COOPERATIVE OF AMERICAN PHYSICIANS

Risk Management & Patient Safety Data Study

July 2019

A Look into Pain Management

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Few things grab our attention more than pain. On the positive side, it teaches us to avoid possible painful events, like playing with fire. Its nature can be anything from an irritant to debilitating, from temporary to permanent, and sometimes have detrimental effects on the quality of life. As Marcia Meldrum PhD[1] put it "Pain is a constant companion for humanity".

Narcotic Use and the Opioid Crisis

One cannot discuss pain management as a specialty without first addressing the role the opioid crisis has played in the issues raised in this study. In the 1980s there was a push for increased use of drugs to treat long term non-cancer related pain citing a "low incidence of addictive behavior" with narcotics[3]. Drug makers jumped on the bandwagon promoting narcotic prescriptions by physicians. In 2001 the Joint Commission, addressing the undertreatment/underassessment of pain, introduced the "5th vital sign"[4] and pain scales. Physicians were criticized for inadequately dealing with pain, and failing to do so got the attention of Medical Boards. Now, the pendulum has swung to the other side and we have an opioid "epidemic", which is causing the Medical Boards to investigate physicians for over-prescribing opiates. There is much debate over the cause of the new opioid epidemic, but what's not up for debate is that narcotics are addictive and need careful coordinated management.

Pain Management as a Specialty

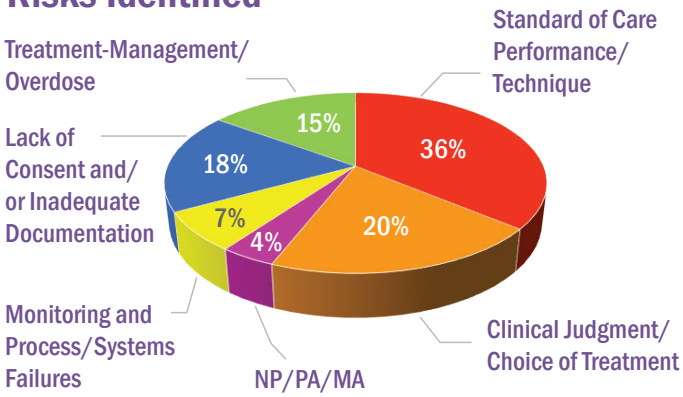
The field of pain management was first proposed as an anesthesia-based service in 1988[2] in the pre, peri and postoperative arenas. Our data study delves into the realm of CAP's experience in both the prescribing of analgesics and the use of epidurals in all the above areas.

What Our Experience Shows

Using a data range from 2005 to 2017, we analyzed 42 cases involving pain management through prescribing and/or epidural methods.

