or unspecified anti-anxiety medications), antiemetics (typically associated with sedation), and any other prescribed medication that might have psychoactive effects. The different classes of medications were further subclassified by duration of action (opioids) or relevant subtypes within each class. Substances classified as illicit included amphetamine, methamphetamine, cocaine, and marijuana. A patient with needle tracks on the arms was also considered to be taking illicit substances of unknown type. If the medication was prescribed by the anesthesiologist or if the anesthesiologist was aware that it was prescribed by another physician, then the medications were considered as managed by the anesthesiologist. Medications that the patient obtained without the anesthesiologist's knowledge, whether from other healthcare providers, family or friends, or unknown sources, or identified through autopsy toxicology screens, were classified as medications not managed by the anesthesiologist (patient took on own).

Classification that the patient did not cooperate in the care plan and inadequate or inappropriate medication management by the pain management anesthesiologist were identified by the on-site reviewer and were reviewed for consistency by three of the authors (D.F., J.R., and E.M.). The patient was considered not cooperative in the care plan if the patient obtained medications from multiple providers without informing the pain management anesthesiologist, escalated doses without permission, lost prescriptions or requested early refills, took medications prescribed for someone else, took additional medications without informing the anesthesiologist, used illicit substances, abused alcohol, failed screening tests (urine or blood tests), or exhibited other explicitly noncompliant behavior. The anesthesiologist's medication management was classified as inadequate or inappropriate if the anesthesiologist failed to communicate with other treating physicians to coordinate the care plan, prescribed inappropriately high doses of opioids, failed to adequately document care, failed to adequately monitor the patient through tests or pill counts, or engaged in clearly unethical or illegal practices.

Claims for death associated with medication management were reviewed by three of the authors (D.F., J.R., and K.D.) to identify the primary cause of death and contributory factors, with agreement by at least two authors required for classification. Suicide was considered the primary cause of death if it was explicitly noted by the on-site reviewer as intentional overdose of medications or suicide. Claims in which at least two of the authors felt an overdose was probably intentional were classified as possible suicide. All other absolute or relative medication overdoses were categorized as nonsuicidal medication-related deaths. Psychiatric comorbidities contributing to death included behavioral indications of substance use disorder as well as explicitly stated

Table 1. Patient and Case Characteristics

| | Medication Management (n = 51) | Other Pain Claims (n = 244) | P Value |
|-------------------------|-----------------------------------|--------------------------------|---------|
| Age | | | |
| Mean (\pm SD) | 39 (\pm 9) | 48 (\pm 14) | < 0.01 |
| 17–35 yr | 18 (35%) | 34 (14%) | < 0.01 |
| 36–50 yr | 27 (53%) | 119 (50%) | |
| 51+ yr | 6 (12%) | 86 (36%) | |
| Male | 29 (57%) | 87 (36%) | < 0.01 |
| ASA physical status 1–2 | 37 (73%) | 168 (70%) | 0.43 |
| Year of event | | | 0.11 |
| 1991–1999 | 9 (18%) | 67 (28%) | |
| 2000–2006 | 42 (82%) | 176 (72%) | |
| Substandard care | 25 (56%) | 112 (51%) | 0.625 |
| Payment made | 20 (39%) | 109 (46%) | 0.439 |
| Payment amount* | | | 0.615 |
| Median | \$174,000 | \$287,500 | |
| Range | \$20,350–\$1,170,000 | \$642–\$2,967,000 | |

Missing data excluded. *P* values by *t* test (age), Kolmogorov-Smirnov test (distribution of payment amounts), or Fisher exact test (all others).

* Payment amounts adjusted to 2007 dollars using the consumer price index. Claims with no payment excluded.

ASA = American Society of Anesthesiologists.

psychiatric diagnoses such as depression. Physical comorbidities contributing to death included such chronic conditions as severe cardiovascular disease. Patient's noncompliance with medication management included any failure to take medications as prescribed, including amount or route of administration. Obtaining additional medications from sources other than the pain management physician was considered multiple source noncompliance.

Appropriateness of anesthetic care was rated as appropriate (standard), substandard, or impossible to judge on the basis of reasonable or prudent practice at the time of the event by the on-site reviewer. A previously published study found reliability of reviewer judgments to be acceptable.¹⁵ Payments were adjusted to 2007 dollar amounts using the Consumer Price Index.^{††}

Statistical Analysis

Medication management claims were compared with other chronic pain claims by chi-square analysis, Fisher exact test, *t* test, and Kolmogorov-Smirnov test, using *P* < 0.05 for statistical significance. Because payments were not distributed normally, the median for all cases where a payment was made and the range are reported. κ was used to assess agreement on classification of factors associated with death. All statistical analysis was conducted with SPSS 16.0.2 for Windows (SPSS Inc., Chicago, IL).

