ECHO IDAHO:
Opioids, Pain & Substance Use Disorders

Risk Management for Prescribing Opioids
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MIEC

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Learning Objectives

• Understand the evolution of opioid prescribing liability risk
• Assess claims case studies for contributing factors
• Identify risk management interventions to reduce patient injury and liability risk
Doctor Found Liable in Suit Over Pain

By MARIA L. La GANZA and TERENCE MONMANEY
June 15, 2001 12 AM PT

TIMES STAFF WRITERS

SAN FRANCISCO — In a decision that could improve how seriously ill Americans are treated for pain, an Alameda County jury ruled that a physician was guilty of elder abuse for failing to give a dying man sufficient medication to relieve his suffering.

The Hayward jury ruled Wednesday that Dr. Wing Chin must pay $1.5 million to the children of William Bergman, who died of lung cancer in 1998 at the age of 85. Chin declined to comment on the case.

“To my knowledge, it’s the first time any jury has found a physician guilty of elder abuse for under-treatment of pain,” said Dr. Brad Stuart, medical director for Sutter VNA and Hospice for Northern California. “The fact that a physician was found guilty of elder abuse is a terrible thing. ... It’s a serious wake-up call to physicians that we must begin treating pain the way we treat disease.”
1st US doctor convicted of murder for overprescribing

- 3 counts 2nd degree murder
- 30 years to life
- 3 young men in their 20s
- Drove hours and paid cash
- No records/ faked records
- 9 patients died in 3-year period

Southern California doctor sentenced in overdose deaths of 3 patients
Jury awarded $7M

Slone had been placed on “an astronomically high dose” of opioids by other clinicians when he was at a nursing facility recovering from surgery. His pain physicians then lowered his dose to one that he had previously been on. And when he misused that prescription, burning through it too fast, they had no choice but to deny a refill until his appointment.
Cases Asserted

<table>
<thead>
<tr>
<th>Cases Asserted</th>
<th>Total Incurred Losses</th>
<th>% Cases Closed</th>
<th>Average Total Incurred</th>
<th>% High Severity Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>83</td>
<td>$10M</td>
<td>99%</td>
<td>$201K</td>
<td>57%</td>
</tr>
</tbody>
</table>

Cases & Avg Total Incurred by Assert Year

Primary Responsible Service Categories by Cases & Total Incurred

Major Allegation Detail

<table>
<thead>
<tr>
<th>Major Allegation Subcategory Description</th>
<th>Cases</th>
<th>Total Incurred</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improper Medication Management</td>
<td>68</td>
<td>$9,022,762</td>
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<tr>
<td>Improper Management Medication Regimen</td>
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<tr>
<td>Other Medication-Related</td>
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<tr>
<td>Ordering Error</td>
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<tr>
<td>Ordering - Wrong Medication</td>
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<tr>
<td>Administration Error</td>
<td>3</td>
<td>$656,439</td>
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</tbody>
</table>

Drug Classification Code

- ALLE0001
- ANES0003
- ANSD0004
- ASTH0005
- BLOD0011
Key points from Claims Data

• Ambulatory care setting
• Family practice; internists = highest frequency
• High injury severity overall compared to other claims
• Treatment of chronic pain far more frequent than other opioid-related allegations
• Patient noncompliance is a frequent factor
Case study #1:

• 38 yo male w/ hx of lumbar radiculopathy, neuropathy and accidental overdose of Rx meds in 2007
• 7/16/13: Pt w chronic pain to pain med MD (pt discharged from prior pain MD practice for “doctor shopping”)
• Pt taking Fentanyl 2 100 mcg patches q 48 hrs, Oxycodone 30 mg 8x/day, Carisoprodol 350 mg 3x/day, Clonazepam 2 mg 1x/day and Gabapentin 600 mg 6x/day.
• MD refilled and continued medications over 28 months.
• Pt involved in MVA and charged with DUI (1/2014)
• Mother reported concern of addiction/SUD as he was “sleeping 20 hrs/day”
• Negative urine screens for prescribed meds (diversion)
• No documentation addressing any of these concerns and no changes to prescriptions
• 6/3/14: Dr. discusses suboxone w pt; never prescribed
• 7/13/14: Pt to ED w/ accidental overdose, treated and discharged in stable condition; still no changes made to prescriptions/doses
• Patient cont’d medications for next 18 months
• 1/11/16: MD prescribed 30 Fentanyl patches
• 1/21/16: Pt found unresponsive at home after a welfare call was placed (pt had not reported to work)
• Pronounced dead at the scene
• Out of the 30 patches prescribed, only 7 were left.
• Closed $55k (including defense)
Lessons Learned

• Known hx of accidental OD and doctor shopping
  • Documented treatment plan addressing heightened SUD risk factors?
  • Consult with addiction medicine specialist?
  • Treatment plan adjusted to reflect heightened risk? More frequent visits?
  • Review of PDMP?
  • Consideration of Narcan Rx?