TOTAL INDEMNITY	$12.488M
TOTAL COSTS	$1.968M

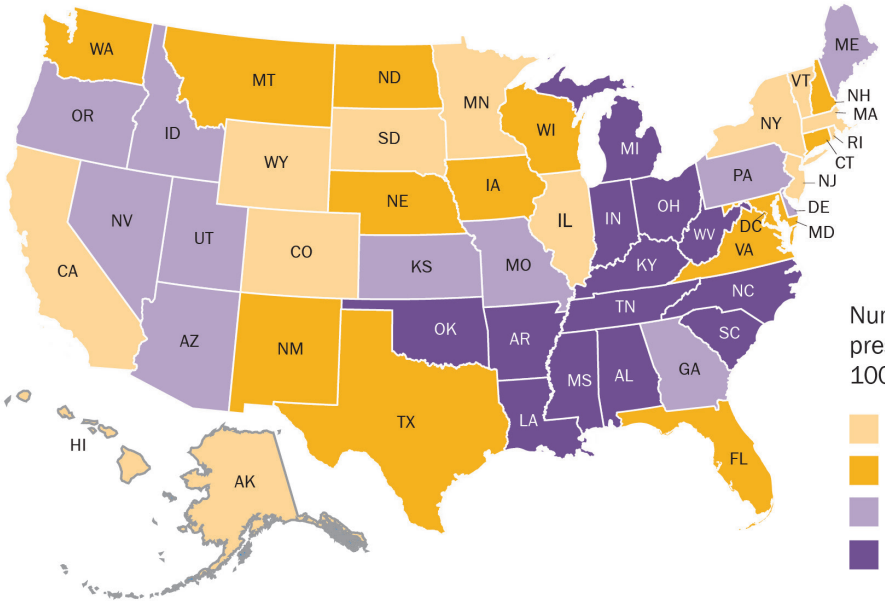
Risks Identified



Study Caveats: By its nature, this study has a commingling of elements of risk with actual patient injury. It is difficult to correlate a single risk factor as the cause of a specific adverse event. For example, issues *with clinical judgment regarding the choice of treatment* occurred in 20% of the claims resulting in a range of injuries shown in the injury graph, including nerve damage, brain damage and death. The extrapolation with precision of those cases of clinical judgment resulting only in nerve damage (for example) is beyond the scope of this review. The same is true with claims resulting from shared issues of clinical judgment and standard of care/technique.

Where Are We Now?

In 2016 the CDC reported the variations in state-to-state opioid prescriptions shown in the figure below[5]:



In brief, states with the highest opioid prescribing rate were six times higher than those with the lowest prescribing rate. Note that California is in the lowest category.

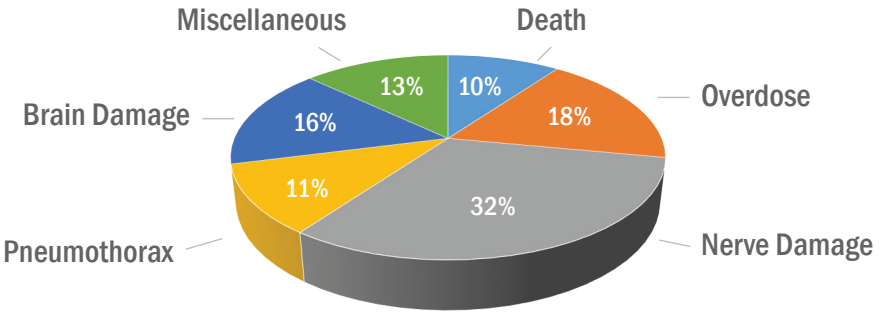
California's method of monitoring patient narcotic use is through the Department of Justice (DOJ) via the Controlled Substance Utilization Review and Evaluation System (CURES 2.0). By now, all licensed California physicians, prescribers, and dispensers are aware of the requirement to register and use CURES. The CURES database allows providers to monitor patient acquisition of narcotics, adherence to "narcotic contracts," or "doctor shopping" for multiple duplicate prescriptions. Conversely, it also means that the DOJ and the Medical Board are monitoring it as well. The Medical Board of California (MBC) has been known to independently launch investigations into prescribing habits based on CURES data provided by the DOJ.

A Few Words About Consent & Documentation

A substantial number of the claims reviewed (18%) lacked either a written consent and/or adequate documentation of the informed consent process. All patients have a right to make an informed decision about their medical care. The practitioner must advise the patient of the nature of the procedure and the potential risks thereof; the consent should be in writing and must be documented. A thorough informed consent process will also help align patient expectations with anticipated results.

You can't go back and write it correctly later. The most important discussion with the patient is the one before the procedure, not the one after an unmentioned complication has occurred. It is important to communicate clearly using simple explanations and document your discussion. Finally, use demonstrative content in your consent discussion whether it be models to doodles—but use something your patients can touch and/or see as you speak with them. Anatomical charts and models are great tools.

Injuries Related to Risks



Claims Reviewed by Injury

Nerve Damage

32%

Nerve damage, including paresthesia and paraplegias, represented the largest single event category, occurring in 32% of the cases reviewed. Slightly more than one third of these cases involved issues with the performance of epidural or other injections. As could be expected, small variations in technique, placement and/or manipulation resulted in outcomes as varied as complete pain relief to long-term nerve related complications. In those cases with unanticipated long-term nerve complications, a failure to preserve fluoroscopy images confirming appropriate needle placement severely compromised the defensibility of the involved care when litigation ensued. Even more problematic were those cases in which the medical record indicated fluoroscopy had been used during the procedure, but the images were no longer available. This situation can give rise to an implication the images were intentionally not preserved; after all, who wouldn't preserve images that demonstrated proper needle placement where the patient suffered an unanticipated nerve injury as a result of the injection?

Moral of the story – It's not enough to document fluoroscopy was used; the actual images should be preserved in the medical record.