Results

Overview of Medication Management Claims

Claims for chronic pain management (n = 295) represented 18% of the 1,627 claims collected between 2005 and 2008 in

the total ASA Closed Claims Project database of 8,954 claims. There were 51 claims for medication management, representing 17% of all chronic pain claims and 3% of all claims collected in this time period. Most (74%) chronic pain management claims cited events that occurred in the year 2000 or later, with 82% of medication management claims occurring in 2000–2006 (table 1).

Compared with patients with other chronic pain management, medication management patients tended to be younger and were men (*P* < 0.01, table 1). All claims were associated with chronic noncancer pain. Back pain was the most common presenting condition in medication management claims (53%, table 2). Other common complaints

Table 2. Sites of Pain in Medication Management Claims (n = 51)

| | n | % of 51 |
|------------------------------|----|---------|
| Site of pain* | | |
| Back | 27 | 53 |
| Neck | 12 | 24 |
| Lower extremity/hip | 9 | 18 |
| Headache | 6 | 12 |
| Pelvic/bladder/urinary tract | 4 | 8 |
| Shoulder | 3 | 6 |
| Upper extremity | 3 | 6 |
| Multiple sites | 3 | 6 |
| Other unspecified sites | 2 | 4 |
| No. pain sites | | |
| Single site | 35 | 69 |
| Two sites | 9 | 18 |
| Three sites | 3 | 6 |
| Multiple sites unspecified | 4 | 8 |

* Percentages sum to more than 100% because some patients had multiple sites. Shoulder pain was never the sole site of pain in a claim. Pain in both upper extremities or in both lower extremities was classified as a single site.

†† Consumer Price Index Inflation Calculator. U.S. Department of Labor, Bureau of Labor Statistics. Available at: <http://www.bls.gov/data/home.htm>. Accessed May 30, 2008.

Table 3. Patient Factors Commonly Associated with Medication Misuse or Addiction

| Factor* | No. Claims | % of 51 |
|---|------------|---------|
| Patient medical history | | |
| Depression | 23 | 45 |
| Suicide attempt† | 3 | 6 |
| Drug or alcohol problems | 18 | 35 |
| Aberrant behaviors | | |
| Getting medications from multiple providers | 18 | 35 |
| Concurrent use of illicit drugs or alcohol | 10 | 20 |
| Escalating dosages without permission | 7 | 14 |
| Losing prescriptions | 2 | 4 |
| Taking medications prescribed to others | 2 | 4 |
| Failed screening tests | 2 | 4 |
| Asking for early refills | 2 | 4 |
| Number of factors‡ | | |
| None | 10 | 20 |
| One | 13 | 25 |
| Two | 16 | 31 |
| Three | 8 | 16 |
| Four | 3 | 6 |
| Five | 1 | 2 |

* Factors sum to more than 100% due to multiple factors in some claims. † All also had a history of depression. ‡ Each factor was counted only once for each patient, even if the behavior (e.g., losing prescriptions) occurred multiple times.

were neck pain (24%), lower extremity pain (18%), and headaches (12%). Although most patients (69%) were being medically treated for only one chronic pain site, one third of patients had two or more sites of pain (table 2).

Most patients exhibited at least one factor commonly associated with medication misuse or addiction (table 3). The most common factors were a history of depression (45%), obtaining medications from multiple providers (35%), history of drug or alcohol problems (35%), or current illicit drug or alcohol abuse (20%, table 3). Three or more of these factors were present in 24% of claims.

Liability characteristics and outcomes were similar between medication management claims and other chronic pain claims (table 1). Care was substandard in approximately half (56%) of medication management claims and payment was made to the plaintiff in 39%. When a payment was made, the median payment was \$174,000 (range, \$20,350–\$1,170,000).

Medications and Events Associated with Medication Management Claims

Nearly all medication management claims (94%) involved prescriptions for opioids (table 4). The three claims that did not involve opioid prescriptions included one claim for adrenal insufficiency after steroid treatments, one claim for a hypnotic, and one claim involving opioid detoxification treat-

ment by an anesthesiologist who had not prescribed the initial opioids. The most common opioids prescribed were controlled- or extended-release oxycodone (41%), methadone (35%), and hydrocodone (22%). In more than half (58%) of the 48 claims involving opioid management, additional psychoactive medications such as antidepressants or sedative or hypnotic agents were also being prescribed to the patient (table 4). In addition to those medications managed by the anesthesiologist, 29% of patients were taking additional opioids, 22% were taking other psychoactive substances, and 20% were taking illicit drugs or alcohol without the anesthesiologists' knowledge (table 4).