• Informed consent
  • Risks of opioids with benzodiazepines (Clonazepam) discussed?
    • FDA Black Box warning not in effect at time of this claim
    • Documented rationale for benefit outweighing risks for this specific patient
  • Documented patient education provided (discussion and in writing)

• Documentation addressing concerns as they arise and adjusting treatment as necessary (DUI, Mom’s concerns, UA indicating diversion)
  • “Monitoring”

• Fentanyl patches: rationale for this change? For amount prescribed?
Case study #2

• 22 yo female to FP 8/21/02 c/o back pain managed with tramadol
• 8/26: returned w/ fever, flank pain. Dx w/ pyelonephritis and Rx’d abx and hydrocodone/acetaminophen with 3 refills
• Pt did not return for 1 yr; Tramadol and hydrocodone/acetaminophen refilled 6 times
• 7/3/03: Pt c/o exacerbation of back pain. Exam noted tightness of SI joint, MRI ordered, renewed narcotic medications.
• Narcotic RX refilled 6 times over 10 months without pt being seen; pt did not obtain MRI. No follow up.
• 5/17/04: Pt c/o ear pressure; back pain. Exam revealed low lumbar paraspinal tenderness
• FP renewed narcotics 10 times over 14 months.
• Pt dx w metastatic (lymph) melanoma and prescribed MS Contin, Oxycodone by oncologist
• 10/22/07: Pt returned to FP c/o ongoing back pain
• 10/22/07 – 7/8/08: FP refilled narcotic pain medications 9 times
• 7/8/08: Pt c/o depression due to uncontrolled pain. FP added Celecoxib to the regimen and continued to refill narcotic medications
• Pt had begun to see other MDs and was filling prescriptions from multiple pharmacies
• No referral to pain management, no SUD screening
• Pt began to purchase Alprazolam online
• Pt presented to FP c/o constant back pain, nausea, vomiting and chills. FP prescribed Promethazine (antihistamine & antiemetic). Did not investigate drug reactions.
• November 2013: Patient’s young daughter found and ingested medication, became critically ill requiring multi-day hospitalization.
• Police investigation found massive amounts of prescription medication in the home. Pt agreed to detox (where dx w anxiety disorder) and residential rehab
• $224K
Lessons Learned

• Initial assessment
  • Documented attempts at non-opioid therapies? (Physical therapy, CBT, massage, etc.)
  • Validated SUD screening tool? (personal and family hx of SUD or behavioral health disorders; hx of physical, emotional or sexual abuse
  • Check PDMP

• Informed consent: Safety of drug storage and disposal; retrieval programs

• No f/u on MRI. If financial barrier, is there an alternative option to evaluate? Programs to refer pt to? Documenting f/u and thought process speaks to “management”

• Re-evaluate SUD risk upon pt report of depression?
Risk Management

• Know your boundaries
  • If you don’t have the requisite knowledge and expertise to safely prescribe for a given patient, refer. If no local community resources, attempt to consult.

• Be familiar with specialty society and other reputable sources of guidelines
  • CDC Clinical Practice Guideline for Prescribing Opioids for Pain: https://www.cdc.gov/overdose-prevention/hcp/clinical-guidance/index.html
    • Referenced in criminal conviction of two Idaho physicians in 2016
Risk Management cont’d

• Use and document PDMP
• Withdraw from care:
  • Noncompliant patient
  • Belligerent/threatening patient
  • Consult your professional liability insurer for patient-specific advice
• Attempt non-opioid therapies first for treatment of chronic pain, or demonstrate failure before prescribing opioids
• Conduct and document a full risk assessment
• Focus on and document a functional assessment, pain symptoms, and physical exam
Risk Management cont’d

• Progress notes should reflect measures of effectiveness of treatment, including psychosocial functioning (ability to perform daily tasks and interact with others and society)
• Medication management agreement: document how addressed if pt does not adhere
• Routine urine testing. Routine screening for SUD
Naloxone

• Discuss Naloxone with pts and consider prescribing to those at increased risk:
  • Concurrently using benzodiazepines or other medications that depress the central nervous system
  • Hx of opioid use disorder or previous overdose
  • Household members, including children or other close contacts at risk for accidental ingestion or opioid overdose
  • FDA 7-23-2020 Drug Safety Communication: https://www.fda.gov/media/140360/download?attachment
Key Points

• Most risk is in treatment of chronic pain
• Essential to assess for SUD risk factors and adjust treatment plan accordingly; re-assess periodically or as new risk factors emerge
• Transfer responsibility to the patient via informed consent, written patient education information, medication management contracts/agreements
• Demonstrate management over time by re-evaluating, seeing patient at appropriate intervals, responding to changes/concerns
• Stay up to date clinically. Be familiar with guidelines.
• Don’t get in over your head; don’t put chronic pain pt management on autopilot