Overdose

18%

Overdose was the cause of injury in 18% of the cases reviewed. The injuries seen in these claims involved brain damage and death, usually resulting from apnea/respiratory depression. The issues raised in the majority of these claims fell into two categories: failing to adequately monitor the patient, and failing to appreciate the compounding effect of other medications. In some cases, allied healthcare provider involvement added another layer of complication.

Case illustration: Patient presented for a refill of her pain pump medication. Both the refill and pump programming were done by a medical assistant (MA). The patient left the office in "good condition." However, the MA failed to document how long the patient was monitored prior to her departure. The patient drove home and was later found unconscious in her car parked in her driveway. Fortunately, the patient made it home before passing out. If she had lost consciousness while driving and injured herself and/or another driver, the physician and his MA would have had to defend their care with a less than adequate medical record. (Yes, you can be held liable to a third party injured under such circumstances.)

Moral of the story - The mandatory use of CURES (Controlled Substance Utilization Review and Evaluation System), effective 2018, may help limit/prevent the number of overdose cases by identifying multiple prescribers and drug seeking behaviors. Monitoring CURES for drug combinations and interactions is important. However, the CURES database will not affect those cases where clinical judgment is involved. Patients need adequate post procedure monitoring and advisements never to drive or participate in other hazardous activities after procedures involving medications known to induce cognitive impairment (with documentation thereof). **And medical assistants are never ever qualified to administer scheduled drugs without adequate training and supervision—period. It is important to develop systems and protocols for post-procedure monitoring, supervision, and follow-up as well as specific discharge instructions for each patient.**

Brain Damage/Death

26%

Brain damage (16%) and death (10%) collectively represent 26% of pain management injuries in the claims reviewed. In several cases involving cervical epidurals with complications involving analgesic effects to life preserving reflexes, the environment in which the procedure was performed proved unequipped or understaffed with the requisite personnel to deliver Advance Cardio Life Support (ACLS). Basic CPR was inadequate to prevent significant harm to the patient prior to EMS arrival and transport.

Moral of the story – Cervical epidurals in the office setting are inherently dangerous with life threatening risks. Perform cervical epidurals in ACLS equipped and licensed/staffed environments.

Pneumothorax

11%

11% of the claims reviewed involved a patient who suffered a pneumothorax, and almost universally this risk was not mentioned in the informed consent documentation. Since most trigger point injections to the chest wall and/or shoulder area are done without radiographic guidance, the chance of a pneumothorax resulting, whether because of anatomic anomaly or technique issues, is present.

Moral of the story – Include pneumothorax and hemothorax as a specific risk in the informed consent process. For a variety of reasons, you can't always prevent this unintended injury from occurring; however, you can always disclose the possibility in your consent discussion.

Miscellaneous

13%

Included in the "Miscellaneous" category are spinal headaches, injection site infections, and wrong site procedures. Infections and spinal headaches are not a purely preventable risk; they can occur despite sterile technique and injections performed in accordance with applicable standards. However, wrong-site procedures are preventable and generally reflect a lack of adequate systems and processes.

As an expert in engineering systems design and processes says, *"If you can't describe what you're doing as a process, you don't know what you're doing"*.[6] Understand and adhere to the patient safety processes and systems in place wherever you work so these preventable errors can be eliminated.

Moral of the story – "X" marks the spot, and you should be able to see it after drapes and scrubs are applied. This is true for any procedure regardless of your 'time-out' process. The marking of the correct site must always be visible. *If you can't see it when you start, you don't know where you are.*

[1]Associate; Dept of Psychiatry and biobehavioral Sciences-UCLA
[2]NCBI The Evolution and Practice of Acute Pain Medicine
[3]The Ongoing Opioid Prescription Epidemic: Historical Context; Marcia Meldrum PhD https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4940677/
[4]Joint Commission's Pain Standards: Origins and Evolution May 5, 2017
[5]PIAA September 2017 Research notes- Managing Opioids: Prescribing Practices and Claims
[6]W. Edwards Denning, Engineer on statistical process design and control; Oct 1990 – Dec 1993

The information in this publication should not be considered legal or medical advice applicable to a specific situation. Legal guidance for individual matters should be obtained from a retained attorney.

Tools and Resources:

Cooperative of American Physicians
www.CAPphysicians.com

The Medical Board of California
www.mbc.ca.gov

American Academy of Pain Medicine
www.painmed.org

American Society of Interventional Pain Management Physicians
www.asipp.org

American Society of Anesthesiologists
www.asahq.org

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