Most medication management claims involved two main underlying events leading to the alleged injury: patients did not cooperate in their care (69%) or there was evidence of inappropriate medication management by physicians (59%, fig. 1). These events occurred in a total of 82% of medication management claims, with both occurring concurrently in 45% of all medication management claims (fig. 1). Payment was more common in claims with inappropriate medication management by physicians (50% with payment) than in claims in which this factor was not identified (24% resulted in payment, $P = 0.044$).

The most common forms of noncooperation in care by patients ($n = 35$) included obtaining prescriptions from multiple providers ($n = 17$), taking opioids ($n = 14$) or additional psychoactive medications ($n = 11$) without the knowledge of the pain management physician, alcohol ($n = 2$) or illicit drug ($n = 8$) abuse, and escalating doses of prescribed pain medications without permission ($n = 7$). Other less common forms of patient noncooperation included losing prescriptions, taking psychoactive medications prescribed for someone else, crushing pills (to inject or inhale) and failing drug toxicology screening ($n = 2$ each), or selling prescribed medications to others ($n = 1$). In the two cases of failed toxicology screening, prescribed opioids were not detected. Six of these 35 patients were discharged from care by the pain physician. More than half (20 of 35, 57%) of them died.

The most common forms of inappropriate medication management by physicians ($n = 30$) were inadequate communication with other prescribing physicians to coordinate the care plan ($n = 9$), inadequate monitoring of medication compliance through screening or pill counts or otherwise failing to recognize signs of medication misuse ($n = 9$), prescribing inappropriately high doses of opioids ($n = 3$), and inappropriate sexual relations with patients ($n = 2$). Other issues included wrong dosage, poor documentation of care, inadequate monitoring of patient's psychologic problems, and inappropriate sale of opioid prescriptions by the anesthesiologist. In nine claims of inappropriate medication management by physicians, patient addiction to pain medications was alleged as the injury in the claim. In 17 claims (57%), the patient died.

Table 4. Medications Involved in Claims

| Drug Class | Drug Category | Anesthesiologist Managed*, n (% of 51) | Patient Took on Own†, n (% of 51) |
|-------------------------------------|----------------------------|--|-----------------------------------|
| Opioids | All/Any opioids | 48 (94) | 15 (29) |
| | Long acting | 40 (78) | 5 (10) |
| | Short acting | 22 (43) | 7 (14) |
| | Unknown duration of action | 5 (10) | 4 (8) |
| Antidepressants | Any antidepressants | 19 (37) | 1 (2) |
| | Tricyclic | 9 (18) | 0 |
| | SSRI | 9 (18) | 0 |
| | Atypical | 2 (4) | 1 (2) |
| Anticonvulsants | | 7 (14) | 0 |
| Antispasmodics | | 1 (2) | 0 |
| Muscle relaxants (centrally acting) | | 7 (14) | 0 |
| Sedative/hypnotics | Barbiturate | 1 (2) | 0 |
| | Benzodiazepines | 12 (24) | 8 (16) |
| | Other | 2 (4) | 0 |
| Anti-emetics | Antihistamine | 3 (6) | 0 |
| Other | Benadryl | 1 (2) | 0 |
| | Unspecified other | 1 (2) | 1 (2) |
| Illicit drugs | | 0 | 8 (16) |
| Alcohol | | 0 | 2 (4) |

* Medications prescribed by the anesthesiologist or medications prescribed by other physicians that the anesthesiologist knew were involved in the patient's care. † Medications the patient took without the anesthesiologist's knowledge, whether prescribed or obtained from an unknown source.

SSRI = selective serotonin reuptake inhibitor.

Outcomes in Medication Management Claims

Death was the most common outcome in medication management claims, accounting for 57% of claims compared with 9% in other chronic pain management claims ($P < 0.01$, fig. 2). Medication management patients who died

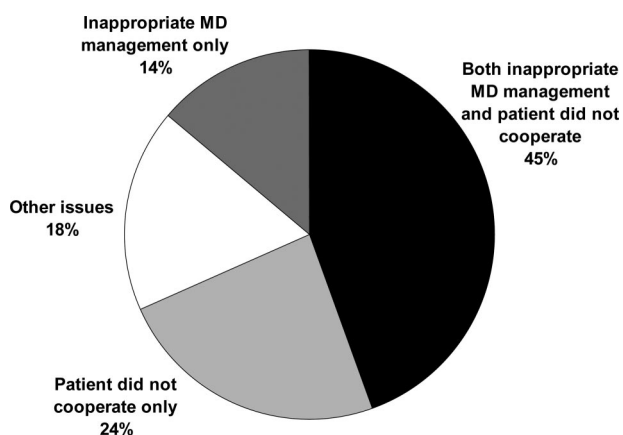


Fig. 1. Most common underlying events in medication management claims ($n = 51$). The main underlying event in 82% of claims was that the patient did not cooperate in the care plan or there was inappropriate medication management by the pain management anesthesiologist or both. In a total of 69% of claims, the patient did not cooperate in the care plan; in 59%, there was inadequate or inappropriate medication management by the pain management anesthesiologist. Other complaints included inadequate pain relief, adverse drug reaction, failure to diagnose, wrong dosage dispensed, and accidental patient overdose ($n = 1$ each). There were three claims associated with patient underlying comorbid conditions, and one unexplained death. Percentages sum to $> 100\%$ due to rounding. MD = pain management anesthesiologist.

were more likely to be receiving long-acting opioids than medication management patients who did not die ($P = 0.005$, table 5). There was no difference in the proportion of patients on methadone management between pain management patients who died (41%) and those who did not die (27%, $P = 0.380$). Medication management patients who died were also more likely to be taking opioids plus nonopioid psychoactive medications ($P = 0.026$, table 5). They were also more likely to be taking additional opioids and psychoactive medications without the pain management physician's knowledge than patients who did not die ($P = 0.015$, table 5). All these patients who died after taking additional nonprescribed medications were also being pre-

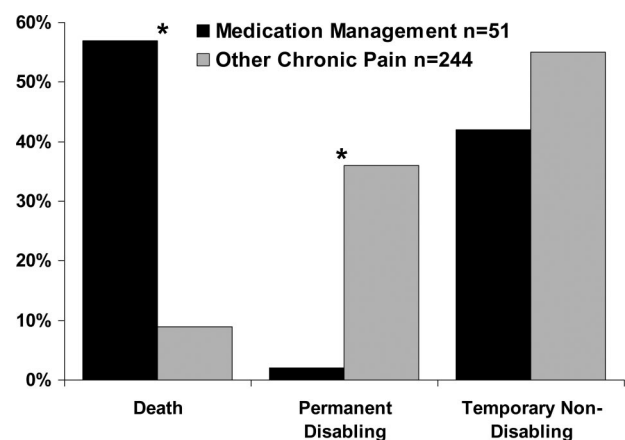


Fig. 2. Severity of injury. Death was the outcome in 57% of medication management claims. * $P < 0.01$ compared with other pain management claims (z test).

Table 5. Medication Management—Death versus Other Outcomes

| | Death (n = 29) | Other Outcome (n = 22) | P Value |
|---|-------------------|------------------------------|------------|
| Medications managed by the anesthesiologist* | | | |
| Opioids | | | |
| Any type† | 29 (100%) | 19 (86%) | 0.074 |
| Long acting | 27 (93%) | 13 (59%) | 0.005 |
| Psychoactive‡ | 20 (69%) | 9 (41%) | 0.053 |
| Opioids + psychoactive | 20 (69%) | 8 (36%) | 0.026 |
| Additional medications taken by patient (unknown to anesthesiologist)§ | | | |
| Opioids | 12 (41%) | 3 (14%) | 0.061 |
| Psychoactive‡ | 9 (31%) | 2 (9%) | 0.088 |
| Opioids + psychoactive | 7 (24%) | 0 | 0.015 |
| Illicit drugs and/or alcohol | 6 (12%) | 4 (18%) | 1.00 |
| Patient exhibited ≥ 3 factors associated with medication misuse | 10 (35%) | 2 (9%) | 0.048 |

* Percentages sum to more than 100% due to multiple medications management per patient. † Some opioids could not be classified according to duration of action. ‡ Nonopioids including antidepressants, hypnotics and sedatives, muscle relaxants (centrally acting), antiemetics, antispasmodics, and selected adjuvant analgesics (see table 4). § All these patients were also taking long-acting opioids managed by the anesthesiologist with or without additional psychoactive medications.

scribed long-acting opioids; consequently, these two factors cannot be independently assessed with regard to their contribution to the patient's deaths. Patients who died were more likely to exhibit ≥ 3 factors or behaviors commonly associated with medication misuse than those who did not die ($P = 0.048$, table 5).

Most deaths (66%) were judged as related to the medications prescribed rather than other factors. Mean agreement on cause of death was 0.68 (κ range, 0.35–1.00). Of the 19 medication-related deaths, patient noncompliance with medication management contributed to 16 (84%), with single prescription source noncompliance in 9 (47%) and multiple sources in 7 (37%); patient psychiatric comorbidities (depression and illicit substance use) may have contributed to 10 (53%) and nonpsychiatric comorbidities to 2 (11%); illicit substance or alcohol use may have contributed to 6 (32%) of these deaths. Mean agreement on contributing factors was 0.48 (κ range, 0.237–1.00). In the 34% of claims for death assessed as unrelated to medications, the primary cause of death was identified as suicide ($n = 3$), possible suicide ($n = 2$), patient comorbidity ($n = 3$), or could not be determined ($n = 2$).

In 24% of medication management claims, the primary complaint was addiction or alleged addiction caused by the

treatment. In five of these 12 claims, the anesthesiologist dismissed the patient from care. No payment was made in these five claims. In one claim, the patient died. Four of the 12 claims for alleged addiction resulted in payment, all in the claims with inappropriate medication management by the pain management physician.

All but one of the remaining claims cited a variety of temporary injuries, including hospital stay for treatment of effects of pain medications (\pm other medications, intentional or unintentional overdose), inadequate pain relief, delayed diagnosis of an underlying medical condition, and emotional distress. There was one claim for permanent injury that alleged adrenal insufficiency related to prescribed steroids.

Discussion

Claims for medication management represented 17% of all chronic pain claims. Death was the most common outcome (57%) in medication management claims and involved a relatively young male patient population. Patients who died were more likely to have received long-acting opioids or opioids plus psychoactive medications than patients with nonfatal outcomes. Problematic issues in medication management claims included patient noncompliance (including taking additional opioids with the knowledge of the pain management anesthesiologist) or inappropriate physician medication management or both.

Trends over Time

Claims for medication management represented 17% of chronic pain malpractice claims, a marked increase compared with our previous reports.^{11,12} The increase in claims is probably due to widespread use of medication management in the treatment of chronic pain in the United States during the past decade.^{9,10} Nearly all our claims involved opioid prescriptions, with the frequency of controlled- or extended-release oxycodone and methadone reflecting the overall increased prescription of opioids for chronic pain management^{16,17} as well as nonmedical prescription drug use.^{18,19} The increasing use of long-acting opioids is associated with an increase in drug-related deaths in the general population,^{20–22} and it is reflected in the high proportion of deaths in our malpractice claims.

Factors Associated with Death

Use of long-acting opioids was significantly associated with death in our study, as was the addition of opioids and other psychoactive medications by the patient without the knowledge of the pain management anesthesiologist (table 5). This association is based on retrospectively collected data in a small cohort of malpractice claims. Our results cannot address whether a long-acting opioid is a risk factor for death or whether patients who receive long-acting opioids were more likely to die. In addition, we do not know whether those who died would have had another outcome, such as addiction, first. Contributors to death in prescription drug events include intentional nonmedical use of medications (typically

opioids) or drug interactions from polypharmacy from either prescribed or illicit substances.²⁰ Between 1999 and 2002, the number of opioid analgesic poisonings in death certificates increased by 91%.²¹ In a study of abuse among unintentional drug overdose in 295 deaths in West Virginia, Hall *et al.*²² found that opioid analgesics were involved in 93% and psychotherapeutic drugs in 49% of all deaths. Twenty-two percent had a nonmedical route of administration and 63% had diverted pharmaceuticals that were not prescribed to the decedent.²² Among the 61 single-drug deaths, however, only one was due to a psychotherapeutic drug, suggesting that fatal overdose is more likely with a single opioid analgesic than a single psychotherapeutic drug.²² Methadone was responsible for more single-drug deaths and was involved in more deaths than any other drug.²² Other reports found that oxycodone or OxyContin[®]^{17,20} (Purdue Pharma LP, Stamford, CT) and methadone^{17,21,22} were associated with unintentional drug-related death. Because of the small size of our study, we were unable to distinguish which, if any, of the long-acting opioids were more likely to be associated with death. Similarly, we were not able to determine the relative influence of single-drug opioid therapy *versus* multidrug therapy (*i.e.*, psychoactive agents and opioids) on mortality.

Patient psychiatric comorbidities may have contributed to a large proportion of the medication-related deaths in our study. Five of the 29 deaths in our study were attributed to suicide or possible suicide. Patients with chronic pain commonly present with psychiatric comorbidities^{23–27} and many patients in our study had a history of depression (45%) or substance use disorder (35%). Frequently described psychiatric comorbidities among patients with chronic pain are depression, anxiety, personality disorders, and substance use disorders,^{23–27} and patients with these disorders receive higher doses of opioids than patients without these disorders.²⁴ Patients with substance use disorders tend to be prescribed higher doses of opioids and are more frequently prescribed long-acting opioids and sedative hypnotic medications in addition to opioids.²⁸ Recognition and appropriate treatment of psychiatric comorbidities in patients with chronic pain may help to reduce deaths associated with opioid treatment of chronic pain.

Factors Associated with Medication Management Claims

We found that 82% of all medication management claims involved inappropriate physician prescribing or patient non-cooperation or both (fig. 1). Patients who died were more likely to exhibit three or more factors commonly associated with medication misuse (table 5). Patient noncompliance is problematic for the long-term care of chronic pain.^{29–31} Aberrant medication-taking behaviors occurred in up to 24% of patients receiving opioid treatment of chronic back pain,²⁹ with an 11.5% prevalence of aberrant drug-related behaviors in a systematic review of 17 studies with 2,466 patients with chronic pain.³¹ Illicit drugs were found on urine toxicology screen in 14.5%.³¹ Drug diversion was more common

among decedents between 18 and 24 yr of age than among older age groups, although doctor shopping occurred in all age groups.²² Younger age, history of cocaine or alcohol abuse, and a drug or driving under the influence conviction were predictors of opioid misuse.³⁰ However, identifying patients with aberrant behaviors is extremely complex and difficult.^{32–34} The development of newly improved methods to detect and prevent aberrant drug behaviors is important to improve patient safety.³⁴

More than half (59%) of the claims in our study had evidence of inappropriate medication management by the pain management anesthesiologist (fig. 1). The most common forms of inappropriate medication management were inadequate communication with other prescribing physicians and inadequate monitoring of medication compliance. Examples of inadequate pain management included no monitoring or use of urine screens for compliance, failure to obtain medical records, failure to obtain psychiatric evaluation, failure to recognize drug-seeking behaviors and substance abuse, lack of communication with primary care physicians and detoxification centers, and extremely poor record keeping. Most (82%) of the events in this report occurred from 2000 to 2006, a time period during which medication management was guided by regulations and guidelines at both state and national levels,^{11**} which are based on the general principles of good medical practice and address appropriate consultation and monitoring. Although discriminating appropriate from inappropriate medication use is difficult, standard care usually relies on certain behavioral signs,³⁵ urine toxicology screening,^{36,37} or a combination of both.³⁸ Many physicians in these malpractice claims were not performing these basic monitoring activities. The high proportion of substandard care reflects the source of data for this study (malpractice claims) rather than the general practice of chronic pain medication management by anesthesiologists. However, these findings raise concerns about the quality of assessment of patient risk factors for aberrant behavior and the quality of monitoring that occurs in medication management practice. There are no data available on adherence to guidelines among pain management physicians.

Claims for Addiction

Addiction or alleged addiction was an issue in 24% of claims. There was insufficient information in most claims to confirm or disconfirm allegations of addiction, although payment was made only in those claims in which the pain management physician failed to provide appropriate medication management. For both women and men, illicit drug use is associated with the nonmedical use of prescription opioids.³⁹ Pharmacologically, prescription drugs of abuse are similar to their nonpharmacologic counterparts. Variables that influence the abuse and addiction potential of these prescription medications include dose and dosing intervals, route of administration and rate of onset of action, coadministration with other psychoactive medications or illicit drugs or alcohol, and context.⁴⁰ Although inappropriate prescription of

opioids to patients with chronic pain may be associated with addiction, the prevalence of this problem is difficult to identify.⁴¹ Because identifying patients at risk for addiction can be difficult, all patients should be initially assessed for known risk factors (personal or family history of addiction), be monitored frequently for noncompliance, and be reevaluated regularly for behaviors that suggest the possibility of addiction or addictive type behaviors.

Study Limitations

The limitations of interpreting the data from the ASA Closed Claims Project Database have been previously described.^{13,14} Malpractice claims data tend to be biased toward more severe and costly injuries because plaintiff attorneys are unlikely to pursue claims with an estimated financial recovery for damage of less than \$50,000.⁴² This may partially explain the high proportion of deaths in these medication management claims. Our data are retrospective and are collected in a non-random manner from a panel of participating malpractice insurers. Although these insurers provide coverage throughout the United States and insure a large number of anesthesiologists, we do not know how this sample relates to the population of anesthesiologists practicing chronic pain management. We do not know how many patients were treated by the anesthesiologists named in these claims, and so we do not have a denominator and cannot provide any numerical estimates of the risks associated with medication management. The data in this report reflect claims collected during a specific time period (2005–2008); some claims for events occurring during this date range are still open and therefore excluded from this report. Statistical analysis of trends in the data was limited by the small sample size. Finally, the database has only the information that the reviewer could obtain from the insurance company files. Incompleteness of specific detailed information regarding the sequence of events or mechanism of injury makes closed claims analysis weaker than prospectively collected data. Relevant to this analysis would be missing information on patients' behaviors and risk factors, as well as possibly missing details on physicians' prescribing and monitoring of compliance. Although our data cannot be used for establishing cause and effect relations, this study of medication management liability provides a unique insight into chronic pain management and identifies risk factors that should be addressed to improve patient safety.

Conclusions

Medication management for patients with chronic noncancer pain is associated with increasing liability. Patient noncooperation with care and inappropriate medication management by physicians were factors in many claims. Inadequate communication with other healthcare providers and insufficient monitoring for patient compliance were common among claims where the care provided was deemed to be inappropriate. Death was the outcome in greater than half of the claims, and the use of opioids or psychoactive

medications (prescribed by the pain management physician or obtained elsewhere) was associated with mortality. Patient noncompliance with medication management contributed to most medication-related deaths. These findings have implications for medical management of patients with chronic pain.

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References

- Portenoy RK: Opioid therapy for chronic nonmalignant pain: A review of the critical issues. *J Pain Symptom Manage* 1996; 11:203–17
- Dworkin RH, O'Connor AB, Backonja M, Farrar JT, Finnerup NB, Jensen TS, Kalso EA, Loeser JD, Miaskowski C, Nurmikko TJ, Portenoy RK, Rice AS, Stacey BR, Treede RD, Turk DC, Wallace MS: Pharmacologic management of neuropathic pain: Evidence-based recommendations. *Pain* 2007; 132:237–51
- Argoff CE, Silvershein DI: A comparison of long- and short-acting opioids for the treatment of chronic noncancer pain: Tailoring therapy to meet patient needs. *Mayo Clin Proc* 2009; 84:602–12
- Lynch ME, Watson CP: The pharmacotherapy of chronic pain: A review. *Pain Res Manag* 2006; 11:11–38
- Seidel S, Aigner M, Ossege M, Pernicka E, Wildner B, Sycha T: Antipsychotics for acute and chronic pain in adults. *Cochrane Database Syst Rev* 2008; (4):CD004844
- Chou R, Huffman LH: Medications for acute and chronic low back pain: A review of the evidence for an American Pain Society/American College of Physicians clinical practice guideline. *Ann Intern Med* 2007; 147:505–14
- van Tulder MW, Touray T, Furlan AD, Solway S, Bouter LM: Muscle relaxants for non-specific low back pain. *Cochrane Database Syst Rev* 2003; (2):CD004252
- Acute Pain Management: Operative or Medical Procedures and Trauma. (Clinical Practice Guideline) Publication No. AHCPR 92–0032. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services, February 1992
- Agency for Health Care Policy and Research: Management of cancer pain guideline overview. *J Natl Med Assoc* 1994; 86:571–3, 634
- A Consensus Statement from the American Academy of Pain Medicine and the American Pain Society: The use of

- opioids for the treatment of chronic pain. *Clin J Pain* 1997; 13:6-8
11. Fitzgibbon DR, Posner KL, Domino KB, Caplan RA, Lee LA, Cheney FW: Chronic pain management: American Society of Anesthesiologists Closed Claims Project. *ANESTHESIOLOGY* 2004; 100:98-105
 12. Liao DW, Fitzgibbon DR, Posner KL, Stephens LS, Domino KB: Trends in chronic pain management malpractice claims. *ANESTHESIOLOGY* 2007; 107:A1892
 13. Cheney FW, Posner K, Caplan RA, Ward RJ: Standard of care and anesthesia liability. *JAMA* 1989; 261:1599-603
 14. Cheney FW: The American Society of Anesthesiologists Closed Claims Project: What have we learned, how has it affected practice, and how will it affect practice in the future? *ANESTHESIOLOGY* 1999; 91:552-6
 15. Posner KL, Sampson PD, Caplan RA, Ward RJ, Cheney FW: Measuring interrater reliability among multiple raters: An example of methods for nominal data. *Stat Med* 1990; 9:1103-15 [published correction appears in *Stat Med* 1992; 11:1401]
 16. Trescot AM, Helm S, Hansen H, Benyamin R, Glaser SE, Adlaka R, Patel S, Manchikanti L: Opioids in the management of chronic non-cancer pain: An update of American Society of the Interventional Pain Physicians' (ASIPP) Guidelines. *Pain Physician* 2008; 11(2 suppl):S5-62
 17. Paulozzi LJ, Ryan GW: Opioid analgesics and rates of fatal drug poisoning in the United States. *Am J Prev Med* 2006; 31:506-11
 18. Cicero TJ, Inciardi JA, Munoz A: Trends in abuse of oxycodone and other opioid analgesics in the United States: 2002-2004. *J Pain* 2005; 6:662-72
 19. Blanco C, Alderson D, Ogburn E, Grant BF, Nunes EV, Hatzenbuehler ML, Hasin DS: Changes in the prevalence of non-medical prescription drug use and drug use disorders in the United States: 1991-1992 and 2001-2002. *Drug Alcohol Depend* 2007; 90:252-60
 20. Cone EJ, Fant RV, Rohay JM, Caplan YH, Ballina M, Reder RF, Spyker D, Haddox JD: Oxycodone involvement in drug abuse deaths: A DAWN-based classification scheme applied to an oxycodone postmortem database containing over 1000 cases. *J Anal Toxicol* 2003; 27:57-67
 21. Paulozzi LJ, Budnitz DS, Xi Y: Increasing deaths from opioid analgesics in the United States. *Pharmacoepidemiol Drug Saf* 2006; 15:618-27
 22. Hall AJ, Logan JE, Toblin RL, Kaplan JA, Kraner JC, Bixler D, Crosby AE, Paulozzi LJ: Patterns of abuse among unintentional pharmaceutical overdose fatalities. *JAMA* 2008; 300:2613-20
 23. McWilliams LA, Goodwin RD, Cox BJ: Depression and anxiety associated with three pain conditions: Results from a nationally representative sample. *Pain* 2004; 111:77-83
 24. Sullivan MD, Edlund MJ, Steffick D, Unutzer J: Regular use of prescribed opioids: Association with common psychiatric disorders. *Pain* 2005; 119:95-103
 25. Edlund MJ, Steffick D, Hudson T, Harris KM, Sullivan M: Risk factors for clinically recognized opioid abuse and dependence among veterans using opioids for chronic non-cancer pain. *Pain* 2007; 129:355-62
 26. Cicero TJ, Lynskey M, Todorov A, Inciardi JA, Surratt HL: Co-morbid pain and psychopathology in males and females admitted to treatment for opioid analgesic abuse. *Pain* 2008; 139:127-35
 27. Tunks ER, Crook J, Weir R: Epidemiology of chronic pain with psychological comorbidity: Prevalence, risk, course, and prognosis. *Can J Psychiatry* 2008; 53:224-34
 28. Weisner CM, Campbell CI, Ray GT, Saunders K, Merrill JO, Banta-Green C, Sullivan MD, Silverberg MJ, Mertens JR, Boudreau D, Von Korff M: Trends in prescribed opioid therapy for non-cancer pain for individuals with prior substance use disorders. *Pain* 2009; 145:287-93
 29. Martell BA, O'Connor PG, Kerns RD, Becker WC, Morales KH, Kosten TR, Fiellin DA: Systematic review: Opioid treatment for chronic back pain: Prevalence, efficacy, and association with addiction. *Ann Intern Med* 2007; 146:116-27
 30. Ives TJ, Chelminski PR, Hammett-Stabler CA, Malone RM, Perhac JS, Potisek NM, Shilliday BB, DeWalt DA, Pignone MP: Predictors of opioid misuse in patients with chronic pain: A prospective cohort study. *BMC Health Serv Res* 2006; 6:46
 31. Fishbain DA, Cole B, Lewis J, Rosomoff HL, Rosomoff RS: What percentage of chronic nonmalignant pain patients exposed to chronic opioid analgesic therapy develop abuse/addiction and/or aberrant drug-related behaviors? A structured evidence-based review. *Pain Med* 2008; 9:444-59
 32. Passik SD: Issues in long-term opioid therapy: Unmet needs, risks, and solutions. *Mayo Clin Proc* 2009; 84:593-601
 33. Turk DC, Swanson KS, Gatchel RJ: Predicting opioid misuse by chronic pain patients: A systematic review and literature synthesis. *Clin J Pain* 2008; 24:497-508
 34. Chou R, Fanciullo GJ, Fine PG, Miaskowski C, Passik SD, Portenoy RK: Opioids for chronic noncancer pain: Prediction and identification of aberrant drug-related behaviors: A review of the evidence for an American Pain Society and American Academy of Pain Medicine clinical practice guideline. *J Pain* 2009; 10:131-46
 35. Chabal C, Erjavec MK, Jacobson L, Mariano A, Chaney E: Prescription opiate abuse in chronic pain patients: Clinical criteria, incidence, and predictors. *Clin J Pain* 1997; 13:150-5
 36. Michna E, Jamison RN, Pham LD, Ross EL, Janfaza D, Nedeljkovic SS, Narang S, Palombi D, Wasan AD: Urine toxicology screening among chronic pain patients on opioid therapy: Frequency and predictability of abnormal findings. *Clin J Pain* 2007; 23:173-9
 37. Tellioglu T: The use of urine drug testing to monitor patients receiving chronic opioid therapy for persistent pain conditions. *Med Health R I* 2008; 91:279-80, 282
 38. Katz NP, Sherburne S, Beach M, Rose RJ, Vielhuth J, Bradley J, Fanciullo GJ: Behavioral monitoring and urine toxicology testing in patients receiving long-term opioid therapy. *Anesth Analg* 2003; 97:1097-102
 39. Tetrault JM, Desai RA, Becker WC, Fiellin DA, Concato J, Sullivan LE: Gender and non-medical use of prescription opioids: Results from a national US survey. *Addiction* 2008; 103:258-68
 40. Compton WM, Volkow ND: Major increases in opioid analgesic abuse in the United States: Concerns and strategies. *Drug Alcohol Depend* 2006; 81:103-7
 41. Noble M, Schoelles K: Opioid treatment for chronic back pain and its association with addiction. *Ann Intern Med* 2007; 147:348-9; author reply 349-50
 42. Huycke LI, Huycke MM: Characteristics of potential plaintiffs in malpractice litigation. *Ann Intern Med* 1994; 120:792-8